

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 1 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMR/T/195-00 Customer:	Batch No.: <u>GF 210301</u> Generic Health Care Pvt. Ltd.

BATCH MANUFACTURING RECORD COVER SHEET

PRODUCT NAME : GENSET
 GENERIC NAME : Cetirizine Tablets BP 10 mg
 LABEL CLAIM : Each film coated tablet contains:
 Cetirizine Hydrochloride BP10 mg
 Excipients q.s.
 Colour: Approved colour used
 MFR No. / Reference Document No. : MFR/T/106-00
 BMR No. : BMR/T/195-00
 REVISION No. : 00
 SUPERSEDES No. : NIL
 BMR EFFECTIVE BATCH NUMBER/DATE : GF 210101 / 01/01/2021
 MFG.LIC No. : PON/DRUGS/19 13 4323
 STORAGE : Store in cool and dry place. Protect from light and moisture.
 BMR ISSUED BY/DATE (QA) : [Signature] 25/03/2021
 BMR CHECKED & RECEIVED BY/DATE (PRODUCTION) : L. Ke 25/03/2021
 SHELF LIFE : 36 Months
 BATCH SIZE : 30,00,000 Tablets (362.400 Kg)
 MFG. DATE: 03/2021 : EXP. DATE: 02/2024

RECOVERY ADDITION RECORD

BATCH NO	MFG	EXP	QUANTITY	REVISED BATCH SIZE
1		NB		1

ALLOTTED BY: [Signature] 25/03/2021
 QA SIGN/DATE:
 DATE OF COMMENCEMENT: 31/03/2021
 DATE OF COMPLETION: 03/05/2021
 RELEASED QUANTITY OF TABLETS FOR PACKING : 2907455 Nos
 RELEASE FOR PACKING STAGE : [Signature] 03/05/2021
 HEAD OF QA SIGN/DATE:

This BMR contains 58 Pages + 10 Additional Pages

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ke</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>31/12/2020</u>

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 2 of 58
	BATCH MANUFACTURING RECORD	Product Code: G13	Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMR/T/195-00	Batch No.: G1F210301
		Customer:	Generic Health Care Pvt. Ltd.

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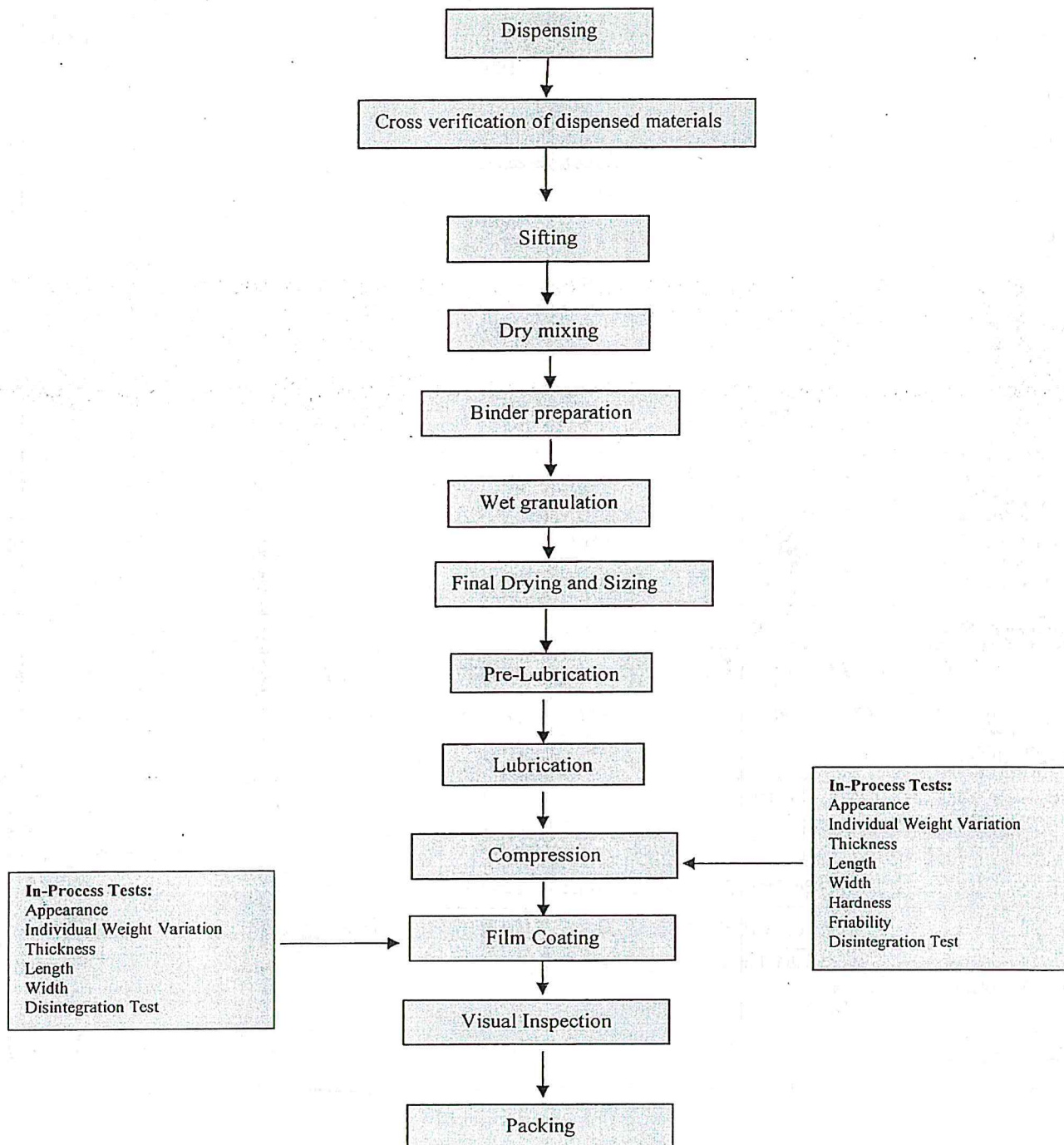
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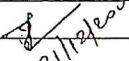
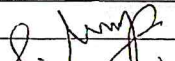
Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	POB	J. M. S.	J. M. S.
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 3 of 58
	BATCH MANUFACTURING RECORD	Product Code: G13	Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMRT/195-00	Batch No.: G13210301
		Customer:	Generic Health Care Pvt. Ltd.

2.0 PROCESS FLOW CHART



Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.			
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 4 of 58
	BATCH MANUFACTURING RECORD	Product Code: G13	Batch Size: 30,00,000 Tablets
	Product	GENSET	BMR. No.: BMR/T/195-00 Batch No.: 5210201 Customer: Generic Health Care Pvt. Ltd.

3.0 INDENT OF ACTIVE PHARMACEUTICAL INGREDIENTS & EXCIPIENTS:

Sr. No.	Name of the Ingredient	Spec.	Item Code	Quantity/ Tablets (mg)	Std. quantity per 30,00,000 tablets (kg)	OA/ PL (%)	Req. quantity per 30,00,000 tablets (kg)
Dry mixing material:							
1	Cetirizine Hydrochloride*	BP	RAI/SP/C018	10.000	30.000	-	30.000
2	Dried Maize Starch**	BP	IRM/SP/M001	59.900	179.700	-	179.700
3	Lactose Monohydrate	BP	REX/SP/L003	32.800	98.400	-	98.400
Binder Material:							
4	Dried Maize Starch	BP	IRM/SP/M001	4.270	12.810	-	12.810
5	Purified Water	BP	NA	q.s.	40.000	-	40.000
Theoretical Weight of Dried Granules				106.970	320.910	-	320.910
Lubrication Material:							
6	Colloidal Silicon Dioxide	BP	REX/GH/C001	0.470	1.410	-	1.410
7	Sodium Starch Glycollate	BP	REX/GH/S001	5.880	17.640	-	17.640
8	Purified Talc	BP	REX/SP/P011	2.340	7.020	-	7.020
9	Magnesium Stearate	BP	REX/GH/M001	2.340	7.020	-	7.020
Theoretical Weight of the Lubricated granules				118.000	354.000	-	354.000
Theoretical weight of Compressed tablet				118.000	354.000	-	354.000
Coating Material:							
10	Instacoat White (IC-U-3849)	IHS	REX/SP/I006	3.500	10.500	-	10.500
11	Purified Water	BP	NA	q.s.	25.000	-	25.000
Theoretical weight of Coated tablet				121.500	364.500	-	364.500
Actual weight of Coated tablet				120.800@	362.400@	-	362.400@

NOTE: *API quantity shall be calculated based on potency.

OA: Overages, PL: Process loss

@Average weight has calculated and rounded off to 80% of coating material

Potency calculation:

Theoretical Quantity of Cetirizine Hydrochloride required in Kg for a batch size of 30,00,000 Tablets are calculated.

** Excess Quantity shall be compensating from Dried Maize Starch

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	POA	31/12/2020	8. [Signature]
Date	31/12/2020	21/12/2020		31/12/2020

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.

BATCH MANUFACTURING RECORD

Batch Size: 30,00,000 Tablets

Batch No.: GF210301

Generic Health Care Pvt. Ltd.

Standard quantity of Dried Maize Starch (B): 179.700 kg

$$\text{Theoretical Qty} = \frac{\text{Label Claim} \times \text{Std. Batch Size (in no's)}}{1000 \times 1000} = \frac{10 \times 30,00,000}{1000 \times 1000} = 30.000 \text{ kg}$$

1) Calculation for Single A. R. No. 241/100060, Assay on dried basis: 99.43 w/w, LOD: 0.210 w/w
Exp. Date...11/10/2024

$$\text{Actual Quantity (Kg) (C)} = \frac{\text{Standard qty. required} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{30.000 \times 100 \times 100}{99.43 \times (100 - 0.210)} = \underline{30.235 \text{ Kg/2}}$$

LOT I: 15.118 Kg, LOT II: 15.118 Kg

Actual Quantity (Kg) (D) = (30.000 Kg + 179.700 Kg) - (C) = 179.465 Kg/2.

LOT I: 89.733 Kg, LOT II: 89.733 Kg

Sr/No.	A. R. No.	Available Qty. (Kg) (E)	Assay % w/w	LOD % w/w	Actual Qty. = $\frac{\text{Available Qty.} \times \text{Assay} \times (100 - \text{LOD})}{100 \times 100}$
Total Actual Quantity (F)					

Theoretical Qty. – Actual Quantity (F) = _____ Kg

AR. No.: _____, Assay on dried basis: 7.0 w/w, LOD: _____ %w/w, Exp. Date: _____

$$\text{Actual Quantity (Kg) (H)} = \frac{\text{Remaining qty. required (G)} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{X \ 100 \times 100}{X(100 - \quad)} = \quad \text{Kg.}$$

Total Qty. of Cetirizine Hydrochloride to be dispensed (I) = (E) + (H) = _____ Kg/2

LOT I: _____ Kg, LOT II: _____ Kg

4) Calculation for Dried Maize Starch:

Actual Quantity (Kg) (J) = (30.000 Kg + 179.700 Kg) - (I) = _____ Kg/2.

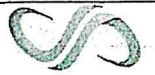
LOT I: _____ Kg, LOT II: _____ Kg

Done By/On (QA):

Checked By/On (Production): L. K. 25/03/2024

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka			
Date	31/12/2020	31/12/2020	31/12/2020	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No: 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 6 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product GENSET	BMR. No.: BMR/T/195-00 Customer:		Batch No.: <u>GF210301</u> Generic Health Care Pvt. Ltd.

5.0 DISPENSING LINE CLEARANCE CHECKS

Date: 26/03/2021 Time: 09:48

Sr. No.	Checks	Observation*	
		Store	IPQA
1	Check and ensure that empty SS containers, polythene bags, Tags, documents and scrap from waste bin of previous batch/product are removed from the area.	✓	✓
2	Check and ensure that display stand and weighing balance are clean.	✓	✓
3	Check and ensure that SS scoop, SS spatula and SS trolley are clean.	✓	✓
4	Check and ensure that area (floor, walls, ceiling, doors and windows) are clean.	✓	✓
5	Check and ensure that Magnehelic gauges, tube light fixtures, supply grills, return riser grills and filters, electrical fixture are clean.	✓	✓
6	Check and ensure that all the sides of dispensing booth is clean	✓	✓
7	Check all the gauges of dispensing booth before switching ON.	✓	✓
8	Check and ensure that weighing balances and pressure gauges to be used are within calibration due date.	✓	✓
9	Check that the daily records (Balance Logbook, RH & Temp. record) are updated and signed.	✓	✓
10	Equipment status is updated for Cleaned and Preventive maintenance.	✓	✓

Note: *Tick mark (✓) if Complies, (X) if does not comply and (NA) if not applicable.

Equipment	Dispensing Booth	Weighing Balance				Area
ID No.	<u>ST/DPB/001</u>	<u>ST/004/004</u>	<u>ST/004/005</u>	<u>ST/004/006</u>	<u>ST/004/007</u>	<u>Dispensing booth</u>
Previous Product	<u>Atorvastatin 10 mg/10 mg</u>					
B. No.	<u>GF210321</u>					
Cleaned by Sign/Date	<u>Perumal / 26/03/2021</u>					
Checked by Store Sign/Date	<u>my / 26/03/2021</u>					
Verified by IPQA Sign/Date	<u>Q / 26/03/2021</u>					

ENVIRONMENTAL CONDITIONS: Date: <u>26/03/2021</u> Time: <u>09:58</u>	Observation	Checked by Store Sign/Date	Verified by IPQA Sign/Date
(For Reference SOP No.: QAGN/011)			
Temperature (Limit: NMT 25°C)	23°C	my 26/03/2021	Q 26/03/21
Relative Humidity % (Limit: NMT 60%)	55%	my 26/03/2021	Q 26/03/21
Differential Pressure (NLT 10 Pascal)	9 Pa/Ga	my 26/03/2021	Q 26/03/21
Differential Pressure across the booth Limit: 5 to 20 mm Water	13 mm	my 26/03/2021	Q 26/03/21

APPROVAL FOR DISPENSING BY IPQA: Sign: <u>[Signature]</u> Date: <u>26/03/2021</u>	
Dispensing start Time <u>10:00</u>	End Time <u>11:10</u>

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>[Signature]</u>

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune,
Puducherry-605009.

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Product

GENSET

BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

BMR. No.: BMR/T/195-00

Batch No.: G1F210301

Customer:

Generic Health Care Pvt. Ltd.

5.1 Dispensing Weighing Sheet:

Balance ID: ST1601004, ST1601005, ST1601006 Date: 26/03/2024 Shift: Gen Time: 10:08

Sr. No.	Ingredients	Spec.	Item code	UOM	Std. Qty.	Req. Qty.	A.R No.	Issued Qty.		Weighed By Store (Sign & Date)	Checked By (IPQA) (Sign & Date)	Cross Checked by	
								Gross Wt.	Net Wt.			Checked Production (Sign & Date)	Verified IPQA (Sign & Date)

LOT - I

Dry mixing material:

1	Cetirizine Hydrochloride*	BP	RAI/SP/C018	Kg	15.000	15.118	RM4100060	15.368	0.230	15.118	26/03/2024	26/03/2024	27/03/2024
2	Dried Maize Starch**	BP	IRM/SP/M001	Kg	89.850	89.733	Qm4101390	50.093	0.900	49.793	26/03/2024	26/03/2024	27/03/2024
3	Lactose Monohydrate	BP	REX/SP/L003	Kg	49.200	49.200	RM4100885	40.200	0.250	2.600	26/03/2024	26/03/2024	27/03/2024

Binder Material:

4	Dried Maize Starch	BP	IRM/SP/M001	Kg	6.405	6.405	Qm4101390	6.475	0.070	6.405	26/03/2024	26/03/2024	27/03/2024
5	Purified Water	BP	NA	Kg	20.000	20.000	PL4103112	---	---	20.00	26/03/2024	26/03/2024	27/03/2024

LOT - II

Dry mixing material:

6	Cetirizine Hydrochloride*	BP	RAI/SP/C018	Kg	15.000	15.118	RM4100060	15.278	0.160	15.118	26/03/2024	26/03/2024	27/03/2024
7	Dried Maize Starch**	BP	IRM/SP/M001	Kg	89.850	89.733	Qm4101390	50.093	0.900	49.793	26/03/2024	26/03/2024	27/03/2024
8	Lactose Monohydrate	BP	REX/SP/L003	Kg	49.200	49.200	RM4100885	40.200	0.250	2.600	26/03/2024	26/03/2024	27/03/2024

Binder Material:

9	Dried Maize Starch	BP	IRM/SP/M001	Kg	6.405	6.405	Qm4101390	6.475	0.070	6.405	26/03/2024	26/03/2024	27/03/2024
10	Purified Water	BP	NA	Kg	20.000	20.000	PL4103112	---	---	20.00	26/03/2024	26/03/2024	27/03/2024

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	1. K2				
Date	31/12/2020				

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 8 of 58	
	BATCH MANUFACTURING RECORD		Product Code: G13	Batch Size: 30,00,000 Tablets
Product	GENSET		BMR. No.: BMR/T/195-00	Batch No.: 01F210301
			Customer:	Generic Health Care Pvt. Ltd.

Sr. No.	Ingredients	Spec.	Item code	UOM	Std. Qty.	Req. Qty.	A.R. No.	Issued Qty.			Weighed By Store (Sign & Date)	Checked By (IPQA) (Sign & Date)	Cross Checked by	
								Gross Wt.	Tare Wt.	Net Wt.			Checked Production (Sign & Date)	Verified IPQA (Sign & Date)
Lubrication Material:														
11	Colloidal Silicon Dioxide	BP	REX/GH/C001	Kg	1.410	1.410	Rm4/00922	1.660	0.250	1.410	26/03/2024	26/03/2024	26/03/2024	26/03/2024
12	Sodium Starch Glycollate	BP	REX/GH/S001	Kg	17.640	17.640	Rm4/00461	17.890	0.250	17.640	26/03/2024	26/03/2024	26/03/2024	26/03/2024
13	Purified Talc	BP	REX/SP/P011	Kg	7.020	7.020	Rm4/00425	7.240	0.250	7.020	26/03/2024	26/03/2024	26/03/2024	26/03/2024
14	Magnesium Stearate	BP	REX/GH/M001	Kg	7.020	7.020	Rm4/00827	7.270	0.250	7.020	26/03/2024	26/03/2024	26/03/2024	26/03/2024
Coating Material:														
LOT I														
15	Instacoat White (IC-U-3849)	IHS	REX/SP/I006	Kg	5.250	5.250	Rm4/00907	5.310	0.060	5.250	26/03/2024	26/03/2024	26/03/2024	26/03/2024
16	Purified Water	BP	NA	Kg	12.500	12.500								
LOT II														
17	Instacoat White (IC-U-3849)	IHS	REX/SP/I006	Kg	5.250	5.250	Rm4/00907	5.310	0.060	5.250	26/03/2024	26/03/2024	26/03/2024	26/03/2024
18	Purified Water	BP	NA	Kg	12.500	12.500								

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production		Head Quality Assurance	
Sign.	L. K.				
Date	31/12/2020				

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

BMR. No.: BMR/T/195-00

Batch No.: GF210301

Customer:

Generic Health Care Pvt. Ltd.

Product: GENSET

6.0 GRANULATION LINE CLEARANCE CHECKS: Date/Shift: 31/03/2021 /

Sr. No.	Checks	Time:	*Observations					
			Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty SS containers, polythene bags, Tags and documents of previous batch/product are removed.	00:45	✓	✓				
2	Check and ensure that Scrap from waste bin is removed and new polythene bag is put into it.		✓	✓				
3	Check and ensure that display, display stand, weighing balance are clean.		✓	✓				
4	Check and ensure that SS storage Cabinet and Drain point are clean.		✓	✓				
5	Check and ensure that absence of previous batch/product from area below machine		✓	✓				
6	Check and ensure that all equipment body and inside the vessel are clean		✓	✓				
7	Check and ensure that Tube light fixture, supply grills, riser grills and filters and electrical fixtures are clean		✓	✓				
8	Check and ensure that instruments to be used are within calibration due date and earthing connection.		✓	✓				
9	Check and ensure that daily records (Logbook, Balance, Temp. & RH) are updated and signed.		✓	✓				
10	Check and ensure that environment condition and record on BMR		✓	✓				
11	Check and ensure that rinse water is released from QC and attached the test request from (TRF)		NA	NA				
12	Equipment status is updated for Cleaned and Preventive maintenance.		✓	✓				

Note: *Tick mark (✓) if Complies, (X) if does not comply and (NA) if not applicable.

Equipment	Sifter	Multimill	RMG	FBD	Area
EQP. ID No.	PD/VRC/009	PD/MMM/002	PD/RMG/001	PD/FBD/001	Granulation-II
Previous Product	Dolix 50				
Batch No.	GF210327				
Cleaned by	Raju				
Checked by					
Verified by	31/03/2021				

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 31/03/2021 Time: 00:47			Date:			Date:		
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	23°C	✓	✓						
RH % (NMT 60%)	52	✓	✓						
DP (NLT 10 Pascal)	10 pascal	✓	✓						

APPROVAL FOR SIFTING AND GRANULATION:

Production Sign/Date:	31/03/2021				
IPQA Sign/Date:	31/03/2021				
Start and End Time:	00:50	04:25			

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. R.				
Date	31/12/2020	21/12/2020	31/12/2020		

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 10 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMR/T/195-00 Customer:	Batch No.: <u>G1F210301</u> Generic Health Care Pvt. Ltd.

7.0 GRANULATION SIFTING INSTRUCTIONS AND SIFTING RECORD: LOT-I Date: 31/03/2021 Shift: III

S. No	Name of Ingredient	Weight before sifting in Kg	Sieve size	ID No.	Sieve Integrity before use	Time		Sieve Integrity after use	Done by	Ckd by
						From	To			
Dry mixing:										
1	Cetirizine Hydrochloride	15.118	40#	PD1305E-40102	OK/ Not OK	00.52	00.53	OK/ Not OK	Rajiv	2
2	Dried Maize Starch	89.733	30#	PD1305E-30102	OK/ Not OK	00.54	00.59	OK/ Not OK	Rajiv	2
3	Lactose Monohydrate	49.200	30#		Not OK	01.00	01.04	Not OK	Rajiv	2
Binder Material:										
4	Dried Maize Starch	6.405	NA		NA			NA		
5	Purified Water	20.0 kg								

7.1 MANUFACTURING PROCESS:

Step No.	Process Instructions	Date: 31/03/2021		Done by	Checked by
		Time			
		Started	Completed		
1	Dry mixing: Transfer the sifted material from step 7.0 (1-3) into the RMG. Mix for 10 minute with impeller at slow speed and chopper 'off'. Impeller Speed: <u>55</u> RPM	01.05	01.15	Rajiv	2
2	Binder Preparation: Take purified water and disperse Dried Maize Starch to form slurry.	00.55	01.00	Seshan	2
3	Take Purified Water in Paste Kettle and heat till reaches 90°C - 95°C.	01.00	01.10	Seshan	2
4	Add the solution from step 7.1(2) to the step 7.1(3) and mix is continuously to form the paste and cool the paste till 40 - 45°C.	01.15	01.15	Seshan	2
5	Wet Granulation: Binder Addition: Add binder from step-7.1(4) into the contents of RMG take <u>2</u> min for binder addition with impeller slow speed and Chopper OFF. Impeller Speed: <u>55</u> RPM	01.16	01.18	Seshan	2
6	After binder addition allow mixing to form a coherent mass. If required allow mixing till required consistency of granules obtained with impeller at slow speed and chopper at slow speed. Total Mixing Time: <u>5</u> mins, Impeller Speed: <u>110</u> RPM, Chopper Speed: <u>2800</u> RPM Additional quantity of Purified Water Kg	01.19	01.24	Seshan	2
7	Note the Ampere at granulation end point <u>25</u> AMP.				
8	Discharge the wet mass to FBD bowl operating slow speed of Impeller and slow speed of Chopper. Impeller Speed: <u>55</u>RPM, Chopper Speed..... RPM	01.25	01.26	Seshan	2

7.2 DRYING:

Step No	Process Instructions	Date : 31/03/2021		Done by	Checked by
		Time			
		Started	Completed		
1	Load the wet mass into the FBD bowl and air dry the wet mass.				
2	Load the wet mass into the cleaned FBD bowl Dry at inlet temperature 45-55°C till the LOD reached up to 1.5 – 2.0% w/w.	01.45	02.41	Seshan	2
3	LOD checking temperature at 105°C (Auto mode). LOD should be 1.5 – 2.0% w/w.	Observed LOD in %		Seshan	2
		1.57 / 1.57 %			

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka				
Date	31/12/2020	31/12/2020	31/12/2020		

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BATCH MANUFACTURING RECORD		Product Code: G13	Batch Size: 30,00,000 Tablets
Product		BMR. No.: BMR/T/195-00	Batch No.: 31F210301
GENSET		Customer:	Generic Health Care Pvt. Ltd.

7.3 FBD Finger bag Integrity checks:

S. No.	Items	Integrity before use	Integrity after use	Checked by (Production)	Verified by QA
1.	FBD finger bag	OK	OK	Q	Q
2.	FBD bowl mesh	OK	OK	Q	Q

7.4 SET PARAMETERS:

Sr. No.	Operation	Started at	Inlet Temp. (45-55°C)	Outlet Temp.	Product Temp. (To be Established)	Completed at	Total Time (mins)	LOD Observed	Done by	Checked By
1.	Air-Drying-I	01.28	NA	NA	NA	01.38	10min	NA	Sethu	Q
2.	Raking-I	01.39	NA	NA	NA	01.44	5min	NA	Sethu	Q
3.	Drying-I	01.45	55	40	40	02.40	55min	* 1.57% 4.85	Sethu	Q
4.	Raking-II	/	NA	NA	NA			NA		
5.	Drying-II				NA					
6.	Raking-III		NA	NA	NA			NA		
7.	Drying-III									
Total Drying Time (Exclude Raking & Air-Drying time): 55min							LOD Verified By IPQA: A 21/03/2021			
Total Drying time: 70min										

7.5 SIFTING AND MILLING:

7.5 SIFTING AND MILLING.					
S. No	Process Instructions	Date : 31/03/2021		Done by	Checked by
		Time			
		Started	Completed		
1.	Sift the dried granules through 30 # sieve. Record the observation.	2.45	2.55	Jayaram	Q
2.	Mill the oversized granules through 1.0 mm multi mill screen fitted with (knives forward medium speed) followed by sifting through 30# sieve on vibrating sifter and collect the sifted granules in double polythene lined cleaned HDPE containers, record the weights.	2.55	3.05	Raju	Q
3.	Unload the granules in to cleaned HDPE containers in double polythene bag.	3.05	3.07	Raju	Q

7.6 SIZING RECORD:

Mesh and screen size	Sieve ID No	Integrity checked before use	Date : 31/03/2021		Integrity checked After use	Done by	Checked by
			Time				
			Started	Completed			
30 #	PD/30SE-20102	OK/ Not OK	2.44	3.06	OK/ Not OK	Jayaram	Q
1.0 mm	PD/1mmSC-10102	OK/ Not OK	2.54	3.00	OK/ Not OK	Rajiv	Q

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. K.	J. P.	J. P.	J. P.	
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 12 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMR/T/195-00 Customer:	Batch No.: 410210301 Generic Health Care Pvt. Ltd.

8.0 GRANULATION SIFTING INSTRUCTIONS AND SIFTING RECORD: LOT-II Date: 31/03/2021 Shift: III

S. No	Name of Ingredient	Weight before sifting in Kg	Sieve size	ID No.	Sieve Integrity before use	Time		Sieve Integrity after use	Done by	Ckd by
						From	To			
Dry mixing:										
1	Cetirizine Hydrochloride	15.118	40#	PD1305E-40102	OK/ Not OK	01.50	01.54	OK/ Not OK	Jayaprakash	2
2	Dried Maize Starch	89.733	30#	PD1305E-30102	OK/ Not OK	01.55	2.05	OK/ Not OK	Jayaprakash	2
3	Lactose Monohydrate	49.200	30#		OK/ Not OK	2.05	2.10	OK/ Not OK	Jayaprakash	2
Binder Material:										
4	Dried Maize Starch	6.405	NA		NA			NA		
5	Purified Water	—								
Lubrication:										
6	Colloidal Silicon Dioxide	1.410	30#	PD1305E-30103	OK/ Not OK	4.50	4.52	OK/ Not OK	Praman	2
7	Sodium Starch Glycollate	17.640	30#		OK/ Not OK	4.53	4.56	OK/ Not OK	Praman	2
8	Purified Talc	7.020	40#	PD1305E-40103	OK/ Not OK	4.57	4.58	OK/ Not OK	Praman	2
9	Magnesium Stearate	7.020	60#	PD1305E-60103	OK/ Not OK	5.00	5.00	OK/ Not OK	Praman	2

8.1 MANUFACTURING PROCESS:

Step No.	Process Instructions	Date: 31/03/2021		Done by	Checked by
		Time			
		Started	Completed		
1	Dry mixing: Transfer the sifted material from step 8.0 (1-3) into the RMG. Mix for 10 minute with impeller at slow speed and chopper 'off'. Impeller Speed: <u>55</u> RPM	2.15	2.25	Jayaprakash	2
2	Binder Preparation: Take purified water and disperse Dried Maize Starch to form slurry.	2.05	2.10	Rajiv	2
3	Take Purified Water in Paste Kettle and heat till reaches 90°C - 95°C.	2.10	2.20	Rajiv	2
4	Add the solution from step 8.1(2) to the step 8.1(3) and mix is continuously to form the paste and cool the paste till 40 - 45°C.	2.20	2.25	Rajiv	2
5	Wet Granulation: Binder Addition: Add binder from step-8.1(4) into the contents of RMG take <u>2</u> min for binder addition with impeller slow speed and Chopper OFF. Impeller Speed: <u>5</u> RPM	2.27	2.29	Sethuraman	2
6	After binder addition allow mixing to form a coherent mass. If required allow mixing till required consistency of granules obtained with impeller at slow speed and chopper at slow speed. Total Mixing Time: <u>5</u> mins, Impeller Speed: <u>110</u> RPM, Chopper Speed: <u>2800</u> RPM Additional quantity of Purified Water <u>5.000</u> Kg	2.30	2.35	Sethuraman	2
7	Note the Ampere at granulation end point <u>2.5</u> AMP.				
8	Discharge the wet mass to FBD bowl operating slow speed of Impeller and slow speed of Chopper. Impeller Speed: <u>55</u> RPM Chopper Speed: <u>2800</u> RPM	2.36	2.38	Sethuraman	2

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. K.	J. P.	J. P.	J. P.	
Date	31/03/2021	31/03/2021	31/03/2021	31/03/2021	

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

BMR. No.: BMR/T/195-00

Batch No.: GTF210301

Product

GENSET

Customer:

Generic Health Care Pvt. Ltd.

8.2 DRYING:

02 DRYING:					
Step No	Process Instructions	Date : 31/03/2021		Done by	Checked by
		Time			
		Started	Completed		
1	Load the wet mass into the FBD bowl and air dry the wet mass.				
2	Load the wet mass into the cleaned FBD bowl Dry at inlet temperature 45-55°C till the LOD reached up to 1.5 – 2.0% w/w.	2.03	4.00	Seethiam	8
3	LOD checking temperature at 105°C (Auto mode). LOD should be 1.5 – 2.0% w/w.	Observed LOD in %		Seethiam	8
		1.59 %			

8.3 FBD Finger bag Integrity checks:

S. No.	Items	Integrity before use	Integrity after use	Checked by (Production)	Verified by QA
1.	FBD finger bag	OK	OK	8	8
2.	FBD bowl mesh	OK	OK	8	8

8.4 SET PARAMETERS:

Sr. No.	Operation	Started at	Inlet Temp. (45-55°C)	Outlet Temp.	Product Temp. (To be Established)	Completed at	Total Time (mins)	LOD Observed	Done by	Checked By
1.	Air-Drying-I	2.45	NA	NA	NA	2.55	10min	NA	Seethiam	8
2.	Raking-I	2.56	NA	NA	NA	3.00	4min	NA	Seethiam	8
3.	Drying-I	3.03	55	40	40	4.00	57min	4.85-59%	Seethiam	8
4.	Raking-II	/	NA	NA	NA			NA		
5.	Drying-II	/			NA					
6.	Raking-III		NA	NA	NA			NA		
7.	Drying-III									
Total Drying Time (Exclude Raking & Air-Drying time): 57 min								LOD Verified By IPQA: 8/31/03/2021		
Total Drying time: 71 min										

8.5 SIFTING AND MILLING:

6.5 SIFTING AND MILLING.					
S. No	Process Instructions	Date : 31/03/2021		Done by	Checked by
		Time			
		Started	Completed		
1.	Sift the dried granules through 30 # sieve. Record the observation.	4.02	4.10	Jaganm	8
2.	Mill the oversized granules through 1.0 mm multi mill screen fitted with (knives forward medium speed) followed by sifting through 30# sieve on vibrating sifter and collect the sifted granules in double polythene lined cleaned HDPE containers, record the weights.	4.11	4.20	Rajv	8
3.	Unload the granules in to cleaned HDPE containers in double polythene bag.	4.21	4.25	Rajv	8

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	8/31/12/2020	8/31/12/2020	8/31/12/2020
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 14 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMR/T/195-00 Customer:	Batch No.: <u>CHF210301</u> Generic Health Care Pvt. Ltd.

8.6 SIZING RECORD:

Mesh and screen size	Sieve ID No	Integrity checked before use	Date : 21/07/2021		Integrity checked After use	Done by	Checked by
			Time				
			Started	Completed			
30 #	Pd30SE-3002	OK/ Not OK	4.05	4.21	OK/ Not OK	Jayaram	2
1.0 mm	Pd1mm-1.0102	OK/ Not OK	4.10	4.15	OK/ Not OK	Rajr	2

8.7 WEIGHING OF DRIED GRANULES:

S. No.	Tare Weight (Kg)	Gross Weight (Kg)	Net Weight (Kg)	Weighed By	Checked By
1	<u>3.200</u>	<u>45.270</u>	<u>42.070</u>	<u>man</u>	<u>2</u>
2	<u>2.300</u>	<u>32.160</u>	<u>29.860</u>	<u>man</u>	<u>2</u>
3	<u>2.500</u>	<u>35.040</u>	<u>32.540</u>	<u>man</u>	<u>2</u>
4	<u>2.500</u>	<u>38.060</u>	<u>35.560</u>	<u>man</u>	<u>2</u>
5	<u>2.300</u>	<u>19.200</u>	<u>16.900</u>	<u>man</u>	<u>2</u>
6	<u>2.500</u>	<u>27.630</u>	<u>25.130</u>	<u>man</u>	<u>2</u>
7	<u>2.300</u>	<u>37.680</u>	<u>35.380</u>	<u>man</u>	<u>2</u>
8	<u>2.500</u>	<u>37.930</u>	<u>35.430</u>	<u>man</u>	<u>2</u>
9	<u>2.500</u>	<u>37.230</u>	<u>34.730</u>	<u>man</u>	<u>2</u>
10	<u>39.300</u>	<u>24.000</u>	<u>21.700</u>	<u>man</u>	<u>2</u>
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
Total			<u>319.300</u>		

Theoretical Weight: 320.910 Kg

Theoretical Yield (Weight): Actually yield will be calculated after 3 validation batches.

Actual Yield (Weight): 319.300 Kg % Yield: 99.77 %

Date: 31/03/2021

Production Executive Sign. /Date: 31/03/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>31/12/2020</u>
Date	<u>31/12/2020</u>			

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 15 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMR/T/195-00	Batch No.: GF210301
		Customer:	Generic Health Care Pvt. Ltd.

9.0 BLENDING LINE CLEARANCE CHECKS: Date/Shift: 31/03/2021 / I.

Sr. No.	Checks	Time	*Observations					
			4.40					
			Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty SS containers, polythene bags, Tags and documents of previous batch/product are removed.		✓	✓				
2	Check and ensure that Scrap from waste bin is removed and new polythene bag is put into it.		✓	✓				
3	Check and ensure that display, display stand, weighing balance are clean.		✓	✓				
4	Check and ensure that SS storage Cabinet and Drain point are clean.		✓	✓				
5	Check and ensure that absence of previous batch/product from area below machine		✓	✓				
6	Check and ensure that all equipment body and inside the vessel are clean		✓	✓				
7	Check and ensure that Tube light fixture, supply grills, riser grills and filters and electrical fixtures are clean		✓	✓				
8	Check and ensure that instruments to be used are within calibration due date and earthing connection.		✓	✓				
9	Check and ensure that daily records (Logbook, Balance, Temp. & RH) are updated and signed.		✓	✓				
10	Check and ensure that environment condition and record on BMR		✓	✓				
11	Check and ensure that rinse water is released from QC and attached the test request from (TRF)		NA	NA				
12	Equipment status is updated for Cleaned and Preventive maintenance.		✓	✓				

Note: *Tick mark (✓) if Complies, (X) if does not comply and (NA) if not applicable.

Equipment	Blender	Area
EQP. ID No.	PD/OCB/002	Blender
Previous Product	Dolex 50	
Batch No.	GF210327	
Cleaned by	Ramya	
Checked by		
Verified by	31/03/2021	

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 31/03/2021 Time: 4.45			Date: Time:			Date: Time:		
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	22	✓	✓						
RH % (NMT 60%)	52	✓	✓						
DP (NLT 10 Pascal)	10	✓	✓						

APPROVAL FOR SIFTING AND BLENDING:

Production Sign/Date:	31/03/2021		
IPQA Sign/Date:	31/03/2021		
Start and End Time:	4.55	5.35	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	31/03/2021	31/03/2021	
Date	31/12/2020			

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: G13210201

Customer:

Generic Health Care Pvt. Ltd.

9.1 BLENDING AND LUBRICATION PROCESS:

Date: 31/03/2021 Shift: 1

Step No.	Process Instructions	Time		Done by	Checked by Prod.
		Started	Completed		
1	Use hand gloves and goggles while handling the materials.				
2	Operate the Octagonal Blender as per the current version of the SOP No. PDOP/009.				
Pre-lubrication:					
1	Load the dried and sifted granules from step 8.7, sifted Material from step 8.0 (6-8) in to the blender and mix at 10 rpm for 15 minutes (To be established).	4.55	5.10	Pravin	2
Lubrication:					
2	Load the Sifted Magnesium Stearate into the above Pre-lubricated blend and mix for further 5 minutes at 10 RPM (To be established).	5.15	5.20	Pravin	2
3	Unload the lubricated blend in HDPE container having double lined polybag.	5.25	5.35	Pravin	2

9.2 WEIGHING OF FINAL BLEND:

Balance I.D. No.: PD/172/1605

Date: 31/03/2021 Shift: 1 Time: 5.40

Sr. No.	Gross Weight(Kg)	Tare Weight(Kg)	Net weight(Kg)	Weighed by	Checked by Prod.	Verified by IPQA
1	42.950	2.500	40.450	Pravin	L	2
2	44.200	2.300	41.900	Pravin	L	2
3	39.500	2.300	37.200	Pravin	L	2
4	41.130	2.300	38.830	Pravin	L	2
5	43.840	2.300	41.540	Pravin	L	2
6	41.240	2.300	38.940	Pravin	L	2
7	78.00	2.500	75.500	Pravin	L	2
8	50.980	2.200	48.780	Pravin	L	2
9	73.800	2.500	71.300	Pravin	L	2
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						
25						
Total:			353.40			

* 353.440

Prepared by:

Checked by:

Approved By:

Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	1. K	208	208	208
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 17 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product GENSET	BMR. No.: BMR/T/195-00		Batch No.: 31F210301
	Customer:		Generic Health Care Pvt. Ltd.

9.3 RECONCILIATION:

1.0	Theoretical weight of blend	:	354.000 Kg
2.0	Actual Weight of blend	:	353.44 Kg
3.0	Manufacturing Loss (Blending stage) @	:	0.560 Kg
4.0	In-process samples		
	A IPQC Samples	:	0.010 Kg.
	B QC Samples	:	0.100 Kg.
	C Validation Samples	:	0.030 Kg.
5.0	Total samples: (A + B + C)	:	0.140 Kg
6.0	Total: (2.0 + 5.0)	:	353.580 Kg
7.0	Yield {6.0 / 1.0 x 100}*	:	99.78 %

* Actually yield will be calculated after 3 validation batches.

@Total rejects destroyed: 0.00 Kg. (Rejected materials shall be destroyed as per SOP: QAGN/048).

Recovery Addition Quantity in Kg: 0.00 (Recovery addition materials shall be as per SOP: QAGN/047).

Done by Production sign/Date: 31/12/2020, Checked By IPQA sign/Date: 31/12/2020

Test request form raised by Prod Sign/Date: 31/12/2020

Test request form received by IPQA Sign/Date: 31/12/2020

9.4 RELEASED FOR COMPRESSION:

Reconciliation checked and blend is released for compression

IPQA Sign: 31/12/2020 Date: 31/12/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	POB	31/12/2020	31/12/2020
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: 616210301

Customer:

Generic Health Care Pvt. Ltd.

10.0 COMPRESSION LINE CLEARANCE CHECKS: Date/Shift: 01/04/2021/02/04/2021 /

Sr. No.	Checks	Time:	*Observations					
			06:07					
			Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty SS containers/ containers polythene bags, Tags, and documents of previous batch/product are removed.		✓	✓				
2	Check and ensure that absence of tablets of previous batch/product from area below machine and inside machine by opening the guard of machine.		✓	✓				
3	Check and ensure that the machine body and machine parts like hoppers, feed frame, dust collection chute, hosepipe and ejection chute and control panel are clean.		✓	✓				
4	Check and ensure that absence of tablet of previous batch/product below the weighing balance, check the cleanliness of area and equipment.		✓	✓				
5	Check and ensure that working desk, analytical balance and other accessories are clean.		✓	✓				
6	Check and ensure that Deduster and hosepipe are clean.		✓	✓				
7	Check and ensure that Tube light fixture, supply grills, riser grills and filters and electrical fixtures are clean.		✓	✓				
8	Check and ensure that instruments to be used are within calibration due date, and Punch inspection record		✓	✓				
9	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.		✓	✓				
10	Check and ensure that environmental conditions are recorded in the BMR.		✓	✓				
11	Area, equipment and preventive maintenance status board is updated.		✓	✓				
12	Check and ensure that rinse water is released from QC and attached the test request from (TRF) in BMR		✓	✓				
13	Equipment status is updated for Cleaned and Preventive Maintenance label.		✓	✓				

Note: *Tick mark (✓) if Complies, (X) if does not comply and (NA) if not applicable.

Equipment	Compression Machine	Deduster	Area
EQP ID No.	PD/COM/002	PD/DED/005, PD/DED/007	Comp-02
Previous Product	Telo 210		
Batch No.	112101C		
Cleaned by	N. Bal		
Checked by	N. Bal 01/04/2021		
Verified by	V. Bal 01/04/2021		

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 01/04/2021 Time: 06:55			Date: Time:			Date: Time:		
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	23°C	N. Bal	V. Bal						
RH % (NMT 60%)	52%	N. Bal	V. Bal						
DP (NLT 10 Pascal)	12 pasc	N. Bal	V. Bal						

APPROVAL FOR COMPRESSION:

Production Sign/Date:	N. Bal 01/04/2021		
IPQA Sign/Date:	V. Bal 01/04/2021		
Start and End Time:	07:02	21:10	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	POA	31/12/2020	
Date	31/12/2020	31/12/2020		

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

BMR. No.: BMR/T/195-00

Batch No.: 7162101801

Customer:

Generic Health Care Pvt. Ltd.

Product

GENSET

11.0 COMPRESSION

11.1 PROCESS INSTRUCTIONS:

Sr. No.	Process Instructions
1	Check the cleanliness of area and equipment.
2	Ensure that the correct punch set are issued as per the Punch issue record.
3	Set the Double Rotary Compression Machine with a. Upper punches: 10.00 x 4.00 mm caplet shaped with breakline punches. b. Lower punches: 10.00 x 4.00 mm caplet shaped plain punches. c. Dies: 10.00 x 4.00 mm suitable for above punches. d. Type of tooling - D. Punch Issued by: sign./Date: 10/11/2024 Checked and Received by Sign./Date: 10/11/2024 Verified by Sign./Date: 10/11/2024
4	Transfer the blend to compression cubicle. Load the blend into hopper manually.
5	Operate the Double Rotary Compression machine as per the current version of SOP: PDOP/010 and reject tablets of the first three round which shall be destroyed as per SOP: QAGN/048.
6	Collect the tablets of one complete rotation and carry out In-process checks for thickness, weight and appearance, record the observations in the BMR. Verify the tablets for uniformity of weight and hardness and record in the BMR.
7	Collect the compressed tablets in double polythene bag lined and labelled cleaned HDPE containers/SS container.
8	Check and record the weight of the compressed tablets.

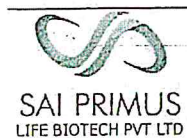
11.2 GRANULES RECEIPT RECORD:

Balance ID. No.: pd/BAL/014 Date: 01/11/2024 Shift: A Time: 06:55

Sr. No.	Gross Weight in Kg	Issued By Production	Checked by Production
1	42.950	L	AK
2	44.200	L	AK
3	39.500	L	AK
4	41.130	L	AK
5	43.840	L	AK
6	41.240	L	AK
7	38.000	L	AK
8	50.980	L	AK
9	33.800	L	AK
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	AK	AK	S. Anand
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: 61210301

Customer:

Generic Health Care Pvt. Ltd.

11.3 COMPRESSION SPECIFICATION / PARAMETERS:

Sr. No.	Parameter	Limits	No. of tablets to be checked from each side	Frequency	
				Production	IPQA
1.	Appearance	White coloured, capsule shaped; beveled edged uncoated tablets with breakline on one side and plain on other side.	20	Every 30 min.	Every 2 Hr.
2.	Average weight(mg)	118.000 mg $\pm$ 2.0 % (115.640 mg – 120.360 mg)	20		
3.	Group Weight	2.360 g $\pm$ 2.0 % (2.313 g to 2.407 g)	20	Every 30 min.	Every 2 Hr.
4.	Uniformity of weight Tablets	118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)	20	Every 2 Hr.	Every 4 Hr.
5.	Hardness	NLT 3.0 Kg (To be established)	4	Every 30 min.	Every 2 Hr.
6.	Thickness (mm)	2.70 mm $\pm$ 0.3 mm (2.40 mm – 3.00 mm) (To be established)	4	Every 30 min.	Every 2 Hr.
7.	Length (mm)	10.10 mm $\pm$ 0.1 mm (10.00 mm – 10.20 mm) (To be established)	30	Initial	
8.	Width (mm)	4.10 mm $\pm$ 0.1 mm (4.00 mm – 4.20 mm) (To be established)	30	Initial	
9.	Friability	NMT 1% w/w	6.5 g	Every 2 Hr.	Every 4 Hr.
10.	Disintegration Time	NMT 15 Minutes	6	Every 2 Hr.	Every 4 Hr.

11.4 COMPRESSION MACHINE RUNNING STATUS:

Date	Shift	Start Time	End Time	M/C Speed	Tablets Output	Done By	Checked By
01/04/2020	G	07:10	21:10	26	2972798	M. Jay	N. Bal

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka			
Date	31/12/2020	31/12/2020	31/12/2020	

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product GENSET

BMR. No.: BMR/T/195-00

Batch No.: 71F210301

Customer:

Generic Health Care Pvt. Ltd.

11.5 INITIAL INPROCESS CHECKS: (Appearance, Uniformity of Weight, Thickness, Length & Width):

Balance I.D. No.: PD1BA4002

Date: 11.04.2021 Shift: 08:00 Time: 00:00

LHS

RHS

Sr. No.	Appearance*	Weight (in mg)	Thickness (in mm)	Length (in mm)	Width (in mm)	Sr. No.	Appearance*	Weight (in mg)	Thickness (in mm)	Length (in mm)	Width (in mm)
1	OK	118	2.71	10.08	4.03	1	OK	118	2.76	10.08	4.03
2	OK	117	2.76	10.04	4.04	2	OK	116	2.71	10.08	4.09
3	OK	116	2.73	10.08	4.03	3	OK	115	2.76	10.08	4.11
4	OK	116	2.78	10.08	4.03	4	OK	116	2.71	10.08	4.04
5	OK	117	2.73	10.11	4.04	5	OK	113	2.76	10.02	4.04
6	OK	116	2.76	10.08	4.04	6	OK	116	2.76	10.08	4.04
7	OK	115	2.73	10.01	4.04	7	OK	117	2.71	10.08	4.04
8	OK	116	2.76	10.08	4.03	8	OK	118	2.71	10.08	4.04
9	OK	116	2.80	10.08	4.05	9	OK	116	2.71	10.08	4.03
10	OK	117	2.73	10.08	4.06	10	OK	113	2.76	10.01	4.05
11	OK	118	2.76	10.08	4.06	11	OK	116	2.71	10.01	4.06
12	OK	117	2.80	10.08	4.05	12	OK	119	2.79	10.08	4.05
13	OK	116	2.71	10.08	4.06	13	OK	118	2.76	10.08	4.06
14	OK	117	2.76	10.02	4.06	14	OK	118	2.71	10.08	4.08
15	OK	118	2.71	10.08	4.01	15	OK	116	2.76	10.08	4.08
16	OK	118	2.71	10.08	4.06	16	OK	119	2.71	10.08	4.06
17	OK	119	2.76	10.08	4.01	17	OK	118	2.76	10.08	4.05
18	OK	116	2.71	10.04	4.06	18	OK	117	2.71	10.08	4.06
19	OK	117	2.76	10.08	4.06	19	OK	118	2.78	10.08	4.03
20	OK	118	2.71	10.08	4.06	20	OK	117	2.71	10.08	4.06
21	OK	118	2.76	10.08	4.05	21	OK	116	2.71	10.08	4.03
22	OK	116	2.71	10.08	4.06	22	OK	117	2.71	10.08	4.03
23	OK	117	2.76	10.08	4.06	23	OK	116	2.76	10.08	4.08
24	OK	118	2.71	10.08	4.01	24	OK	118	2.71	10.08	4.08
25	OK	112	2.76	10.08	4.06	25	OK	113	2.76	10.08	4.08
26	OK	116	2.71	10.08	4.03	26	OK	116	2.76	10.08	4.08
27	OK	118	2.76	10.08	4.06	27	OK	118	2.76	10.08	4.08
28	OK	117	2.71	10.08	4.01	28	OK	116	2.74	10.08	4.03
29	OK	118	2.76	10.08	4.06	29	OK	117	2.76	10.08	4.08
30	OK	119	2.73	10.08	4.05	30	OK	118	2.71	10.08	4.08

Note: * Write OK if complies and (X) if does not comply.

Done by Production Sign/Date: N. Bal 01/04/2021

Checked by IPQA Sign/Date: 01/04/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	POB	21/04/2021	S. Bal
Date	31/12/2020	31/12/2020		

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SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: 31F210301

Customer:

Generic Health Care Pvt. Ltd.

11.6 COMPRESSION SPECIFICATION AND PARAMETERS: Date: 01/04/2024 Shift: 1 Time: 07:36

Parameters	Instrument used	Equip ID No.	Observations of LHS		Observations of RHS		Limits
			Min	Max	Min	Max	
Appearance	Visual	NA	OK		OK		White coloured, capsule shaped, beveled edged uncoated tablets with breakline on one side and plain on other side.
Group Weight	Electronic Balance	PD/BAL/008	2-338 g		2.343 g		2.360 g $\pm$ 2.0 % (2.313 g to 2.407 g)
Average weight	Electronic Balance		116.90 mg		117.40 mg		118.000 mg $\pm$ 2.0 % (115.640 mg – 120.360 mg)
Individual weight	Electronic Balance		115 mg	119 mg	115 mg	118 mg	118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)
Uniformity of weight	Electronic Balance		1-10.65%	1-7.6%	1-2.08%	0.50%	
Thickness	Vernier Caliper	BA/FIL/002	2.70 mm	2.80 mm	2.70 mm	2.75 mm	2.70 mm $\pm$ 0.3 mm (2.40 mm – 3.00 mm) (To be established)
Hardness	Hardness Tester	BA/HPT/001	3	3.5	3.0	3.5	NLT 3.0 Kg (To be established)
Friability	Friabilator	BA/FRT/001	0.06%		0.09%		NMT 1.0% w/w
DT	DT Apparatus	BA/DT/001	02 min 20 sec		02 min 36 sec		NMT 15 minutes

M/C set done by Operator Name: A. Jeyapriya M/C set up Checked by (Prod. Sign/Date): N. Belar 01/04/2024
M/C Speed: 15 RPM (To be Established)

Initial Setting Tablets Destroyed by: Sign: N. Belar Date: 01/04/2024 Quantity in Kg: 0.120 Quantity in No: 106

Approval for Batch Compression by IPQA: Sign: S Date: 01/04/2024 Time: 07:40

N. Belar 01/04/2024

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	POB	S. S. S. S.	
Date	31/12/2020	31/12/2020	31/12/2020	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 23 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product GENSET	BMR. No.: BMR/T/195-00 Customer:		Batch No.: 71F210301 Generic Health Care Pvt. Ltd.

11.7 IN-PROCESS CHECKS: (For Production)

Time	Appearance		Weight of 20 Tablets		Hardness				Thickness				Done by Production
	LHS	RHS	LHS	RHS	LHS	LHS	RHS	RHS	LHS	LHS	RHS	RHS	
	White coloured, capsule shaped, beveled edged uncoated tablets with breakline on one side and plain on other side.		2.360 g $\pm$ 2.0 % (2.313 g to 2.407 g)		NLT 3.0 Kg (To be established)				2.70 mm $\pm$ 0.3 mm (2.40 mm – 3.00 mm) (To be established)				
01/04/2020	OK	OK	2.261	2.379	3.5	3	3	3	2.71	2.80	2.71	2.71	N. Bal
07:40	OK	OK	2.251	2.278	3	3.5	3	3	2.76	2.76	2.76	2.76	N. Bal
08:10	OK	OK	2.261	2.362	3	3.5	3	3	2.81	2.80	2.77	2.80	N. Bal
08:40	OK	OK	2.276	2.276	3.5	3.0	3.5	3	2.71	2.76	2.76	2.78	N. Bal
09:10	OK	OK	2.279	2.361	3	3.5	3.5	3	2.76	2.78	2.78	2.79	N. Bal
09:40	OK	OK	2.279	2.281	3.5	3	3	3.5	2.74	2.78	2.80	2.81	N. Bal
10:12	OK	OK	2.285	2.292	3	3.5	3	3.5	2.75	2.80	2.79	2.76	N. Bal
10:45	OK	OK	2.292	2.310	3.5	3	3.5	3	2.73	2.76	2.75	2.76	N. Bal
11:20	OK	OK	2.292	2.312	3	3.5	3	3.5	2.72	2.75	2.80	2.79	N. Bal
11:52	OK	OK	2.318	2.290	3.5	3	3	3.5	2.79	2.73	2.80	2.78	N. Bal
12:25	OK	OK	2.320	2.298	3	3.5	3	3.5	2.76	2.78	2.78	2.72	N. Bal
12:58	OK	OK	2.310	2.298	3	3.5	3	3.5	2.76	2.76	2.76	2.76	AK
13:30	OK	OK	2.290	2.312	3.5	3	3	3.5	2.78	2.78	2.78	2.78	AK
14:00	OK	OK	2.292	2.292	3	3.5	3.5	3	2.80	2.80	2.80	2.76	AK
14:32	OK	OK	2.312	2.312	3.5	3.5	3	3.5	2.78	2.73	2.79	2.75	AK
15:05	OK	OK	2.292	2.312	3	3.5	3	3.5	2.79	2.75	2.78	2.74	AK
15:37	OK	OK	2.310	2.291	3.5	3.5	3	3.5	2.76	2.77	2.76	2.76	AK
16:10	OK	OK	2.310	2.292	3	3	3.5	3	2.75	2.79	2.75	2.75	AK
16:42	OK	OK	2.292	2.302	3.5	3	3.5	3.5	2.76	2.80	2.74	2.72	AK
17:15	OK	OK	2.291	2.301	3	3	3.5	3	2.76	2.79	2.79	2.75	AK
17:47	OK	OK	2.312	2.302	3.5	3	3	3.5	2.80	2.78	2.80	2.74	AK
18:18	OK	OK	2.312	2.301	3	3	3	3.5	2.78	2.79	2.78	2.76	AK
18:50	OK	OK	2.292	2.292	3.5	3.5	3	3.5	2.76	2.80	2.76	2.79	AK
19:22	OK	OK	2.310	2.291	3	3	3.5	3	2.75	2.79	2.78	2.71	AK
19:55	OK	OK	2.302	2.291	3.5	3.5	3	3.5	2.74	2.71	2.80	2.80	AK
20:30	OK	OK	2.301	2.292	3	3.5	3	3.5	2.76	2.74	2.76	2.79	AK
21:00	OK	OK											

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	[Signature]	[Signature]	[Signature]
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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SAI PRIMUS
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SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: 41F210301

Customer:

Generic Health Care Pvt. Ltd.

11.8 IN-PROCESS CHECKS: (For Production)

Time	Appearance		Weight of 20 Tablets		Hardness				Thickness				Done by Production
	White coloured, capsule shaped, beveled edged uncoated tablets with breakline on one side and plain on other side.		2.360 g ± 2.0 % (2.313 g to 2.407 g)		NLT 3.0 Kg (To be established)				2.70 mm ± 0.3 mm (2.40 mm – 3.00 mm) (To be established)				
	LHS	RHS	LHS	RHS	LHS	LHS	RHS	RHS	LHS	LHS	RHS	RHS	
21:32	OK	OK	2.302	2.298	3.5	3	3	3.5	2.71	2.74	2.73	2.74	AK
22:05	OK	OK	2.298	2.302	3	3.5	3	3.5	2.72	2.76	2.75	2.76	AK
22:30	OK	OK	2.310	2.305	3	3	3.5	3.5	2.76	2.73	2.71	2.77	AK
23:04	OK	OK	2.286	2.311	3.5	3	3.5	3.5	2.73	2.75	2.75	2.74	AK
23:30	OK	OK	2.291	2.303	3	3.5	3.5	3	2.74	2.71	2.77	2.73	AK
00:05	OK	OK	2.296	2.293	3	3.5	3	3.5	2.77	2.74	2.76	2.75	AK
00:31	OK	OK	2.284	2.295	3.5	3	3	3.5	2.72	2.76	2.72	2.76	AK
01:00	OK	OK	2.316	2.298	3.5	3.5	3	3	2.73	2.77	2.74	2.74	AK
01:36	OK	OK	2.311	2.289	3.5	3	3	3.5	2.71	2.73	2.71	2.77	AK
02:05	OK	OK	2.291	2.307	3	3	3.5	3	2.76	2.74	2.71	2.72	AK
02:30	OK	OK	2.289	2.299	3.5	3	3.5	3	2.75	2.73	2.77	2.75	AK
03:06	OK	OK	2.301	2.312	3.5	3.5	3	3.5	2.72	2.73	2.76	2.74	AK
03:32	OK	OK	2.351	2.360	3.5	3	3	3	2.75	2.74	2.71	2.77	AK
04:05	OK	OK	2.361	2.357	3	2.5	3.5	3	2.71	2.76	2.73	2.74	AK
04:36	OK	OK	2.341	2.349	3.5	3	3	3.5	2.75	2.74	2.77	2.72	AK
05:02	OK	OK	2.361	2.355	3	3.5	3	3.5	2.77	2.74	2.71	2.73	AK
05:34	OK	OK	2.354	2.360	3.5	3	3.5	3.5	2.76	2.73	2.77	2.71	AK
06:07	OK	OK	2.349	2.351	3	3.5	3.5	3	2.75	2.76	2.71	2.73	AK
06:36	OK	OK	2.356	2.361	3.5	3	3.5	3	2.73	2.72	2.76	2.74	AK
07:05	OK	OK	2.366	2.352	3	3.5	3	3.5	2.74	2.72	2.71	2.75	AK
07:33	OK	OK	2.339	2.350	3.5	3.5	3.5	3	2.76	2.71	2.75	2.77	AK
08:02	OK	OK	2.361	2.343	3	3.5	3	3.5	2.73	2.76	2.71	2.74	AK
08:35	OK	OK	2.357	2.362	3.5	3	3.5	3	2.71	2.75	2.76	2.72	AK
09:06	OK	OK	2.349	2.350	3.5	3	3	3.5	2.75	2.72	2.74	2.77	AK
09:30	OK	OK	2.362	2.341	3.5	3	3	3	2.77	2.74	2.71	2.76	AK
10:02	OK	OK	2.351	2.361	3	3.5	3	3.5	2.74	2.77	2.72	2.73	AK

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K	AK	AK	AK
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: G13210301

Customer:

Generic Health Care Pvt. Ltd.

11.9 IN-PROCESS CHECKS: (For Production)

Time	Appearance		Weight of 20 Tablets		Hardness				Thickness				Done by Production
	White coloured, capsule shaped, beveled edged uncoated tablets with breakline on one side and plain on other side.		2.360 g $\pm$ 2.0 % (2.313 g to 2.407 g)		NLT 3.0 Kg (To be established)				2.70 mm $\pm$ 0.3 mm (2.40 mm – 3.00 mm) (To be established)				
	LHS	RHS	LHS	RHS	LHS	LHS	RHS	RHS	LHS	LHS	RHS	RHS	
10:35	OK	OK	2.346	2.367	3	3.5	3	3.5	2.76	2.74	2.72	2.75	AS
11:06	OK	OK	2.361	2.352	3.5	3	3.5	3	2.71	2.77	2.73	2.76	AS
11:32	OK	OK	2.355	2.366	3	3.5	3.5	3	2.74	2.72	2.76	2.75	AS
12:04	OK	OK	2.347	2.341	3.5	3	3	3.5	2.77	2.71	2.74	2.76	AS
12:30	OK	OK	2.341	2.359	3.5	3	3.5	3	2.75	2.76	2.77	2.71	AS
13:02	OK	OK	2.369	2.357	3	3.5	2	3.5	2.73	2.75	2.71	2.76	AS
13:35	OK	OK	2.351	2.342	3	3	3.5	3	2.76	2.71	2.75	2.74	AS
14:10	OK	OK	2.349	2.351	3.5	3	3.5	3	2.74	2.76	2.73	2.71	AS
14:37	OK	OK	2.362	2.360	3	3.5	3	3.5	2.71	2.75	2.77	2.76	AS
15:08	OK	OK	2.369	2.357	3	3.5	3.5	2	2.73	2.77	2.71	2.75	AS
15:33	OK	OK	2.356	2.349	3.5	3	3	3.5	2.77	2.72	2.74	2.76	AS
16:02	OK	OK	2.351	2.364	3.5	3	3.5	3	2.75	2.74	2.77	2.77	AS
16:36	OK	OK	2.369	2.341	3	3.5	3.5	3	2.71	2.77	2.73	2.71	AS
17:04	OK	OK	2.371	2.351	3.5	3	3	3.5	2.74	2.75	2.71	2.73	AS
17:35	OK	OK	2.349	2.367	3.5	3	3.5	3	2.77	2.71	2.74	2.76	AS
18:06	OK	OK	2.359	2.348	3	3.5	3	3.5	2.73	2.74	2.76	2.75	AS
18:33	OK	OK	2.352	2.364	3	3.5	3.5	3	2.75	2.76	2.75	2.71	AS
19:04	OK	OK	2.364	2.353	3.5	3	3.5	3	2.72	2.73	2.77	2.76	AS
19:35	OK	OK	2.361	2.351	3	3.5	3	3.5	2.76	2.75	2.78	2.75	AS
20:08	OK	OK	2.356	2.358	3.5	3	3.5	3	2.73	2.78	2.74	2.71	AS
20:40	OK	OK	2.350	2.350	3	3.5	3	3.5	2.71	2.76	2.76	2.73	AS
21:10	OK	OK	2.346	2.359	3.5	3	3.5	3	2.73	2.72	2.71	2.76	AS

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	1.12	21/12/2020	21/12/2020	21/12/2020
Date	31/12/2020	21/12/2020	21/12/2020	21/12/2020

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: 41-210301

Customer:

Generic Health Care Pvt. Ltd.

11.10 IN-PROCESS CHECKS: (For Production)

[illegible]

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.			
Date	31/12/2020	31/12/2020	31/12/2020	

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product GENSET

BMR. No.: BMR/T/195-00

Batch No.: 51F210301

Customer:

Generic Health Care Pvt. Ltd.

11.11 IN-PROCESS CHECKS: (For IPQA)

11.11 IN-PROCESS CHECKS: (For IPQA)													
Time	Appearance		Weight of 20 Tablets		Hardness				Thickness				Done by IPOA
	White coloured, capsule shaped, beveled edged uncoated tablets with breakline on one side and plain on other side.		2.360 g $\pm$ 2.0 % (2.313 g to 2.407 g)		NLT 3.0 Kg (To be established)				2.70 mm $\pm$ 0.3 mm (2.40 mm – 3.00 mm) (To be established)				
	LHS	RHS	LHS	RHS	LHS	LHS	RHS	RHS	LHS	LHS	RHS	RHS	
01:04/24 02:00	Full Hopper OK	OK	2.383	2.377	3.0	3.0	3.0	3.0	2.80	2.82	2.83	2.83	Q
10:05	OK	OK	2.369	2.368	3.0	3.0	3.0	3.0	2.82	2.82	2.81	2.84	Q
12:15	OK	OK	2.366	2.370	3.0	3.0	3.0	3.0	2.83	2.84	2.82	2.85	Q
14:30	OK	OK	2.371	2.374	3.0	3.0	3.0	3.0	2.82	2.84	2.83	2.84	Q
16:40	OK	OK	2.371	2.369	3.0	3.0	3.0	3.0	2.84	2.82	2.83	2.85	Q
18:30	OK	OK	2.364	2.374	3.0	3.0	3.0	3.5	2.80	2.82	2.84	2.85	Q
20:35	OK	OK	2.364	2.367	3.0	3.0	3.0	3.0	2.82	2.84	2.81	2.83	Q
22:40 02:04/202	OK	OK	2.377	2.379	3.5	3.0	3.0	3.5	2.89	2.86	2.82	2.84	Q
00:30	Mid Hopper OK	OK	2.368	2.371	3.0	3.5	3.0	3.0	2.82	2.80	2.82	2.83	Q
02:35	OK	OK	2.374	2.369	3.0	3.5	3.0	3.0	2.83	2.82	2.81	2.82	Q
04:45	OK	OK	2.364	2.370	3.5	3.0	3.5	3.0	2.80	2.82	2.81	2.84	Q
06:40	OK	OK	2.367	2.373	3.5	3.0	3.5	3.0	2.82	2.83	2.84	2.84	Q
08:35	OK	OK	2.365	2.369	3.5	3.5	3.0	3.0	2.84	2.80	2.82	2.85	Q
10:35	OK	OK	2.364	2.374	3.0	3.5	3.5	3.0	2.82	2.83	2.84	2.83	Q
12:45	OK	OK	2.377	2.369	3.5	3.0	3.0	3.0	2.80	2.78	2.83	2.84	Q
14:40	OK	OK	2.374	2.366	3.5	3.0	3.0	3.0	2.84	2.83	2.82	2.83	Q
16:35	OK	OK	2.358	2.364	3.5	3.0	3.5	3.5	2.80	2.80	2.80	2.82	Q
18:20	End Hopper OK	OK	2.364	2.379	3.0	3.0	3.0	3.5	2.80	2.82	2.83	2.83	Q
18:30	L ¹ RPM OK	OK	2.379	2.381	3.0	3.0	3.5	3.0	2.82	2.80	2.82	2.84	Q
18:32	H ¹ RPM OK	OK	2.376	2.384	3.0	3.5	3.0	3.0	2.80	2.78	2.79	2.80	Q
18:45	L ¹ thickness OK	OK	2.366	2.372	3.0	3.0	3.0	3.0	2.87	2.88	2.89	2.86	Q
18:48	H ¹ thickness OK	OK	2.382	2.377	4.0	4.0	4.0	4.0	2.78	2.79	2.76	2.77	Q
18:55	composite OK	OK	2.376	2.381	3.0	3.5	3.0	3.5	2.80	2.81	2.83	2.82	Q

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. K.	PAV	21/12/2020	S. Jeyaraj	
Date	31/12/2020	31/12/2020			

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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Product Code: G13

Batch Size: 30,00,000 Tablets

GENSET

BMR, No.: BMR/T/195-00

Batch No.: HF210301

Customer:

Generic Health Care Pvt. Ltd.

11.12 IN-PROCESS CHECKS: (For IPQA)

[illegible]

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. K.</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	31/12/2020	31/12/2020	31/12/2020	

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

BATCH MANUFACTURING RECORD

Batch Size: 30,00,000 Tablets

Batch No.: 71F210301

GENSET

Generic Health Care Pvt. Ltd.

[illegible]

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	P. K.	[Signature]	[Signature]
Date	31/12/2020	31/12/2020	31/12/2020	8. [Signature]

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

BMR. No.: BMRT/195-00

Batch No.: 4F210301

Customer:

Generic Health Care Pvt. Ltd.

Product: GENSET

NOTE: Initially first 2 entries-2 Hours once remaining entries 4 Hours once for production.

11.14 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date: 01/04/2021		Time: 08:26		Shift: G	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	118	8	116	15	116
2	118	9	118	16	118
3	118	10	113	17	118
4	118	11	116	18	118
5	119	12	117	19	118
6	116	13	118	20	118
7	118	14	118		
Balance ID No.: PD 1BAU008			M/C Speed: 26 RPM		
Group weight of 20 Tablets: 2244.4...g. Avg. wt.: 112.22mg			Group weight of 20 Tablets: 2245.0...g. Avg. wt.: 112.25mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight: 116 mg Max. weight: 118 mg			Min weight: 116 mg Max. weight: 119 mg		
LHS		RHS			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.09%		0.07%	
Disintegration Time (Limit - NMT 15 minutes)		02 min 38 sec		02 min 11 sec	
Equipment ID No.: QA/FRT/ 002		Equipment ID No.: QA/DTA/ 002			
Done by: N. S. R. L. (Production)					
Date: 01/04/2021		Time: 10:35		Shift: G	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	116	8	116	15	118
2	117	9	119	16	119
3	115	10	118	17	118
4	118	11	117	18	117
5	119	12	116	19	116
6	117	13	115	20	115
7	118	14	119		
Balance ID No.: PD 1BAU008			M/C Speed: 25 RPM		
Group weight of 20 Tablets: 2342.0...g. Avg. wt.: 117.10mg			Group weight of 20 Tablets: 2349.0...g. Avg. wt.: 117.45mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight: 115 mg Max. weight: 119 mg			Min weight: 115 mg Max. weight: 119 mg		
LHS		RHS			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.09%		0.07%	
Disintegration Time (Limit - NMT 15 minutes)		02 min 14 sec		02 min 20 sec	
Equipment ID No.: QA/FRT/ 002		Equipment ID No.: QA/DTA/ 002			
Done by: N. S. R. L. (Production)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka			
Date	31/12/2020	31/12/2020	31/12/2020	

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

BMR. No.: BMR/T/195-00

Batch No.: 618210301

Customer:

Generic Health Care Pvt. Ltd.

11.15 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 4 hours):

Date: 01/04/2021		Time: 14:40		Shift: C							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	116	8	119	15	117	1	118	8	118	15	119
2	115	9	117	16	116	2	119	9	117	16	118
3	117	10	116	17	115	3	116	10	116	17	119
4	118	11	115	18	119	4	117	11	119	18	117
5	119	12	117	19	118	5	119	12	118	19	116
6	120	13	119	20	117	6	120	13	116	20	119
7	118	14	118			7	119	14	117		
Balance ID No.: p01 BAC/008				M/C Speed: 25 RPM							
Group weight of 20 Tablets: 2.316.....g. Avg. wt: 117.30..mg				Group weight of 20 Tablets: 2.357.....g. Avg. wt: 117.85..mg							
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)				Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)							
Min weight: 115.....mg Max. weight: 120.....mg				Min weight: 116.....mg Max. weight: 120.....mg							
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		LHS		RHS		Equipment ID No.: QA/FRT/ 002					
Disintegration Time (Limit - NMT 15 minutes)		0.10%		0.12%		Equipment ID No.: QA/DTA/ 002					

Done by: (Production)

Date: 01/04/2021		Time: 18:59		Shift: B							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	117	8	119	15	116	1	117	8	120	15	117
2	119	9	117	16	115	2	119	9	119	16	116
3	120	10	116	17	119	3	116	10	118	17	119
4	119	11	118	18	117	4	115	11	117	18	119
5	117	12	119	19	118	5	116	12	116	19	117
6	116	13	117	20	116	6	117	13	119	20	116
7	118	14	119			7	119	14	119		
Balance ID No.: p01 BAC/001				M/C Speed: 25 RPM							
Group weight of 20 Tablets: 2.352.....g. Avg. wt: 117.60..mg				Group weight of 20 Tablets: 2.351.....g. Avg. wt: 117.55mg							
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)				Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)							
Min weight: 115.....mg Max. weight: 120.....mg				Min weight: 115.....mg Max. weight: 120.....mg							
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		LHS		RHS		Equipment ID No.: QA/FRT/ 002					
Disintegration Time (Limit - NMT 15 minutes)		0.10%		0.12%		Equipment ID No.: QA/DTA/ 002					

Done by: (Production)

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	P. K.	P. K.	P. K.
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No:33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 32 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMR/T/195-00 Customer:	Batch No.: CTB210201 Generic Health Care Pvt. Ltd.

11.16 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 4 hours):

Date: 01/04/2021		Time: 23:05		Shift: C							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	118	8	117	15	118	1	119	8	117	15	119
2	116	9	119	16	117	2	117	9	116	16	117
3	119	10	115	17	116	3	116	10	120	17	118
4	117	11	118	18	118	4	118	11	118	18	120
5	115	12	116	19	115	5	115	12	116	19	116
6	118	13	118	20	119	6	120	13	115	20	115
7	117	14	119			7	119	14	118		
Balance ID No.: PD/BAL/008				M/C Speed: 25 RPM							
Group weight of 20 Tablets: 2345 g. Avg. wt: 117.25 mg				Group weight of 20 Tablets: 2349 g. Avg. wt: 117.45 mg							
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)				Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)							
Min weight: 115 mg Max. weight: 119 mg				Min weight: 115 mg Max. weight: 120 mg							
				LHS		RHS					
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				0.08%		0.06%					
Disintegration Time (Limit - NMT 15 minutes)				03m40s		03m40s					
Equipment ID No.: QA/FRT/				Equipment ID No.: QA/DTA/							
Done by: (Signature) (Production)											
Date: 02/04/2021		Time: 03:10		Shift: C							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	119	8	118	15	118	1	118	8	118	15	120
2	116	9	116	16	116	2	119	9	116	16	117
3	117	10	119	17	118	3	117	10	120	17	118
4	115	11	117	18	117	4	120	11	117	18	119
5	118	12	120	19	116	5	120	12	119	19	116
6	120	13	115	20	115	6	117	13	118	20	120
7	115	14	120			7	119	14	118		
Balance ID No.: PD/BAL/008				M/C Speed: 25 RPM							
Group weight of 20 Tablets: 2345 g. Avg. wt: 117.25 mg				Group weight of 20 Tablets: 2346 g. Avg. wt: 118.3 mg							
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)				Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)							
Min weight: 115 mg Max. weight: 120 mg				Min weight: 116 mg Max. weight: 120 mg							
				LHS		RHS					
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				0.07%		0.08%					
Disintegration Time (Limit - NMT 15 minutes)				03m40s		03m40s					
Equipment ID No.: QA/FRT/				Equipment ID No.: QA/DTA/							
Done by: (Signature) (Production)											

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L.K.	(Signature)	(Signature)	(Signature)	
Date	31/12/2020	31/12/2020	31/12/2020		

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Generic Health Care Pvt. Ltd.

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: 04F210301

Customer:

Generic Health Care Pvt. Ltd.

11.18 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 4 hours):

Date: 02/04/2021		Time: 15:10		Shift: B							
LHS: Individual weight of 20 tablets (in mg).						RHS: Individual weight of 20 tablets (in mg).					
1	117	8	119	15	116	1	119	8	120	15	118
2	118	9	117	16	117	2	117	9	119	16	118
3	119	10	118	17	119	3	115	10	118	17	120
4	116	11	116	18	118	4	116	11	116	18	117
5	120	12	120	19	119	5	118	12	115	19	119
6	115	13	120	20	118	6	118	13	119	20	116
7	118	14	118			7	119	14	119		

Balance ID No.: DD/RAL/008

M/C Speed: 25 RPM

Group weight of 20 Tablets: 2.358 g. Avg.
wt.: 117.9 mgGroup weight of 20 Tablets: 2.354 g. Avg.
wt.: 117.7 mgLimit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)

Min weight: 115 mg Max. weight: 120 mg

Min weight: 115 mg Max. weight: 120 mg

	LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	0.06%	0.02%	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)	01 min 58 sec	02 min 26 sec	Equipment ID No.: QA/DTA/002

Done by: AK/02/04/2021 (Production)

Date:	02/04/2021	Time:	19:15	Shift:	B						
LHS: Individual weight of 20 tablets (in mg).						RHS: Individual weight of 20 tablets (in mg).					
1	115	8	114	15	113	1	117	8	115	15	117
2	113	9	115	16	121	2	116	9	116	16	115
3	114	10	113	17	120	3	119	10	116	17	119
4	116	11	115	18	119	4	121	11	114	18	113
5	115	12	115	19	115	5	120	12	116	19	115
6	117	13	117	20	117	6	121	13	119	20	112
7	116	14	120			7	120	14	119		

Balance ID No.: DD/RAL/008

M/C Speed: 26 RPM

Group weight of 20 Tablets: 2.462 g. Avg.
wt.: 118.1 mgGroup weight of 20 Tablets: 2.339 g. Avg.
wt.: 116.95 mgLimit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)

Min weight: 113 mg Max. weight: 121 mg

Min weight: 112 mg Max. weight: 121 mg

	LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	0.08%	0.06%	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)	02 min 51 sec	02 min 26 sec	Equipment ID No.: QA/DTA/002

Done by: AK/02/04/2021 (Production)

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K.	AK	gill/ak	gill/ak
Date	31/12/2020	21/12/2020	31/12/2020	31/12/2020

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 35 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMR/T/195-00 Customer:	Batch No.: G13210301 Generic Health Care Pvt. Ltd.

11.19 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 4 hours):

Date:		Time :		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Balance ID No.:				M/C Speed: RPM			
Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg) Min weight. :..... mg Max. weight: mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg) Min weight. :..... mg Max. weight: mg			
				LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)				Equipment ID No.: QA/DTA/			
Done by:(Production)							
Date:		Time :		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Balance ID No.:				M/C Speed: RPM			
Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg) Min weight. :..... mg Max. weight: mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg) Min weight. :..... mg Max. weight: mg			
				LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)				Equipment ID No.: QA/DTA/			
Done by:(Production)							

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K.	[Signature]	[Signature]	[Signature]
Date	31/12/2020	21/12/2020	31/12/2020	31/12/2020

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BATCH MANUFACTURING RECORD		Product Code: G13	Batch Size: 30,00,000 Tablets
Product		BMR. No.: BMR/T/195-00	Batch No.: CHF210301
GENSET		Customer:	Generic Health Care Pvt. Ltd.

11.20 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 4 hours):

Date:		Time :		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Balance ID No.:				M/C Speed: RPM			
Group weight of 20 Tablets:.....g. Avg. wt:.....mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg			
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)				Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			
Min weight. :..... mg Max. weight.: mg				Min weight. :..... mg Max. weight.: mg			
				LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						Equipment ID No.: QA/FRT/	
Disintegration Time (Limit - NMT 15 minutes)						Equipment ID No.: QA/DTA/	
Done by:(Production)							
Date:		Time :		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Balance ID No.:				M/C Speed: RPM			
Group weight of 20 Tablets:.....g. Avg. wt:.....mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg			
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)				Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			
Min weight. :..... mg Max. weight.: mg				Min weight. :..... mg Max. weight.: mg			
				LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						Equipment ID No.: QA/FRT/	
Disintegration Time (Limit - NMT 15 minutes)						Equipment ID No.: QA/DTA/	
Done by:(Production)							

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	31/12/2020	31/12/2020	31/12/2020
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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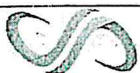
 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 37 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMR/T/195-00 Customer:	Batch No.: G13 10301 Generic Health Care Pvt. Ltd.

11.21 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date: 01/04/2021		Time: 08:15		Shift: G1	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	118	8	118	15	117
2	119	9	119	16	119
3	118	10	117	17	118
4	117	11	118	18	117
5	119	12	118	19	119
6	117	13	117	20	118
7	120	14	118		
Balance ID No.: QA/BAL/002			M/C Speed: 20 RPM		
Group weight of 20 Tablets: 2.361 g. Avg. wt.: 118.05 mg Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg) Min weight: 117 mg Max. weight: 120 mg			Group weight of 20 Tablets: 2.359 g. Avg. wt.: 117.95 mg Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg) Min weight: 116 mg Max. weight: 119 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			LHS: 0.10% RHS: 0.06% Equipment ID No.: QA/FRT/002		
Disintegration Time (Limit - NMT 15 minutes)			LHS: 2 min 38 sec RHS: 2 min 17 sec Equipment ID No.: QA/DTA/002		
Done by: 8/04/2021 (IPQA)					
Date: 01/04/2021		Time: 12:36		Shift: G1	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	117	8	117	15	118
2	118	9	118	16	118
3	119	10	118	17	118
4	118	11	119	18	119
5	117	12	120	19	117
6	118	13	117	20	119
7	117	14	118		
Balance ID No.: QA/BAL/002			M/C Speed: 25 RPM		
Group weight of 20 Tablets: 2.362 g. Avg. wt.: 118.10 mg Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg) Min weight: 117 mg Max. weight: 120 mg			Group weight of 20 Tablets: 2.366 g. Avg. wt.: 118.30 mg Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg) Min weight: 117 mg Max. weight: 119 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			LHS: 0.13% RHS: 0.14% Equipment ID No.: QA/FRT/002		
Disintegration Time (Limit - NMT 15 minutes)			LHS: 2 min 55 sec RHS: 2 min 44 sec Equipment ID No.: QA/DTA/		
Done by: 8/04/2021 (IPQA)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K			
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: G13210301

Customer:

Generic Health Care Pvt. Ltd.

11.22 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date: 01/04/2021		Time: 14:40		Shift: G1	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	117	8	117	15	118
2	117	9	119	16	119
3	118	10	120	17	117
4	117	11	112	18	119
5	119	12	119	19	118
6	120	13	112	20	117
7	121	14	117		
Balance ID No.: QA/BAL/002			M/C Speed: 25 RPM		
Group weight of 20 Tablets: 2367.....g. Avg. wt.: 118.35.....mg			Group weight of 20 Tablets: 2368.....g. Avg. wt.: 118.40.....mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight: 117.....mg Max. weight: 121.....mg			Min weight: 117.....mg Max. weight: 120.....mg		
		LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.13%	0.14%	Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)		2 min 29 sec	2 min 51 sec	Equipment ID No.: QA/DTA/002	
Done by: S. J. A. (IPQA)					
Date: 01/04/2021		Time: 16:50		Shift: G1	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	116	8	120	15	117
2	117	9	117	16	119
3	118	10	119	17	120
4	119	11	118	18	121
5	120	12	117	19	117
6	117	13	119	20	119
7	119	14	120		
Balance ID No.: QA/BAL/002			M/C Speed: 25 RPM		
Group weight of 20 Tablets: 2365.....g. Avg. wt.: 118.25.....mg			Group weight of 20 Tablets: 2371.....g. Avg. wt.: 118.55.....mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight: 116.....mg Max. weight: 120.....mg			Min weight: 117.....mg Max. weight: 119.....mg		
		LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.17%	0.14%	Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)		2 min 29 sec	2 min 24 sec	Equipment ID No.: QA/DTA/002	
Done by: S. J. A. (IPQA)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	PO	S. J. A.	S. J. A.
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 39 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMRT/195-00 Customer:	Batch No.: G1F210301 Generic Health Care Pvt. Ltd.

11.23 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date: 01/04/2021		Time: 18:45		Shift: B	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	116	8	117	15	119
2	117	9	119	16	120
3	119	10	117	17	121
4	120	11	119	18	117
5	121	12	120	19	116
6	122	13	118	20	117
7	119	14	117		
Balance ID No.: QA/BDL/002			M/C Speed: 25 RPM		
Group weight of 20 Tablets: 2372.2 g. Avg. wt.: 118.6 mg Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg) Min weight: 116 mg Max. weight: 122 mg			Group weight of 20 Tablets: 2390.0 g. Avg. wt.: 119.5 mg Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg) Min weight: 117 mg Max. weight: 123 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			LHS	RHS	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)			0.15 sec	0.19 sec	Equipment ID No.: QA/DTA/002
Done by: [Signature] 01/04/2021 (IPQA)					
Date: 01/04/2021		Time: 00:45		Shift: B	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	117	8	117	15	118
2	117	9	118	16	119
3	118	10	116	17	119
4	119	11	117	18	120
5	118	12	118	19	122
6	119	13	119	20	120
7	117	14	120		
Balance ID No.: QA/B44/002			M/C Speed: 25 RPM		
Group weight of 20 Tablets: 2362.0 g. Avg. wt.: 118.1 mg Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg) Min weight: 116 mg Max. weight: 122 mg			Group weight of 20 Tablets: 2386.0 g. Avg. wt.: 119.3 mg Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg) Min weight: 118 mg Max. weight: 122 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			LHS	RHS	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)			0.14 sec	0.19 sec	Equipment ID No.: QA/DTA/002
Done by: [Signature] 01/04/2021 (IPQA)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	POB	[Signature]	[Signature]
Date	31/12/2020	31/12/2020	31/12/2020	

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMRT/195-00

Batch No.: GF210301

Customer:

Generic Health Care Pvt. Ltd.

11.24 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date: 01/04/2021						Time: 02:50						Shift: B																																			
LHS: Individual weight of 20 tablets (in mg).												RHS: Individual weight of 20 tablets (in mg).																																			
1	119	8	117	15	117	1	119	8	117	15	119	2	118	9	119	16	118	3	118	10	118	17	119	4	119	11	118	18	117	5	117	12	117	19	119	6	119	13	118	20	118	7	118	14	119		
Balance ID No.: QA-BAL-002												M/C Speed: 25 RPM																																			
Group weight of 20 Tablets: 2362 g. Avg. wt: 118.1 mg												Group weight of 20 Tablets: 2365 g. Avg. wt: 118.25 mg																																			
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)												Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)																																			
Min weight: 117 mg Max. weight: 119 mg												Min weight: 117 mg Max. weight: 119 mg																																			
LHS												RHS																																			
Friability (Limit: NMT 1% after 4 minutes/100 rotations): 0.21%												Equipment ID No.: QA/FRT/002																																			
Disintegration Time (Limit - NMT 15 minutes): 2 min 49.5 sec												Equipment ID No.: QA/DTA/002																																			
Done by: (Signature) (IPQA)																																															
Date: 02/04/2021						Time: 08:40						Shift: C																																			
LHS: Individual weight of 20 tablets (in mg).												RHS: Individual weight of 20 tablets (in mg).																																			
1	118	8	117	15	119	1	119	8	117	15	117	2	118	9	116	16	119	3	117	10	119	17	118	4	119	11	118	18	117	5	118	12	117	19	116	6	118	13	118	20	117	7	120	14	117		
Balance ID No.: QA-BAL-002												M/C Speed: 25 RPM																																			
Group weight of 20 Tablets: 2374 g. Avg. wt: 118.7 mg												Group weight of 20 Tablets: 2371 g. Avg. wt: 118.55 mg																																			
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)												Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)																																			
Min weight: 117 mg Max. weight: 120 mg												Min weight: 117 mg Max. weight: 120 mg																																			
LHS												RHS																																			
Friability (Limit: NMT 1% after 4 minutes/100 rotations): 0.14%												Equipment ID No.: QA/FRT/002																																			
Disintegration Time (Limit - NMT 15 minutes): 2 min 26.5 sec												Equipment ID No.: QA/DTA/002																																			
Done by: (Signature) (IPQA)																																															

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	PKA	(Signature)	(Signature)
Date	31/12/2020	31/12/2020	31/12/2020	

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMRT/195-00

Batch No.: G13210201

Customer:

Generic Health Care Pvt. Ltd.

11.25 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date: <u>02/03/2021</u>		Time: <u>02:45</u>		Shift: <u>C</u>	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	118	8	119	15	118
2	120	9	120	16	119
3	119	10	117	17	118
4	112	11	119	18	119
5	118	12	118	19	120
6	119	13	119	20	121
7	120	14	121		
Balance ID No.: <u>QA/BAC/002</u>			M/C Speed: <u>26</u> RPM		
Group weight of 20 Tablets: <u>2342</u> g. Avg. wt: <u>117.10</u> mg			Group weight of 20 Tablets: <u>2342</u> g. Avg. wt: <u>117.10</u> mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight: <u>117</u> mg Max. weight: <u>121</u> mg			Min weight: <u>117</u> mg Max. weight: <u>121</u> mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		LHS	RHS	Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)		<u>2 min 31 sec</u>	<u>2 min 37 sec</u>	Equipment ID No.: QA/DTA/002	
Done by: <u>S. Jeyaraj</u> (IPQA)					
Date: <u>02/04/2021</u>		Time: <u>09:55</u>		Shift: <u>C</u>	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	119	8	119	15	119
2	119	9	120	16	118
3	120	10	119	17	117
4	121	11	118	18	119
5	122	12	119	19	120
6	120	13	120	20	121
7	121	14	121		
Balance ID No.: <u>QA/EAC/002</u>			M/C Speed: <u>26</u> RPM		
Group weight of 20 Tablets: <u>2388</u> g. Avg. wt: <u>119.40</u> mg			Group weight of 20 Tablets: <u>2388</u> g. Avg. wt: <u>119.40</u> mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight: <u>117</u> mg Max. weight: <u>122</u> mg			Min weight: <u>117</u> mg Max. weight: <u>122</u> mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		LHS	RHS	Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)		<u>2 min 44 sec</u>	<u>2 min 44 sec</u>	Equipment ID No.: QA/DTA/002	
Done by: <u>S. Jeyaraj</u> (IPQA)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K.</u>	<u>S. Jeyaraj</u>	<u>S. Jeyaraj</u>	<u>S. Jeyaraj</u>
Date	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>31/12/2020</u>

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: 31F210301

Customer:

Generic Health Care Pvt. Ltd.

11.26 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

End Hopper

Date: 02/04/2021						Time: 06:50 18:30						Shift: C																																			
LHS: Individual weight of 20 tablets (in mg).												RHS: Individual weight of 20 tablets (in mg).																																			
1	119	8	117	15	112	1	119	8	116	15	119	2	120	9	117	16	120	3	121	10	112	17	112	4	119	11	112	18	119	5	112	12	119	19	120	6	117	13	120	20	119	7	112	14	119		
Balance ID No.: QA/RAL/002												M/C Speed: 26 RPM																																			
Group weight of 20 Tablets: 2.374 g. Avg. wt: 118.70 mg												Group weight of 20 Tablets: 2.371 g. Avg. wt: 118.55 mg																																			
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)												Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)																																			
Min weight: 117 mg Max. weight: 121 mg												Min weight: 117 mg Max. weight: 121 mg																																			
Friability (Limit: NMT 1% after 4 minutes/100 rotations): 0.19%												Equipment ID No.: QA/FRT/002																																			
Disintegration Time (Limit - NMT 15 minutes): 2 min 14 sec												Equipment ID No.: QA/DTA/002																																			
Done by: 02/04/2021 (IPQA)												L. RPM																																			
Date: 02/04/2021						Time: 08:45 18:40						Shift: C																																			
LHS: Individual weight of 20 tablets (in mg).												RHS: Individual weight of 20 tablets (in mg).																																			
1	112	8	112	15	119	1	112	8	112	15	119	2	120	9	119	16	112	3	121	10	117	17	119	4	119	11	119	18	112	5	112	12	120	19	119	6	112	13	120	20	119	7	119	14	120		
Balance ID No.: QA/RAL/002												M/C Speed: 10 RPM																																			
Group weight of 20 Tablets: 2.386 g. Avg. wt: 119.3 mg												Group weight of 20 Tablets: 2.381 g. Avg. wt: 118.27 mg																																			
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)												Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)																																			
Min weight: 112 mg Max. weight: 121 mg												Min weight: 117 mg Max. weight: 121 mg																																			
Friability (Limit: NMT 1% after 4 minutes/100 rotations): 0.14%												Equipment ID No.: QA/FRT/002																																			
Disintegration Time (Limit - NMT 15 minutes): 2 min 14 sec												Equipment ID No.: QA/DTA/002																																			
Done by: 02/04/2021 (IPQA)																																															

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. K.	P. K.			
Date	31/12/2020	31/12/2020	31/12/2020		

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Generic Health Care Pvt. Ltd.

Done by: (IPQA)

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 44 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET		Batch No.: G13210301 Customer: Generic Health Care Pvt. Ltd.

11.28 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours): H. H. H. H.

Date: 02/04/2021		Time: 12:58		Shift: B	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	112	8	114	15	116
2	119	9	119	16	119
3	120	10	120	17	120
4	121	11	121	18	121
5	122	12	122	19	122
6	113	13	117	20	117
7	119	14	119		
Balance ID No.: QA/BAL/002			M/C Speed: 26 RPM		
Group weight of 20 Tablets: 2.383 g. Avg. wt: 119.15 mg Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg) Min weight: 117 mg Max. weight: 122 mg			Group weight of 20 Tablets: 2.390 g. Avg. wt: 119.5 mg Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg) Min weight: 117 mg Max. weight: 122 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations): 0.14%			RHS: 0.13%		
Disintegration Time (Limit - NMT 15 minutes): 2 min 45 sec			RHS: 2 min 45 sec		
Done by: S. S. S. S. (IPQA)			Composite		
Date: 02/04/2021		Time: 19:04		Shift: B	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	120	8	118	15	119
2	112	9	114	16	120
3	119	10	118	17	114
4	120	11	119	18	119
5	121	12	120	19	118
6	117	13	122	20	119
7	119	14	120		
Balance ID No.: QA/BAL/002			M/C Speed: 26 RPM		
Group weight of 20 Tablets: 2.380 g. Avg. wt: 119.0 mg Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg) Min weight: 117 mg Max. weight: 122 mg			Group weight of 20 Tablets: 2.387 g. Avg. wt: 119.35 mg Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg) Min weight: 117 mg Max. weight: 122 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations): 0.16%			RHS: 0.13%		
Disintegration Time (Limit - NMT 15 minutes): 2 min 45 sec			RHS: 2 min 45 sec		
Done by: S. S. S. S. (IPQA)			Composite		

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. K.				
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020	

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

BMR. No.: BMR/T/195-00

Batch No.: 51F210301

Customer:

Generic Health Care Pvt. Ltd.

Product **GENSET**

11.29 WEIGHING RECORD OF COMPRESSED TABLETS:

S. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Weighed by	Checked by Prod.	Verified by IPQA
1	32.160	2.200	29.960	Drem	Ah	<u>R</u>
2	32.150	2.200	29.950	Drem	Ah	<u>R</u>
3	32.200	2.200	30.000	Drem	Ah	<u>R</u>
4	32.490	2.200	30.290	Drem	Ah	<u>R</u>
5	31.830	2.200	29.630	Drem	Ah	<u>R</u>
6	31.650	2.200	29.450	Drem	Ah	<u>R</u>
7	31.910	2.200	29.710	Drem	Ah	<u>R</u>
8	31.870	2.200	29.670	Drem	Ah	<u>R</u>
9	32.270	2.200	30.070	Drem	Ah	<u>R</u>
10	32.720	2.200	30.520	Drem	Ah	<u>R</u>
11	30.290	2.200	28.090	Drem	Ah	<u>R</u>
12	25.010	2.200	22.810	Drem	Ah	<u>R</u>
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						
25						
26						
27						
28						
29						
30						

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L.K</u>	<u>R</u>	<u>S. Jeyaraj</u>	<u>S. Jeyaraj</u>
Date	31/12/2020	31/12/2020	21/12/2020	31/12/2020

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur. Commune, Puducherry-605009.		Page 46 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMR/T/195-00 Customer:	Batch No.: 618210301 Generic Health Care Pvt. Ltd.

11.30 RECONCILIATION (COMPRESSION STAGE):

Average weight of Uncoated Tablet: 11.2.....mg

1.0	Standard Batch size	:	354.000 Kg.	30,00,000 No.
2.0	Actual weight of Lubricated granules	:	353.440 Kg.	29,95,254 Nos.
3.0	Weight of compressed tablets	:	353.150 Kg.	29,92,198 Nos.
4.0	Rejection during Compression @	:	0.120 Kg.	
5.0	In-process samples of all stages			
	A	IPQC Samples	: 0.120 Kg.	
	B	QC Samples	: 0.010 Kg.	
	C	Validation Samples	: 0.040 Kg.	
6.0	Total in process samples: (A + B + C)	:	0.170 Kg.	
7.0	Total: (3.0 + 6.0)	:	353.320 Kg.	2994231 Nos.
8.0	Yield {7.0 / 1.0 x 100}*	:		99.80 %

* Actually yield will be calculated after 3 validation batches

@Total rejects destroyed: 0.120 Kg. (Rejected materials shall be destroyed as per SOP No.: QAGN/048)

Done by Production Sign/Date: MK/01/04/2021 Checked by IPQA Sign/Date: S/01/04/2021

Test request form raised by Prod Sign/Date: MK/01/04/2021

Test request form received by IPQA Sign/Date: S/01/04/2021

12.0 RELEASED FOR COATING:

Reconciliation checked and compressed tablets released for coating:	
IPQA Sign: <u>S</u>	Date: <u>02/04/2021</u>

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L.K</u>	<u>POB</u>	<u>S/01/04/2021</u>	<u>S/01/04/2021</u>
Date	<u>31/12/2020</u>	<u>31/12/2020</u>		

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: G1310301

Customer:

Generic Health Care Pvt. Ltd.

13.0 LINE CLEARANCE FOR COATING SOLUTION PREPARATION:

Date/Shift/Time: 02/04/2021 / A / 19:02 /

Sr. No.	Checks	*Observation			
		Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty containers, polythene bags, Tags and documents of previous batch/product are removed.	✓	✓		
2	Check and ensure that absence of previous batch/product from area below machine and inside machine.	✓	✓		
3	Check and ensure that machine body, machine parts and control panel are clean.	✓	✓		
4	Check and ensure that absence of previous batch/product below container weighing balance.	✓	✓		
5	Check and ensure that working desk, analytical balance and other accessories are clean.	✓	✓		
6	Check and ensure that Tube light fixture, supply grills, riser grills and filters, electrical fixtures and Drain point are clean.	✓	✓		
7	Check and ensure that instruments to be used are within calibration due date.	✓	✓		
8	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.	✓	✓		
9	Check and ensure that environmental conditions are recorded in the BMR.	✓	✓		
10	Check and ensure that rinse water is released from QC and attached the test request from (TRF) in BMR	✓	✓		
11	Equipment status is updated for Cleaned, Qualification and Preventive maintenance.	✓	✓		

Note: *Tick mark (✓) if Complies and (X) if does not comply.

Equipment	Solution preparation vessel and stirrer	Colloidal Mill	Area
Equipment ID No.	NA	Polcml/001	Soln prep Area
Previous product	Dolox 50		
Batch No.	G1310301		
Cleaned by	bagga		
Checked by Production Sign/Date:	02/04/2021		
Verified by IPQA Sign/Date:	02/04/2021		

ENVIRONMENTAL CONDITIONS:

		Date: 02/04/2021 Time: 19:40			Date: Time:		
		Observation	Prod. Sign.	Verified by IPQA	Observation	Prod. Sign.	Verified by IPQA
(Refer to SOP No.: QAGN/011)	Temperature °C Limit: NMT 25 °C	22°C	✓	✓			
	Relative Humidity % Limit: NMT 60%	50%	✓	✓			

APPROVAL FOR COATING SOLUTION PREPARATION:

Production Sign/Date:.....	02/04/2021
Line Clearance IPQA Sign. / Date:.....	02/04/2021
Start Time/Date:.....	19:46 / 02/04/2021
End Time/Date:.....	23:25 / 02/04/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	POA	21/12/2020	
Date	31/12/2020	31/12/2020		

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 48 of 58
	BATCH MANUFACTURING RECORD	Product Code: G13 BMR. No.: BMR/T/195-00 Customer:	Batch Size: 30,00,000 Tablets Batch No.: <u>G13F210301</u> Generic Health Care Pvt. Ltd.
Product	GENSET		

14.0 Coating Procedure:

14.1 General Instructions:

1. Prepare the coating solution lot wise.
2. Do not use synthetic containers for storage/ transfer of coating solution
3. Do not use high speed stirrer for preparing coating solution. Avoid direct contact of body with Solvent & coating solution. Solvent based coating should be done in spark proof area.

14.2 TABLETS RECEIPT RECORD OF UNCOATED TABLETS FOR COATING:

Balance ID. No.: PD/BAL/OIA

Sr. No.	Description	Observations	Checked By (Production)	Verified By (IPQA)
1.	Total Quantity (Net Qty.in Kg)	353.150	N. BEL 02/04/2021	Q
2.	Number of Containers	12	N. BEL 02/04/2021	Q

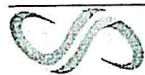
14.3 COATING SOLUTION PREPARATION

14.5 COATING SOLUTION PREPARATION

Sr. No.	General Instructions	Balance ID.:					
1.	Check the cleanliness of the Solution Preparation area and operation as per current version of SOP.						
2.	Use hand gloves while handling the materials						
3.	Transfer the verified coating materials to Coating solution preparation area.						
Step No.	Name of Ingredient & Operation	Time		Done by	Checked by Prod.	Verified by IPQA	
		Start	Finish				
1	LOT I Charge Purified water and Instacoat White (IC-U-3849) in a ss container slowly under continuous stirring. Continue stirring until uniform solution is obtained. If required mill the solution in colloidal mill until uniform solution is obtained. If required filter the solution through 100 nylon mesh if necessary	19:48	20:05	SS99	Q	Q	
2	LOT II Charge Purified water and Instacoat White (IC-U-3849) in a ss container slowly under continuous stirring. Continue stirring until uniform solution is obtained. If required mill the solution in colloidal mill until uniform solution is obtained. If required filter the solution through 100 nylon mesh if necessary	20:30	20:46	SS99	N. BEL	Q	
3	Sieve integrity of 100 nylon mesh before Use	OK #	Not OK #	Checked by	Verified by	Remarks	
		OK	NA	Q	Q		
		OK	NA	N. BEL	Q		
4	Sieve integrity of 100 nylon mesh after Use	OK	NA	Q	Q		
		OK	NA	N. BEL	Q		

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	TOP	3/11/2020	Q. N. K.
Date	31/12/2020	21/12/2020		21/12/2020

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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Product

GENSET

BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

BMR. No.: BMR/T/195-00

Batch No.: G1F210301

Customer:

Generic Health Care Pvt. Ltd.

15.0 COATING AREA:

15.1 LINE CLEARANCE CHECKS: Date/Shift/Time: 02/04/2021...../...../.....

Sr. No.	Checks	*Observation			
		Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty containers, polythene bags, Tags and documents of previous batch/product are removed.	✓	✓		
2	Check and ensure that absence of previous batch/product from area below machine and inside machine.	✓	✓		
3	Check and ensure that machine body, machine parts and control panel are clean.	✓	✓		
4	Check and ensure that absence of previous batch/product below container weighing balance.	✓	✓		
5	Check and ensure that working desk, analytical balance and other accessories are clean.	✓	✓		
6	Check and ensure that Tube light fixture, supply grills, riser grills and filters, electrical fixtures and Drain point are clean.	✓	✓		
7	Check and ensure that instruments to be used are within calibration due date.	✓	✓		
8	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.	✓	✓		
9	Check and ensure that environmental conditions are recorded in the BMR.	✓	✓		
10	Check and ensure that rinse water is released from QC and attached the test request from (TRF)	✓	✓		
11	Equipment status is updated for Cleaned, Qualification and Preventive maintenance.	✓	✓		

Note: *Tick mark (✓) if Complies and (X) if does not comply.

Equipment	Coating Machine	Area
Equipment ID No.	PD/NEC/001	Coating area
Previous product	PD/0250	
Batch No.	G1F210304	
Cleaned by	8099	
Checked by Production Sign/Date:	02/04/2021	
Verified by IPQA Sign/Date:	02/04/2021	

ENVIRONMENTAL
CONDITIONS:

	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Refer to SOP No.: QAGN/011	Temperature °C Limit: NMT 25 °C	23 °C	✓	✓					
	Relative Humidity % Limit: NMT 60%	53 %	✓	✓					
	Differential Pressure (NLT 10 Pascal)	12 pascals	✓	✓					

APPROVAL FOR COATING:

Production Sign/Date:.....	02/04/2021
Line Clearance IPQA Sign. / Date:.....	02/04/2021
Start Time/Date:.....	20:02/02/04/2021
End Time/Date:.....	23:15/02/04/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	✓	✓	✓
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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SAI PRIMUS
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SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: G1F210301

Customer:

Generic Health Care Pvt. Ltd.

16.0 COATING

16.1 INSTRUCTION FOR FILM COATING:

Transfer the compressed tablets to coating area.

1. Load the tablets in coater.
2. Pre-warm the tablets with inlet temp. 55 °C - 60 °C and exhaust temp. 50 °C - 55 °C.
3. Set the spray gun connected to peristaltic pump by silicon tubing and start coating.
4. Carry out in process check after every 30 min. and record.
5. After completion of coating, dry the film coated tablets in the coating pan for about 10 min. with inlet temp. 55 °C - 60 °C.

Note: The film coating suspension need to be stirred slowly during the coating process to prevent suspended solids from setting.

16.2 COATING PROCESS:

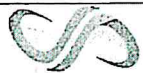
Process Steps						
Step No.	Name of Ingredient & Operation	Time		Done by	Checked by Prod.	Verified by IPQA
		Start	Finish			
LOT I						
1	Transfer the compressed tablets in to the coating Area	20:08	20:13	Sagg	FF	Ar
2	Pre-warm the tablet with inlet temp. 55°C - 60°C and exhaust temp. 50°C - 55°C.	20:14	20:20	Sagg	FF	Ar
3	Arrange the spray gun in such a way that the spray droplets just touch the tablet bed on upper rim. The spray should not fall on the wall of the pan. Weight gain obtained: <u>1.96</u> % (Approx. 2.0%)	20:23	21:30	Sagg	FF	Ar
4	When the spraying is complete, dry the tablets perfectly, in the pan by hot air at NMT 45°C with intermittently flipping the tablets, until no more solvent odour is observed. Caution: Ensure the tablet bed temperature does not rise excessively.	21:32	21:39	Sagg	FF	Ar
5	Found Disintegration Time: <u>02 minutes</u> (Limit: NMT 30 minutes).	21:40	21:45	Sagg	FF	Ar
6	Unload the film coated tablets in a HDPE container lined with double polybag.			Sagg	FF	Ar
LOT II						
7	Transfer the compressed tablets in to the coating Area	21:48	21:50	Sagg	N-BL	Ar
8	Pre-warm the tablet with inlet temp. 55°C - 60°C and exhaust temp. 50°C - 55°C.	21:51	22:56	Sagg	N-BL	Ar
9	Arrange the spray gun in such a way that the spray droplets just touch the tablet bed on upper rim. The spray should not fall on the wall of the pan. Weight gain obtained: <u>1.96</u> % (Approx. 2.0%)	22:59	23:02	Sagg	N-BL	Ar
10	When the spraying is complete, dry the tablets perfectly, in the pan by hot air at NMT 45°C with intermittently flipping the tablets, until no more solvent odour is observed. Caution: Ensure the tablet bed temperature does not rise excessively.	23:01	23:16	Sagg	N-BL	Ar
11	Found Disintegration Time: <u>02 minutes</u> (Limit: NMT 30 minutes).	23:17	23:19	Sagg	N-BL	Ar
12	Unload the film coated tablets in a HDPE container lined with double polybag.			Sagg	N-BL	Ar

16.1 INITIAL CHECKS OF COATING PARAMETERS:

S. No	Parameter	Set	Observed	
			LOT I	LOT II
1	Inlet Temp.	55 °C - 60 °C (To be established)	55°C	55°C
2	Exhaust air Temp.	50 °C - 55 °C (To be established)	52°C	52°C
3	Tablet Bed temp.	50 °C - 55 °C (To be established)	49°C	49°C
4	Atomization air pressure	1.5 - 3 Kg/cm ² (To be established)	2.5 kg/cm ²	2.5 kg/cm ²
5	Pan speed	2.0 - 4.0 RPM (To be established)	3.0 rpm	3.0 rpm
6	Spray rate	50 ml/min - 100 ml/min (To be established)	750 ml/min	750 ml/min
Checked by Production/ Date			Ar 02/04/2021	N-BL 02/04/2021
Verified by IPQA/ Date			Ar 02/04/2021	Ar 02/04/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	Ar	Ar	Ar
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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SAI PRIMUS
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SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: G1F210301

Customer:

Generic Health Care Pvt. Ltd.

16.3 INDIVIDUAL WEIGHT CHECKING OF PRE-WARMED TABLETS:

Sr. No.	Weight (mg)		Sr. No.	Weight (mg)	
	LOT I	LOT II		LOT I	LOT II
1	118	117	11	116	119
2	116	117	12	118	119
3	117	118	13	119	120
4	117	118	14	117	120
5	118	117	15	118	118
6	117	118	16	116	118
7	118	117	17	118	117
8	117	118	18	119	118
9	118	119	19	118	119
10	117	118	20	117	117
Total			2.349 g		
Avg. Weight			117.45 mg		
% of Weight Build up			LOT I: 2.21 %		
			LOT II: 2.21 %		

16.4 PERCENTAGE OF COATING WEIGHT BUILDS UP:

% of Weight buildup = $\frac{\text{Avg. wt. of coated tablets} - \text{Avg. wt. of core tablet (Pre-warmed)}}{\text{Avg. wt. of core tablets (Pre-warmed)}}$

=

16.5 COATING IN-PROCESS CHECKS FOR UNIFORMITY OF WEIGHT: (Frequency: Every 1-Hour for production and 2 hour for IPQA)

Date: 02/04/2021 Shift: B Time: 20:01

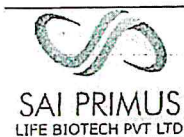
Date	Time	Blower Temp. 55-60 °C (To be established)	Exhaust Air Temp 50-55 °C (To be established)	Bed Temp. 50-55 °C (To be established)	Atomizing Air Pressure 1.5- 3.0 Kg/cm ² (To be established)	Pan RPM 2.0 to 4.0 RPM (To be established)	Weight of 20 Tablets 2.416 g ± 3 % (2.344 g - 2.488 g)	Checked by	Verified by
02/04/2021	20:24	55°C	49°C	40°C	2.5 kg/cm ²	3.0 rpm	2.345 g	IP	IP
02/04/2021	21:26	55°C	49°C	40°C	2.5 kg/cm ²	3.0 rpm	2.398 g	IP	IP
02/04/2021	22:57	55°C	49°C	40°C	2.5 kg/cm ²	3.0 rpm	2.351	MBL	IP
02/04/2021	23:06	55°C	49°C	40°C	2.5 kg/cm ²	3.0 rpm	2.376	MBL	IP

Checked by Production
Sign & Date: IP 02/04/2021

Verified by IPQA
Sign & Date: IP 02/04/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K	IP	IP	IP
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMRT/195-00

Batch No.: HF210301

Customer:

Generic Health Care Pvt. Ltd.

16.6 FINAL COATING PARAMETERS CHECKS: (PRODUCTION)

Parameters	Limits	Observed	
		LOT I	LOT II
Description	White coloured capsule shaped film coated tablets with breakline on one side and plain on other side	OK	OK
Theoretical weight per tablet	120.800 mg $\pm$ 3 % (117.176 mg – 124.424 mg)	120 mg	119
Weight of 20 tablets	2.416 g $\pm$ 3 % (2.344 g – 2.488 g)	2.400 g	2.376
Uniformity of weight	120.800 mg $\pm$ 5 % (114.760 mg – 126.840 mg)	20.66	20.83
Length (mm)	10.20 mm $\pm$ 0.1 mm (10.10 mm – 10.30 mm) (To be established)	10.16 mm	10.17
Width (mm)	4.10 mm $\pm$ 0.1 mm (4.00 mm – 4.20 mm) (To be established)	4.13 mm	4.14
Thickness	(2.50 mm – 3.10 mm) (To be established)	2.87 mm	2.89
Disintegration test	NMT 30 min	03 min 12 sec	03 min 13 sec
Checked by Production/ Date		<u>02/04/2021</u>	<u>02/04/2021</u>

16.7 FINAL COATING PARAMETERS CHECKS: (IPQA)

Parameters	Limits	Observed	
		LOT I	LOT II
Description	White coloured capsule shaped film coated tablets with breakline on one side and plain on other side	OK	OK
Theoretical weight per tablet	120.800 mg $\pm$ 3 % (117.176 mg – 124.424 mg)	119.19	120.10
Weight of 20 tablets	2.416 g $\pm$ 3 % (2.344 g – 2.488 g)	2.3879	2.3999
Uniformity of weight	120.800 mg $\pm$ 5 % (114.760 mg – 126.840 mg)	+1.51%	0.75%
Length (mm)	10.20 mm $\pm$ 0.1 mm (10.10 mm – 10.30 mm) (To be established)	10.15 mm	10.16
Width (mm)	4.10 mm $\pm$ 0.1 mm (4.00 mm – 4.20 mm) (To be established)	4.13 mm	4.12
Thickness	(2.50 mm – 3.10 mm) (To be established)	2.88 mm	2.87
Disintegration test	NMT 30 min	3 min 2-88 mm	3 min 20 sec
Checked by IPQA/ Date		<u>02/04/2021</u>	<u>02/04/2021</u>

16.8 UNIFORMITY CHECKS FOR COATED TABLETS (PRODUCTION)

Sample No.	1	2	3	4	5	6	7	8	9	10
Weight	119	120	121	120	117	119	120	121	120	121
Sample No.	11	12	13	14	15	16	17	18	19	20
Weight	120	119	118	119	119	117	120	120	121	120
Thickness	2.86	2.85	2.86	2.85	2.89					
Group Weight of 20 tablets: <u>2.033</u>										
Checked by Production: <u>N.B.L.</u> <u>02/04/2021</u> Date: <u>02/04/2021</u>										

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L.K.</u>	<u>P.B.</u>	<u>S.K.</u>	<u>S.K.</u>
Date	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>31/12/2020</u>

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: CAF210301

Customer:

Generic Health Care Pvt. Ltd.

16.9 UNIFORMITY CHECKS FOR COATED TABLETS (IPQA)

Sample No.	1	2	3	4	5	6	7	8	9	10
Weight	120	118	119	120	121	119	118	119	119	120
Sample No.	11	12	13	14	15	16	17	18	19	20
Weight	119	120	119	119	120	119	119	120	120	119
Thickness	2.88	2.89	2.88	2.87	2.87					

Group Weight of 20 tablets: 2.3929

Checked by Production:

Date: 02/04/2021

16.10 ACTUAL AVERAGE WEIGHT OF COATED TABLETS:

Weight of 100 coated tablet = 120.05 mg
100

16.11 WEIGHT OF FILM COATED TABLETS:

Container No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Weighed by	Checked by Production	Verified by-IPQA
1	31.420	2.200	29.220	hgf	N. B. L	hgf
2	36.080	2.200	33.880	hgf	N. B. L	hgf
3	35.330	2.200	33.130	hgf	N. B. L	hgf
4	27.530	2.200	25.330	hgf	N. B. L	hgf
5	37.710	2.200	35.510	hgf	N. B. L	hgf
6	44.530	2.200	42.330	hgf	N. B. L	hgf
7	43.940	2.200	41.740	hgf	N. B. L	hgf
8	33.040	2.200	30.840	hgf	N. B. L	hgf
9	39.510	2.200	37.310	hgf	N. B. L	hgf
10	52.150	2.250	49.900	hgf	N. B. L	hgf
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						
25						
26						
27						
28						
29						
30						
TOTAL			359.240			

Prepared by:

Checked by:

Approved By:

Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	hgf	hgf	hgf
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: 78710301

Customer:

Generic Health Care Pvt. Ltd.

16.12 RECONCILIATION (COATING STAGE):

Average weight of coated Tablet: 120.05 mg

1.0	Batch size	:	362.400 Kg.	30,00,000 Nos.
2.0	Weight of coated tablets	:	359.240 Kg.	2992419 Nos.
3.0	Coating loss@	:	0.020 Kg.	
4.0	In-process samples of all stages			
	A	IPQC Samples	: 0.050 Kg.	
	B	QC Samples	: 0.010 Kg.	
	C	Validation Samples	: N/A Kg.	
5.0	Total in process samples: (A + B + C)	:	0.060 Kg.	
6.0	Total: (2.0 + 5.0)	:	359.800 Kg.	2992419 Nos.
7.0	Yield {6.0 x 100 / 1.0}*	:		99.76 %

* Actually yield will be calculated after 3 validation batches

@Total rejects destroyed: 0.020 Kg. (Rejected materials shall be destroyed as per SOP No.: QAGN/048)

Done by Production Sign/Date: N. B. 02/04/2021 Checked by IPQA Sign/Date: 02/04/2021

Test request form raised by Prod Sign/Date: N. B. 02/04/2021

Test request form received by IPQA Sign/Date: 02/04/2021

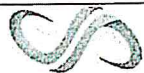
16.13 RELEASE FOR INSPECTION:

Reconciliation checked and Coated tablets released for inspection

IPQA Sign: S Date: 03/05/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	31/12/2020	31/12/2020	31/12/2020
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMRT/195-00

Batch No.: G1F210301

Customer:

Generic Health Care Pvt. Ltd.

17.0 INSPECTION LINE CLEARANCE:

Date/Shift/Time: 03/05/2021 / A / 10:04 /

Sr. No.	Checks	*Observation			
		Prod	IPQA	Prod	IPQA
1	Check and ensure that empty containers, polythene bags, Tags and documents of previous batch/product are removed.	✓	✓		
2	Check and ensure that absence of previous batch/product from area below machine and inside machine.	✓	✓		
3	Check and ensure that machine body, machine parts and control panel are clean.	✓	✓		
4	Check and ensure that absence of previous batch/product below container weighing balance.	✓	✓		
5	Check and ensure that working desk, analytical balance and other accessories are clean.	✓	✓		
6	Check and ensure that Tube light fixture, supply grills, riser grills and filters, electrical fixtures and Drain point are clean.	✓	✓		
7	Check and ensure that instruments to be used are within calibration due date.	✓	✓		
8	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.	✓	✓		
9	Check and ensure that environmental conditions are recorded in the BMR.	✓	✓		
10	Check and ensure that rinse water is released from QC and attached the test request from (TRF) in BMR	NA	NA		
11	Equipment status is updated for Cleaned, Qualification and Preventive maintenance.	✓	✓		

Note: *Tick mark (✓) if Complies and (X) if does not comply.

Equipment	Inspection Belt	Metal Detector	Area
Equipment ID No.	PD/ENB/001	PD/MED/001	Inspection - 01
Previous product	Calciflex - XT		
Batch No.	FC032103E		
Cleaned by	Bangertha		
Checked by Production Sign/Date:	03/05/2021		
Verified by IPQA Sign/Date:	03/05/2021		

ENVIRONMENTAL CONDITIONS:

Date: 03/05/2021 Time: 10:09

Date: Time:

Observation	Prod. Sign.	Verified by IPQA	Observation	Prod. Sign.	Verified by IPQA
28°C	✓	✓			
52% RH	✓	✓			

(Refer to SOP No.: QAGN/011)
Temperature °C Limit: NMT 25 °C
Relative Humidity % Limit: NMT 60%

APPROVAL FOR INSPECTION:

Production Sign/Date: 03/05/2021

Line Clearance IPQA Sign. / Date: 03/05/2021

Start Time/Date: 10:18 / 03/05/2021

End Time/Date: 14:30 / 03/05/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	✓	✓	✓
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMR/T/195-00 Customer:	Batch No.: 718210301 Generic Health Care Pvt. Ltd.

18.0 INSPECTION PROCESS

18.1 INSTRUCTIONS

S. No.	Process Instructions
1	Carry out visual inspection of tablets on inspection belt area as per the SOP No. PDOP/019.
2	Collect inspected tablets in containers lined with polythene bags. Weigh the containers and record the weight.
3	Intimate In-process Quality Assurance.

18.2 PERFORMANCE CHECKS RECORD FOR METAL DETECTOR:

Sr. No.	Process instructions
1.	At the start of the activity, after each break and at the end of operation/shift) as per SOP No. PDGN/022.
2.	Testing frequency: Startup, End of the activity and after every break time.
3.	Acceptance Criteria: 1. Ferrous, Stainless steel & Non-Ferrous shall be detected & rejected.
	2. Nonmetallic shall not be detected.

Date & Time	Trial No.	Metal Detector ID No.: PD/MED/001 & PD/MED/002				Result	Checked by Production	Verified By IPQA
		Ferrous (0.3 mm)	Stainless steel (0.5 mm)	Non-Ferrous (0.3 mm)	Non-metallic			
03/05/2021 10:20	1	✓	✓	✓	x	Pass		
	2	✓	✓	✓	x	Pass		
	3	✓	✓	✓	x	Pass		
03/05/2021 14:30	1	✓	✓	✓	x	Pass		
	2	✓	✓	✓	x	Pass		
	3	✓	✓	✓	x	Pass		
	1							
	2							
	3							
	1							
	2							
	3							
	1							
	2							
	3							

Note: Put ✓ mark for detection and x mark for non-detection
 If during the test Metal Detector fails to reject any of the Standard chips then mention the corrective action taken.

..... (To be filled by Production)

Note: Take QA Approval before proceeding to next stage

18.3 TABLETS VISUAL INSPECTION RECORD:

Date	Container No		Time		Total Quantity Rejected	Tablet Inspection Done by/Date	Checked by/Date
	From	To	Started	Completed			
03/05/2021	10:20	14:30	10:20	14:30	10.190kg	Sanguthi nandh 03/05/2021	03/05/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	P. Ka	S. Ka	S. Ka
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GTF210301

Customer:

Generic Health Care Pvt. Ltd.

18.4 WEIGHING RECORD OF INSPECTED TABLETS:

Container No	Gross weight Kg	Tare weight Kg	Net. weight Kg	Container No	Gross weight Kg	Tare weight Kg	Net. weight Kg
1	31.410	2.200	29.210	16			
2	36.070	2.200	33.870	17			
3	35.320	2.200	33.120	18			
4	27.520	2.200	25.320	19			
5	37.700	2.200	35.500	20			
6	44.520	2.200	42.320	21			
7	43.930	2.200	41.730	22			
8	33.030	2.200	30.830	23			
9	39.510	2.200	37.310	24			
10	42.03	2.200	39.830	25			
11				26			
12				27			
13				28			
14				29			
15				30			
Total			Kg	Total			349.04 Kg
				Grand Total			Kg

Weighing Done By: Checked By Prod./ Date: Verified by IPQA Sign./Date:

18.5 RECONCILIATION: (INSPECTION OF TABLETS)

1.0	Theoretical weight of Tablets	:	362.400 Kg	30,00,000 No's
2.0	Tablets transferred for Inspection	:	359.240 kg	2992419 No's
3.0	Total weight of good Tablets	:	349.04 kg	2907455 No's
4.0	Rejected Tablets	:	10.190 kg	84963 No's
5.0	*Yield = $\frac{3.0}{1.0} \times 100$	:		96.96 %

*Actually yield will be calculated after 3 validation batches.

Total rejects destroyed: Kg.

Rejected materials should be destroyed in the presence of QA.

Done by Production sign/Date:

Checked by IPQA sign/Date:

18.6 RELEASE FOR PACKING:

BMR reviewed by IPQA Sign/Date :

BMR Released for packing by QA Head Sign/Date:

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	DOH	8/11/2020	J. P. M.
Date	31/12/2020	31/12/2020		21/12/2020

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: 51F210301

Customer:

Generic Health Care Pvt. Ltd.

19.0 BMR REVIEW DETAILS:

Reviewed by	Name	Sign./Date
Production Executive	Jarathiaman	[Signature] 03/05/2021
QA Executive	C. Prabhakaran	[Signature] 03/05/2021
Production Assistant Manager/ HOD	Balesubramanian	[Signature] 03/05/2021
QA Manager/ HOD	K. S. Balasubramanian	[Signature] 03/05/2021

20.0 REVISION HISTORY:

Sr. No.	Document No.	Reason for Revision	Supersedes No.
1	BMR/T/195-00	New Document	Nil

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	[Signature]	[Signature]	[Signature]	[Signature]
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMRT/195-00

Batch No.: GF 210216

Customer:

Generic Health Care Pvt. Ltd.

BATCH MANUFACTURING RECORD COVER SHEET

PRODUCT NAME : GENSET

GENERIC NAME : Cetirizine Tablets BP 10 mg

LABEL CLAIM : Each film coated tablet contains:
Cetirizine Hydrochloride BP10 mg
Excipients q.s.
Colour: Approved colour used

MFR No. / Reference Document No. : MFR/T/106-00

BMR No. : BMRT/195-00

REVISION No. : 00

SUPERSEDES No. : NIL

BMR EFFECTIVE BATCH NUMBER/DATE : GF 21 01 01 / 01 / 01 / 2021

MFG.LIC No. : PON/DRUGS/19 13 4323

STORAGE : Store in cool and dry place. Protect from light and moisture.

BMR ISSUED BY/DATE (QA) : 22/02/2021

BMR CHECKED & RECEIVED BY/DATE (PRODUCTION) : P. Anand 23/02/2021

SHELF LIFE : 36 Months

BATCH SIZE : 30,00,000 Tablets (362.400 Kg)

MFG. DATE: 02/2021 EXP. DATE: 01/2024

RECOVERY ADDITION RECORD

BATCH NO	MFG	EXP	QUANTITY	REVISED BATCH SIZE
1	N/A			

ALLOTTED BY: 22/02/2021

QA SIGN/DATE: 22/02/2021

COUNTER CHECKED BY: 22/02/2021

QA SIGN/DATE: 22/02/2021

DATE OF COMMENCEMENT: 25/02/2021

DATE OF COMPLETION: 01/03/2021

RELEASED QUANTITY OF TABLETS FOR PACKING : 2978413 tablets.

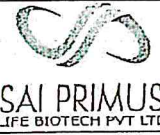
RELEASE FOR PACKING STAGE : 01/02/2024

HEAD OF QA SIGN/DATE:

This BMR contains 58 Pages + Nil Additional Pages

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ke	P. Anand	S. Anand	S. Anand
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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	BATCH MANUFACTURING RECORD	Product Code: G13	Batch Size: 30,00,000 Tablets
	Product	BMR. No.: BMR/T/195-00	Batch No.: GF 210216
		Customer:	Generic Health Care Pvt. Ltd.

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Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	P. Ka	P. Ka	P. Ka
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

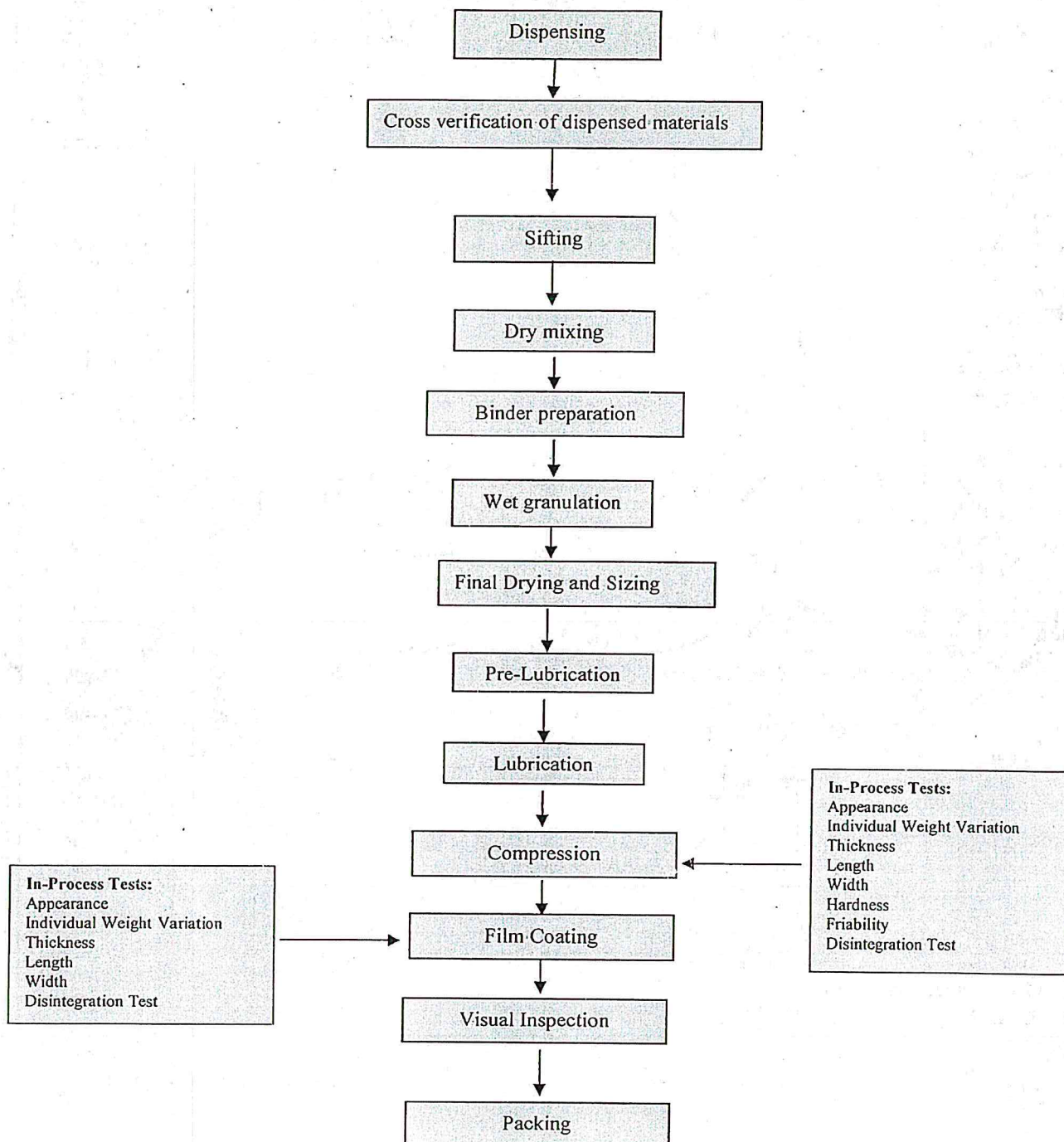
BMR. No.: BMR/T/195-00

Batch No.: GF 210216

Customer:

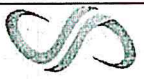
Generic Health Care Pvt. Ltd.

2.0 PROCESS FLOW CHART



Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K. S.	P. S.	S. S.	S. S.
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 4 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13
	Product		Batch Size: 30,00,000 Tablets
GENSET		BMR No.: BMR/T/195-00	Batch No.: 4F210216
		Customer:	Generic Health Care Pvt. Ltd.

3.0 INDENT OF ACTIVE PHARMACEUTICAL INGREDIENTS & EXCIPIENTS:

Sr. No.	Name of the Ingredient	Spec.	Item Code	Quantity/ Tablets (mg)	Std. quantity per 30,00,000 tablets (kg)	OA/ PL (%)	Req. quantity per 30,00,000 tablets (kg)
Dry mixing material:							
1✓	Cetirizine Hydrochloride*	BP	RAI/SP/C018	10.000	30.000	-	30.000
2	Dried Maize Starch**	BP	IRM/SP/M001	59.900	179.700	-	179.700
3✓	Lactose Monohydrate	BP	REX/SP/L003	32.800	98.400	-	98.400
Binder Material:							
4	Dried Maize Starch	BP	IRM/SP/M001	4.270	12.810	-	12.810
5	Purified Water	BP	NA	q.s.	40.000	-	40.000
Theoretical Weight of Dried Granules				106.970	320.910	-	320.910
Lubrication Material:							
6✓	Colloidal Silicon Dioxide	BP	REX/GH/C001	0.470	1.410	-	1.410
7✓	Sodium Starch Glycollate	BP	REX/GH/S001	5.880	17.640	-	17.640
8✓	Purified Talc	BP	REX/SP/P011	2.340	7.020	-	7.020
9✓	Magnesium Stearate	BP	REX/GH/M001	2.340	7.020	-	7.020
Theoretical Weight of the Lubricated granules				118.000	354.000	-	354.000
Theoretical weight of Compressed tablet				118.000	354.000	-	354.000
Coating Material:							
10✓	Instacoat White (IC-U-3849)	IHS	REX/SP/I006	3.500	10.500	-	10.500
11	Purified Water	BP	NA	q.s	25.000	-	25.000
Theoretical weight of Coated tablet				121.500	364.500	-	364.500
Actual weight of Coated tablet				120.800@	362.400@	-	362.400@

NOTE: *API quantity shall be calculated based on potency.

OA: Overages, PL: Process loss

@Average weight has calculated and rounded off to 80% of coating material

Potency calculation:

Theoretical Quantity of Cetirizine Hydrochloride required in Kg for a batch size of 30,00,000 Tablets are calculated.

** Excess Quantity shall be compensating from Dried Maize Starch

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	POA	J. Thirumala	S. Pragasam
Date	31/12/2020	21/12/2020	31/12/2020	31/12/2020

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210216

Customer:

Generic Health Care Pvt. Ltd.

Note: If assay of API is more than 100%, it should be considered as 100% at the time of calculation.

Standard quantity of Cetirizine Hydrochloride (A): 30.000 Kg

Standard quantity of Dried Maize Starch (B): 179.700 kg

Calculation for Cetirizine Hydrochloride:

$$\text{Theoretical Qty} = \frac{\text{Label Claim} \times \text{Std. Batch Size (in no's)}}{1000 \times 1000} = \frac{10 \times 30,00,000}{1000 \times 1000} = 30.000 \text{ kg}$$

1) Calculation for Single A. R. No. 1244/80530, Assay on dried basis: 100.135 w/w, LOD: 0.410 w/w
Exp. Date: 09.12.2024

$$\text{Actual Quantity (Kg) (C)} = \frac{\text{Standard qty. required} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{30.200 \times 100 \times 100}{100 \times (100 - 0.410)} = \frac{30.124}{1} \text{ Kg/2}$$

LOT I: 15.062 Kg, LOT II: 15.062 Kg

2) Calculation for Dried Maize Starch:

Actual Quantity (Kg) (D) = (30.000 Kg + 179.700 Kg) - (C) = 179.576 Kg/2.

LOT I: 89.788 Kg, LOT II: 89.788 Kg

3) Calculation for Cetirizine Hydrochloride Multiple A. R. No.:

Sr. No.	A. R. No.	Available Qty. (Kg) (E)	Assay % w/w	LOD % w/w	Actual Qty. = $\frac{\text{Available Qty.} \times \text{Assay} \times (100 - \text{LOD})}{100 \times 100}$
Total Actual Quantity (F)					

Calculation for Remaining Quantity Required (G):

Theoretical Qty. – Actual Quantity (F) = _____ Kg

AR. No.: _____, Assay on dried basis: _____ w/w, LOD: _____ %w/w, Exp. Date: _____

$$\text{Actual Quantity (Kg) (H)} = \frac{\text{Remaining qty. required (G)} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{\cancel{X} \cdot 100 \times 100}{\cancel{X} (100 -)} = \text{_____ Kg.}$$

Total Qty. of Cetirizine Hydrochloride to be dispensed (I) = (E) + (H) = _____ Kg/2

LOT I: _____ Kg, LOT II: _____ Kg

4) Calculation for Dried Maize Starch:

Actual Quantity (Kg) (J) = (30.000 Kg + 179.700 Kg) – (I) = _____ Kg/2.

LOT I: Kg, LOT II: Kg

Done By/On (QA):

Checked By/On (Production):

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	31/12/2020	31/12/2020	31/12/2020	<i>[Signature]</i>

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210216

Customer:

Generic Health Care Pvt. Ltd.

5.0 DISPENSING LINE CLEARANCE CHECKS

Date: 24/2/21... Time: 10:35

Sr. No.	Checks	Observation*	
		Store	IPQA
1	Check and ensure that empty SS containers, polythene bags, Tags, documents and scrap from waste bin of previous batch/product are removed from the area.	✓	✓
2	Check and ensure that display stand and weighing balance are clean.	✓	✓
3	Check and ensure that SS scoop, SS spatula and SS trolley are clean.	✓	✓
4	Check and ensure that area (floor, walls, ceiling, doors and windows) are clean.	✓	✓
5	Check and ensure that Magnehelic gauges, tube light fixtures, supply grills, return riser grills and filters, electrical fixture are clean.	✓	✓
6	Check and ensure that all the sides of dispensing booth is clean	✓	✓
7	Check all the gauges of dispensing booth before switching ON.	✓	✓
8	Check and ensure that weighing balances and pressure gauges to be used are within calibration due date.	✓	✓
9	Check that the daily records (Balance Logbook, RH & Temp. record) are updated and signed.	✓	✓
10	Equipment status is updated for Cleaned and Preventive maintenance.	✓	✓

Note: *Tick mark (✓) if Complies, (X) if does not comply and (NA) if not applicable.

Equipment	Dispensing Booth	Weighing Balance			Area
ID No.	ST/DPR/001	ST/BM/006	ST/BM/005		D/B
Previous Product	P Pan - DSR				
B. No.	P012103B				
Cleaned by Sign/Date	Ramesh 24/2/21				
Checked by Store Sign/Date	M 24/2/21				
Verified by IPQA Sign/Date	S 24/2/21				

ENVIRONMENTAL CONDITIONS: Date: 24/2/2021. Time: 10:14	Observation	Checked by Store Sign/Date	Verified by IPQA Sign/Date
(For Reference SOP No.: QAGN/011)			
Temperature (Limit: NMT 25°C)	25°	M 24/2/21	S 24/2/21
Relative Humidity % (Limit: NMT 60%)	55%	M 24/2/21	S 24/2/21
Differential Pressure (NLT 10 Pascal)	10 P	M 24/2/21	S 24/2/21
Differential Pressure across the booth Limit: 5 to 20 mm Water	11	M 24/2/21	S 24/2/21

APPROVAL FOR DISPENSING BY IPQA: Sign: [Signature] Date: 24/2/21

Dispensing start Time 10:45 End Time 13:00

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ke	[Signature]	[Signature]	[Signature]
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune,
Puducherry-605009.

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Product

GENSET

BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Spec.

Item code

UOM

Req. Qty.

A.R No.

Gross Wt.

Issued Qty.

Net Wt.

Weighted By Store (Sign & Date)

Checked By (IPQA) (Sign & Date)

Cross Checked by (Sign & Date)

5.1 Dispensing Weighing Sheet:

Balance ID: Date: 24/12/2020 Shift: 1st Time: 10:45

Sr. No.	Ingredients	Spec.	Item code	UOM	Std. Qty.	Req. Qty.	A.R No.	Gross Wt.	Issued Qty.	Net Wt.	Weighted By Store (Sign & Date)	Checked By (IPQA) (Sign & Date)	Cross Checked by (Sign & Date)

LOT - I

Dry mixing material:

1	Cetirizine Hydrochloride*	BP	RAI/SP/C018	Kg	15.000	15.062	15.062	0.220	15.062	15.062	24/12/2020	24/12/2020	24/12/2020
2	Dried Maize Starch**	BP	IRM/SP/M001	Kg	89.850	89.788	89.788	0.220	89.788	89.788	24/12/2020	24/12/2020	24/12/2020
3	Lactose Monohydrate	BP	REX/SP/L003	Kg	49.200	49.200	49.200	0.220	49.200	49.200	24/12/2020	24/12/2020	24/12/2020

Binder Material:

4	Dried Maize Starch	BP	IRM/SP/M001	Kg	6.405	6.405	6.405	0.090	6.405	6.405	24/12/2020	24/12/2020	24/12/2020
5	Purified Water	BP	NA	Kg	20.000	20.000	20.000						

LOT - II

Dry mixing material:

6	Cetirizine Hydrochloride*	BP	RAI/SP/C018	Kg	15.000	15.062	15.062	0.220	15.062	15.062	24/12/2020	24/12/2020	24/12/2020
7	Dried Maize Starch**	BP	IRM/SP/M001	Kg	89.850	89.788	89.788	0.220	89.788	89.788	24/12/2020	24/12/2020	24/12/2020
8	Lactose Monohydrate	BP	REX/SP/L003	Kg	49.200	49.200	49.200	0.220	49.200	49.200	24/12/2020	24/12/2020	24/12/2020

Binder Material:

9	Dried Maize Starch	BP	IRM/SP/M001	Kg	6.405	6.405	6.405	0.090	6.405	6.405	24/12/2020	24/12/2020	24/12/2020
10	Purified Water	BP	NA	Kg	20.000	20.000	20.000						

Prepared by:

Production

Checked by:

Quality Assurance

Approved By:

Head Quality Assurance

Dept.

Sign.

Date

1. kg

31/12/2020

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Factory: R.S. No. 4/3, Kurumbapet Industrial Estate, Villianur Commune,
Puducherry-605009.

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Product

GENSET

BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

BMR. No.: BMR/T/195-00

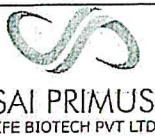
Batch No.: G F 21 0216

Customer: Generic Health Care Pvt. Ltd.

Sr. No.	Ingredients	Spec.	Item code	UOM	Std. Qty.	Req. Qty.	A.R. No.	Issued Qty.			Weighed By Store (Sign & Date)	Checked By (IPQA) (Sign & Date)	Cross Checked by	
								Gross Wt.	Tare Wt.	Net Wt.			Checked Production (Sign & Date)	Verified IPQA (Sign & Date)
Lubrication Material:														
11	Colloidal Silicon Dioxide	BP	REX/GH/C001	Kg	1.410	1.410	PRN/00114	1.630	0.220	1.410	MR/24/21	MR/24/21	MR/24/21	MR/24/21
12	Sodium Starch Glycollate	BP	REX/GH/S001	Kg	17.640	17.640	PRN/00114	17.860	0.220	17.640	MR/24/21	MR/24/21	MR/24/21	MR/24/21
13	Purified Talc	BP	REX/SP/P011	Kg	7.020	7.020	PRN/00114	7.110	0.090	7.020	MR/24/21	MR/24/21	MR/24/21	MR/24/21
14	Magnesium Stearate	BP	REX/GH/M001	Kg	7.020	7.020	PRN/00114	7.240	0.220	7.020	MR/24/21	MR/24/21	MR/24/21	MR/24/21
Coating Material:														
LOT I														
15	Instacoat White (IC-U-3849)	IHS	REX/SP/I006	Kg	5.250	5.250	PRN/00447	5.340	0.090	5.250	MR/24/21	MR/24/21	MR/24/21	MR/24/21
16	Purified Water	BP	NA	Kg	12.500	12.500					MR			
LOT II														
17	Instacoat White (IC-U-3849)	IHS	REX/SP/I006	Kg	5.250	5.250	PRN/00447	5.340	0.090	5.250	MR/24/21	MR/24/21	MR/24/21	MR/24/21
18	Purified Water	BP	NA	Kg	12.500	12.500					MR			

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Quality Assurance		Head Quality Assurance	
Sign.	L. Ka	MR/24/21		MR/24/21	
Date	31/12/2020	21/12/2020		21/12/2020	

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	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 9 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMR/T/195-00 Customer:	Batch No.: 17F210216 Generic Health Care Pvt. Ltd.

6.0 GRANULATION LINE CLEARANCE CHECKS: Date/Shift: 25/02/2021 / 1

Sr. No.	Checks	Time:	*Observations					
			12:00					
			Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty SS containers, polythene bags, Tags and documents of previous batch/product are removed.		✓	✓				
2	Check and ensure that Scrap from waste bin is removed and new polythene bag is put into it.		✓	✓				
3	Check and ensure that display, display stand, weighing balance are clean.		✓	✓				
4	Check and ensure that SS storage Cabinet and Drain point are clean.		✓	✓				
5	Check and ensure that absence of previous batch/product from area below machine		✓	✓				
6	Check and ensure that all equipment body and inside the vessel are clean		✓	✓				
7	Check and ensure that Tube light fixture, supply grills, riser grills and filters and electrical fixtures are clean		✓	✓				
8	Check and ensure that instruments to be used are within calibration due date and earthing connection.		✓	✓				
9	Check and ensure that daily records (Logbook, Balance, Temp. & RH) are updated and signed.		✓	✓				
10	Check and ensure that environment condition and record on BMR		✓	✓				
11	Check and ensure that rinse water is released from QC and attached the test request from (TRF)		NA	NA				
12	Equipment status is updated for Cleaned and Preventive maintenance.		✓	✓				

Note: *Tick mark (✓) if Complies, (X) if does not comply and (NA) if not applicable.

Equipment	Sifter	Multimill	RMG	FBD	Area
E.Q. ID No.	PD/VB3/002	PD/MLM1002	PD/RMG1001	PD/FBD1001	Granulation - II
Previous Product	Dried Maize Starch				
Batch No.	EM10211213				
Cleaned by	Vinayagam				
Checked by	[Signature]				
Verified by	[Signature]				

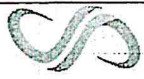
ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 25/02/21 Time: 12:00			Date:			Date:		
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	28°C	✓	✓						
RH % (NMT 60%)	52%	✓	✓						
DP (NLT 10 Pascal)	10 Pascal	✓	✓						

APPROVAL FOR SIFTING AND GRANULATION:

Production Sign/Date:	[Signature] 25/02/21		
IPQA Sign/Date:	[Signature] 25/02/2021		
Start and End Time:	12:05	18:37	

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	[Signature]	[Signature]	[Signature]	[Signature]	
Date	31/12/2020	21/12/2020	31/12/2020	31/12/2020	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur. Commune, Puducherry-605009.		Page 10 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMR/T/195-00 Customer:	Batch No.: 7P210216 Generic Health Care Pvt. Ltd.

7.0 GRANULATION SIFTING INSTRUCTIONS AND SIFTING RECORD: LOT-I Date: 25/02/21 Shift: 9

S. No	Name of Ingredient	Weight before sifting in Kg	Sieve size	ID No.	Sieve Integrity before use	Time		Sieve Integrity after use	Done by	Ckd by
						From	To			
Dry mixing:										
1	Cetirizine Hydrochloride	15.062	40#	10/30-SG-40/02	OK/Not OK	12:05	12:15	OK/Not OK	Mani	L
2	Dried Maize Starch	89.788	30#	10/30-SG-30/04	OK/Not OK	12:16	12:21	OK/Not OK	Mani	L
3	Lactose Monohydrate	49.200	30#		12:22	12:30	Not OK	Mani	L	
Binder Material:										
4	Dried Maize Starch	6.405	NA		NA	NA		NA		
5	Purified Water	90.000								

7.1 MANUFACTURING PROCESS:

Step No.	Process Instructions	Date: 25/02/21		Done by	Checked by
		Time			
		Started	Completed		
1	Dry mixing: Transfer the sifted material from step 7.0 (1-3) into the RMG. Mix for 10 minute with impeller at slow speed and chopper 'off'. Impeller Speed: <u>55</u> RPM	12:31	12:41	Mani	L
2	Binder Preparation: Take purified water and disperse Dried Maize Starch to form slurry.	12:42	12:51	Mani	L
3	Take Purified Water in Paste Kettle and heat till reaches 90°C - 95°C.	12:52	13:00	Mani	L
4	Add the solution from step 7.1(2) to the step 7.1(3) and mix is continuously to form the paste and cool the paste till 40 - 45°C.	13:01	13:10	Mani	L
5	Wet Granulation: Binder Addition: Add binder from step-7.1(4) into the contents of RMG take ____ min for binder addition with impeller slow speed and Chopper OFF. Impeller Speed: <u>55</u> RPM	13:11	13:16	Mani	L
6	After binder addition allow mixing to form a coherent mass. If required allow mixing till required consistency of granules obtained with impeller at slow speed and chopper at slow speed. Total Mixing Time: <u>10</u> mins, Impeller Speed: <u>110</u> RPM, Chopper Speed: <u>2800</u> RPM Additional quantity of Purified Water: <u>19.000</u> Kg	13:17	13:27	Mani	L
7	Note the Ampere at granulation end point <u>25.2</u> AMP.				L
8	Discharge the wet mass to FBD bowl operating slow speed of Impeller and slow speed of Chopper. Impeller Speed: <u>55</u> RPM. Chopper Speed: <u>1440</u> RPM	13:29	13:55	Mani	L

7.2 DRYING:

7.2 DRYING:					
Step No	Process Instructions	Date : 25/02/21		Done by	Checked by
		Time			
		Started	Completed		
1	Load the wet mass into the FBD bowl and air dry the wet mass.				
2	Load the wet mass into the cleaned FBD bowl Dry at inlet temperature 45-55°C till the LOD reached up to 1.5 – 2.0% w/w.	14:17	16:17	Mani	L
3	LOD checking temperature at 105°C (Auto mode). LOD should be 1.5 – 2.0% w/w.	Observed LOD in %		Mani	L
		1.90%			

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. K				
Date	31/12/2020	31/12/2020	31/12/2020		

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SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: 2510216

Customer:

Generic Health Care Pvt. Ltd.

7.3 FBD Finger bag Integrity checks:

S. No.	Items	Integrity before use	Integrity after use	Checked by (Production)	Verified by QA
1.	FBD finger bag	OK	OK	L	H
2.	FBD bowl mesh	OK	OK	L	H

7.4 SET PARAMETERS:

Sr. No.	Operation	Started at	Inlet Temp. (45-55°C)	Outlet Temp.	Product Temp. (To be Established)	Completed at	Total Time (mins)	LOD Observed	Done by	Checked By
1.	Air-Drying-I	14:00	NA	NA	NA	14:10	10	NA	Mami	L
2.	Raking-I	14:11	NA	NA	NA	14:16	05	NA	Mami	L
3.	Drying-I	14:17	55°C	45°C	45°C	16:17	120	1.90%	Mami	L
4.	Raking-II		NA	NA	NA			NA		
5.	Drying-II									
6.	Raking-III		NA	NA	NA			NA		
7.	Drying-III									

Total Drying Time (Exclude Raking & Air-Drying time): 120 min

Total Drying time: 135 min

LOD Verified By IPQA: H
25/02/2021

7.5 SIFTING AND MILLING:

S. No	Process Instructions	Date : 25 / 02 / 21		Done by	Checked by
		Time			
		Started	Completed		
1.	Sift the dried granules through 30 # sieve. Record the observation.	16 : 20	16 : 30	Mami	L
2.	Mill the oversized granules through 1.0 mm multi mill screen fitted with (knives forward medium speed) followed by sifting through 30# sieve on vibrating sifter and collect the sifted granules in double polythene lined cleaned HDPE containers, record the weights.	16 : 31	16 : 41	Mami	L
3.	Unload the granules in to cleaned HDPE containers in double polythene bag.	16 : 42	16 : 50	Mami	L

7.6 SIZING RECORD:

Mesh and screen size	Sieve ID No	Integrity checked before use	Date : 25 / 02 / 21		Integrity checked After use	Done by	Checked by
			Time				
			Started	Completed			
30 #	Pd / 30-55-30/2	OK / Not OK	16 : 20	16 : 41	OK / Not OK	mani	L
1.0 mm	Pd / 1mm-55-1.0/2	OK / Not OK	16 : 31	16 : 46	OK / Not OK	mani	L

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K	PQ		
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: 2510216

Customer:

Generic Health Care Pvt. Ltd.

8.0 GRANULATION SIFTING INSTRUCTIONS AND SIFTING RECORD: LOT-II Date: 25/12/21 Shift: P

S. No	Name of Ingredient	Weight before sifting in Kg	Sieve size	ID No.	Sieve Integrity before use	Time		Sieve Integrity after use	Done by	Ckd by
						From	To			
Dry mixing:										
1	Cetirizine Hydrochloride	15.062	40#	PD/30-SE-40/02	OK/Not OK	14:00	14:07	OK/Not OK	Vinay	P
2	Dried Maize Starch	89.788	30#	PD/30-SE-30/02	OK/Not OK	14:09	14:15	OK/Not OK	Vinay	P
3	Lactose Monohydrate	49.200	30#		OK/Not OK	14:16	14:25	OK/Not OK	Vinay	P
Binder Material:										
4	Dried Maize Starch	6.105	NA		NA			NA		
5	Purified Water									
Lubrication:										
6	Colloidal Silicon Dioxide	1.410	30#	PD/30-SE-30/02	OK/Not OK	14:00	14:02	OK/Not OK	Jayraj	P
7	Sodium Starch Glycollate	17.640	30#		OK/Not OK	14:03	14:04	OK/Not OK	Jayraj	P
8	Purified Talc	7.020	40#	PD/30-SE-40/02	OK/Not OK	14:08	14:10	OK/Not OK	Jayraj	P
9	Magnesium Stearate	7.020	60#	PD/30-SE-60/02	OK/Not OK	14:12	14:14	OK/Not OK	Jayraj	P

8.1 MANUFACTURING PROCESS:

Step No.	Process Instructions	Date: 25/02/21		Done by	Checked by
		Time			
		Started	Completed		
1	Dry mixing: Transfer the sifted material from step 8.0 (1-3) into the RMG. Mix for 10 minute with impeller at slow speed and chopper 'off'. Impeller Speed: <u>55</u> RPM	14:30	14:40	Vinay	P
2	Binder Preparation: Take purified water and disperse Dried Maize Starch to form slurry.	14:22	14:27	mani	P
3	Take Purified Water in Paste Kettle and heat till reaches 90°C - 95°C.	14:27	14:37	mani	P
4	Add the solution from step 8.1(2) to the step 8.1(3) and mix is continuously to form the paste and cool the paste till 40 - 45°C.	14:37	14:41	mani	P
5	Wet Granulation: Binder Addition: Add binder from step-8.1(4) into the contents of RMG take <u>5</u> min for binder addition with impeller slow speed and Chopper OFF. Impeller Speed: <u>55</u> RPM	14:42	14:47	Vinay	P
6	After binder addition allow mixing to form a coherent mass. If required allow mixing till required consistency of granules obtained with impeller at slow speed and chopper at slow speed. Total Mixing Time: <u>10</u> mins, Impeller Speed: <u>110</u> RPM, Chopper Speed: <u>2800</u> RPM Additional quantity of Purified Water <u>10.000</u> Kg	14:48	14:58	Vinay	P
7	Note the Ampere at granulation end point <u>25.000</u> AMP.				P
8	Discharge the wet mass to FBD bowl operating slow speed of Impeller and slow speed of Chopper. Impeller Speed: <u>55</u> RPM Chopper Speed: <u>1400</u> RPM	14:51	15:01	Vinay	P

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka				
Date	31/12/2020	31/12/2020	31/12/2020		

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 13 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
	Product: GENSET	BMR. No.: BMR/T/195-00 Customer:	Batch No.: <i>CF216216</i> Generic Health Care Pvt. Ltd.

8.2 DRYING:

Step No	Process Instructions	Date : 25/02/21		Done by	Checked by
		Time			
		Started	Completed		
1	Load the wet mass into the FBD bowl and air dry the wet mass.				
2	Load the wet mass into the cleaned FBD bowl Dry at inlet temperature 45-55°C till the LOD reached up to 1.5 – 2.0% w/w.	16:50	18:10	Vinay	L
3	LOD checking temperature at 105°C (Auto mode). LOD should be 1.5 – 2.0% w/w.	Observed LOD in %		Vinay	L
		1.82 %			

8.3 FBD Finger bag Integrity checks:

S. No.	Items	Integrity before use	Integrity after use	Checked by (Production)	Verified by QA
1.	FBD finger bag	<i>OK</i>	<i>OK</i>	<i>L</i>	<i>H</i>
2.	FBD bowl mesh	<i>OK</i>	<i>OK</i>	<i>L</i>	<i>H</i>

8.4 SET PARAMETERS:

Sr. No.	Operation	Started at	Inlet Temp. (45-55°C)	Outlet Temp.	Product Temp. (To be Established)	Completed at	Total Time (mins)	LOD Observed	Done by	Checked By
1.	Air-Drying-I	<i>16:20</i>	<i>55</i>	<i>50</i>	<i>50</i>	<i>16:30</i>	<i>10 min</i>	<i>NA</i>	<i>Vinay</i>	<i>L</i>
2.	Raking-I	<i>16:31</i>	<i>NA</i>	<i>NA</i>	<i>NA</i>	<i>16:37</i>	<i>6 min</i>	<i>NA</i>	<i>Mani</i>	<i>L</i>
3.	Drying-I	<i>16:39</i>	<i>55</i>	<i>50</i>	<i>50</i>	<i>18:10</i>	<i>91 min</i>	<i>1.82 %</i>	<i>Vinay</i>	<i>L</i>
4.	Raking-II	<i>18:11</i>	<i>NA</i>	<i>NA</i>	<i>NA</i>			<i>NA</i>		
5.	Drying-II									
6.	Raking-III		<i>NA</i>	<i>NA</i>	<i>NA</i>			<i>NA</i>		
7.	Drying-III									<i>L</i>
Total Drying Time (Exclude Raking & Air-Drying time): <i>91 min</i>								LOD Verified By IPQA:		
Total Drying time: <i>107 min</i>										

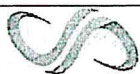
8.5 SIFTING AND MILLING:

DIS SIFTING AND MILLING

S. No	Process Instructions	Date : 25/02/21		Done by	Checked by
		Time			
		Started	Completed		
1.	Sift the dried granules through 30 # sieve. Record the observation.	18:12	18:25	Vinay	L
2.	Mill the oversized granules through 1.0 mm multi mill screen fitted with (knives forward medium speed) followed by sifting through 30# sieve on vibrating sifter and collect the sifted granules in double polythene lined cleaned HDPE containers, record the weights.	18:25	18:34	Vinay	L
3.	Unload the granules in to cleaned HDPE containers in double polythene bag.	18:38	18:40	Vinay	L

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. K.</i>	<i>POB</i>	<i>P. S.</i>	<i>S. Anand</i>
Date	<i>31/12/2020</i>	<i>31/12/2020</i>	<i>31/12/2020</i>	<i>31/12/2020</i>

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LIFE BIOTECH PVT LTD

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: 67F210216

Customer:

Generic Health Care Pvt. Ltd.

8.6 SIZING RECORD:

Mesh and screen size	Sieve ID No	Integrity checked before use	Date : 25/02/21		Integrity checked After use	Done by	Checked by
			Time				
			Started	Completed			
30 #	Pd/30 JE-30/02	OK/Not OK	18:12	18:37	OK/Not OK	Vinay	R
1.0 mm	Pd/1mm. SL-1.0/02	OK/Not OK	18:25	18:30	OK/Not OK	Vinay	R

8.7 WEIGHING OF DRIED GRANULES:

S. No.	Tare Weight (Kg)	Gross Weight (Kg)	Net Weight (Kg)	Weighed By	Checked By
1	2.300	36.420	34.120	Mani	R
2	3.100	41.990	38.890	Mani	R
3	2.600	45.170	42.570	Mani	R
4	2.400	31.610	29.210	Mani	R
5	2.300	17.310	15.010	Mani	R
6	2.300	40.510	38.210	Mani	R
7	2.300	40.860	38.560	Mani	R
8	3.000	46.410	43.410	Mani	R
9	2.300	42.720	40.420	Mani	R
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
Total			320.400		

Theoretical Weight: 320.910 Kg

Theoretical Yield (Weight): Actually yield will be calculated after 3 validation batches.

Actual Yield (Weight): 320.400 Kg % Yield: 99.84 %

Date: 25/02/2022

Production Executive Sign. /Date: 25/02/2024

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.			
Date	31/12/2020	31/12/2020	21/12/2020	31/12/2020

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SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: G13 210216

Customer:

Generic Health Care Pvt. Ltd.

9.0 BLENDING LINE CLEARANCE CHECKS: Date/Shift: 25/02/2021 / 11

Sr. No.	Checks	Time	*Observations					
			19.30					
			Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty SS containers, polythene bags, Tags and documents of previous batch/product are removed.		✓	✓				
2	Check and ensure that Scrap from waste bin is removed and new polythene bag is put into it.		✓	✓				
3	Check and ensure that display, display stand, weighing balance are clean.		✓	✓				
4	Check and ensure that SS storage Cabinet and Drain point are clean.		✓	✓				
5	Check and ensure that absence of previous batch/product from area below machine		✓	✓				
6	Check and ensure that all equipment body and inside the vessel are clean		✓	✓				
7	Check and ensure that Tube light fixture, supply grills, riser grills and filters and electrical fixtures are clean		✓	✓				
8	Check and ensure that instruments to be used are within calibration due date and earthing connection.		✓	✓				
9	Check and ensure that daily records (Logbook, Balance, Temp. & RH) are updated and signed.		✓	✓				
10	Check and ensure that environment condition and record on BMR		✓	✓				
11	Check and ensure that rinse water is released from QC and attached the test request from (TRF)		NA	NA				
12	Equipment status is updated for Cleaned and Preventive maintenance.		✓	✓				

Note: *Tick mark (✓) if Complies, (X) if does not comply and (NA) if not applicable.

Equipment	Blender	Area
EQP. ID No.	PD/003/002	Blender
Previous Product	Ultra B Complex	
Batch No.	UBB 21015	
Cleaned by	Jayaram	
Checked by	8	
Verified by	25/02/2021	

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 25/02/2021 Time: 19.35			Date: Time:			Date: Time:		
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	23	2	21						
RH % (NMT 60%)	53	2	21						
DP (NLT 10 Pascal)	11	2	21						

APPROVAL FOR SIFTING AND BLENDING:

Production Sign/Date:	25/02/2021		
IPQA Sign/Date:	25/02/2021		
Start and End Time:	19.40	20.15	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	25/02/2021	25/02/2021	25/02/2021
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 21 0216

Customer:

Generic Health Care Pvt. Ltd.

9.1 BLENDING AND LUBRICATION PROCESS:

Date 25/02/2021 Shift II

Step No.	Process Instructions	Time		Done by	Checked by Prod.
		Started	Completed		
1	Use hand gloves and goggles while handling the materials.				
2	Operate the Octagonal Blender as per the current version of the SOP No. PDOP/009.				
Pre-lubrication:					
1	Load the dried and sifted granules from step 8.7, sifted Material from step 8.0 (6-8) in to the blender and mix at 10 rpm for 15 minutes (To be established).	19.40	19.55	Jayanti	2
Lubrication:					
2	Load the Sifted Magnesium Stearate into the above Pre-lubricated blend and mix for further 5 minutes at 10 RPM.(To be established).	19.57	20.02	Jayanti	2
3	Unload the lubricated blend in HDPE container having double lined polybag.	20.05	20.15	Jayanti	2

9.2 WEIGHING OF FINAL BLEND:

Balance I.D. No.: P.D.B.A.4005

Date 25/2/2021 Shift II Time: 20.20

Sr. No.	Gross Weight(Kg)	Tare Weight(Kg)	Net weight(Kg)	Weighed by	Checked by Prod.	Verified by IPQA
1	49.770	3.00	46.770	Jayanti	P. Viji	2
2	41.470	2.300	39.170	Ragupathi	P. Viji	2
3	48.310	3.00	45.310	Ragupathi	P. Viji	2
4	47.050	2.400	44.650	Ragupathi	P. Viji	2
5	38.930	2.100	36.830	Ragupathi	P. Viji	2
6	40.890	2.300	38.590	Ragupathi	P. Viji	2
7	42.970	2.300	39.670	Ragupathi	P. Viji	2
8	26.640	2.300	24.340	Ragupathi	P. Viji	2
9	40.470	2.300	38.170	Ragupathi	P. Viji	2
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						
25						
Total:			353.400			

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	I. Ka	DDP	31/12/2020	31/12/2020
Date	31/12/2020	31/12/2020		

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	BATCH MANUFACTURING RECORD	Product Code: G13 BMR. No.: BMR/T/195-00 Customer:	Batch Size: 30,00,000 Tablets Batch No.: G13 210216 Generic Health Care Pvt. Ltd.
Product	GENSET		

9.3 RECONCILIATION:

1.0	Theoretical weight of blend	:	354.000 Kg
2.0	Actual Weight of blend	:	353.400 Kg
3.0	Manufacturing Loss (Blending stage) @	:	0.600 Kg
4.0	In-process samples		
	A IPQC Samples	:	0.030 Kg.
	B QC Samples	:	0.010 Kg.
	C Validation Samples	:	0.050 Kg.
5.0	Total samples: (A + B + C)	:	0.080 Kg
6.0	Total: (2.0 + 5.0)	:	353.480 Kg
7.0	Yield {6.0 / 1.0 x 100}*	:	99.85 %

* Actually yield will be calculated after 3 validation batches.

@Total rejects destroyed: 0.300 Kg. (Rejected materials shall be destroyed as per SOP: QAGN/048).

Recovery Addition Quantity in Kg: 0.04 (Recovery addition materials shall be as per SOP: QAGN/047).

Done by Production sign/Date: P. V. H. 25/02/2021. Checked By IPQA sign/Date: P. V. H. 25/02/2021.

Test request form raised by Prod Sign/Date: P. V. H. 25/02/2021.

Test request form received by IPQA Sign/Date: P. V. H. 25/02/2021.

9.4 RELEASED FOR COMPRESSION:

Reconciliation checked and blend is released for compression

IPQA Sign: P. V. H. 25/02/2021 Date: 25/02/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	P. V. H.	P. V. H.	P. V. H.
Date	31/12/2020	21/12/2020	31/12/2020	21/12/2020

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	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMR/T/195-00 Customer:	Batch No.: <u>GF 210216</u> Generic Health Care Pvt. Ltd.

10.0 COMPRESSION LINE CLEARANCE CHECKS: Date/Shift: 26/02/2021 / C

Sr. No.	Checks	Time:	*Observations					
			05:45					
			Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty SS containers/ containers polythene bags, Tags, and documents of previous batch/product are removed.		✓	✓				
2	Check and ensure that absence of tablets of previous batch/product from area below machine and inside machine by opening the guard of machine.		✓	✓				
3	Check and ensure that the machine body and machine parts like hoppers, feed frame, dust collection chute, hosepipe and ejection chute and control panel are clean.		✓	✓				
4	Check and ensure that absence of tablet of previous batch/product below the weighing balance, check the cleanliness of area and equipment.		✓	✓				
5	Check and ensure that working desk, analytical balance and other accessories are clean.		✓	✓				
6	Check and ensure that Deduster and hosepipe are clean.		✓	✓				
7	Check and ensure that Tube light fixture, supply grills, riser grills and filters and electrical fixtures are clean.		✓	✓				
8	Check and ensure that instruments to be used are within calibration due date, and Punch inspection record		✓	✓				
9	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.		✓	✓				
10	Check and ensure that environmental conditions are recorded in the BMR.		✓	✓				
11	Area, equipment and preventive maintenance status board is updated.		✓	✓				
12	Check and ensure that rinse water is released from QC and attached the test request from (TRF) in BMR		NA	NA				
13	Equipment status is updated for Cleaned and Preventive Maintenance label.		✓	✓				

Note: *Tick mark (✓) if Complies, (X) if does not comply and (NA) if not applicable.

Equipment	Compression Machine	Deduster	Area
EQP ID No.	PD/COM/002	PD/DED/003, PD/DED/004	Compression - II
Previous Product	Ascorbic acid chewable tablet		
Batch No.	ST033B21		
Cleaned by	Azhageppan		
Checked by	AK		
Verified by	AK		

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 26/02/2021	Time: 05:48	Date:	Time:	Date:	Time:
	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	23°C	AK	AK			
RH % (NMT 60%)	52%	AK	AK			
DP (NLT 10 Pascal)	10 pascal	AK	AK			

APPROVAL FOR COMPRESSION:

Production Sign/Date:	AK/26/02/2021		
IPQA Sign/Date:	26/02/2021		
Start and End Time:	05:52	18:35	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	POA	31/12/2020	
Date	31/12/2020	21/12/2020	31/12/2020	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 19 of 58
	BATCH MANUFACTURING RECORD	Product Code: G13 BMR. No.: BMR/T/195-00 Customer:	Batch Size: 30,00,000 Tablets Batch No.: GF 210216 Generic Health Care Pvt. Ltd.
Product	GENSET		

11.0 COMPRESSION

11.1 PROCESS INSTRUCTIONS:

Sr. No.	Process Instructions
1	Check the cleanliness of area and equipment.
2	Ensure that the correct punch set are issued as per the Punch issue record.
3	Set the Double Rotary Compression Machine with a. Upper punches: 10.00 x 4.00 mm caplet shaped with breakline punches. b. Lower punches: 10.00 x 4.00 mm caplet shaped plain punches. c. Dies: 10.00 x 4.00 mm suitable for above punches. d. Type of tooling - D.
4	Punch Issued by: sign./Date: <u>AK/26/02/2021</u> Checked and Received by Sign./Date: <u>AK/26/02/2021</u> Verified by Sign./Date: <u>AK/26/02/2021</u>
4	Transfer the blend to compression cubicle. Load the blend into hopper manually.
5	Operate the Double Rotary Compression machine as per the current version of SOP: PDOP/010 and reject tablets of the first three round which shall be destroyed as per SOP: QAGN/048.
6	Collect the tablets of one complete rotation and carry out In-process checks for thickness, weight and appearance, record the observations in the BMR. Verify the tablets for uniformity of weight and hardness and record in the BMR.
7	Collect the compressed tablets in double polythene bag lined and labelled cleaned HDPE containers/SS container.
8	Check and record the weight of the compressed tablets.

11.2 GRANULES RECEIPT RECORD:

Balance ID. No.: PD/BAL/005014 Date: 26/02/2021 Shift: C Time: 05:55

Sr. No.	Gross Weight in Kg	Issued By Production	Checked by Production
1	49.770	P. Vijay	AK
2	41.970	P. Vijay	AK
3	48.310	P. Vijay	AK
4	47.050	P. Vijay	AK
5	38.930	P. Vijay	AK
6	40.890	P. Vijay	AK
7	42.070	P. Vijay	AK
8	26.640	P. Vijay	AK
9	40.470	P. Vijay	AK
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>I. K.</u>	<u>AK</u>	<u>AK</u>	<u>AK</u>
Date	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>31/12/2020</u>

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF910216

Customer:

Generic Health Care Pvt. Ltd.

11.3 COMPRESSION SPECIFICATION / PARAMETERS:

Sr. No.	Parameter	Limits	No. of tablets to be checked from each side	Frequency	
				Production	IPQA
1.	Appearance	White coloured, capsule shaped, beveled edged uncoated tablets with breakline on one side and plain on other side.	20	Every 30 min.	Every 2 Hr.
2.	Average weight(mg)	118.000 mg $\pm$ 2.0 % (115.640 mg – 120.360 mg)	20		
3.	Group Weight	2.360 g $\pm$ 2.0 % (2.313 g to 2.407 g)	20	Every 30 min.	Every 2 Hr.
4.	Uniformity of weight Tablets	118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)	20	Every 2 Hr.	Every 4 Hr.
5.	Hardness	NLT 3.0 Kg (To be established)	4	Every 30 min.	Every 2 Hr.
6.	Thickness (mm)	2.70 mm $\pm$ 0.3 mm (2.40 mm – 3.00 mm) (To be established)	4	Every 30 min.	Every 2 Hr.
7.	Length (mm)	10.10 mm $\pm$ 0.1 mm (10.00 mm – 10.20 mm) (To be established)	30	Initial	
8.	Width (mm)	4.10 mm $\pm$ 0.1 mm (4.00 mm – 4.20 mm) (To be established)	30	Initial	
9.	Friability	NMT 1% w/w	6.5 g	Every 2 Hr.	Every 4 Hr.
10.	Disintegration Time	NMT 15 Minutes	6	Every 2 Hr.	Every 4 Hr.

11.4 COMPRESSION MACHINE RUNNING STATUS:

Date	Shift	Start Time	End Time	M/C Speed	Tablets Output	Done By	Checked By
31/12/2020	G	06:02	18:25	25	2986355	Vimal	N. Behera

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka			
Date	31/12/2020	31/12/2020	31/12/2020	

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210216

Customer:

Generic Health Care Pvt. Ltd.

11.5 INITIAL INPROCESS CHECKS: (Appearance, Uniformity of Weight, Thickness, Length & Width):

Balance I.D. No.: PD/BAL/008

Date: 26/02/2021. Shift: C Time: 06:02...

LHS

RHS

Sr. No.	Appearance*	Weight (in mg)	Thickness (in mm)	Length (in mm)	Width (in mm)	Sr. No.	Appearance*	Weight (in mg)	Thickness (in mm)	Length (in mm)	Width (in mm)
1	OK	117	2.66	10.04	4.04	1	OK	116	2.67	10.01	4.05
2	OK	119	2.68	10.03	4.05	2	OK	118	2.66	10.03	4.06
3	OK	116	2.71	10.03	4.04	3	OK	117	2.68	10.05	4.04
4	OK	118	2.67	10.02	4.06	4	OK	119	2.71	10.01	4.05
5	OK	117	2.64	10.05	4.05	5	OK	117	2.69	10.03	4.04
6	OK	116	2.66	10.04	4.04	6	OK	117	2.67	10.01	4.05
7	OK	118	2.66	10.03	4.06	7	OK	117	2.66	10.05	4.07
8	OK	117	2.71	10.05	4.04	8	OK	119	2.69	10.03	4.06
9	OK	117	2.68	10.04	4.06	9	OK	116	2.72	10.01	4.04
10	OK	118	2.64	10.03	4.05	10	OK	118	2.71	10.05	4.06
11	OK	117	2.66	10.05	4.04	11	OK	119	2.70	10.03	4.07
12	OK	119	2.67	10.01	4.06	12	OK	119	2.62	10.01	4.06
13	OK	117	2.68	10.02	4.04	13	OK	120	2.60	10.02	4.05
14	OK	118	2.66	10.05	4.06	14	OK	117	2.71	10.03	4.04
15	OK	120	2.65	10.03	4.04	15	OK	119	2.73	10.05	4.07
16	OK	116	2.68	10.01	4.05	16	OK	118	2.71	10.03	4.06
17	OK	118	2.68	10.04	4.06	17	OK	117	2.68	10.03	4.05
18	OK	117	2.71	10.01	4.04	18	OK	118	2.66	10.03	4.07
19	OK	117	2.68	10.05	4.06	19	OK	117	2.64	10.05	4.08
20	OK	119	2.67	10.06	4.05	20	OK	119	2.67	10.01	4.07
21	OK	118	2.71	10.04	4.05	21	OK	117	2.68	10.05	4.06
22	OK	117	2.72	10.02	4.07	22	OK	116	2.71	10.03	4.06
23	OK	119	2.68	10.04	4.06	23	OK	120	2.71	10.01	4.08
24	OK	118	2.67	10.05	4.04	24	OK	120	2.66	10.03	4.05
25	OK	117	2.65	10.04	4.06	25	OK	117	2.66	10.04	4.04
26	OK	120	2.68	10.07	4.04	26	OK	119	2.68	10.06	4.03
27	OK	116	2.65	10.06	4.05	27	OK	117	2.67	10.05	4.05
28	OK	119	2.71	10.03	4.06	28	OK	117	2.68	10.03	4.03
29	OK	117	2.66	10.05	4.05	29	OK	118	2.71	10.04	4.04
30	OK	117	2.68	10.06	4.04	30	OK	117	2.70	10.02	4.06

Note: * Write OK if complies and (X) if does not comply.

Done by Production Sign/Date: AK/26/02/2021...

Checked by IPQA Sign/Date: 26/02/2021...

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K.</u>	<u>PKB</u>	<u>26/02/2021</u>	<u>S. Jeyaraj</u>
Date	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>31/12/2020</u>

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 22 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET		BMR. No.: BMR/T/195-00 Batch No.: GF 210216 Customer: Generic Health Care Pvt. Ltd.

11.6 COMPRESSION SPECIFICATION AND PARAMETERS: Date: 26/02/2021 Shift: I Time: 06:20

Parameters	Instrument used	Equip ID No.	Observations of LHS		Observations of RHS		Limits
			Min	Max	Min	Max	
Appearance	Visual	NA	OK		OK		White coloured, capsule shaped, beveled edged uncoated tablets with breakline on one side and plain on other side.
Group Weight	Electronic Balance	PO/BAL/008	2.353 g		2.360 g		2.360 g $\pm$ 2.0 % (2.313 g to 2.407 g)
Average weight	Electronic Balance		117.65 mg		118 mg		118.000 mg $\pm$ 2.0 % (115.640 mg – 120.360 mg)
Individual weight	Electronic Balance		116 mg	120 mg	117 mg	120 mg	118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)
Uniformity of weight	Electronic Balance		101.42%	111.95%	108.5%	116.6%	
Thickness	Vernier Caliper	QA/VEC/001	2.66 mm	2.71 mm	2.60 mm	2.72 mm	2.70 mm $\pm$ 0.3 mm (2.40 mm – 3.00 mm) (To be established)
Hardness	Hardness Tester	QA/HRD/001	3	3.0	3.1	3.0	NLT 3.0 Kg (To be established)
Friability	Friabilator	QA/FRI/002	0.21%		0.19		NMT 1.0% w/w
DT	DT Apparatus	QA/DTA/002	09 min 01 sec		09 min 20 sec		NMT 15 minutes

M/C set done by Operator Name: Anglagappan.... M/C set up Checked by (Prod. Sign/Date): 14/02/2021
 M/C Speed: 12 RPM (To be Established)

Initial Setting Tablets Destroyed by: Sign: Anglagappan... Date: 26/02/2021 Quantity in Kg.: 0.41 Quantity in No.: 347.....

Approval for Batch Compression by IPQA: Sign: [Signature] Date: 26/02/2021 Time: 06:20

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	[Signature]	[Signature]	[Signature]
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: G F 210216

Customer:

Generic Health Care Pvt. Ltd.

11.7 IN-PROCESS CHECKS: (For Production)

Time	Appearance		Weight of 20 Tablets		Hardness				Thickness				Done by Production
	White coloured, capsule shaped, beveled edged uncoated tablets with breakline on one side and plain on other side.		2.360 g $\pm$ 2.0 % (2.313 g to 2.407 g)		NLT 3.0 Kg (To be established)				2.70 mm $\pm$ 0.3 mm (2.40 mm – 3.00 mm) (To be established)				
	LHS	RHS	LHS	RHS	LHS	LHS	RHS	RHS	LHS	LHS	RHS	RHS	
06:30	OK	OK	2.370	2.362	3.5	3.0	3.5	3.0	2.68	2.71	2.67	2.66	AK
07:02	OK	OK	2.325	2.356	3.0	3.5	3.0	3.5	2.72	2.68	2.69	2.70	AK
07:35	OK	OK	2.368	2.376	3.5	3.0	3.5	3.0	2.71	2.72	2.68	2.70	AK
08:05	OK	OK	2.365	2.352	3.0	3.5	3.0	3.5	2.70	2.70	2.71	2.72	AK
08:36	OK	OK	2.362	2.354	3.0	3.5	3.5	3.0	2.70	2.61	2.62	2.63	N. Bel
09:10	OK	OK	2.371	2.351	3.5	3.0	3.0	3.0	2.68	2.68	2.67	2.62	N. Bel
09:40	OK	OK	2.368	2.368	3.0	3.0	3.5	3.5	2.62	2.71	2.72	2.73	N. Bel
10:10	OK	OK	2.357	2.362	3.5	3.0	2.5	3.0	2.62	2.62	2.61	2.68	N. Bel
10:40	OK	OK	2.354	2.354	3.0	3.5	3.0	3.5	2.65	2.63	2.62	2.67	N. Bel
11:10	OK	OK	2.354	2.356	3.5	3.0	3.5	3.0	2.61	2.71	2.72	2.73	N. Bel
11:40	OK	OK	2.363	2.354	3.0	3.5	3.0	3.0	2.72	2.73	2.72	2.68	N. Bel
12:10	OK	OK	2.376	2.491	3.5	3.0	3.0	3.5	2.73	2.72	2.71	2.72	N. Bel
12:40	OK	OK	2.354	2.496	3.0	3.5	3.5	3.0	2.72	2.72	2.62	2.68	N. Bel
13:10	OK	OK	2.362	2.351	3.5	3.0	3.0	3.5	2.65	2.76	2.76	2.76	N. Bel
13:40	OK	OK	2.371	2.362	3.0	3.5	3.5	3.0	2.64	2.72	2.68	2.77	N. Bel
14:10	OK	OK	2.356	2.354	3.5	3.0	3.0	3.0	2.63	2.76	2.71	2.61	N. Bel
14:40	OK	OK	2.341	2.356	3.0	3.5	3.0	3.5	2.61	2.71	2.76	2.68	N. Bel
15:10	OK	OK	2.352	2.342	3.5	3.0	3.5	3.0	2.65	2.73	2.75	2.71	AK
15:45	OK	OK	2.324	2.368	3.0	3.5	3.0	3.5	2.71	2.75	2.68	2.74	AK
16:15	OK	OK	2.362	2.372	3.5	3.0	3.5	3.0	2.68	2.72	2.72	2.63	AK
16:50	OK	OK	2.372	2.296	3.0	3.5	3.0	3.5	2.73	2.69	2.78	2.61	AK
17:20	OK	OK	2.361	2.372	3.5	3.0	3.5	3.0	2.71	2.67	2.71	2.64	AK
17:55	OK	OK	2.350	2.351	3.0	3.5	3.0	3.5	2.69	2.73	2.71	2.73	AK
18:28	OK	OK	2.353	2.496	3.5	3.0	3.5	3.0	2.72	2.71	2.68	2.75	AK
19:00	OK	OK	2.372	2.363	3.5	3.0	3.5	3.0	2.75	2.68	2.72	2.68	AK
19:32	OK	OK	2.361	2.374	3.0	3.5	3.0	3.5	2.68	2.73	2.73	2.77	AK

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	P. K.	P. K.	
Date	31/12/2020	31/12/2020	31/12/2020	

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur.
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210216

Customer:

Generic Health Care Pvt. Ltd.

11.8 IN-PROCESS CHECKS: (For Production)

Time	Appearance		Weight of 20 Tablets		Hardness				Thickness				Done by Production
	White coloured, capsule shaped, beveled edged uncoated tablets with breakline on one side and plain on other side.		2.360 g $\pm$ 2.0 % (2.313 g to 2.407 g)		NLT 3.0 Kg (To be established)				2.70 mm $\pm$ 0.3 mm (2.40 mm – 3.00 mm) (To be established)				
	LHS	RHS	LHS	RHS	LHS	LHS	RHS	RHS	LHS	LHS	RHS	RHS	
20:05	OK	OK	2.352	2.348	3.5	3.0	3.5	3.0	2.68	2.71	2.73	2.69	AK
20:35	OK	OK	2.342	2.356	3.0	3.5	3.0	3.5	2.73	2.75	2.77	2.72	AK
21:10	OK	OK	2.349	2.340	3.5	3.0	3.5	3.0	2.78	2.72	2.69	2.70	AK
21:42	OK	OK	2.362	2.296	3.0	3.5	3.0	3.5	2.73	2.71	2.68	2.72	AK
22:15	OK	OK	2.358	2.352	3.5	3.0	3.5	3.0	2.75	2.69	2.72	2.75	AK
22:48	OK	OK	2.351	2.365	3.0	3.5	3.0	3.5	2.78	2.73	2.71	2.68	AK
23:20	OK	OK	2.346	2.358	3.5	3.0	3.5	3.0	2.72	2.75	2.69	2.73	AK
23:50	OK	OK	2.342	2.321	3.0	3.5	3.0	3.5	2.68	2.77	2.72	2.75	AK
00:20	OK	OK	2.368	2.315	3.5	3.0	3.5	3.0	2.75	2.72	2.78	2.73	AK
00:52	OK	OK	2.347	2.378	3.0	3.5	3.0	3.5	2.72	2.68	2.71	2.71	AK
01:30	OK	OK	2.352	2.363	3.5	3.0	3.5	3.0	2.70	2.75	2.69	2.75	AK
02:02	OK	OK	2.348	2.336	3.0	3.5	3.0	3.5	2.68	2.72	2.72	2.77	AK
02:35	OK	OK	2.365	2.325	3.5	3.0	3.5	3.0	2.72	2.69	2.68	2.69	AK
03:05	OK	OK	2.347	2.356	3.0	3.5	3.0	3.5	2.69	2.67	2.72	2.65	AK
03:40	OK	OK	2.366	2.362	3.5	3.0	3.5	3.0	2.71	2.65	2.69	2.72	AK
04:20	OK	OK	2.370	2.352	3.0	3.5	3.0	3.5	2.75	2.72	2.75	2.75	AK
04:55	OK	OK	2.326	2.316	3.5	3.0	3.5	3.0	2.67	2.78	2.68	2.67	AK
05:25	OK	OK	2.342	2.348	3.0	3.5	3.0	3.5	2.69	2.69	2.75	2.69	AK
05:58	OK	OK	2.365	2.360	3.5	3.0	3.5	3.0	2.72	2.71	2.74	2.72	AK
06:30	OK	OK	2.325	2.378	3.0	3.5	3.0	3.5	2.75	2.73	2.78	2.75	AK
07:05	OK	OK	2.348	2.324	3.5	3.0	3.5	3.0	2.77	2.68	2.80	2.68	AK
07:35	OK	OK	2.365	2.352	3.0	3.5	3.0	3.5	2.72	2.72	2.76	2.72	AK
08:08	OK	OK	2.368	2.348	3.5	3.0	3.5	3.0	2.67	2.71	2.67	2.75	AK
08:40	OK	OK	2.375	2.324	3.0	3.5	3.0	3.5	2.69	2.67	2.69	2.72	AK
09:10	OK	OK	2.362	2.340	3.5	3.0	3.5	3.0	2.72	2.73	2.72	2.77	AK
09:40	OK	OK	2.358	2.367	3.0	3.5	3.0	3.5	2.75	2.69	2.75	2.69	AK

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka	AK	AK	AK	
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020	

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210 216

Customer:

Generic Health Care Pvt. Ltd.

11.9 IN-PROCESS CHECKS: (For Production)

[illegible]

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

BATCH MANUFACTURING RECORD

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: 67 F 210216

Customer:

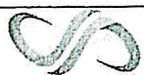
Generic Health Care Pvt. Ltd.

11.10 IN-PROCESS CHECKS: (For Production)

[illegible]

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	31/12/2020	31/12/2020	31/12/2020	

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210216

Customer:

Generic Health Care Pvt. Ltd.

11.11 IN-PROCESS CHECKS: (For IPQA)

Time	Appearance		Weight of 20 Tablets		Hardness				Thickness				Done by IPOA
	White coloured, capsule shaped, beveled edged uncoated tablets with breakline on one side and plain on other side.		2.360 g $\pm$ 2.0 % (2.313 g to 2.407 g)		NLT 3.0 Kg (To be established)				2.70 mm $\pm$ 0.3 mm (2.40 mm – 3.00 mm) (To be established)				
	LHS	RHS	LHS	RHS	LHS	LHS	RHS	RHS	LHS	LHS	RHS	RHS	
20/02/24 06:45	OK	OK	2.377	2.377	3.0	3.5	3.0	3.5	2.74	2.73	2.75	2.76	Q
08:50	OK	OK	2.351	2.365	2.0	3.5	3.0	3.5	2.75	3.72	2.76	2.78	Q
10:15	OK	OK	2.365	2.357	3.0	3.0	3.0	3.5	2.78	2.75	2.78	2.77	Q
12:50	OK	OK	2.359	2.369	3.5	3.0	3.5	3.0	2.77	2.78	2.79	2.76	Q
14:40	OK	OK	2.365	2.379	3.0	3.5	2.5	3.0	2.78	2.79	2.74	2.79	Q
16:35	OK	OK	2.381	2.369	2.0	3.5	3.0	3.0	2.80	2.77	2.76	2.78	Q
18:40	OK	OK	2.374	2.370	3.0	3.5	3.0	3.5	2.77	2.76	2.78	2.77	Q
20:40	OK	OK	2.383	2.364	3.5	2.0	3.0	3.5	2.79	2.80	2.77	2.76	AL
22:40	OK	OK	2.365	2.352	2.0	2.0	3.0	3.5	2.70	2.83	2.86	2.75	AL
27/02/2023 08:38	OK	OK	2.382	2.375	3.5	3.5	3.5	3.5	2.72	2.76	2.77	2.73	Q
02:41	OK	OK	2.374	2.369	3.5	3.5	3.0	3.0	2.76	2.77	2.72	2.79	Q
04:27	OK	OK	2.380	2.370	3.0	3.5	3.5	3.0	2.72	2.78	2.74	2.76	Q
06:40	OK	OK	2.360	2.371	3.0	3.5	3.0	3.5	2.74	2.76	2.75	2.74	Q
08:45	OK	OK	2.374	2.366	3.0	3.5	3.0	3.5	2.76	2.77	2.78	2.76	Q
10:50	OK	OK	2.369	2.375	3.0	3.5	3.0	3.5	2.77	2.75	2.76	2.77	Q
12:45	OK	OK	2.378	2.371	3.0	3.5	3.0	3.5	2.76	2.78	2.74	2.75	Q
14:50	OK	OK	2.320	2.367	3.0	3.5	3.0	3.5	2.77	2.78	2.76	2.75	Q
16:50	OK	OK	2.361	2.373	2.0	2.0	3.5	3.0	2.72	2.69	2.74	2.75	AL
18:05	OK	OK	2.380	2.374	3.0	3.5	3.0	3.5	2.74	2.75	2.73	2.75	AL
18:10	OK	OK	2.367	2.371	3.0	3.6	3.5	3.0	2.75	2.74	2.75	2.74	AL
18:15	OK	OK	2.369	2.364	3.0	3.5	3.0	3.5	2.76	2.75	2.76	2.74	AL
18:20	OK	OK	2.370	2.366	3.0	2.0	3.0	3.0	2.78	2.79	2.80	2.81	AL
18:25	OK	OK	2.374	2.370	4.0	4.0	4.0	4.0	2.70	2.68	2.70	2.70	AL
18:30	OK	OK	2.378	2.364	3.5	3.0	2.5	3.5	2.76	3.78	3.74	3.76	AL

Prepared by:

Checked by:

Approved By:

Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	QAV	2/1/2020	
Date	31/12/2020	31/12/2020		

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210216

Customer:

Generic Health Care Pvt. Ltd.

11.12 IN-PROCESS CHECKS: (For IPQA)

[illegible]

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. K.</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Pudukcherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210216

Customer:

Generic Health Care Pvt. Ltd.

11.13 IN-PROCESS CHECKS: (For IPQA)

[illegible]

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	P. K.	<i>[Signature]</i>	<i>[Signature]</i>
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 30 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMR/T/195-00 Customer:	Batch No.: <u>G1F 210216</u> Generic Health Care Pvt. Ltd.

NOTE: Initially first 2 entries-2 Hours once remaining entries 4 Hours once for production.

11.14 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date: <u>26/02/2021</u>		Time: <u>06:40</u>		Shift: <u>6</u>							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	116	8	117	15	117	1	116	8	118	15	119
2	115	9	118	16	118	2	117	9	119	16	116
3	116	10	116	17	116	3	119	10	118	17	119
4	117	11	117	18	117	4	120	11	119	18	116
5	116	12	116	19	116	5	120	12	118	19	119
6	119	13	119	20	119	6	116	13	116	20	118
7	116	14	116			7	117	14	117		
Balance ID No.: <u>PDI BAL 1008</u>				M/C Speed: <u>25</u> RPM							
Group weight of 20 Tablets: <u>2337</u> ...g. Avg. wt: <u>116.85</u> ..mg				Group weight of 20 Tablets: <u>2357</u> ...g. Avg. wt: <u>117.85</u> ..mg							
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)				Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)							
Min weight: <u>115</u> mg Max. weight: <u>119</u> mg				Min weight: <u>116</u> mg Max. weight: <u>120</u> mg							
		LHS		RHS							
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				0.09%		Equipment ID No.: QA/FRT/ 502					
Disintegration Time (Limit - NMT 15 minutes)				0.03 min		Equipment ID No.: QA/DTA/ 001					
Done by: <u>N. Bal 26/02/2021</u> (Production)											
Date: <u>26/02/2021</u>		Time: <u>08:21</u>		Shift: <u>6</u>							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	117	8	121	15	119	1	120	8	119	15	118
2	119	9	120	16	119	2	121	9	118	16	119
3	120	10	120	17	120	3	120	10	119	17	120
4	120	11	120	18	120	4	119	11	120	18	118
5	118	12	119	19	120	5	118	12	119	19	116
6	119	13	120	20	119	6	116	13	116	20	117
7	120	14	118			7	117	14	117		
Balance ID No.: <u>PDI BAL 1008</u>				M/C Speed: <u>25</u> RPM							
Group weight of 20 Tablets: <u>2386</u> ...g. Avg. wt: <u>119.30</u> ..mg				Group weight of 20 Tablets: <u>2366</u> ...g. Avg. wt: <u>118.30</u> ..mg							
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)				Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)							
Min weight: <u>117</u> mg Max. weight: <u>120</u> mg				Min weight: <u>116</u> mg Max. weight: <u>121</u> mg							
		LHS		RHS							
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				0.06%		Equipment ID No.: QA/FRT/ 002					
Disintegration Time (Limit - NMT 15 minutes)				0.03 min		Equipment ID No.: QA/DTA/ 001					
Done by: <u>N. Bal 26/02/2021</u> (Production)											

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<u>L. Ka</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	
Date	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>31/12/2020</u>	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 31 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
	Product	GENSET	BMR. No.: BMR/T/195-00 Customer:

11.15 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 4 hours):

Date: 26/02/2021		Time: 12:16		Shift: G	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	118	8	119	15	120
2	116	9	119	16	120
3	119	10	120	17	116
4	119	11	119	18	119
5	120	12	119	19	116
6	119	13	119	20	119
7	119	14	119		
Balance ID No.: PD1BAL1008			M/C Speed: 25 RPM		
Group weight of 20 Tablets: 2373.73 g. Avg. wt: 118.68 mg			Group weight of 20 Tablets: 2388.00 g. Avg. wt: 119.40 mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight: 116 mg Max. weight: 120 mg			Min weight: 116 mg Max. weight: 121 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		LHS		RHS	
Disintegration Time (Limit - NMT 15 minutes)		0.02%		0.09%	
Equipment ID No.: QA/FRT/002		0.02%		0.09%	
Equipment ID No.: QA/DTA/002		0.02%		0.09%	
Done by: N. P. 26/02/2021 (Production)					
Date: 26/02/2021		Time: 18:19		Shift: G	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	120	8	120	15	117
2	119	9	119	16	118
3	120	10	118	17	119
4	120	11	119	18	120
5	119	12	118	19	120
6	120	13	116	20	120
7	121	14	119		
Balance ID No.: PD1BAL1008			M/C Speed: 25 RPM		
Group weight of 20 Tablets: 2382.00 g. Avg. wt: 119.10 mg			Group weight of 20 Tablets: 2373.00 g. Avg. wt: 118.65 mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight: 117 mg Max. weight: 121 mg			Min weight: 116 mg Max. weight: 120 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		LHS		RHS	
Disintegration Time (Limit - NMT 15 minutes)		0.12%		0.09%	
Equipment ID No.: QA/FRT/002		0.12%		0.09%	
Equipment ID No.: QA/DTA/001		0.12%		0.09%	
Done by: M. 26/02/2021 (Production)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	P. K.	S. K.	S. K.
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: G F 210216

Customer:

Generic Health Care Pvt. Ltd.

11.16 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 4 hours):

Date: 26/02/2021		Time: 20:25		Shift: B	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	117	8	120	15	116
2	118	9	117	16	118
3	119	10	118	17	116
4	117	11	117	18	118
5	118	12	116	19	117
6	115	13	119	20	118
7	118	14	120		
Balance ID No.: PD/BAL/008			M/C Speed: 25 RPM		
Group weight of 20 Tablets: 2355 g. Avg. wt: 117.75 mg			Group weight of 20 Tablets: 2361 g. Avg. wt: 118.05 mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight: 116 mg Max. weight: 120 mg			Min weight: 116 mg Max. weight: 120 mg		
		LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.03	0.06	Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)		04 mins 11.11s	04 mins 30.11s	Equipment ID No.: QA/DTA/002	
Done by: AK (Production)					
Date: 27/02/2021		Time: 06:30		Shift: B* C	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	119	8	118	15	121
2	121	9	121	16	119
3	118	10	115	17	117
4	116	11	119	18	118
5	117	12	119	19	119
6	119	13	119	20	118
7	118	14	121		
Balance ID No.: PD/BAL/008			M/C Speed: 25 RPM		
Group weight of 20 Tablets: 2372 g. Avg. wt: 118.60 mg			Group weight of 20 Tablets: 2369 g. Avg. wt: 118.45 mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight: 116 mg Max. weight: 121 mg			Min weight: 116 mg Max. weight: 120 mg		
		LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.06%	0.04%	Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)		04 mins 36.11s	04 mins 17.11s	Equipment ID No.: QA/DTA/002	
Done by: AK (Production)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K			
Date	31/12/2020	31/12/2020	31/12/2020	

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: G13/210216

Customer:

Generic Health Care Pvt. Ltd.

11.17 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 4 hours):

Date: 27/02/2021			Time: 04:25			Shift: C					
LHS: Individual weight of 20 tablets (in mg).						RHS: Individual weight of 20 tablets (in mg).					
1	120	8	123	15	116	1	118	8	122	15	118
2	118	9	118	16	118	2	120	9	117	16	120
3	119	10	116	17	117	3	117	10	119	17	119
4	117	11	118	18	119	4	118	11	115	18	117
5	118	12	120	19	118	5	117	12	118	19	119
6	117	13	117	20	117	6	119	13	116	20	120
7	119	14	117			7	119	14	118		

Balance ID No.: PD/BAL/008

M/C Speed: 25 RPM

Group weight of 20 Tablets: 2.362 g. Avg.
wt: 118.10 mg

Group weight of 20 Tablets: 2.366 g. Avg.
wt: 118.30 mg

Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)

Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)

Min weight: 116 mg Max. weight: 123 mg

Min weight: 115 mg Max. weight: 122 mg

	LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	0.02%	0.04%	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)	04 min 02 sec	04 min 46 sec	Equipment ID No.: QA/DTA/002

Done by: AL (Production)

Date: 27/02/2021						Time: 08:30						Shift: C											
LHS: Individual weight of 20 tablets (in mg).												RHS: Individual weight of 20 tablets (in mg).											
1	117	8	119	15	119	1	116	8	118	15	117												
2	118	9	116	16	117	2	118	9	120	16	119												
3	119	10	118	17	118	3	117	10	119	17	121												
4	117	11	114	18	122	4	119	11	122	18	118												
5	117	12	120	19	120	5	118	12	118	19	120												
6	119	13	118	20	119	6	119	13	116	20	119												
7	120	14	117			7	117	14	118														

Balance ID No.: PD/BAL/008

M/C Speed: 25 RPM

Group weight of 20 Tablets: 2.444 g. Avg.
wt: 122.20 mg

Group weight of 20 Tablets: 2.325 g. Avg.
wt: 116.25 mg

Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)

Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)

Min weight: 114 mg Max. weight: 122 mg

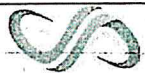
Min weight: 116 mg Max. weight: 122 mg

	LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	0.01%	0.03%	Equipment ID No.: QA/FRT/02
Disintegration Time (Limit - NMT 15 minutes)	01 min 17 sec	01 min 42 sec	Equipment ID No.: QA/DTA/02

Done by: AL (Production)

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	PD	31/12/2020	31/12/2020
Date	31/12/2020	31/12/2020		

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210216

Customer:

Generic Health Care Pvt. Ltd.

11.18 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 4 hours):

Date: 27/02/2021		Time: 12:35		Shift: A	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	119	8	116	15	117
2	118	9	118	16	119
3	116	10	119	17	116
4	117	11	118	18	118
5	118	12	116	19	116
6	117	13	118	20	119
7	119	14	117		
Balance ID No.: PD/BAL/008			M/C Speed: 25 RPM		
Group weight of 20 Tablets: 2.351 g. Avg. wt: 117.55 mg			Group weight of 20 Tablets: 2.352 g. Avg. wt: 117.60 mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight: 116 mg Max. weight: 119 mg			Min weight: 115 mg Max. weight: 122 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		LHS	RHS	Equipment ID No.: QA/FRT/ 002	
Disintegration Time (Limit - NMT 15 minutes)		0.02 %	0.04 %	Equipment ID No.: QA/DTA/ 002	
Done by: AL (Production)					
Date: 27/02/2021		Time: 16:30		Shift: B	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	118	8	117	15	118
2	119	9	119	16	116
3	118	10	118	17	117
4	118	11	116	18	119
5	117	12	118	19	118
6	120	13	120	20	117
7	119	14	119		
Balance ID No.: PD/BAL/008			M/C Speed: 25 RPM		
Group weight of 20 Tablets: 2.361 g. Avg. wt: 118.05 mg			Group weight of 20 Tablets: 2.367 g. Avg. wt: 118.35 mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight: 116 mg Max. weight: 120 mg			Min weight: 116 mg Max. weight: 121 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		LHS	RHS	Equipment ID No.: QA/FRT/ 002	
Disintegration Time (Limit - NMT 15 minutes)		0.03 %	0.05 %	Equipment ID No.: QA/DTA/ 002	
Done by: AL (Production)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	21/12/2020	21/12/2020	21/12/2020
Date	31/12/2020			

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: 61F210216

Customer:

Generic Health Care Pvt. Ltd.

11.19 UNIFORMITY OF WEIGHT IN PROCESS CHECKS FOR PRODUCTION (Frequency: Every 4 hours):

Date: 27/12/2020		Time: 18:32		Shift: B	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	118	8	118	15	118
2	117	9	116	16	116
3	118	10	117	17	118
4	116	11	119	18	117
5	118	12	119	19	119
6	117	13	118	20	118
7	119	14	117		
Balance ID No.: PD1PAT1008			M/C Speed: 25 RPM		
Group weight of 20 Tablets: 2358 g. Avg. wt: 117.9 mg			Group weight of 20 Tablets: 2359 g. Avg. wt: 117.95 mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight: 116 mg Max. weight: 119 mg			Min weight: 116 mg Max. weight: 119 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		LHS	RHS	Equipment ID No.: QA/FRT/	
Disintegration Time (Limit - NMT 15 minutes)		0.03%	0.02%	Equipment ID No.: QA/DTA/	
Done by: (Production)					
Date:		Time:		Shift:	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1		8		15	
2		9		16	
3		10		17	
4		11		18	
5		12		19	
6		13		20	
7		14			
Balance ID No.:			M/C Speed: RPM		
Group weight of 20 Tablets: g. Avg. wt: mg			Group weight of 20 Tablets: g. Avg. wt: mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight: mg Max. weight: mg			Min weight: mg Max. weight: mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		LHS	RHS	Equipment ID No.: QA/FRT/	
Disintegration Time (Limit - NMT 15 minutes)				Equipment ID No.: QA/DTA/	
Done by: (Production)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K.	POH	31/12/2020	31/12/2020
Date	31/12/2020	31/12/2020		

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210216

Customer:

Generic Health Care Pvt. Ltd.

11.20 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 4 hours):

Date:		Time :		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Balance ID No.:				M/C Speed: RPM			
Group weight of 20 Tablets:.....g. Avg. wt:.....mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg			
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)				Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			
Min weight. :..... mg Max. weight.: mg				Min weight. :..... mg Max. weight.: mg			
		LHS	RHS				
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)				Equipment ID No.: QA/DTA/			
Done by:(Production)							
Date:		Time :		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Balance ID No.:				M/C Speed: RPM			
Group weight of 20 Tablets:.....g. Avg. wt:.....mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg			
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)				Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			
Min weight. :..... mg Max. weight.: mg				Min weight. :..... mg Max. weight.: mg			
		LHS	RHS				
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)				Equipment ID No.: QA/DTA/			
Done by:(Production)							

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	POB	31/12/2020	31/12/2020
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210216

Customer:

Generic Health Care Pvt. Ltd.

11.21 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours): Full Hopper

Date: 26/02/2021

Time: 06:55

Shift: A

LHS: Individual weight of 20 tablets (in mg).

RHS: Individual weight of 20 tablets (in mg).

1	119	8	118	15	119
2	118	9	117	16	121
3	119	10	119	17	120
4	120	11	119	18	121
5	121	12	118	19	117
6	118	13	119	20	118
7	119	14	120		

1	119	8	120	15	119
2	120	9	121	16	120
3	121	10	119	17	121
4	118	11	118	18	119
5	119	12	119	19	120
6	119	13	120	20	119
7	121	14	121		

Balance ID No.: QA/BAL/002

M/C Speed: 25 RPM

Group weight of 20 Tablets: 2.382 g. Avg.
wt: 119.10 mgGroup weight of 20 Tablets: 2.393 g. Avg.
wt: 119.65 mgLimit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)

Min weight: 117 mg Max. weight: 121 mg

Min weight: 119 mg Max. weight: 121 mg

LHS

RHS

Friability (Limit: NMT 1% after 4 minutes/100 rotations):

0.07% 0.22%

Equipment ID No.: QA/FRT/002

Disintegration Time (Limit - NMT 15 minutes)

4 min 19 sec 4 min 37 sec

Equipment ID No.: QA/DTA/001

Done by: 26/02/2021 (IPQA)

Date: 26/02/2021

Time: 10:45

Shift: A

LHS: Individual weight of 20 tablets (in mg).

RHS: Individual weight of 20 tablets (in mg).

1	120	8	119	15	117
2	119	9	118	16	121
3	118	10	119	17	122
4	117	11	118	18	123
5	119	12	119	19	120
6	120	13	119	20	119
7	119	14	120		

1	120	8	119	15	119
2	121	9	120	16	120
3	119	10	121	17	121
4	120	11	122	18	123
5	119	12	120	19	121
6	121	13	119	20	122
7	121	14	120		

Balance ID No.: QA/BAL/002

M/C Speed: 25 RPM

Group weight of 20 Tablets: 2.386 g. Avg.
wt: 119.30 mgGroup weight of 20 Tablets: 2.408 g. Avg.
wt: 120.40 mgLimit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)

Min weight: 117 mg Max. weight: 123 mg

Min weight: 119 mg Max. weight: 123 mg

LHS

RHS

Friability (Limit: NMT 1% after 4 minutes/100 rotations):

0.09% 0.13%

Equipment ID No.: QA/FRT/002

Disintegration Time (Limit - NMT 15 minutes)

4 min 24 sec 4 min 47 sec

Equipment ID No.: QA/DTA/001

Done by: 26/02/2021 (IPQA)

Prepared by:

Checked by:

Approved By:

Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K	208	31/12/2020	31/12/2020
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: G F 21 0216

Customer:

Generic Health Care Pvt. Ltd.

11.22 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date: 26/02/2020						Time: 14:50						Shift: G											
LHS: Individual weight of 20 tablets (in mg).												RHS: Individual weight of 20 tablets (in mg).											
1	119	8	117	15	120	1	119	8	119	15	116												
2	119	9	119	16	114	2	119	9	120	16	119												
3	112	10	120	17	119	3	112	10	121	17	120												
4	117	11	119	18	117	4	119	11	119	18	121												
5	119	12	112	19	119	5	112	12	112	19	122												
6	120	13	114	20	126	6	119	13	117	20	120												
7	121	14	119			7	117	14	117														
Balance ID No.: QA/BAL/002												M/C Speed: 25 RPM											
Group weight of 20 Tablets: 2.374 g. Avg. wt: 118.70 mg												Group weight of 20 Tablets: 2.378 g. Avg. wt: 118.90 mg											
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)												Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)											
Min weight: 117 mg Max. weight: 120 mg												Min weight: 117 mg Max. weight: 122 mg											
Friability (Limit: NMT 1% after 4 minutes/100 rotations):												LHS: 0.19% RHS: 0.23% Equipment ID No.: QA/FRT/002											
Disintegration Time (Limit - NMT 15 minutes)												4 min 14 sec 4 min 24 sec Equipment ID No.: QA/DTA/001											
Done by: 26/02/2021 (IPQA)												red Hopper											
Date: 26/02/2021						Time: 18:45						Shift: G											
LHS: Individual weight of 20 tablets (in mg).												RHS: Individual weight of 20 tablets (in mg).											
1	117	8	119	15	121	1	119	8	120	15	112												
2	119	9	120	16	119	2	120	9	119	16	119												
3	120	10	121	17	120	3	119	10	120	17	120												
4	121	11	119	18	121	4	112	11	119	18	121												
5	119	12	112	19	119	5	117	12	117	19	119												
6	112	13	119	20	120	6	119	13	112	20	120												
7	117	14	120			7	120	14	119														
Balance ID No.: QA/BAL/002												M/C Speed: 25 RPM											
Group weight of 20 Tablets: 2.386 g. Avg. wt: 119.3 mg												Group weight of 20 Tablets: 2.381 g. Avg. wt: 119.05 mg											
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)												Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)											
Min weight: 117 mg Max. weight: 121 mg												Min weight: 117 mg Max. weight: 120 mg											
Friability (Limit: NMT 1% after 4 minutes/100 rotations):												LHS: 0.18 RHS: 0.19 Equipment ID No.: QA/FRT/002											
Disintegration Time (Limit - NMT 15 minutes)												4 min 40 sec 4 min 44 sec Equipment ID No.: QA/DTA/001											
Done by: 26/02/2021 (IPQA)																							

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka	PQ	21/12/2020	21/12/2020	
Date	31/12/2020				

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210216

Customer:

Generic Health Care Pvt. Ltd.

11.23 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Mid Hopoo

Date: 26/02/2021

Time: 22:45

Shift: B

LHS: Individual weight of 20 tablets (in mg).

RHS: Individual weight of 20 tablets (in mg).

1	116	8	118	15	119
2	117	9	121	16	120
3	119	10	120	17	116
4	120	11	119	18	117
5	122	12	116	19	118
6	115	13	115	20	119
7	119	14	117		

1	118	8	120	15	119
2	120	9	119	16	120
3	120	10	117	17	121
4	119	11	118	18	120
5	116	12	116	19	119
6	117	13	117	20	118
7	119	14	119		

Balance ID No.: QA/BAL/002

M/C Speed: 25 RPM

Group weight of 20 Tablets: 2363 g. Avg.
wt: 118.15 mg

Group weight of 20 Tablets: 2371 g. Avg.
wt: 118.55 mg

Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)

Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)

Min weight: 115 mg Max. weight: 122 mg

Min weight: 116 mg Max. weight: 121 mg

LHS

RHS

Friability (Limit: NMT 1% after 4 minutes/100 rotations):

0.15%

0.12%

Equipment ID No.: QA/FRT/ 002

Disintegration Time (Limit - NMT 15 minutes)

04 mins 19 sec

04 mins 19 sec

Equipment ID No.: QA/DTA/ 001

Done by: AT (IPQA)

Date: 26/02/2021

Time: 09:45

Shift: C

LHS: Individual weight of 20 tablets (in mg).

RHS: Individual weight of 20 tablets (in mg).

1	117	8	119	15	119
2	119	9	119	16	120
3	117	10	121	17	121
4	119	11	121	18	119
5	120	12	120	19	121
6	117	13	119	20	120
7	116	14	121		

1	117	8	119	15	116
2	117	9	119	16	117
3	119	10	120	17	121
4	121	11	119	18	117
5	120	12	120	19	118
6	119	13	121	20	118
7	120	14	121		

Balance ID No.: QA/BAL/002

M/C Speed: 25 RPM

Group weight of 20 Tablets: 2385 g. Avg.
wt: 119.25 mg

Group weight of 20 Tablets: 2379 g. Avg.
wt: 118.95 mg

Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)

Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)

Min weight: 116 mg Max. weight: 121 mg

Min weight: 116 mg Max. weight: 121 mg

LHS

RHS

Friability (Limit: NMT 1% after 4 minutes/100 rotations):

0.23%

0.25%

Equipment ID No.: QA/FRT/ 002

Disintegration Time (Limit - NMT 15 minutes)

04 min 24 sec

04 min 19 sec

Equipment ID No.: QA/DTA/ 001

Done by: AT (IPQA)

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>POB</u>	<u>21/12/2020</u>	<u>J. Jeyaraj</u>
Date	<u>31/12/2020</u>	<u>31/12/2020</u>		<u>21/12/2020</u>

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210216

Customer:

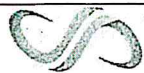
Generic Health Care Pvt. Ltd.

11.24 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date: 27/02/2021		Time: 06:44		Shift: C	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	117	8	117	15	119
2	117	9	119	16	117
3	119	10	121	17	117
4	121	11	120	18	119
5	119	12	120	19	122
6	118	13	120	20	119
7	117	14	119		
Balance ID No.: QA/BALL/100			M/C Speed: 25 RPM		
Group weight of 20 Tablets: 2.377 g. Avg. wt: 118.85 mg			Group weight of 20 Tablets: 2.345 g. Avg. wt: 117 mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight: 117 mg Max. weight: 122 mg			Min weight: 117 mg Max. weight: 122 mg		
			LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			0.17%	0.21%	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)			03 min 47.5 sec	03 min 46.3 sec	Equipment ID No.: QA/DTA/001
Done by: [Signature] (IPQA)					
Date: 27/02/2021		Time: 10:58		Shift: C	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	119	8	117	15	119
2	117	9	117	16	117
3	119	10	119	17	120
4	117	11	117	18	121
5	117	12	118	19	120
6	119	13	118	20	118
7	119	14	118		
Balance ID No.: QA/BALL/100			M/C Speed: 25 RPM		
Group weight of 20 Tablets: 2.366 g. Avg. wt: 118.3 mg			Group weight of 20 Tablets: 2.392 g. Avg. wt: 119.6 mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight: 117 mg Max. weight: 121 mg			Min weight: 117 mg Max. weight: 121 mg		
			LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			0.22%	0.25%	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)			05 min 21.8 sec	04 min 57.3 sec	Equipment ID No.: QA/DTA/001
Done by: [Signature] (IPQA)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	[Signature]	[Signature]	[Signature]
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GT-210216

Customer:

Generic Health Care Pvt. Ltd.

11.25 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date: 27/02/2021 Time: 12:55 Shift: G1

LHS: Individual weight of 20 tablets (in mg).

RHS: Individual weight of 20 tablets (in mg).

1	119	8	118	15	118	1	118	8	118	15	119
2	117	9	119	16	119	2	119	9	116	16	118
3	116	10	116	17	120	3	120	10	117	17	118
4	118	11	118	18	119	4	119	11	119	18	119
5	119	12	117	19	118	5	120	12	121	19	118
6	120	13	119	20	119	6	121	13	122	20	120
7	121	14	121			7	119	14	120		

Balance ID No.: QA/BAL/002

M/C Speed: 25 RPM

Group weight of 20 Tablets: 2137 g. Avg.
wt: 118.55 mg

Group weight of 20 Tablets: 2138 g. Avg.
wt: 119.05 mg

Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)

Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)

Min weight: 116 mg Max. weight: 121 mg

Min weight: 116 mg Max. weight: 121 mg

	LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	<u>0.17%</u>	<u>0.15%</u>	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)	<u>4 min 50 sec</u>	<u>4 min 47 sec</u>	Equipment ID No.: QA/DTA/001

Done by: (Signature) (IPQA)

Date: 27/02/2021

Time: 12:55

Shift: G1

LHS: Individual weight of 20 tablets (in mg).

RHS: Individual weight of 20 tablets (in mg).

1	117	8	119	15	118	1	118	8	119	15	119
2	120	9	118	16	117	2	119	9	118	16	121
3	119	10	119	17	119	3	120	10	119	17	119
4	118	11	118	18	120	4	121	11	118	18	118
5	119	12	117	19	119	5	119	12	119	19	120
6	117	13	118	20	118	6	118	13	118	20	120
7	118	14	119			7	119	14	119		

Balance ID No.: QA/BAL/002

M/C Speed: 25 RPM

Group weight of 20 Tablets: 2137 g. Avg.
wt: 118.35 mg

Group weight of 20 Tablets: 2138 g. Avg.
wt: 119.05 mg

Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)

Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)

Min weight: 117 mg Max. weight: 120 mg

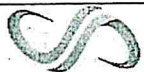
Min weight: 117 mg Max. weight: 121 mg

	LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	<u>0.15%</u>	<u>0.17%</u>	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)	<u>5 min 02 sec</u>	<u>4 min 51 sec</u>	Equipment ID No.: QA/DTA/001

Done by: (Signature) (IPQA)

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>(Signature)</u>	<u>(Signature)</u>	<u>(Signature)</u>
Date	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>31/12/2020</u>

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF210216

Customer:

Generic Health Care Pvt. Ltd.

11.26 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours): End Hopper

Date: 27/02/2024		Time: 18:10		Shift: B	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	119	8	121	15	120
2	112	9	119	16	121
3	119	10	120	17	122
4	120	11	121	18	119
5	121	12	119	19	120
6	119	13	120	20	121
7	120	14	119		
Balance ID No.: QA/BAL/002			M/C Speed: 25 RPM		
Group weight of 20 Tablets: 2390 g. Avg. wt: 119.5 mg			Group weight of 20 Tablets: 2398 g. Avg. wt: 119.9 mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight: 117 mg Max. weight: 121 mg			Min weight: 117 mg Max. weight: 122 mg		
		LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.18%	0.14%	Equipment ID No.: QA/FRT/004	
Disintegration Time (Limit - NMT 15 minutes)		1 min 5 sec	1 min 8 sec	Equipment ID No.: QA/DTA/002	
Done by: [Signature] (IPQA)					
Date: 27/02/2024		Time: 18:15		Shift: B	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	120	8	120	15	119
2	117	9	121	16	120
3	113	10	119	17	121
4	116	11	118	18	122
5	117	12	119	19	119
6	120	13	120	20	120
7	121	14	121		
Balance ID No.: QA/BAL/002			M/C Speed: 10 RPM		
Group weight of 20 Tablets: 2326 g. Avg. wt: 116.3 mg			Group weight of 20 Tablets: 2372 g. Avg. wt: 118.6 mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight: 116 mg Max. weight: 122 mg			Min weight: 118 mg Max. weight: 122 mg		
		LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.18%	0.21%	Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)		5 min 02 sec	5 min 05 sec	Equipment ID No.: QA/DTA/001	
Done by: [Signature] (IPQA)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	[Signature]	[Signature]	[Signature]
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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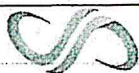


Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.

Generic Health Care Pvt. Ltd.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. K.</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	21/12/2020	21/12/2020	21/12/2020	21/12/2020

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SAI PRIMUS
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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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Product	GENSET	BATCH MANUFACTURING RECORD	Product Code: G13	Batch Size: 30,00,000 Tablets
			BMR. No.: BMRT/195-00	Batch No.: GF 210216
			Customer:	Generic Health Care Pvt. Ltd.

11.28 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours): H. Haidnars

Date: 24/02/2021	Time: 18:28	Shift: 2
LHS: Individual weight of 20 tablets (in mg).		RHS: Individual weight of 20 tablets (in mg).
1 120 8 121 15 119	1 120 8 120 15 119	
2 119 9 122 16 118	2 119 9 121 16 120	
3 121 10 121 17 117	3 120 10 119 17 121	
4 119 11 122 18 119	4 121 11 120 18 119	
5 118 12 120 19 120	5 119 12 121 19 120	
6 117 13 121 20 121	6 117 13 119 20 121	
7 119 14 120	7 116 14 120	
Balance ID No.: QA/BAL/001		M/C Speed: 25 RPM
Group weight of 20 Tablets: 2382 g. Avg. wt: 119.1 mg		Group weight of 20 Tablets: 2392 g. Avg. wt: 119.6 mg
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)
Min weight: 117 mg Max. weight: 122 mg		Min weight: 117 mg Max. weight: 120 mg
		LHS RHS
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.4% 0.19% Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)		5 min 10 sec 5 min 34 sec Equipment ID No.: QA/DTA/002
Done by: As 24/02/2021 (IPQA) Composite		
Date: 24/02/2021	Time: 18:35	Shift: 2
LHS: Individual weight of 20 tablets (in mg).		RHS: Individual weight of 20 tablets (in mg).
1 119 8 121 15 118	1 119 8 120 15 119	
2 121 9 119 16 119	2 120 9 121 16 117	
3 121 10 120 17 120	3 121 10 120 17 120	
4 120 11 121 18 121	4 118 11 119 18 119	
5 118 12 119 19 119	5 120 12 120 19 121	
6 119 13 120 20 120	6 120 13 121 20 116	
7 120 14 119	7 118 14 120	
Balance ID No.: QA/BAL/002		M/C Speed: 25 RPM
Group weight of 20 Tablets: 2390 g. Avg. wt: 119.5 mg		Group weight of 20 Tablets: 2382 g. Avg. wt: 119.1 mg
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)
Min weight: 118 mg Max. weight: 121 mg		Min weight: 116 mg Max. weight: 121 mg
		LHS RHS
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.21% 0.19% Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)		4 min 14 sec 4 min 27 sec Equipment ID No.: QA/DTA/002
Done by: As 24/02/2021 (IPQA)		

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	10/1	21/12/2020	8. 21/12/2020
Date	31/12/2020	21/12/2020		

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210216

Customer:

Generic Health Care Pvt. Ltd.

11.29 WEIGHING RECORD OF COMPRESSED TABLETS:

S. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Weighed by	Checked by Prod.	Verified by IPQA
1	26.230	2.200	24.030	Vimal	N.B.L	✓
2	26.920	2.200	24.720	Vimal	N.B.L	✓
3	29.200	2.200	27.000	Vimal	N.B.L	✓
4	28.660	2.200	26.460	Vimal	N.B.L	✓
5	18.600	2.200	16.400	Vimal	N.B.L	✓
6	27.900	2.200	25.700	Vimal	N.B.L	✓
7	35.920	2.200	33.720	Vimal	N.B.L	✓
8	36.400	2.200	34.200	Vimal	N.B.L	✓
9	36.260	2.200	34.060	Vimal	N.B.L	✓
10	36.380	2.200	34.180	Vimal	N.B.L	✓
11	27.120	2.200	24.920	Vimal	N.B.L	✓
12	49.200	2.200	47.000	Vimal	N.B.L	✓
13						
14						
15						
16						
17						
18						
19						
20						
21						
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25						
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29						
30						

27/12/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	✓	✓	✓
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMRT/195-00 Customer:	Batch No.: 6F 210216 Generic Health Care Pvt. Ltd.

11.30 RECONCILIATION (COMPRESSION STAGE):

Average weight of Uncoated Tablet: ...118...mg

1.0	Standard Batch size	:	354.000 Kg.	30,00,000 No.
2.0	Actual weight of Lubricated granules	:	353.140 Kg	2994915 Nos.
3.0	Weight of compressed tablets	:	352.390 Kg	2986355 Nos.
4.0	Rejection during Compression @	:	0.390 Kg.	
5.0	In-process samples of all stages			
	A	IPQC Samples	:	0.270 Kg.
	B	QC Samples	:	0.190 Kg.
	C	Validation Samples	:	0.240 Kg.
6.0	Total in process samples: (A + B + C)	:	0.690 Kg.	
7.0	Total: (3.0 + 6.0)	:	353.080 Kg.	2991610 Nos.
8.0	Yield {7.0 / 1.0 x 100}*	:		99.72 %

* Actually yield will be calculated after 3 validation batches

@Total rejects destroyed:0.290...Kg. (Rejected materials shall be destroyed as per SOP No.: QAGN/048)

Done by Production Sign/Date: ...N. R. S. 25/10/2021... Checked by IPQA Sign/Date: ...[Signature] 25/10/2021...

Test request form raised by Prod Sign/Date: ...N. R. S. 25/10/2021...

Test request form received by IPQA Sign/Date: ...[Signature] 25/10/2021...

12.0 RELEASED FOR COATING:

Reconciliation checked and compressed tablets released for coating:

IPQA Sign.....[Signature]..... Date:.....27/10/2021.....

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K.</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>31/12/2020</u>

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	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMRT/195-00 Customer:	Batch No.: <u>GF 210216</u> Generic Health Care Pvt. Ltd.

13.0 LINE CLEARANCE FOR COATING SOLUTION PREPARATION:

Date/Shift/Time: 27/02/2021 / 19:57 / NA

Sr. No.	Checks	*Observation			
		Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty containers, polythene bags, Tags and documents of previous batch/product are removed.	✓	✓		
2	Check and ensure that absence of previous batch/product from area below machine and inside machine.	✓	✓		
3	Check and ensure that machine body, machine parts and control panel are clean.	✓	✓		
4	Check and ensure that absence of previous batch/product below container weighing balance.	✓	✓		
5	Check and ensure that working desk, analytical balance and other accessories are clean.	✓	✓		
6	Check and ensure that Tube light fixture, supply grills, riser grills and filters, electrical fixtures and Derain point are clean.	✓	✓		
7	Check and ensure that instruments to be used are within calibration due date.	✓	✓		
8	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.	✓	✓		
9	Check and ensure that environmental conditions are recorded in the BMR.	✓	✓		
10	Check and ensure that rinse water is released from QC and attached the test request from (TRF) in BMR	NA	NA		
11	Equipment status is updated for Cleaned, Qualification and Preventive maintenance.	✓	✓		

Note: *Tick mark (✓) if Complies and (X) if does not comply.

Equipment	Solution preparation vessel and stirrer	Colloidal Mill	Area
Equipment ID No.	-NA-	PD/CLM/001	Auto Coating-I
Previous product	Ultra B-Complex		
Batch No.	UBB2102S		
Cleaned by	Abi		
Checked by Production Sign/Date:	AK 27/02/2021		
Verified by IPQA Sign/Date:			

ENVIRONMENTAL CONDITIONS:

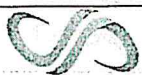
(Refer to SOP No.: QAGN/011)	Temperature °C Limit: NMT 25 °C	Observation	Prod. Sign.	Verified by IPQA	Date: 27/02/2021 Time: 19:57	Observation	Prod. Sign.	Verified by IPQA	Date: 27/02/2021 Time: 19:57
	Relative Humidity % Limit: NMT 60%	52%	AK						

APPROVAL FOR COATING SOLUTION PREPARATION:

Production Sign/Date: <u>AK 27/02/2021</u>	
Line Clearance IPQA Sign. / Date: <u>27/02/2021</u>	
Start Time/Date: <u>19:57 27/02/2021</u>	End Time/Date: <u>21:26 27/02/2021</u>

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L.K.</u>	<u>POA</u>	<u>27/02/2021</u>	<u>27/02/2021</u>
Date	<u>31/12/2020</u>	<u>31/12/2020</u>		

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210216

Customer:

Generic Health Care Pvt. Ltd.

14.0 Coating Procedure:

14.1 General Instructions:

1. Prepare the coating solution lot wise.
2. Do not use synthetic containers for storage/ transfer of coating solution
3. Do not use high speed stirrer for preparing coating solution. Avoid direct contact of body with Solvent & coating solution. Solvent based coating should be done in spark proof area.

14.2 TABLETS RECEIPT RECORD OF UNCOATED TABLETS FOR COATING:

Balance ID. No.: PB1BA1014

Sr. No.	Description	Observations	Checked By (Production)	Verified By (IPQA)
1.	Total Quantity (Net Qty.in Kg)	352.390	N.B.L 27/10/2024	
2.	Number of Containers	12	N.B.L 27/10/2024	

14.3 COATING SOLUTION PREPARATION

Sr. No.		General Instructions		Balance ID.: <u>PB/MB14</u>		
1.		Check the cleanliness of the Solution Preparation area and operation as per current version of SOP.				
2.		Use hand gloves while handling the materials				
3.		Transfer the verified coating materials to Coating solution preparation area.				
Step No.	Name of Ingredient & Operation	Time		Done by	Checked by Prod.	Verified by IPQA
		Start	Finish			
1.	LOT I Charge Purified water and Instacoat White (IC-U-3849) in a ss container slowly under continuous stirring. Continue stirring until uniform solution is obtained. If required mill the solution in colloidal mill until uniform solution is obtained. If required filter the solution through 100 nylon mesh if necessary	20:00	20:25	<u>[Signature]</u>	N.B.L	<u>[Signature]</u>
2.	LOT II Charge Purified water and Instacoat White (IC-U-3849) in a ss container slowly under continuous stirring. Continue stirring until uniform solution is obtained. If required mill the solution in colloidal mill until uniform solution is obtained. If required filter the solution through 100 nylon mesh if necessary	20:50	21:06	<u>[Signature]</u>	N.B.L	<u>[Signature]</u>
3.	Sieve integrity of 100 nylon mesh before Use	OK #	Not OK #	Checked by	Verified by	Remarks
		OK	NA	N.B.L	<u>[Signature]</u>	OK
		OK	NA	N.B.L	<u>[Signature]</u>	OK
4.	Sieve integrity of 100 nylon mesh after Use	OK	NA	N.B.L	<u>[Signature]</u>	OK
		OK	NA	N.B.L	<u>[Signature]</u>	OK

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMR/T/195-00 Customer:	Batch No.: G1F 210216 Generic Health Care Pvt. Ltd.

15.0 COATING AREA:

15.1 LINE CLEARANCE CHECKS: Date/Shift/Time: 28/12/2021 / 15:00 / 20:26

Sr. No.	Checks	*Observation					
		Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty containers, polythene bags, Tags and documents of previous batch/product are removed.	✓	✓				
2	Check and ensure that absence of previous batch/product from area below machine and inside machine.	✓	✓				
3	Check and ensure that machine body, machine parts and control panel are clean.	✓	✓				
4	Check and ensure that absence of previous batch/product below container weighing balance.	✓	✓				
5	Check and ensure that working desk, analytical balance and other accessories are clean.	✓	✓				
6	Check and ensure that Tube light fixture, supply grills, riser grills and filters, electrical fixtures and Drain point are clean.	✓	✓				
7	Check and ensure that instruments to be used are within calibration due date.	✓	✓				
8	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.	✓	✓				
9	Check and ensure that environmental conditions are recorded in the BMR.	✓	✓				
10	Check and ensure that rinse water is released from QC and attached the test request from (TRF)	NA	NA				
11	Equipment status is updated for Cleaned, Qualification and Preventive maintenance.	✓	✓				

Note: *Tick mark (✓) if Complies and (X) if does not comply.

Equipment	Coating Machine	Area
Equipment ID No.	PD/NEC/001	Coating area - I
Previous product	Ultra B-Complex	
Batch No.	UBB2102S	
Cleaned by	Abi	
Checked by Production Sign/Date:	AK 28/12/2021	
Verified by IPQA Sign/Date:		

ENVIRONMENTAL CONDITIONS:	Date: 28/12/2021	Time: 15:00	Date:	Time:	Date:	Time:
(Refer to SOP No.: QAGN/011)	Temperature °C	Limit: NMT 25 °C	23 °C	AK		
	Relative Humidity %	Limit: NMT 60%	52 %	AK		
	Differential Pressure (NLT 10 Pascal)		10 pascal	AK		

APPROVAL FOR COATING:

Production Sign/Date: AK 28/12/2021

Line Clearance IPQA Sign. / Date: 28/12/2021

Start Time/Date: 20:32 / 28/12/2021

End Time/Date: 00:15 / 29/12/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	AK	AK	AK
Date	31/12/2020	21/12/2020	31/12/2020	31/12/2020

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210216

Customer:

Generic Health Care Pvt. Ltd.

16.0 COATING

16.1 INSTRUCTION FOR FILM COATING:

Transfer the compressed tablets to coating area.

1. Load the tablets in coater.
2. Pre-warm the tablets with inlet temp. 55 °C - 60 °C and exhaust temp. 50 °C - 55 °C.
3. Set the spray gun connected to peristaltic pump by silicon tubing and start coating.
4. Carry out in process check after every 30 min. and record.
5. After completion of coating, dry the film coated tablets in the coating pan for about 10 min. with inlet temp. 55 °C - 60 °C.

Note: The film coating suspension need to be stirred slowly during the coating process to prevent suspended solids from setting.

16.2 COATING PROCESS:

Process Steps

Step No.	Name of Ingredient & Operation	Time		Done by	Checked by Prod.	Verified by IPQA
		Start	Finish			
LOT I						
1	Transfer the compressed tablets in to the coating Area	20:39	20:40	ABH	N.B.L	Q
2	Pre-warm the tablet with inlet temp. 55°C - 60°C and exhaust temp. 50°C - 55°C.	20:41	20:42	ABH	N.B.L	Q
3	Arrange the spray gun in such a way that the spray droplets just touch the tablet bed on upper rim. The spray should not fall on the wall of the pan. Weight gain obtained: <u>2.03</u> % (Approx. 2.0%)	20:43	21:56	ABH	N.B.L	Q
4	When the spraying is complete, dry the tablets perfectly, in the pan by hot air at NMT 45°C with intermittently flipping the tablets, until no more solvent odour is observed. Caution: Ensure the tablet bed temperature does not rise excessively.	21:57	22:16	ABH	N.B.L	Q
5	Found Disintegration Time: <u>04min 20sec</u> (Limit: NMT 30 minutes).	22:17	22:19	ABH	N.B.L	Q
6	Unload the film coated tablets in a HDPE container lined with double polybag.			ABH	N.B.L	Q
LOT II						
7	Transfer the compressed tablets in to the coating Area	22:25	22:30	ABH	N.B.L	Q
8	Pre-warm the tablet with inlet temp. 55°C - 60°C and exhaust temp. 50°C - 55°C.	22:31	22:39	ABH	N.B.L	Q
9	Arrange the spray gun in such a way that the spray droplets just touch the tablet bed on upper rim. The spray should not fall on the wall of the pan. Weight gain obtained: <u>2.16</u> % (Approx. 2.0%)	22:40	23:56	ABH	N.B.L	Q
10	When the spraying is complete, dry the tablets perfectly, in the pan by hot air at NMT 45°C with intermittently flipping the tablets, until no more solvent odour is observed. Caution: Ensure the tablet bed temperature does not rise excessively.	23:57	00:16	ABH	N.B.L	Q
11	Found Disintegration Time: <u>04min 49sec</u> (Limit: NMT 30 minutes).	00:11	00:19	ABH	N.B.L	Q
12	Unload the film coated tablets in a HDPE container lined with double polybag.			ABH	N.B.L	Q

16.1 INITIAL CHECKS OF COATING PARAMETERS:

S. No	Parameter	Set	Observed	
			LOT I	LOT II
1	Inlet Temp.	55 °C - 60 °C (To be established)	56 °C	57 °C
2	Exhaust air Temp.	50 °C - 55 °C (To be established)	42 °C	43 °C
3	Tablet Bed temp.	50 °C - 55 °C (To be established)	40 °C	41 °C
4	Atomization air pressure	1.5 - 3 Kg/cm ² (To be established)	2.5 kg/cm ²	2.5 kg/cm ²
5	Pan speed	2.0 - 4.0 RPM (To be established)	2.5 kg/min	3.0 RPM
6	Spray rate	50 ml/min - 100 ml/min (To be established)	700 ml/min	700 ml/min
Checked by Production/ Date			ABH 27/12/2024	ABH 27/12/2024
Verified by IPQA/ Date			Q 27/12/2024	Q 27/12/2024

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	Q	Q	Q
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210216

Customer:

Generic Health Care Pvt. Ltd.

16.3 INDIVIDUAL WEIGHT CHECKING OF PRE-WARMED TABLETS:

Sr. No.	Weight (mg)		Sr. No.	Weight (mg)	
	LOT I	LOT II		LOT I	LOT II
1	119	119	11	120	126
2	117	117	12	119	119
3	116	116	13	121	119
4	118	119	14	119	119
5	117	126	15	117	129
6	118	119	16	119	119
7	118	118	17	118	129
8	117	119	18	117	119
9	119	118	19	119	118
10	116	117	20	118	117
Total			2.362		
Avg. Weight			118.10		
% of Weight Build up			LOT I: 1.69%		
			LOT II: 1.69%		

16.4 PERCENTAGE OF COATING WEIGHT BUILDS UP:

% of Weight buildup = $\frac{\text{Avg. wt. of coated tablets} - \text{Avg. wt. of core tablet (Pre-warmed)}}{\text{Avg. wt. of core tablets (Pre-warmed)}}$

$$= 1.69\%$$

16.5 COATING IN-PROCESS CHECKS FOR UNIFORMITY OF WEIGHT: (Frequency: Every 1-Hour for production and 2 hour for IPQA)

Date: 27/12/2021 Shift: 1 Time: 20:44

Date	Time	Blower Temp. 55-60 °C (To be established)	Exhaust Air Temp 50-55 °C (To be established)	Bed Temp. 50-55 °C (To be established)	Atomizing Air Pressure 1.5- 3.0 Kg/cm ² (To be established)	Pan RPM 2.0 to 4.0 RPM (To be established)	Weight of 20 Tablets 2.416 g ± 3 % (2.344 g – 2.488 g)	Checked by	Verified by
27/12/2021	20:45	56°C	42°C	40°C	2.5 kg/cm ²	3.5 RPM	2.382 (g)	AK	✓
27/12/2021	21:52	56°C	42°C	40°C	2.5 kg/cm ²	3.0 RPM	2.396 (g)	N.B.L	✓
27/12/2021	22:42	56°C	42°C	40°C	2.5 kg/cm ²	3.0 RPM	2.376 (g)	N.B.L	✓
27/12/2021	23:54	56°C	42°C	40°C	2.5 kg/cm ²	3.0 RPM	2.397 (g)	N.B.L	✓

Checked by Production

Sign & Date:

N.B.L 27/12/2021

Verified by IPQA

Sign & Date:

27/12/2021

N.B.L
27/12/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	AK	AK	AK
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: 31F 210816

Customer:

Generic Health Care Pvt. Ltd.

16.6 FINAL COATING PARAMETERS CHECKS: (PRODUCTION)

Parameters	Limits	Observed	
		LOT I	LOT II
Description	White coloured capsule shaped film coated tablets with breakline on one side and plain on other side	OK	OK
Theoretical weight per tablet	120.800 mg $\pm$ 3 % (117.176 mg – 124.424 mg)	120.110	120.096
Weight of 20 tablets	2.416 g $\pm$ 3 % (2.344 g – 2.488 g)	2.402	2.396
Uniformity of weight	120.800 mg $\pm$ 5 % (114.760 mg – 126.840 mg)		
Length (mm)	10.20 mm $\pm$ 0.1 mm (10.10 mm – 10.30 mm) (To be established)	10.15 mm	10.14
Width (mm)	4.10 mm $\pm$ 0.1 mm (4.00 mm – 4.20 mm) (To be established)	4.11 mm	4.12 mm
Thickness	(2.50 mm – 3.10 mm) (To be established)	2.82 mm	2.86
Disintegration test	NMT 30 min	04 min 40 sec	04 min 19 sec
Checked by Production/ Date		N.B. 27/10/2021	N.B. 27/10/2021

16.7 FINAL COATING PARAMETERS CHECKS: (IPQA)

Parameters	Limits	Observed	
		LOT I	LOT II
Description	White coloured capsule shaped film coated tablets with breakline on one side and plain on other side	OK	OK
Theoretical weight per tablet	120.800 mg $\pm$ 3 % (117.176 mg – 124.424 mg)	119.9	121.06
Weight of 20 tablets	2.416 g $\pm$ 3 % (2.344 g – 2.488 g)	2.386	2.400
Uniformity of weight	120.800 mg $\pm$ 5 % (114.760 mg – 126.840 mg)	-0.75%	-2.52%
Length (mm)	10.20 mm $\pm$ 0.1 mm (10.10 mm – 10.30 mm) (To be established)	10.14 mm	10.16 mm
Width (mm)	4.10 mm $\pm$ 0.1 mm (4.00 mm – 4.20 mm) (To be established)	4.13 mm	4.15 mm
Thickness	(2.50 mm – 3.10 mm) (To be established)	2.82 mm	2.84 mm
Disintegration test	NMT 30 min	04 min 46 sec	5 min 44 sec
Checked by IPQA/ Date		27/10/2021	27/10/2021

16.8 UNIFORMITY CHECKS FOR COATED TABLETS (PRODUCTION)

Sample No.	1	2	3	4	5	6	7	8	9	10
Weight	118	119	121	120	121	120	121	119	118	121
Sample No.	11	12	13	14	15	16	17	18	19	20
Weight	120	121	118	119	120	119	118	120	121	120
Thickness	2.83	2.81	2.82	2.83	2.84					

Group Weight of 20 tablets: 2.394

Checked by Production: N.B. 27/10/2021

Date: 27/10/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K.	N.B.	N.B.	N.B.
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210216

Customer:

Generic Health Care Pvt. Ltd.

16.9 UNIFORMITY CHECKS FOR COATED TABLETS (IPQA)

Sample No.	1	2	3	4	5	6	7	8	9	10
Weight	113	119	118	119	118	119	121	121	120	119
Sample No.	11	12	13	14	15	16	17	18	19	20
Weight	119	121	121	119	118	118	119	121	120	120
Thickness	2.83	2.84	2.81	2.82	2.80					

Group Weight of 20 tablets: 2.385

Checked by Production: *[Signature]*

Date: 27/02/2021

16.10 ACTUAL AVERAGE WEIGHT OF COATED TABLETS:

Weight of 100 coated tablet = 119.98 mg
100

16.11 WEIGHT OF FILM COATED TABLETS:

Container No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Weighed by	Checked by Production	Verified by IPQA
1	29.560	2.200	27.360	Kastly	N. Bel	P
2	33.240	2.200	31.040	Kastly	N. Bel	P
3	32.940	2.200	30.740	Kastly	N. Bel	P
4	33.880	2.200	31.680	Kastly	N. Bel	P
5	34.020	2.200	31.820	Kastly	N. Bel	P
6	31.860	2.200	29.660	Kastly	N. Bel	P
7	31.360	2.200	29.160	Kastly	N. Bel	P
8	33.620	2.200	30.920	Kastly	N. Bel	P
9	32.730	2.200	30.530	Kastly	N. Bel	P
10	27.760	2.200	25.560	Kastly	N. Bel	P
11	31.450	2.200	29.250	Kastly	N. Bel	P
12	32.690	2.200	30.490	Kastly	N. Bel	P
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						
25						
26						
27						
28						
29						
30						
TOTAL			258.210			

M. B. 25/02/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 54 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13. Batch Size: 30,00,000 Tablets
Product GENSET	BMR. No.: BMR/T/195-00 Customer:		Batch No.: <u>GF 210216</u> Generic Health Care Pvt. Ltd.

16.12 RECONCILIATION (COATING STAGE):

Average weight of coated Tablet: 119.17 mg

1.0	Batch size	:	362.400 Kg.	30,00,000 Nos.
2.0	Weight of coated tablets	:	<u>358.210</u> Kg.	<u>2985580</u> Nos.
3.0	Coating loss [@]	:	<u>0.090</u> Kg.	
4.0	In-process samples of all stages			
	A	IPQC Samples	:	<u>0.030</u> Kg.
	B	QC Samples	:	<u>0.040</u> Kg.
	C	Validation Samples	:	<u>NA</u> Kg.
5.0	Total in process samples: (A + B + C)	:	<u>0.070</u> Kg.	
6.0	Total: (2.0 + 5.0)	:	<u>358.280</u> Kg.	<u>2986164</u> Nos.
7.0	Yield {6.0 x 100 / 1.0}*	:		<u>99.53</u> %

* Actually yield will be calculated after 3 validation batches

@Total rejects destroyed: 0.090 Kg. (Rejected materials shall be destroyed as per SOP No: QAGN/048)

Done by Production Sign/Date: N. R. 28/02/2021 Checked by IPQA Sign/Date: [Signature] 28/02/2021

Test request form raised by Prod Sign/Date: N. R. 28/02/2021

Test request form received by IPQA Sign/Date: [Signature] 28/02/2021

16.13 RELEASE FOR INSPECTION:

Reconciliation checked and Coated tablets released for inspection

IPQA Sign: [Signature] Date: 01/03/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K.</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>31/12/2020</u>

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LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210216

Customer:

Generic Health Care Pvt. Ltd.

17.0 INSPECTION LINE CLEARANCE:

Date/Shift/Time: 01/03/2021 / 01/09:00/

Sr. No.	Checks	*Observation			
		Prod	IPQA	Prod	IPQA
1	Check and ensure that empty containers, polythene bags, Tags and documents of previous batch/product are removed.	✓	✓		
2	Check and ensure that absence of previous batch/product from area below machine and inside machine.	✓	✓		
3	Check and ensure that machine body, machine parts and control panel are clean.	✓	✓		
4	Check and ensure that absence of previous batch/product below container weighing balance.	✓	✓		
5	Check and ensure that working desk, analytical balance and other accessories are clean.	✓	✓		
6	Check and ensure that Tube light fixture, supply grills, riser grills and filters, electrical fixtures and Drain point are clean.	✓	✓		
7	Check and ensure that instruments to be used are within calibration due date.	✓	✓		
8	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.	✓	✓		
9	Check and ensure that environmental conditions are recorded in the BMR.	✓	✓		
10	Check and ensure that rinse water is released from QC and attached the test request from (TRF) in BMR	✓	✓		
11	Equipment status is updated for Cleaned, Qualification and Preventive maintenance.	✓	✓		

Note: *Tick mark (✓) if Complies and (X) if does not comply.

Equipment	Inspection Belt	Metal Detector	Area
Equipment ID No.	PD/INB/002	PD/MTD/002	Inspection - 02
Previous product	Alimiprine-mr		
Batch No.	GF2210213		
Cleaned by	REW		
Checked by Production Sign/Date:	01/03/2021		
Verified by IPQA Sign/Date:	01/03/2021		

ENVIRONMENTAL CONDITIONS:

(Refer to SOP No.: QAGN/011)	Temperature °C Limit: NMT 25 °C Relative Humidity % Limit: NMT 60%	Date: 01/03/2021 Time: 09:00			Date: Time:		
		Observation	Prod. Sign.	Verified by IPQA	Observation	Prod. Sign.	Verified by IPQA
		24.6	CR	PD			
		56.7	CR	PD			

APPROVAL FOR INSPECTION:

Production Sign/Date: 01/03/2021
Line Clearance IPQA Sign. / Date: 01/03/2021
Start Time/Date: 09:00 / 01/03/2021
End Time/Date: 12:26 / 01/03/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K	PD	01/03/2021	01/03/2021
Date	31/12/2020	31/12/2020		

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 56 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
	Product: GENSET	BMR. No.: BMR/T/195-00 Customer:	Batch No.: G1F 210216 Generic Health Care Pvt. Ltd.

18.0 INSPECTION PROCESS

18.1 INSTRUCTIONS

S. No.	Process Instructions
1	Carry out visual inspection of tablets on inspection belt area as per the SOP No. PDOP/019.
2	Collect inspected tablets in containers lined with polythene bags. Weigh the containers and record the weight.
3	Intimate In-process Quality Assurance.

18.2 PERFORMANCE CHECKS RECORD FOR METAL DETECTOR:

Sr. No	Process instructions
1.	At the start of the activity, after each break and at the end of operation/shift) as per SOP No. PDGN/022.
2.	Testing frequency: Startup, End of the activity and after every break time.
3.	Acceptance Criteria: 1. Ferrous, Stainless steel & Non-Ferrous shall be detected & rejected. 2. Nonmetallic shall not be detected.

Date & Time	Trial No.	Metal Detector ID No.: PD/MED/02...&PD/MED/...Nt...				Result	Checked by Production	Verified By IPQA
		Ferrous (0.3 mm)	Stainless steel (0.5 mm)	Non-Ferrous (0.3 mm)	Non-metallic			
01/02/2021 09:15	1	✓	✓	✓	X	Pass	N.B.L	P
	2	✓	✓	✓	X	Pass	N.B.L	P
	3	✓	✓	✓	X	Pass	N.B.L	P
01/02/2021 10:55	1	✓	✓	✓	X	Pass	N.B.L	P
	2	✓	✓	✓	X	Pass	N.B.L	P
	3	✓	✓	✓	X	Pass	N.B.L	P
01/02/2021 11:25	1	✓	✓	✓	X	Pass	N.B.L	P
	2	✓	✓	✓	X	Pass	N.B.L	P
	3	✓	✓	✓	X	Pass	N.B.L	P
	1	✓	✓	✓	X	Pass	N.B.L	P
	2							
	3							
	1							
	2							
	3							

Note: Put ✓ mark for detection and x mark for non-detection
 If during the test Metal Detector fails to reject any of the Standard chips then mention the corrective action taken.
 (To be filled by Production)
 Note: Take QA Approval before proceeding to next stage

18.3 TABLETS VISUAL INSPECTION RECORD:

Date	Container No		Time		Total Quantity Rejected	Tablet Inspection Done by/Date	Checked by/Date
	From	To	Started	Completed			
01/02/2021	01	04	09:30	12:04	0.862	Dem, pumph	N.B.L 01/02/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	P. Ka	S. Ka	S. Ka
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: G13 21 02 16

Customer:

Generic Health Care Pvt. Ltd.

18.4 WEIGHING RECORD OF INSPECTED TABLETS:

Container No	Gross weight Kg	Tare weight Kg	Net. weight Kg	Container No	Gross weight Kg	Tare weight Kg	Net. weight Kg
1	29.520	2.200	27.320	16			
2	33.220	2.200	31.020	17			
3	32.920	2.200	30.720	18			
4	33.820	2.200	31.620	19			
5	34.040	2.200	31.840	20			
6	31.830	2.200	29.630	21			
7	31.330	2.200	29.130	22			
8	33.100	2.200	30.900	23			
9	32.720	2.200	30.520	24			
10	27.770	2.200	25.570	25			
11	31.410	2.200	29.210	26			
12	32.090	2.200	29.890	27			
13				28			
14				29			
15				30			
Total			357.350 Kg	Total			357.350 Kg
				Grand Total			357.350 Kg

Weighing Done By: P. R. S. / 01/03/2021 Checked By Prod./ Date: P. R. S. / 01/03/2021 Verified by IPQA Sign./Date: P. R. S. / 01/03/2021

18.5 RECONCILIATION: (INSPECTION OF TABLETS)

1.0	Theoretical weight of Tablets	:	362.400 Kg	30,00,000 No's
2.0	Tablets transferred for Inspection	:	358.210 kg	2985520 No's
3.0	Total weight of good Tablets	:	357.350 kg	2978413 No's
4.0	Rejected Tablets	:	0.860 kg	7167 No's
5.0	*Yield = $\frac{3.0}{1.0} \times 100$	:		99.28 %

*Actually yield will be calculated after 3 validation batches.

Total rejects destroyed: 0.860 Kg.

Rejected materials should be destroyed in the presence of QA.

Done by Production sign/Date: P. R. S. / 01/03/2021

Checked by IPQA sign/Date: P. R. S. / 01/03/2021

18.6 RELEASE FOR PACKING:

BMR reviewed by IPQA Sign/Date : P. R. S. / 01/03/2021

BMR Released for packing by QA Head Sign/Date: P. R. S. / 01/03/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>P. R. S.</u>	<u>P. R. S.</u>	<u>P. R. S.</u>
Date	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>31/12/2020</u>

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapei Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210216

Customer:

Generic Health Care Pvt. Ltd.

19.0 BMR REVIEW DETAILS:

Reviewed by	Name	Sign./Date
Production Executive	N. BALABASKAR	N. Bal 01/03/2021
QA Executive	Ram Kumar	Ram Kumar 01/03/2021
Production Assistant Manager/ HOD	BAVASUBRAMANIAN B	Balasubramanian B 01/03/2021
QA Manager/ HOD	Stephen R	Stephen R 01/03/21

20.0 REVISION HISTORY:

Sr. No.	Document No.	Reason for Revision	Supersedes No.
1	BMR/T/195-00	New Document	Nil

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K.	[Signature]	[Signature]	[Signature]
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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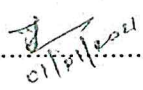
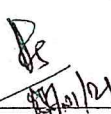
 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 1 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMR/T/195-00 Customer:	Batch No.: GF210101 Generic Health Care Pvt. Ltd.

BATCH MANUFACTURING RECORD COVER SHEET

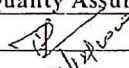
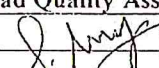
PRODUCT NAME	: GENSET
GENERIC NAME	: Cetirizine Tablets BP 10 mg
LABEL CLAIM	Each film coated tablet contains: Cetirizine Hydrochloride BP10 mg Excipients q.s. Colour: Approved colour used
MFR No. / Reference Document No.	: MFR/T/106-00
BMR No.	: BMR/T/195-00
REVISION No.	: 00
SUPERSEDES No.	: NIL
BMR EFFECTIVE BATCH NUMBER/DATE	: GF210101 / 01/01/2021
MFG.LIC No.	: PON/DRUGS/19 13 4323
STORAGE	: Store in cool and dry place. Protect from light and moisture.
BMR-ISSUED BY/DATE (QA)	:  01/10/2021
BMR CHECKED & RECEIVED BY/DATE (PRODUCTION)	:  01/10/2021
SHELF LIFE	: 36 Months
BATCH SIZE	: 30,00,000 Tablets (362.400 Kg)
MFG. DATE: 01/01/2021	: EXP. DATE: 12/12/2023

RECOVERY ADDITION RECORD

BATCH NO	MFG	EXP	QUANTITY	REVISED BATCH SIZE

ALLOTTED BY: QA SIGN/DATE:  01/10/2021	COUNTER CHECKED BY:  QA SIGN/DATE: 01/10/2021
DATE OF COMMENCEMENT: 02/01/2021...	DATE OF COMPLETION: 05/01/2021
RELEASED QUANTITY OF TABLETS FOR PACKING	: 2973278 tablets.
RELEASE FOR PACKING STAGE HEAD OF QA SIGN/DATE:  01/10/2021	

This BMR contains 58 Pages + Nil Additional Pages

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka			
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 2 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMR/T/195-00 Customer:	Batch No.: GF210101 Generic Health Care Pvt. Ltd.

1.0 INDEX

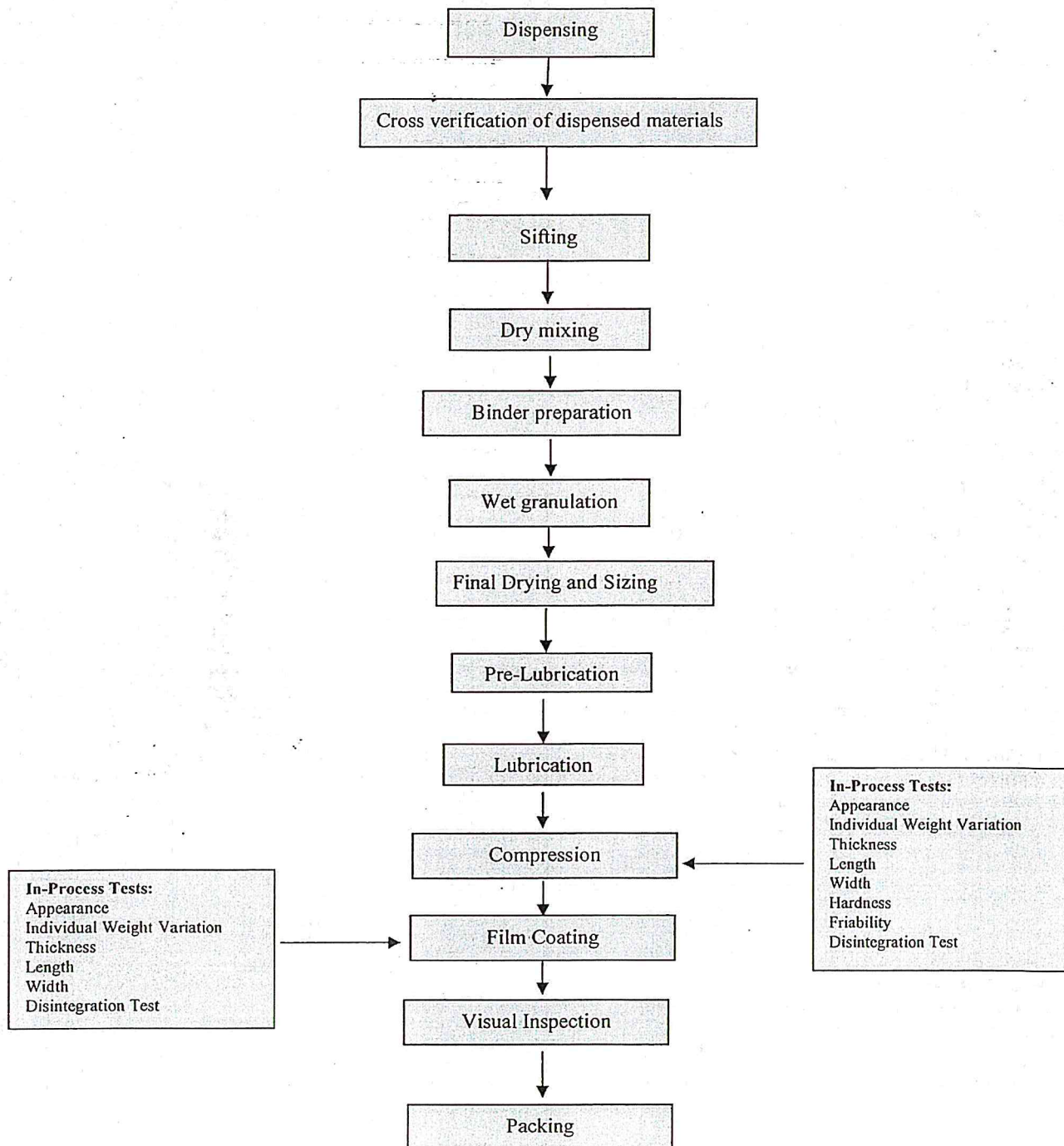
Sr. No.	Content	Page No.
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2.0	Flow Chart	3
3.0	Indent of active pharmaceutical ingredients & excipients	4
4.0	Calculation	5
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Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	P. K. P.	P. K. P.	S. P. P.
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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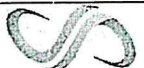
 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 3 of 58
	BATCH MANUFACTURING RECORD	Product Code: G13	Batch Size: 30,00,000 Tablets
	Product	GENSET	Batch No.: GF210101
		Customer:	Generic Health Care Pvt. Ltd.

2.0 PROCESS FLOW CHART



Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. Ka</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 4 of 58
	BATCH MANUFACTURING RECORD	Product Code: G13	Batch Size: 30,00,000 Tablets
	Product	GENSET	Batch No.: GF 210101
		Customer:	Generic Health Care Pvt. Ltd.

3.0 INDENT OF ACTIVE PHARMACEUTICAL INGREDIENTS & EXCIPIENTS:

Sr. No.	Name of the Ingredient	Spec.	Item Code	Quantity/ Tablets (mg)	Std. quantity per 30,00,000 tablets (kg)	OA/ PL (%)	Req. quantity per 30,00,000 tablets (kg)
Dry mixing material:							
1	Cetirizine Hydrochloride*	BP	RAI/SP/C018	10.000	30.000	-	30.000
2	Dried Maize Starch**	BP	IRM/SP/M001	59.900	179.700	-	179.700
3	Lactose Monohydrate	BP	REX/SP/L003	32.800	98.400	-	98.400
Binder Material:							
4	Dried Maize Starch	BP	IRM/SP/M001	4.270	12.810	-	12.810
5	Purified Water	BP	NA	q.s.	40.000	-	40.000
Theoretical Weight of Dried Granules				106.970	320.910	-	320.910
Lubrication Material:							
6	Colloidal Silicon Dioxide	BP	REX/GH/C001	0.470	1.410	-	1.410
7	Sodium Starch Glycollate	BP	REX/GH/S001	5.880	17.640	-	17.640
8	Purified Talc	BP	REX/SP/P011	2.340	7.020	-	7.020
9	Magnesium Stearate	BP	REX/GH/M001	2.340	7.020	-	7.020
Theoretical Weight of the Lubricated granules				118.000	354.000	-	354.000
Theoretical weight of Compressed tablet				118.000	354.000	-	354.000
Coating Material:							
10	Instacoat White (IC-U-3849)	IHS	REX/SP/I006	3.500	10.500	-	10.500
11	Purified Water	BP	NA	q.s	25.000	-	25.000
Theoretical weight of Coated tablet				121.500	364.500	-	364.500
Actual weight of Coated tablet				120.800@	362.400@	-	362.400@

NOTE: *API quantity shall be calculated based on potency.

OA: Overages, PL: Process loss

@Average weight has calculated and rounded off to 80% of coating material

Potency calculation:

Theoretical Quantity of Cetirizine Hydrochloride required in Kg for a batch size of 30,00,000 Tablets are calculated.

** Excess Quantity shall be compensating from Dried Maize Starch

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	POF	J. Jeyaraj	S. Pragasam
Date	31/12/2020	21/12/2020	31/12/2020	31/12/2020

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF210101

Customer:

Generic Health Care Pvt. Ltd.

Note: If assay of API is more than 100%, it should be considered as 100% at the time of calculation.

Standard quantity of Cetirizine Hydrochloride (A): 30.000 Kg

Standard quantity of Dried Maize Starch (B): 179.700 kg

$$\text{Theoretical Qty} = \frac{\text{Label Claim} \times \text{Std. Batch Size (in no's)}}{1000 \times 1000} = \frac{10 \times 30,00,000}{1000 \times 1000} = 30.000 \text{ kg}$$

1) Calculation for Single A. R. No. Ray/00524, Assay on dried basis: 100.735 w/w, LOD: 0.41 w/w
Exp. Date...07/2024

$$\text{Actual Quantity (Kg) (C)} = \frac{\text{Standard qty. required} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{30.20 \times 100 \times 100}{100 \times (100 - 0.41)} = \frac{30.124}{1} \text{ Kg/2}$$

LOT I: 15.062 Kg, LOT II: 15.062 Kg

Actual Quantity (Kg) (D) = (30.000 Kg + 179.700 Kg) - (C) = 179.576 Kg/2.

LOT I: 89.785 Kg, LOT II: 89.788 Kg

Sr. No.	A. R. No.	Available Qty. (Kg) (E)	Assay % w/w	LOD % w/w	Actual Qty. = $\frac{\text{Available Qty.} \times \text{Assay} \times (100 - \text{LOD})}{100 \times 100}$
Total-Actual Quantity (F)					

Calculation for Remaining Quantity Required (G):

Theoretical Qty. – Actual Quantity (F) = _____ Kg

AR. No.: _____, Assay on dried basis: _____ w/w, LOD: _____ %w/w, Exp. Date-----

$$\text{Actual Quantity (Kg) (H)} = \frac{\text{Remaining qty. required (G)} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{\cancel{X} \times 100 \times 100}{\cancel{X} (100 -)} = \text{Kg.}$$

Total Qty. of Cetirizine Hydrochloride to be dispensed (I) = (E) + (H) = _____ Kg/2

LOT I: _____ Kg, LOT II: _____ Kg

Actual Quantity (Kg) (J) = (30.000 Kg + 179.700 Kg) - (I) = _____ Kg/2.

LOT I: _____ Kg, LOT II: _____ Kg

Done By/On (QA):

Checked By/On (Production):

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	5/12/2020	5/12/2020	5/12/2020	

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF210101

Customer:

Generic Health Care Pvt. Ltd.

5.0 DISPENSING LINE CLEARANCE CHECKS

Date: 01/01/2021 Time: 11:20

Sr. No.	Checks	Observation*	
		Store	IPQA
1	Check and ensure that empty SS containers, polythene bags, Tags, documents and scrap from waste bin of previous batch/product are removed from the area.	✓	✓
2	Check and ensure that display stand and weighing balance are clean.	✓	✓
3	Check and ensure that SS scoop, SS spatula and SS trolley are clean.	✓	✓
4	Check and ensure that area (floor, walls, ceiling, doors and windows) are clean.	✓	✓
5	Check and ensure that Magnehelic gauges, tube light fixtures, supply grills, return riser grills and filters, electrical fixture are clean.	✓	✓
6	Check and ensure that all the sides of dispensing booth is clean	✓	✓
7	Check all the gauges of dispensing booth before switching ON.	✓	✓
8	Check and ensure that weighing balances and pressure gauges to be used are within calibration due date.	✓	✓
9	Check that the daily records (Balance Logbook, RH & Temp. record) are updated and signed.	✓	✓
10	Equipment status is updated for Cleaned and Preventive maintenance.	✓	✓

Note: *Tick mark (✓) if Complies, (X) if does not comply and (NA) if not applicable.

Equipment	Dispensing Booth	Weighing Balance	Area
ID No.	SDP01001	SS Ball 005 SS Ball 006	Dispensing booth
Previous Product	Gabapentin - 100		
B. No.	G03L101A		
Cleaned by Sign/Date	Ravi 01/01/2021		
Checked by Store Sign/Date	N. A. 01/01/2021		
Verified by IPQA Sign/Date	Maya 01/01/2021		

ENVIRONMENTAL CONDITIONS: Date: 01/01/2021 Time: 11:23

(For Reference SOP No.: QAGN/011)

	Observation	Checked by Store Sign/Date	Verified by IPQA Sign/Date
Temperature (Limit: NMT 25°C)	23°C	N. A. 01/01/2021	Maya 01/01/2021
Relative Humidity % (Limit: NMT 60%)	48%	N. A. 01/01/2021	Maya 01/01/2021
Differential Pressure (NLT 10 Pascal)	10 pasc	N. A. 01/01/2021	Maya 01/01/2021
Differential Pressure across the booth Limit: 5 to 20 mm Water	11 mm	N. A. 01/01/2021	Maya 01/01/2021

APPROVAL FOR DISPENSING BY IPQA: Sign: Maya Date: 01/01/2021

Dispensing start Time: 11:40 End Time: 15:30

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	31/12/2020	31/12/2020	31/12/2020
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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 SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Kurumbapet Industrial Estate, Villianur Commune, Pudukcherry-605009.	SAI PRIMUS LIFE BIOTECH PVT LTD Page 7 of 58	
	BATCH MANUFACTURING RECORD Product Code: G13 Batch Size: 30,00,000 Tablets	
	GENSET BMR. No.: BMR/T/195-00 Batch No.: G17 210101 Customer: Generic Health Care Pvt. Ltd.	

5.1 Dispensing Weighing Sheet:

Balance ID: 5112005 Date: 31/12/2020 Shift: 1 Time: 11:45

Sr. No.	Ingredients	Spec.	Item code	UOM	Std. Qty.	Req. Qty.	A.R. No.	Issued Qty.		Weighed By Store (Sign & Date)	Checked By (IPQA) (Sign & Date)	Cross Checked by	
								Gross Wt.	Tare Wt.			Checked Production (Sign & Date)	Verified IPQA (Sign & Date)

LOT - I

Dry mixing material:

1	Cetirizine Hydrochloride*	BP	RAI/SP/C018	Kg	15.000	15.062	Pack 100584	15.160	0.160	15.000	15.000	15.000	15.000
2	Dried Maize Starch**	BP	IRM/SP/M001	Kg	89.850	89.782	Pack 100584	89.782	0.068	89.850	89.850	89.850	89.850
3	Lactose Monohydrate	BP	REX/SP/L003	Kg	49.200	49.200	Pack 100584	49.200	0.000	49.200	49.200	49.200	49.200

Binder Material:

4	Dried Maize Starch	BP	IRM/SP/M001	Kg	6.405	6.405	Pack 100584	6.405	0.000	6.405	6.405	6.405	6.405
5	Purified Water	BP	NA	Kg	20.000	20.000	Pack 100584	20.000	0.000	20.000	20.000	20.000	20.000

LOT - II

Dry mixing material:

6	Cetirizine Hydrochloride*	BP	RAI/SP/C018	Kg	15.000	15.062	Pack 100584	15.160	0.160	15.000	15.000	15.000	15.000
7	Dried Maize Starch**	BP	IRM/SP/M001	Kg	89.850	89.782	Pack 100584	89.782	0.068	89.850	89.850	89.850	89.850
8	Lactose Monohydrate	BP	REX/SP/L003	Kg	49.200	49.200	Pack 100584	49.200	0.000	49.200	49.200	49.200	49.200

Binder Material:

9	Dried Maize Starch	BP	IRM/SP/M001	Kg	6.405	6.405	Pack 100584	6.405	0.000	6.405	6.405	6.405	6.405
10	Purified Water	BP	NA	Kg	20.000	20.000	Pack 100584	20.000	0.000	20.000	20.000	20.000	20.000

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<u>1. K</u>	<u>1. K</u>	<u>1. K</u>	<u>1. K</u>	
Date	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>31/12/2020</u>	

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune,
Puducherry-605009.

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Product

GENSET

BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

BMR. No.: BMR/T/195-00

Batch No.: G1F 210101

Customer:

Generic Health Care Pvt. Ltd.

Sr. No.	Ingredients	Spec.	Item code	UOM	Std. Qty.	Req. Qty.	A.R. No.	Issued Qty.		Weighed By Store (Sign & Date)	Checked By (IPQA) (Sign & Date)	Cross Checked by	
								Gross Wt.	Tare Wt.			Net Wt.	Checked Production (Sign & Date)
Lubrication Material:													
11	Colloidal Silicon Dioxide	BP	REX/GH/C001	Kg	1.410	1.410	Recd 100416	1.630	0.220	1.410	10/10/2021	10/10/2021	10/10/2021
12	Sodium Starch Glycollate	BP	REX/GH/S001	Kg	17.640	17.640	Recd 100431	17.840	0.200	17.640	10/10/2021	10/10/2021	10/10/2021
13	Purified Talc	BP	REX/SP/P011	Kg	7.020	7.020	Recd 1004102	7.110	0.090	7.020	10/10/2021	10/10/2021	10/10/2021
14	Magnesium Stearate	BP	REX/GH/M001	Kg	7.020	7.020	Recd 100489	7.110	0.090	7.020	10/10/2021	10/10/2021	10/10/2021
Coating Material:													
LOT I													
15	Instacoat White (IC-U-3849)	IHS	REX/SP/I006	Kg	5.250	5.250	Recd 100447	5.340	0.090	5.250	10/10/2021	10/10/2021	10/10/2021
16	Purified Water	BP	NA	Kg	12.500	12.500	Recd 100445		NA	12.500	10/10/2021	10/10/2021	10/10/2021
LOT II													
17	Instacoat White (IC-U-3849)	IHS	REX/SP/I006	Kg	5.250	5.250	Recd 100447	5.340	0.090	5.250	10/10/2021	10/10/2021	10/10/2021
18	Purified Water	BP	NA	Kg	12.500	12.500	Recd 100415		NA	12.500	10/10/2021	10/10/2021	10/10/2021

Prepared by:		Checked by:		Approved By:	
Dept.	Production		Quality Assurance	Head Quality Assurance	
Sign.	L. Ka			S. Jeyaraj	
Date	31/12/2020				

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SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMRT/195-00

Batch No.: G1F210101

Customer:

Generic Health Care Pvt. Ltd.

6.0 GRANULATION LINE CLEARANCE CHECKS: Date/Shift: 02/01/2021 / G /

Sr. No.	Checks	Time:	*Observations					
			Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty SS containers, polythene bags, Tags and documents of previous batch/product are removed.	9.00	✓	✓				
2	Check and ensure that Scrap from waste bin is removed and new polythene bag is put into it.		✓	✓				
3	Check and ensure that display, display stand, weighing balance are clean.		✓	✓				
4	Check and ensure that SS storage Cabinet and Drain point are clean.		✓	✓				
5	Check and ensure that absence of previous batch/product from area below machine		✓	✓				
6	Check and ensure that all equipment body and inside the vessel are clean		✓	✓				
7	Check and ensure that Tube light fixture, supply grills, riser grills and filters and electrical fixtures are clean		✓	✓				
8	Check and ensure that instruments to be used are within calibration due date and earthing connection.		✓	✓				
9	Check and ensure that daily records (Logbook, Balance, Temp. & RH) are updated and signed.		✓	✓				
10	Check and ensure that environment condition and record on BMR		✓	✓				
11	Check and ensure that rinse water is released from QC and attached the test request from (TRF)		✓	✓				
12	Equipment status is updated for Cleaned and Preventive maintenance.		✓	✓				

Note: *Tick mark (✓) if Complies, (X) if does not comply and (NA) if not applicable.

Equipment	Sifter	Multimill	RMG	FBD	Area
EQP. ID No.	PD/VBS/002	PD/M2M/002	PD/RMG/001	PD/FBD/001	Granulation II
Previous Product	Lila cold flu				
Batch No.	G1F210102				
Cleaned by	Karthi				
Checked by					
Verified by	H 02/01/2021				

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 02/1/2021 Time: 9.05			Date: Time:			Date: Time:		
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	23°C	L	HA						
RH % (NMT 60%)	52%	L	HA						
DP (NLT 10 Pascal)	10 pascal	L	HA						

APPROVAL FOR SIFTING AND GRANULATION:

Production Sign/Date:	L 02/1/2021		
IPQA Sign/Date:	H 02/01/2021		
Start and End Time:	09.06	12.29	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	POB	g. 31/12/2020	g. 31/12/2020
Date	31/12/2020	21/12/2020		

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 10 of 58
	BATCH MANUFACTURING RECORD	Product Code: G13	Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMR/T/195-00	Batch No.: GF 210101
		Customer:	Generic Health Care Pvt. Ltd.

7.0 GRANULATION SIFTING INSTRUCTIONS AND SIFTING RECORD: LOT-I Date: 21/11/2020 Shift: ...Gh.....

S. No	Name of Ingredient	Weight before sifting in Kg	Sieve size	ID No.	Sieve Integrity before use	Time		Sieve Integrity after use	Done by	Ckd by
						From	To			
Dry mixing:										
1	Cetirizine Hydrochloride	15.642	40#	PD/30-SE-40/02	OK/ Not OK	9.06	9.09	OK/ Not OK	karthe	P.vij
2	Dried Maize Starch	89.209	30#	PD/30-SE-30/02	OK/ Not OK	9.10	9.15	OK/ Not OK	karthe	P.vij
3	Lactose Monohydrate	119.200	30#			9.16	9.20		karthe	P.vij
Binder Material:										
4	Dried Maize Starch	6.405	NA	NA	NA	-	-	NA	karthe	P.vij
5	Purified Water	20.00				-	-		karthe	P.vij

7.1 MANUFACTURING PROCESS:

7.1 MANUFACTURING PROCESS:					
Step No.	Process Instructions	Date: 21/11/2020		Done by	Checked by
		Time			
		Started	Completed		
1	Dry mixing: Transfer the sifted material from step 7.0 (1-3) into the RMG. Mix for 10 minute with impeller at slow speed and chopper 'off'. Impeller Speed: <u>55</u> RPM	9.21	9.31	karthe	P.vij
2	Binder Preparation: Take purified water and disperse Dried Maize Starch to form slurry.	9.10	9.16	karthe	P.vij
3	Take Purified Water in Paste Kettle and heat till reaches 90°C - 95°C.	9.17	9.30	karthe	P.vij
4	Add the solution from step 7.1(2) to the step 7.1(3) and mix is continuously to form the paste and cool the paste till 40 - 45°C.	9.31	9.33	karthe	P.vij
5	Wet Granulation: Binder Addition: Add binder from step-7.1(4) into the contents of RMG take <u>5</u> min for binder addition with impeller slow speed and Chopper OFF. Impeller Speed: <u>55</u> RPM	9.35	9.40	karthe	P.vij
6	After binder addition allow mixing to form a coherent mass. If required allow mixing till required consistency of granules obtained with impeller at slow speed and chopper at slow speed. Total Mixing Time: <u>4</u> mins, Impeller Speed: <u>55</u> RPM, Chopper Speed: <u>-</u> RPM Additional quantity of Purified Water <u>4.2</u> Kg	9.41	9.45	karthe	P.vij
7	Note the Ampere at granulation end point AMP.				P.vij
8	Discharge the wet mass to FBD bowl operating slow speed of Impeller and slow speed of Chopper. Impeller Speed: <u>55</u> RPM, Chopper Speed: <u>-</u> RPM	9.46	9.49	karthe	P.vij

7.2 DRYING:

7.2 DRYING:

Step No	Process Instructions	Date : 9.50		Done by	Checked by
		Time			
		Started	Completed		
1	Load the wet mass into the FBD bowl and air dry the wet mass.				
2	Load the wet mass into the cleaned FBD bowl Dry at inlet temperature 45-55°C till the LOD reached up to 1.5 – 2.0% w/w.	9.51	10.57	karthe	P.vij
3	LOD checking temperature at 105°C (Auto mode). LOD should be 1.5 – 2.0% w/w.	Observed LOD in %		karthe	P.vij
		1.73			

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka	P. Vij	P. Vij	P. Vij	
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 11 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMR/T/195-00 Customer:	Batch No.: <i>GF210101</i> Generic Health Care Pvt. Ltd.

7.3 FBD Finger bag Integrity checks:

S. No.	Items	Integrity before use	Integrity after use	Checked by (Production)	Verified by QA
1.	FBD finger bag	OK	OK	P.vij	Ⓢ
2.	FBD bowl mesh	OK	OK	P.vij	Ⓢ

7.4 SET PARAMETERS:

Sr. No.	Operation	Started at	Inlet Temp. (45-55°C)	Outlet Temp.	Product Temp. (To be Established)	Completed at	Total Time (mins)	LOD Observed	Done by	Checked By
1.	Air-Drying-I	9.51	NA	NA	NA	10.01	10min	NA	mithe	P.vij
2.	Raking-I	10.02	NA	NA	NA	10.06	4min	NA	karthe	P.vij
3.	Drying-I	10.07	55°C	49°C	45°C	10.57	50min	1.73	karthe	P.vij
4.	Raking-II		NA	NA	NA			NA		
5.	Drying-II									
6.	Raking-III		NA	NA	NA			NA		
7.	Drying-III									
Total Drying Time (Exclude Raking & Air-Drying time): 50 min							LOD Verified By IPQA: <i>02/01/2020</i>			
Total Drying time: 64 min										

7.5 SIFTING AND MILLING:

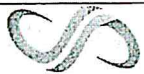
S. No	Process Instructions	Date : 02/01/2020		Done by	Checked by
		Time			
		Started	Completed		
1.	Sift the dried granules through 30 # sieve. Record the observation.	10.58	11.03	vinayakam	P.viji
2.	Mill the oversized granules through 1.0 mm multi mill screen fitted with (knives forward medium speed) followed by sifting through 30# sieve on vibrating sifter and collect the sifted granules in double polythene lined cleaned HDPE containers, record the weights.	11.04	11.09	vinayakam	P.viji
3.	Unload the granules in to cleaned HDPE containers in double polythene bag.	11.10	11.13	Jothi	P.viji

7.6 SIZING RECORD:

Mesh and screen size	Sieve ID No	Integrity checked before use	Date : 02/01/2020		Integrity checked After use	Done by	Checked by
			Time				
			Started	Completed			
30 #	PD/30-SE-30/02	OK/ Not OK	10.58	11.03	OK/ Not OK	Jothi	P.vij
1.0 mm	PD/1MM-SE-1/02	OK/ Not OK	11.04	11.09	OK/ Not OK	Jothi	P.vij

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L.Ka</i>	<i>P.vij</i>	<i>Jothi</i>	<i>S. Anand</i>
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 12 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMR/T/195-00 Customer:	Batch No.: <u>GIF 210101</u> Generic Health Care Pvt. Ltd.

8.0 GRANULATION SIFTING INSTRUCTIONS AND SIFTING RECORD: LOT-II Date: 02/12/2020 Shift: 1.....

S. No	Name of Ingredient	Weight before sifting in Kg	Sieve size	ID No.	Sieve Integrity before use	Time		Sieve Integrity after use	Done by	Ckd by
						From	To			
Dry mixing:										
1	Cetirizine Hydrochloride	15.642	40#	PD/30-SE-40/02	OK/ Not OK	9.55	9.57	OK/ Not OK	karthi	P.vij
2	Dried Maize Starch	89.209	30#	PD/30-SE-30/02	OK/ Not OK	9.58	10.03	OK/ Not OK	karthi	P.vij
3	Lactose Monohydrate	49.200	30#			10.04	10.08		karthi	P.vij
Binder Material:										
4	Dried Maize Starch	6.405	NA	NA	NA	-	-	NA	karthi	P.vij
5	Purified Water	20.00				-	-		karthi	P.vij
Lubrication:										
6	Colloidal Silicon Dioxide	1.410	30#	PD/30-SE-30/02	OK/ Not OK	10.10	10.12	OK/ Not OK	Jothi	P.vij
7	Sodium Starch Glycollate	17.640	30#			10.13	10.15		Jothi	P.vij
8	Purified Talc	7.020	40#	PD/30-SE-40/02	OK/ Not OK	10.16	10.18	OK/ Not OK	Jothi	P.vij
9	Magnesium Stearate	7.020	60#	PD/30-SE-60/02	OK/ Not OK	10.19	10.21	OK/ Not OK	Jothi	P.vij

8.1 MANUFACTURING PROCESS:

8.1 MANUFACTURING PROCESS:					
Step No.	Process Instructions	Date: 02/01/2024		Done by	Checked by
		Time			
		Started	Completed		
1	Dry mixing: Transfer the sifted material from step 8.0 (1-3) into the RMG. Mix for 10 minute with impeller at slow speed and chopper 'off'. Impeller Speed: <u>55</u> RPM	10.22	10.32	karthi	P.vij
2	Binder Preparation: Take purified water and disperse Dried Maize Starch to form slurry.	9.55	10.00	karthi	P.vij
3	Take Purified Water in Paste Kettle and heat till reaches 90°C - 95°C.	10.01	10.15	karthi	P.vij
4	Add the solution from step 8.1(2) to the step 8.1(3) and mix is continuously to form the paste and cool the paste till 40 - 45°C.	10.16	10.20	karthi	P.vij
5	Wet Granulation: Binder Addition: Add binder from step-8.1(4) into the contents of RMG take <u>5</u> min for binder addition with impeller slow speed and Chopper OFF. Impeller Speed: <u>55</u> RPM	10.33	10.38	karthi	P.vij
6	After binder addition allow mixing to form a coherent mass. If required allow mixing till required consistency of granules obtained with impeller at slow speed and chopper at slow speed. Total Mixing Time: <u>04</u> mins, Impeller Speed: <u>55</u> RPM, Chopper Speed: <u>NTA</u> RPM Additional quantity of Purified Water <u>5.00</u> Kg	10.39	10.43	karthi	P.vij
7	Note the Ampere at granulation end point AMP.				P.vij
8	Discharge the wet mass to FBD bowl operating slow speed of Impeller and slow speed of Chopper. Impeller Speed: <u>60</u> RPM Chopper Speed: <u>NTA</u> RPM	10.44	10.47	karthi	P.vij

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<u>L. K.</u>	<u>P.vij</u>	<u>P.vij</u>	<u>P.vij</u>	
Date	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>31/12/2020</u>	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 13 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMR/T/195-00 Customer:	Batch No.: GF210101 Generic Health Care Pvt. Ltd.

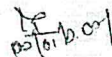
8.2 DRYING:

Step No	Process Instructions	Date : 21/12/21		Done by	Checked by
		Time			
		Started	Completed		
1	Load the wet mass into the FBD bowl and air dry the wet mass.				
2	Load the wet mass into the cleaned FBD bowl Dry at inlet temperature 45-55°C till the LOD reached up to 1.5 – 2.0% w/w.	11.00	12.11	karthi	P.viji
3	LOD checking temperature at 105°C (Auto mode). LOD should be 1.5 – 2.0% w/w.	Observed LOD in %		karthi	P.viji
		1.83			

8.3 FBD Finger bag Integrity checks:

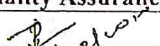
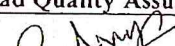
S. No.	Items	Integrity before use	Integrity after use	Checked by (Production)	Verified by QA
1.	FBD finger bag	OK	OK	P.vij	TK
2.	FBD bowl mesh	OK	OK	P.vij	TK

8.4 SET PARAMETERS:

Sr. No.	Operation	Started at	Inlet Temp. (45-55°C)	Outlet Temp.	Product Temp. (To be Established)	Completed at	Total Time (mins)	LOD Observed	Done by	Checked By
1.	Air-Drying-I	11.00	NA	NA	NA	11.10	10min	NA	karthi	P.vij
2.	Raking-I	11.11	NA	NA	NA	11.15	4min	NA	karthi	P.vij
3.	Drying-I	11.16	55°C	45°C	45°C	12.11	55min	1.83	karthi	P.vij
4.	Raking-II		NA	NA	NA			NA		
5.	Drying-II									
6.	Raking-III		NA	NA	NA			NA		
7.	Drying-III									
Total Drying Time (Exclude Raking & Air-Drying time): 55min								LOD Verified By IPQA: 		
Total Drying time: 69min										

8.5 SIFTING AND MILLING:

S. No	Process Instructions	Date : 21/12/2021		Done by	Checked by
		Time			
		Started	Completed		
1.	Sift the dried granules through 30 # sieve. Record the observation.	12.13	12.18	Karthi	P.vij
2.	Mill the oversized granules through 1.0 mm multi mill screen fitted with (knives forward medium speed) followed by sifting through 30# sieve on vibrating sifter and collect the sifted granules in double polythene lined cleaned HDPE containers, record the weights.	12.19	12.24	Karthi	P.vij
3.	Unload the granules in to cleaned HDPE containers in double polythene bag.	12.25	12.29	Karthi	P.vij

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ka			
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210101

Customer:

Generic Health Care Pvt. Ltd.

8.6 SIZING RECORD:

Mesh and screen size	Sieve ID No	Integrity checked before use	Date : 21/12/21		Integrity checked After use	Done by	Checked by
			Started	Completed			
30 #	PD/30-SE-3/02	OK/Not OK	12.13	12.18	OK/Not OK	karthi	P.vij
1.0 mm	PD/MM-E-1/02	OK/Not OK	12.19	12.24	OK/Not OK	karthi	P.vij

8.7 WEIGHING OF DRIED GRANULES:

S. No.	Tare Weight (Kg)	Gross Weight (Kg)	Net Weight (Kg)	Weighed By	Checked By
1	2.300	38.490	36.190	karthi	P.vij
2	2.300	34.680	32.380	karthi	P.vij
3	2.400	40.700	38.300	karthi	P.vij
4	2.300	39.290	36.990	karthi	P.vij
5	2.300	33.110	30.810	karthi	P.vij
6	2.300	36.810	34.510	karthi	P.vij
7	2.500	47.190	44.690	karthi	P.vij
8	2.400	39.920	37.520	karthi	P.vij
9	2.300	30.380	28.08	karthi	P.vij
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
Total			319.470		

Theoretical Weight: 320.910 Kg

Theoretical Yield (Weight): Actually yield will be calculated after 3 validation batches.

Actual Yield (Weight): 319.470 Kg % Yield: 99.55 %

Date: 21/12/21

Production Executive Sign. /Date: P.vij 21/12/21

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	P. Vij	P. Vij	
Date	31/12/2020	31/12/2020	31/12/2020	

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

BMR. No.: BMR/T/195-00

Batch No.: GF210101

Customer:

Generic Health Care Pvt. Ltd.

Product: GENSET

9.0 BLENDING LINE CLEARANCE CHECKS: Date/Shift: 02/01/2021 11

Sr. No.	Checks	Time	*Observations					
			Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty SS containers, polythene bags, Tags and documents of previous batch/product are removed.	20:30	✓	✓				
2	Check and ensure that Scrap from waste bin is removed and new polythene bag is put into it.		✓	✓				
3	Check and ensure that display, display stand, weighing balance are clean.		✓	✓				
4	Check and ensure that SS storage Cabinet and Drain point are clean.		✓	✓				
5	Check and ensure that absence of previous batch/product from area below machine		✓	✓				
6	Check and ensure that all equipment body and inside the vessel are clean		✓	✓				
7	Check and ensure that Tube light fixture, supply grills, riser grills and filters and electrical fixtures are clean		✓	✓				
8	Check and ensure that instruments to be used are within calibration due date and earthing connection.		✓	✓				
9	Check and ensure that daily records (Logbook, Balance, Temp. & RH) are updated and signed.		✓	✓				
10	Check and ensure that environment condition and record on BMR		✓	✓				
11	Check and ensure that rinse water is released from QC and attached the test request from (TRF)		NA	NA				
12	Equipment status is updated for Cleaned and Preventive maintenance.		✓	✓				

Note: *Tick mark (✓) if Complies, (X) if does not comply and (NA) if not applicable.

Equipment	Blender	Area
EQP. ID No.	P5042/002	Blend 8
Previous Product	Lgracold Flo	
Batch No.	GF210102	
Cleaned by	Jayanti	
Checked by	R	
Verified by		

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 02/01/2021 Time: 20:51			Date: Time:			Date: Time:		
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	23	✓	✓						
RH % (NMT 60%)	54	✓	✓						
DP (NLT 10 Pascal)	10	✓	✓						

APPROVAL FOR SIFTING AND BLENDING:

Production Sign/Date:	02/01/2021		
IPQA Sign/Date:	02/01/2021		
Start and End Time:	20:55	21:25	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	PDP	31/12/2020	S. Jany
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: G1F210101

Customer:

Generic Health Care Pvt. Ltd.

9.1 BLENDING AND LUBRICATION PROCESS:

Date: 21/01/2021 Shift: II

Step No.	Process Instructions	Time		Done by	Checked by Prod.
		Started	Completed		
1	Use hand gloves and goggles while handling the materials.				
2	Operate the Octagonal Blender as per the current version of the SOP No. PDOP/009.				
Pre-lubrication:					
1	Load the dried and sifted granules from step 8.7, sifted Material from step 8.0 (6-8) in to the blender and mix at 10 rpm for 15 minutes (To be established).	20:55	21:10	Jayaram	2
Lubrication:					
2	Load the Sifted Magnesium Stearate into the above Pre-lubricated blend and mix for further 5 minutes at 10 RPM (To be established).	21:11	21:16	Jayaram	2
3	Unload the lubricated blend in HDPE container having double lined polybag.	21:17	21:25	Jayaram	2

9.2 WEIGHING OF FINAL BLEND:

Balance I.D. No.: P.D. 12001002

Date: 21/01/2021 Shift: II Time: 21:30

Sr. No.	Gross Weight(Kg)	Tare Weight(Kg)	Net weight(Kg)	Weighed by	Checked by Prod.	Verified by IPQA
1	39.220	2.300	36.920	Jayaram	2	2
2	102.810	2.300	100.510	Jayaram	2	2
3	142.070	2.400	139.670	Jayaram	2	2
4	38.970	2.400	36.570	Jayaram	2	2
5	27.380	2.300	25.080	Jayaram	2	2
6	40.830	2.300	38.530	Jayaram	2	2
7	52.560	3.000	49.560	Jayaram	2	2
8	60.580	2.300	58.280	Jayaram	2	2
9	38.510	2.300	36.210	Jayaram	2	2
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						
25						
Total:			352.230			

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	1. R	DOF	31/12/2020	31/12/2020
Date	31/12/2020	31/12/2020		

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD		Product Code: G13	Batch Size: 30,00,000 Tablets
Product		BMR. No.: BMR/T/195-00	Batch No.: GF 210101
GENSET		Customer:	Generic Health Care Pvt. Ltd.

9.3 RECONCILIATION:

1.0	Theoretical weight of blend	:	354.000 Kg
2.0	Actual Weight of blend	:	352.23 Kg
3.0	Manufacturing Loss (Blending stage) @	:	1.51 Kg
4.0	In-process samples		
	A IPQC Samples	:	0.010 Kg.
	B QC Samples	:	0.100 Kg.
	C Validation Samples	:	0.159 Kg.
5.0	Total samples: (A + B + C)	:	0.269 Kg
6.0	Total: (2.0 + 5.0)	:	352.49 Kg
7.0	Yield {6.0 / 1.0 x100}*	:	99.57 %

* Actually yield will be calculated after 3 validation batches.

@Total rejects destroyed: 1.780 Kg. (Rejected materials shall be destroyed as per SOP: QAGN/048).

Recovery Addition Quantity in Kg: NA (Recovery addition materials shall be as per SOP: QAGN/047).

Done by Production sign/Date: 21/01/2021 Checked By IPQA sign/Date: 21/01/2021

Test request form raised by Prod Sign/Date: 21/01/2021

Test request form received by IPQA Sign/Date: 21/01/2021

9.4 RELEASED FOR COMPRESSION:

Reconciliation checked and blend is released for compression

IPQA Sign: 21/01/2021 Date: 21/01/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	POF	31/12/2020	8. P. Jeyaraj
Date	31/12/2020	21/12/2020	31/12/2020	31/12/2020

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 18 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMRT/195-00 Customer:	Batch No.: GF 210101 Generic Health Care Pvt. Ltd.

10.0 COMPRESSION LINE CLEARANCE CHECKS: Date/Shift: 03/01/2021, T/

Sr. No.	Checks	Time:	*Observations					
			09:30					
			Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty SS containers/ containers polythene bags, Tags, and documents of previous batch/product are removed.		✓	✓	✓	✓		
2	Check and ensure that absence of tablets of previous batch/product from area below machine and inside machine by opening the guard of machine.		✓	✓	✓	✓		
3	Check and ensure that the machine body and machine parts like hoppers, feed frame, dust collection chute, hosepipe and ejection chute and control panel are clean.		✓	✓	✓	✓		
4	Check and ensure that absence of tablet of previous batch/product below the weighing balance, check the cleanliness of area and equipment.		✓	✓	✓	✓		
5	Check and ensure that working desk, analytical balance and other accessories are clean.		✓	✓	✓	✓		
6	Check and ensure that Deduster and hosepipe are clean.		✓	✓	✓	✓		
7	Check and ensure that Tube light fixture, supply grills, riser grills and filters and electrical fixtures are clean.		✓	✓	✓	✓		
8	Check and ensure that instruments to be used are within calibration due date, and Punch inspection record		✓	✓	✓	✓		
9	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.		✓	✓	✓	✓		
10	Check and ensure that environmental conditions are recorded in the BMR.		✓	✓	✓	✓		
11	Area, equipment and preventive maintenance status board is updated.		✓	✓	✓	✓		
12	Check and ensure that rinse water is released from QC and attached the test request from (TRF) in BMR		✓	✓	✓	✓		
13	Equipment status is updated for Cleaned and Preventive Maintenance label.		✓	✓	✓	✓		

Note: *Tick mark (✓) if Complies, (X) if does not comply and (NA) if not applicable.

Equipment	Compression Machine	Deduster	Area
EQP ID No.	PD/COM/001	PD/DED/001, PD/DED/002	Compression-001
Previous Product	Telmisartan AM		
Batch No.	T0700081		
Cleaned by	Bala		
Checked by	J		
Verified by	EP 03/01/2021		

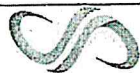
ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 03/01/2021 Time: 09:30			Date: 04/01/2021 Time: 08:30			Date: Time:		
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	23°C	J	EP	22°C	J	B			
RH % (NMT 60%)	52%	J	EP	50%	J	B			
DP (NLT 10 Pascal)	12 Pascal	J	EP	10 Pascal	J	B			

APPROVAL FOR COMPRESSION:

Production Sign/Date:	J 03/01/2021	J 04/01/2021	
IPQA Sign/Date:	EP 03/01/2021	B 04/01/2021	
Start and End Time:	09:40 23:30	00:01 17:30	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	POA	J	J. Praveen
Date	31/12/2020	21/12/2020	31/12/2020	31/12/2020

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LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMRT/195-00

Batch No.: GF 210101

Customer:

Generic Health Care Pvt. Ltd.

11.0 COMPRESSION

11.1 PROCESS INSTRUCTIONS:

Sr. No.	Process Instructions
1	Check the cleanliness of area and equipment.
2	Ensure that the correct punch set are issued as per the Punch issue record.
3	Set the Double Rotary Compression Machine with a. Upper punches: 10.00 x 4.00 mm caplet shaped with breakline punches. b. Lower punches: 10.00 x 4.00 mm caplet shaped plain punches. c. Dies: 10.00 x 4.00 mm suitable for above punches. d. Type of tooling - D. Punch Issued by: sign./Date: <i>N. 03/01/2021</i> Checked and Received by Sign./Date: <i>J 03/01/2021</i> Verified by Sign./Date: <i>P 03/01/2021</i>
4	Transfer the blend to compression cubicle. Load the blend into hopper manually.
5	Operate the Double Rotary Compression machine as per the current version of SOP: PDOP/010 and reject tablets of the first three round which shall be destroyed as per SOP: QAGN/048.
6	Collect the tablets of one complete rotation and carry out In-process checks for thickness, weight and appearance, record the observations in the BMR. Verify the tablets for uniformity of weight and hardness and record in the BMR.
7	Collect the compressed tablets in double polythene bag lined and labelled cleaned HDPE containers/SS container.
8	Check and record the weight of the compressed tablets.

11.2 GRANULES RECEIPT RECORD:

Balance ID. No.: PD/BAU/01A Date: 03/01/2021 Shift: A Time: 09:40

Sr. No.	Gross Weight in Kg	Issued By Production	Checked by Production
1	39.220	<i>L</i>	<i>L</i>
2	42.810	<i>L</i>	<i>L</i>
3	43.070	<i>L</i>	<i>L</i>
4	38.970	<i>L</i>	<i>L</i>
5	37.380	<i>L</i>	<i>L</i>
6	40.820	<i>L</i>	<i>L</i>
7	52.560	<i>L</i>	<i>L</i>
8	40.580	<i>L</i>	<i>L</i>
9	38.510	<i>L</i>	<i>L</i>
10		<i>L</i>	
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. K.</i>	<i>P. K.</i>	<i>P. K.</i>	<i>S. K.</i>
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 20 of 58
	BATCH MANUFACTURING RECORD	Product Code: G13	Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMR/T/195-00	Batch No.: GF 210101
		Customer:	Generic Health Care Pvt. Ltd.

11.3 COMPRESSION SPECIFICATION / PARAMETERS:

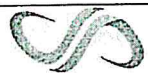
Sr. No.	Parameter	Limits	No. of tablets to be checked from each side	Frequency	
				Production	IPQA
1.	Appearance	White coloured, capsule shaped, beveled edged uncoated tablets with breakline on one side and plain on other side.	20	Every 30 min.	Every 2 Hr.
2.	Average weight(mg)	118.000 mg $\pm$ 2.0 % (115.640 mg – 120.360 mg)	20		
3.	Group Weight	2.360 g $\pm$ 2.0 % (2.313 g to 2.407 g)	20	Every 30 min.	Every 2 Hr.
4.	Uniformity of weight Tablets	118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)	20	Every 2 Hr.	Every 4 Hr.
5.	Hardness	NLT 3.0 Kg (To be established)	4	Every 30 min.	Every 2 Hr.
6.	Thickness (mm)	2.70 mm $\pm$ 0.3 mm (2.40 mm – 3.00 mm) (To be established)	4	Every 30 min.	Every 2 Hr.
7.	Length (mm)	10.10 mm $\pm$ 0.1 mm (10.00 mm – 10.20 mm) (To be established)	30	Initial	
8.	Width (mm)	4.10 mm $\pm$ 0.1 mm (4.00 mm – 4.20 mm) (To be established)	30	Initial	
9.	Friability	NMT 1% w/w	6.5 g	Every 2 Hr.	Every 4 Hr.
10.	Disintegration Time	NMT 15 Minutes	6	Every 2 Hr.	Every 4 Hr.

11.4 COMPRESSION MACHINE RUNNING STATUS:

Date	Shift	Start Time	End Time	M/C Speed	Tablets Output	Done By	Checked By
03/01/2024	A	09:40	17:30	22	2976355	Bals	N. Bal
04/01/2024	B						

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka			
Date	31/12/2020	31/12/2020	31/12/2020	

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210101

Customer:

Generic Health Care Pvt. Ltd.

11.5 INITIAL INPROCESS CHECKS: (Appearance, Uniformity of Weight, Thickness, Length & Width):

Balance I.D. No.: 9018A/007

Date: 02/12/2021 Shift: A Time: 09:45

LHS

RHS

Sr. No.	Appearance*	Weight (in mg)	Thickness (in mm)	Length (in mm)	Width (in mm)	Sr. No.	Appearance*	Weight (in mg)	Thickness (in mm)	Length (in mm)	Width (in mm)
1	OK	117	2.65	10.06	4.09	1	OK	118	2.65	10.06	4.09
2	OK	118	2.66	10.06	4.09	2	OK	119	2.66	10.05	4.09
3	OK	116	2.65	10.07	4.08	3	OK	117	2.69	10.06	4.08
4	OK	117	2.64	10.08	4.09	4	OK	119	2.68	10.07	4.09
5	OK	117	2.65	10.09	4.08	5	OK	116	2.69	10.08	4.08
6	OK	118	2.69	10.09	4.09	6	OK	117	2.68	10.07	4.08
7	OK	118	2.70	10.06	4.09	7	OK	118	2.67	10.06	4.09
8	OK	117	2.65	10.07	4.08	8	OK	119	2.66	10.07	4.08
9	OK	116	2.64	10.06	4.09	9	OK	119	2.69	10.09	4.09
10	OK	118	2.63	10.07	4.08	10	OK	118	2.68	10.09	4.09
11	OK	119	2.65	10.07	4.08	11	OK	117	2.67	10.08	4.09
12	OK	119	2.64	10.06	4.09	12	OK	116	2.66	10.07	4.08
13	OK	118	2.65	10.06	4.09	13	OK	118	2.67	10.06	4.08
14	OK	118	2.69	10.06	4.09	14	OK	117	2.68	10.05	4.09
15	OK	119	2.70	10.04	4.09	15	OK	116	2.69	10.09	4.09
16	OK	118	2.70	10.06	4.08	16	OK	116	2.69	10.09	4.09
17	OK	118	2.64	10.06	4.09	17	OK	119	2.68	10.08	4.09
18	OK	119	2.64	10.07	4.09	18	OK	118	2.67	10.09	4.08
19	OK	117	2.69	10.08	4.09	19	OK	117	2.66	10.07	4.08
20	OK	116	2.63	10.06	4.08	20	OK	117	2.67	10.06	4.08
21	OK	117	2.69	10.05	4.09	21	OK	118	2.68	10.08	4.09
22	OK	118	2.69	10.05	4.09	22	OK	118	2.69	10.09	4.09
23	OK	119	2.70	10.06	4.09	23	OK	119	2.68	10.06	4.09
24	OK	116	2.68	10.04	4.08	24	OK	117	2.67	10.07	4.08
25	OK	119	2.65	10.05	4.08	25	OK	118	2.66	10.08	4.08
26	OK	117	2.66	10.06	4.09	26	OK	117	2.69	10.09	4.08
27	OK	118	2.70	10.05	4.09	27	OK	119	2.67	10.06	4.09
28	OK	117	2.70	10.06	4.08	28	OK	118	2.68	10.07	4.09
29	OK	118	2.69	10.07	4.09	29	OK	119	2.69	10.09	4.07
30	OK	116	2.68	10.09	4.09	30	OK	119	2.68	10.09	4.08

Note: * Write OK if complies and (X) if does not comply.

Done by Production Sign/Date: N. Bal 02/12/2021

Checked by IPQA Sign/Date: 02/12/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	IPQA	21/12/2021	S. J.
Date	31/12/2020	31/12/2020		21/12/2021

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: G13 210101

Customer:

Generic Health Care Pvt. Ltd.

11.6 COMPRESSION SPECIFICATION AND PARAMETERS: Date: 03/01/2021 Shift: 1 Time: 09:52

Parameters	Instrument used	Equip ID No.	Observations of LHS		Observations of RHS		Limits
			Min	Max	Min	Max	
Appearance	Visual	NA	OK		OK		White coloured, capsule shaped, beveled edged uncoated tablets with breakline on one side and plain on other side.
Group Weight	Electronic Balance	Qa/bm/002	2.353 g		2.342 g		2.360 g $\pm$ 2.0 % (2.313 g to 2.407 g)
Average weight	Electronic Balance		117.65 mg		117.10 mg		118.000 mg $\pm$ 2.0 % (115.640 mg – 120.360 mg)
Individual weight	Electronic Balance		116 mg	119 mg	116 mg	119 mg	118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)
Uniformity of weight	Electronic Balance		(-)-1.12 %	(+)-1.13 %	(-)-0.91 %	(+)-1.59 %	
Thickness	Vernier Caliper	Qa/bm/002	2.68 mm	2.70 mm	2.65 mm	2.70 mm	2.70 mm $\pm$ 0.3 mm (2.40 mm – 3.00 mm) (To be established)
Hardness	Hardness Tester	Qa/bm/001	3	3	3	3	NLT 3.0 Kg (To be established)
Friability	Friabilator	Qa/bm/002	0.04 %		0.02 %		NMT 1.0% w/w
DT	DT Apparatus	Qa/bm/002	02 mins 03 sec		02 mins 10 sec		NMT 15 minutes

M/C set done by Operator Name: L. K. M/C set up Checked by (Prod. Sign/Date): N. Pal 03/01/2021
M/C Speed: 13 RPM (To be Established)

Initial Setting Tablets Destroyed by: Sign: N. Pal Date: 03/01/2021 Quantity in Kg. 0.300 Quantity in No. 847

Approval for Batch Compression by IPQA: Sign: [Signature] Date: 03/01/2021 Time: 10:00

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K.</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>[Signature]</u>

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210101

Customer:

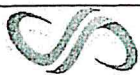
Generic Health Care Pvt. Ltd.

11.7 IN-PROCESS CHECKS: (For Production)

11.7 IN-PROCESS CHECKS: (For Production)														
Time	Appearance		Weight of 20 Tablets		Hardness				Thickness				Done by Production	
	White coloured, capsule shaped, beveled edged uncoated tablets with breakline on one side and plain on other side.		2.360 g $\pm$ 2.0 % (2.313 g to 2.407 g)		NLT 3.0 Kg (To be established)				2.70 mm $\pm$ 0.3 mm (2.40 mm – 3.00 mm) (To be established)					
	LHS	RHS	LHS	RHS	LHS	LHS	RHS	RHS	LHS	LHS	RHS	RHS		
10:03	OK	OK	2.341	2.347	3.0	3.0	3.5	3.0	2.63	2.69	2.67	2.69	N.Bal	
10:33	OK	OK	2.350	2.346	3.05	3.0	3.05	3.0	2.64	2.69	2.69	2.68	N.Bal	
11:04	OK	OK	2.343	2.350	3.5	3.0	3.5	3.0	2.64	2.64	2.70	2.73	N.Bal	
11:35	OK	OK	2.347	2.346	3.0	3.5	3.5	3.0	2.63	2.69	2.71	2.74	N.Bal	
12:05	OK	OK	2.350	2.342	3.5	3.0	3.0	3.5	2.64	2.69	2.72	2.71	N.Bal	
12:36	OK	OK	2.356	2.349	3.0	3.5	3.0	3.0	2.69	2.68	2.69	2.66	N.Bal	
13:09	OK	OK	2.354	2.349	3.5	3.0	3.5	3.5	2.73	2.70	2.68	2.69	N.Bal	
13:39	OK	OK	2.359	2.359	3.0	3.0	3.5	3.0	2.73	2.72	2.68	2.69	N.Bal	
14:08	OK	OK	2.362	2.348	3.0	3.5	3.0	3.5	2.68	2.73	2.66	2.70	N.Bal	
14:30	OK	OK	2.358	2.359	3.5	3.5	3.0	3.0	2.67	2.70	2.71	2.69	N.Bal	
15:00	OK	OK	2.356	2.357	3.0	3.5	3.5	3.0	2.68	2.66	2.68	2.73	N.Bal	
15:30	OK	OK	2.359	2.349	3.5	3.0	3.5	3.5	2.69	2.68	2.69	2.74	N.Bal	
16:01	OK	OK	2.357	2.352	3.0	3.5	3.0	3.5	2.72	2.69	2.67	2.69	N.Bal	
16:32	OK	OK	2.360	2.351	3.5	3.0	3.5	3.5	2.70	2.73	2.72	2.71	N.Bal	
17:00	OK	OK	2.362	2.359	3.5	3.0	3.0	3.5	2.68	2.72	2.71	2.69	N.Bal	
17:31	OK	OK	2.349	2.351	3.0	3.0	3.5	3.5	2.73	2.70	2.71	2.68	N.Bal	
18:02	OK	OK	2.365	2.354	3.0	3.0	3.5	3.5	2.69	2.68	2.73	2.69	N.Bal	
18:30	OK	OK	2.361	2.360	3.5	3.0	3.0	3.0	2.70	2.67	2.66	2.69	N.Bal	
19:00	OK	OK	2.358	2.362	3.5	3.0	3.5	3.0	2.66	2.68	2.66	2.67	FF	
19:31	OK	OK	2.360	2.349	3.0	3.5	3.0	3.0	2.72	2.64	2.69	2.68	FF	
20:02	OK	OK	2.360	2.352	3.5	3.0	3.5	3.5	2.72	2.66	2.70	2.70	FF	
20:30	OK	OK	2.362	2.361	3.0	3.0	3.5	3.5	2.73	2.67	2.71	2.69	FF	
21:02	OK	OK	2.358	2.361	3.5	3.0	3.5	3.0	2.67	2.66	2.67	2.66	FF	
21:35	OK	OK	2.362	2.364	3.5	3.0	3.5	3.0	2.69	2.67	2.69	2.69	FF	
22:04	OK	OK	2.354	2.350	3.5	3.0	3.5	3.0	2.70	2.69	2.68	2.73	FF	
22:25	OK	OK	2.361	2.355	3.0	3.5	3.0	3.5	2.73	2.70	2.70	2.75	FF	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	FF	31/12/2020	8. [Signature]
Date	31/12/2020	31/12/2020	31/12/2020	

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LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: 4F210101

Customer:

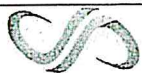
Generic Health Care Pvt. Ltd.

11.8 IN-PROCESS CHECKS: (For Production)

Time	Appearance		Weight of 20 Tablets		Hardness				Thickness				Done by Production
	White coloured, capsule shaped, beveled edged uncoated tablets with breakline on one side and plain on other side.		2.360 g ± 2.0 % (2.313 g to 2.407 g)		NLT 3.0 Kg (To be established)				2.70 mm ± 0.3 mm (2.40 mm – 3.00 mm) (To be established)				
	LHS	RHS	LHS	RHS	LHS	LHS	RHS	RHS	LHS	LHS	RHS	RHS	
23:00	OK	OK	2.358	2.363	3.0	3.5	3.0	3.0	2.69	2.67	2.70	2.71	J
23:30	OK	OK	2.352	2.350	3.5	3.0	3.5	3.0	2.68	2.65	2.72	2.69	J
00:01	OK	OK	2.360	2.357	3.5	3.0	3.5	3.5	2.69	2.69	2.68	2.71	J
00:30	OK	OK	2.351	2.361	3.0	3.0	3.5	3.5	2.70	2.68	2.67	2.73	J
01:00	OK	OK	2.361	2.354	3.0	3.0	3.5	3.0	2.72	2.71	2.66	2.67	J
01:31	OK	OK	2.364	2.350	3.0	3.5	3.5	3.0	2.69	2.70	2.71	2.71	J
02:01	OK	OK	2.362	2.359	3.0	3.5	3.0	3.5	2.66	2.69	2.67	2.69	J
02:32	OK	OK	2.362	2.354	3.5	3.0	3.5	3.0	2.64	2.62	2.63	2.69	J
03:01	OK	OK	2.357	2.350	3.0	3.5	3.0	3.5	2.73	2.71	2.65	2.61	J
03:31	OK	OK	2.356	2.359	3.0	3.5	3.0	3.0	2.69	2.68	2.69	2.69	J
04:02	OK	OK	2.354	2.363	3.5	3.0	3.5	3.0	2.70	2.69	2.70	2.67	J
04:30	OK	OK	2.351	2.361	3.5	3.0	3.5	3.5	2.71	2.71	2.71	2.69	J
05:01	OK	OK	2.362	2.369	3.0	3.5	3.0	3.5	2.72	2.72	2.72	2.69	J
05:32	OK	OK	2.357	2.354	3.0	3.5	3.0	3.0	2.68	2.73	2.64	2.68	J
06:02	OK	OK	2.341	2.358	3.0	3.5	3.5	3.0	2.69	2.71	2.70	2.71	J
06:34	OK	OK	2.351	2.362	3.5	3.5	3.0	3.5	2.72	2.69	2.73	2.74	N.B.L
07:02	OK	OK	2.362	2.349	3.0	3.5	3.5	3.5	2.71	2.67	2.74	2.71	N.B.L
07:31	OK	OK	2.356	2.359	3.0	3.0	3.5	3.5	2.74	2.69	2.71	2.71	N.B.L
08:02	OK	OK	2.346	2.357	3.0	3.0	3.5	3.5	2.70	2.71	2.71	2.69	N.B.L
08:33	OK	OK	2.356	2.361	3.0	3.0	3.0	3.5	2.69	2.73	2.70	2.64	N.B.L
09:04	OK	OK	2.354	2.363	3.0	3.0	3.5	3.5	2.66	2.71	2.64	2.66	N.B.L
09:36	OK	OK	2.363	2.361	3.0	3.5	3.5	3.0	2.67	2.70	2.69	2.69	N.B.L
10:04	OK	OK	2.354	2.353	3.0	3.5	3.5	3.0	2.69	2.74	2.69	2.69	N.B.L
10:36	OK	OK	2.349	2.354	3.5	3.0	3.5	3.0	2.68	2.69	2.68	2.66	N.B.L
11:01	OK	OK	2.344	2.369	3.5	3.0	3.5	3.0	2.64	2.71	2.72	2.71	N.B.L
11:32	OK	OK	2.359	2.359	3.0	3.5	3.0	3.5	2.74	2.69	2.68	2.74	N.B.L

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K	J	J	J
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR No.: BMR/T/195-00

Batch No.: GF210101

Customer:

Generic Health Care Pvt. Ltd.

11.9 IN-PROCESS CHECKS: (For Production)

Time	Appearance		Weight of 20 Tablets		Hardness				Thickness				Done by Production
	White coloured, capsule shaped, beveled edged uncoated tablets with breakline on one side and plain on other side.		2.360 g ± 2.0 % (2.313 g to 2.407 g)		NLT 3.0 Kg (To be established)				2.70 mm ± 0.3 mm (2.40 mm – 3.00 mm) (To be established)				
	LHS	RHS	LHS	RHS	LHS	LHS	RHS	RHS	LHS	LHS	RHS	RHS	
12:02	OK	OK	2.364	2.364	3.0	3.0	3.5	3.0	2.64	2.63	2.68	2.74	N. Bel
12:34	OK	OK	2.354	2.361	3.5	3.0	3.0	3.5	2.72	2.74	2.72	2.68	N. Bel
13:04	OK	OK	2.356	2.359	3.0	3.5	3.0	3.5	2.70	2.68	2.72	2.69	N. Bel
13:36	OK	OK	2.349	2.349	3.5	3.0	3.5	3.0	2.69	2.68	2.71	2.74	N. Bel
14:04	OK	OK	2.359	2.361	3.0	3.5	3.5	3.0	2.74	2.68	2.66	2.73	N. Bel
14:34	OK	OK	2.354	2.364	3.5	3.5	3.0	3.5	2.68	2.64	2.71	2.73	N. Bel
15:01	OK	OK	2.351	2.364	3.0	3.5	3.0	3.5	2.69	2.74	2.73	2.66	N. Bel
15:32	OK	OK	2.362	2.361	3.0	3.0	3.5	3.0	2.67	2.66	2.67	2.67	N. Bel
16:02	OK	OK	2.346	2.358	3.0	3.5	3.0	3.5	2.74	2.71	2.71	2.70	N. Bel
16:34	OK	OK	2.351	2.369	3.5	3.0	3.5	3.0	2.70	2.70	2.67	2.66	N. Bel
17:06	OK	OK	2.349	2.349	3.0	3.0	3.5	3.0	2.72	2.71	2.70	2.70	N. Bel
17:30	OK	OK	2.368	2.366	3.5	3.0	3.5	3.0	2.64	2.70	2.71	2.75	N. Bel
N/A													

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	J. K.	[Signature]	[Signature]	[Signature]
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210101

Customer:

Generic Health Care Pvt. Ltd.

11.10 IN-PROCESS CHECKS: (For Production)

[illegible]

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. K.</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	31/12/2020	31/12/2020	31/12/2020	

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

BMR. No.: BMR/T/195-00

Batch No.: GF 210101

Customer:

Generic Health Care Pvt. Ltd.

Product GENSET

11.11 IN-PROCESS CHECKS: (For IPQA)

11.11 IN-PROCESS CHECKS: (For IPQA)													
Time	Appearance		Weight of 20 Tablets		Hardness				Thickness				Done by IPQA
	White coloured, capsule shaped, beveled edged uncoated tablets with breakline on one side and plain on other side.		2.360 g $\pm$ 2.0 % (2.313 g to 2.407 g)		NLT 3.0 Kg (To be established)				2.70 mm $\pm$ 0.3 mm (2.40 mm – 3.00 mm) (To be established)				
	LHS	RHS	LHS	RHS	LHS	LHS	RHS	RHS	LHS	LHS	RHS	RHS	
10:15	Ok	Full Hopper Ok	2.339	2.350	3.0	3.0	3.0	3.0	2.61	2.74	2.61	2.76	EP
12:10	Ok	Ok	2.347	2.354	3.5	3.0	3.5	3.0	2.75	2.79	2.76	2.74	EP
14:05	Ok	Ok	2.351	2.352	3.0	3.0	3.5	3.0	2.61	2.64	2.77	2.72	EP
15:10	Ok	Ok	2.355	2.346	3.0	3.0	3.0	3.5	2.68	2.71	2.66	2.72	EP
18:15	Ok	Ok	2.360	2.359	3.5	3.0	3.5	3.5	2.64	2.66	2.69	2.70	EP
20:20	Ok	Ok	2.349	2.350	3.5	3.0	3.0	3.5	2.69	2.70	2.67	2.68	EP
22:25	Ok	Ok	2.352	2.364	3.5	3.0	3.5	3.0	2.76	2.78	2.75	2.80	EP
00:25	Ok	Ok	2.350	2.349	3.5	3.0	3.0	3.0	2.75	2.74	2.76	2.78	EP
02:30	Ok	Mid Hopper Ok	2.347	2.353	3.5	3.0	3.0	3.0	2.76	2.79	2.74	2.75	EP
04:35	Ok	Ok	2.349	2.355	3.5	3.5	3.0	3.0	2.74	2.76	2.74	2.72	EP
06:40	Ok	Ok	2.351	2.354	3.5	3.5	3.0	3.0	2.79	2.72	2.79	2.74	EP
08:45	Ok	Ok	2.347	2.357	3.0	3.0	3.0	3.5	2.74	2.72	2.79	2.73	EP
10:40	Ok	Ok	2.347	2.347	3.5	3.5	3.0	3.0	2.73	2.76	2.79	2.78	Q
12:40	Ok	Ok	2.351	2.354	3.0	3.5	3.0	3.0	2.74	2.79	2.74	2.76	Q
14:40	Ok	Full Hopper Ok	2.351	2.350	3.5	3.5	3.0	3.5	2.76	2.72	2.74	2.69	Q
16:35	Ok	Full Hopper Ok	2.355	2.345	3.0	3.0	3.5	3.0	2.75	2.79	2.76	2.74	Q
16:45	Ok	L RPM Ok	2.354	2.340	3.50	3.5	3.5	3.0	2.78	2.76	2.76	2.65	Q
16:50	Ok	H RPM Ok	2.360	2.351	3.0	3.5	3.0	3.5	2.67	2.72	2.74	2.69	Q
17:00	Ok	L Handw Ok	2.354	2.352	3.0	3.0	3.0	3.0	2.72	2.74	2.75	2.76	Q
17:05	Ok	H Handw Ok	2.355	2.350	4.0	4.0	4.0	3.5	2.64	2.62	2.65	2.67	Q
17:15	Ok	Composite Ok	2.356	2.350	3.5	3.0	3.5	3.0	2.65	2.67	2.69	2.71	Q

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K	PAV	21/12/2020	8.12/2020
Date	31/12/2020	31/12/2020		

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: G1F 210101

Customer:

Generic Health Care Pvt. Ltd.

11.12 IN-PROCESS CHECKS: (For IPQA)

[illegible]

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	31/12/2020	31/12/2020	31/12/2020	

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210101

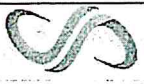
Customer:

Generic Health Care Pvt. Ltd.

[illegible]

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	POB	W 21/12/2020	8. W 21/12/2020
Date	31/12/2020	31/12/2020		

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur - Commune, Puducherry-605009.		Page 30 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET		Batch No.: GF 21010 Generic Health Care Pvt. Ltd.
		BMR. No.: BMR/T/195-00 Customer:	

NOTE: Initially first 2 entries-2 Hours once remaining entries 4 Hours once for production.

11.14 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date: 03/01/2021						Time: 10:21						Shift: 6																																			
LHS: Individual weight of 20 tablets (in mg).												RHS: Individual weight of 20 tablets (in mg).																																			
1	116	8	118	15	116	1	118	8	116	15	117	2	117	9	117	16	116	3	118	10	118	17	117	4	119	11	119	18	116	5	118	12	118	19	117	6	118	13	116	20	118	7	119	14	119		
Balance ID No.: PD/BAL/007												M/C Speed: 18 RPM																																			
Group weight of 20 Tablets: 235.8 g. Avg. wt: 117.90 mg												Group weight of 20 Tablets: 234.2 g. Avg. wt: 117.10 mg																																			
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)												Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)																																			
Min weight: 116 mg Max. weight: 119 mg												Min weight: 116 mg Max. weight: 119 mg																																			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):												Equipment ID No.: QA/FRT/ 001																																			
Disintegration Time (Limit - NMT 15 minutes)												Equipment ID No.: QA/DTA/ 002																																			
Done by: N. Bal (Production)																																															
Date: 03/01/2021						Time: 12:19						Shift: 6																																			
LHS: Individual weight of 20 tablets (in mg).												RHS: Individual weight of 20 tablets (in mg).																																			
1	115	8	119	15	120	1	116	8	116	15	116	2	119	9	116	16	120	3	117	10	117	17	116	4	117	11	116	18	119	5	116	12	119	19	116	6	119	13	116	20	119	7	116	14	117		
Balance ID No.: PD/BAL/007												M/C Speed: 18 RPM																																			
Group weight of 20 Tablets: 235.6 g. Avg. wt: 117.80 mg												Group weight of 20 Tablets: 235.0 g. Avg. wt: 117.50 mg																																			
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)												Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)																																			
Min weight: 115 mg Max. weight: 120 mg												Min weight: 116 mg Max. weight: 119 mg																																			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):												Equipment ID No.: QA/FRT/ 001																																			
Disintegration Time (Limit - NMT 15 minutes)												Equipment ID No.: QA/DTA/ 002																																			
Done by: N. Bal (Production)																																															

4 W.B N. Bal
03/01/2021

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka	R. Ka	R. Ka	S. Ka	
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020	

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

BMR. No.: BMRT/195-00

Batch No.: GF 210101

Product

GENSET

Customer:

Generic Health Care Pvt. Ltd.

11.15 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 4 hours):

Date: 03/01/2021		Time: 16:25		Shift: B	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	118	8	119	15	118
2	117	9	118	16	117
3	119	10	118	17	116
4	118	11	117	18	118
5	118	12	118	19	117
6	117	13	117	20	119
7	118	14	118		
Balance ID No.: PD/BAL/007			M/C Speed: 22 RPM		
Group weight of 20 Tablets: 2355 g. Avg. wt: 117.75 mg			Group weight of 20 Tablets: 2354 g. Avg. wt: 117.70 mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight: 116 mg Max. weight: 119 mg			Min weight: 115 mg Max. weight: 120 mg		
		LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.01%	0.02%	Equipment ID No.: QA/FRT/ 001	
Disintegration Time (Limit - NMT 15 minutes)		02 mins 16 sec	02 mins 16 sec	Equipment ID No.: QA/DTA/ 002	
Done by: N. Bal (Production)					
Date: 03/01/2021		Time: 20:22		Shift: B	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	117	8	117	15	118
2	118	9	118	16	119
3	117	10	118	17	119
4	118	11	117	18	118
5	117	12	119	19	118
6	119	13	118	20	119
7	118	14	117		
Balance ID No.: PD/BAL/007			M/C Speed: 22 RPM		
Group weight of 20 Tablets: 2355 g. Avg. wt: 117.75 mg			Group weight of 20 Tablets: 2360 g. Avg. wt: 118 mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight: 117 mg Max. weight: 119 mg			Min weight: 117 mg Max. weight: 120 mg		
		LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.02%	0.01%	Equipment ID No.: QA/FRT/ 001	
Disintegration Time (Limit - NMT 15 minutes)		02 mins 09 sec	02 mins 12 sec	Equipment ID No.: QA/DTA/ 002	
Done by: N. Bal (Production)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	P. K.	P. K.	P. K.
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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BATCH MANUFACTURING RECORD		Product Code: G13	Batch Size: 30,00,000 Tablets
Product		BMR. No.: BMR/T/195-00	Batch No.: G13 210101
GENSET		Customer:	Generic Health Care Pvt. Ltd.

11.16 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 4 hours):

Date: 04/01/2021		Time: 00:17		Shift: C	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	118	8	117	15	118
2	117	9	118	16	116
3	119	10	116	17	117
4	117	11	119	18	119
5	120	12	119	19	118
6	118	13	118	20	119
7	119	14	119		
Balance ID No.: DD/BAL/007			M/C Speed: 22 RPM		
Group weight of 20 Tablets:.....2.359...g. Avg. wt:.....117.95mg			Group weight of 20 Tablets:.....2.355.g. Avg. wt:.....117.75mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight:116..... mg Max. weight:120..... mg			Min weight:116..... mg Max. weight:119..... mg		
		LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.01%	0.02%	Equipment ID No.: QA/FRT/ 002	
Disintegration Time (Limit - NMT 15 minutes)		02min 21sec	02min 31sec	Equipment ID No.: QA/DTA/ 001	
Done by: K. K. 04/01/2021.....(Production)					
Date: 04/01/2021		Time: 04:19		Shift: C	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	118	8	118	15	118
2	117	9	119	16	120
3	119	10	117	17	118
4	117	11	118	18	117
5	118	12	119	19	118
6	119	13	119	20	118
7	117	14	117		
Balance ID No.: DD/BAL/007			M/C Speed: 22 RPM		
Group weight of 20 Tablets:.....2.353...g. Avg. wt:.....117.65mg			Group weight of 20 Tablets:.....2.355.g. Avg. wt:.....117.75mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight:117..... mg Max. weight:120..... mg			Min weight:116..... mg Max. weight:119..... mg		
		LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.02%	0.01%	Equipment ID No.: QA/FRT/ 001	
Disintegration Time (Limit - NMT 15 minutes)		02min 19sec	02min 21sec	Equipment ID No.: QA/DTA/ 002	
Done by: K. K. 04/01/2021.....(Production)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.			
Date	31/12/2020	31/12/2020	31/12/2020	

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

BMR. No.: BMR/T/195-00

Batch No.: GF 210101

Customer:

Generic Health Care Pvt. Ltd.

Product

GENSET

11.17 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 4 hours):

Date: 04/01/2021		Time: 08:16		Shift: C	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	116	8	116	15	120
2	118	9	119	16	116
3	119	10	118	17	117
4	118	11	116	18	116
5	116	12	116	19	117
6	119	13	116	20	116
7	118	14	118		
Balance ID No.: PD/BAL/007			M/C Speed: 22 RPM		
Group weight of 20 Tablets: 2336 g. Avg. wt: 116.80 mg			Group weight of 20 Tablets: 2354 g. Avg. wt: 117.70 mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight: 116 mg Max. weight: 120 mg			Min weight: 116 mg Max. weight: 119 mg		
		LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.01%	0.02%	Equipment ID No.: QA/FRT/ 002	
Disintegration Time (Limit - NMT 15 minutes)		02 mins 03 sec	02 min 11 sec	Equipment ID No.: QA/DTA/ 001	
Done by: N. Bal (Production)					
Date: 04/01/2021		Time: 12:13		Shift: B	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	117	8	116	15	119
2	116	9	119	16	116
3	119	10	116	17	119
4	116	11	119	18	116
5	119	12	116	19	119
6	116	13	119	20	117
7	119	14	116		
Balance ID No.: PD/BAL/007			M/C Speed: 22 RPM		
Group weight of 20 Tablets: 2349 g. Avg. wt: 117.45 mg			Group weight of 20 Tablets: 2356 g. Avg. wt: 117.80 mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight: 116 mg Max. weight: 119 mg			Min weight: 116 mg Max. weight: 119 mg		
		LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.01%	0.02%	Equipment ID No.: QA/FRT/ 002	
Disintegration Time (Limit - NMT 15 minutes)		02 mins 01 sec	02 mins 04 sec	Equipment ID No.: QA/DTA/ 001	
Done by: N. Bal (Production)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.			
Date	31/12/2020	21/12/2020	31/12/2020	

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210101

Customer:

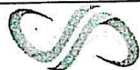
Generic Health Care Pvt. Ltd.

11.18 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 4 hours):

Date:		Time :		Shift:	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	8	15	1	8	15
2	9	16	2	9	16
3	10	17	3	10	17
4	11	18	4	11	18
5	12	19	5	12	19
6	13	20	6	13	20
7	14		7	14	
Balance ID No.:			M/C Speed: RPM		
Group weight of 20 Tablets:.....g. Avg. wt:.....mg			Group weight of 20 Tablets:.....g. Avg. wt:.....mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight. :..... mg Max. weight:..... mg			Min weight. :..... mg Max. weight:..... mg		
LHS		RHS			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			Equipment ID No.: QA/FRT/		
Disintegration Time (Limit - NMT 15 minutes)			Equipment ID No.: QA/DTA/		
Done by:(Production)					
Date:		Time :		Shift:	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	8	15	1	8	15
2	9	16	2	9	16
3	10	17	3	10	17
4	11	18	4	11	18
5	12	19	5	12	19
6	13	20	6	13	20
7	14		7	14	
Balance ID No.:			M/C Speed: RPM		
Group weight of 20 Tablets:.....g. Avg. wt:.....mg			Group weight of 20 Tablets:.....g. Avg. wt:.....mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight. :..... mg Max. weight:..... mg			Min weight. :..... mg Max. weight:..... mg		
LHS		RHS			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			Equipment ID No.: QA/FRT/		
Disintegration Time (Limit - NMT 15 minutes)			Equipment ID No.: QA/DTA/		
Done by:(Production)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K			
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210101

Customer:

Generic Health Care Pvt. Ltd.

11.19 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 4 hours):

Date:		Time :		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Balance ID No.:				M/C Speed: RPM			
Group weight of 20 Tablets:.....g. Avg. wt:.....mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg			
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)				Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			
Min weight. :..... mg Max. weight.:..... mg				Min weight. :..... mg Max. weight.:..... mg			
				LHS RHS			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)				Equipment ID No.: QA/DTA/			
Done by:(Production)							
Date:		Time :		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Balance ID No.:				M/C Speed: RPM			
Group weight of 20 Tablets:.....g. Avg. wt:.....mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg			
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)				Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			
Min weight. :..... mg Max. weight.:..... mg				Min weight. :..... mg Max. weight.:..... mg			
				LHS RHS			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)				Equipment ID No.: QA/DTA/			
Done by:(Production)							

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K.	PAH	31/12/2020	J. Kung
Date	31/12/2020	21/12/2020	31/12/2020	31/12/2020

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 36 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET		Batch No.: GF 210101 Customer: Generic Health Care Pvt. Ltd.

11.20 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 4 hours):

Date:		Time :		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Balance ID No.:				M/C Speed: RPM			
Group weight of 20 Tablets:.....g. Avg. wt:.....mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg			
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)				Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			
Min weight. :..... mg Max. weight:..... mg				Min weight. :..... mg Max. weight:..... mg			
				LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)				Equipment ID No.: QA/DTA/			
Done by:(Production)							
Date:		Time :		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Balance ID No.:				M/C Speed: RPM			
Group weight of 20 Tablets:.....g. Avg. wt:.....mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg			
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)				Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			
Min weight. :..... mg Max. weight:..... mg				Min weight. :..... mg Max. weight:..... mg			
				LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)				Equipment ID No.: QA/DTA/			
Done by:(Production)							

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	PO	31/12/2020	31/12/2020
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: G F 210101

Customer:

Generic Health Care Pvt. Ltd.

11.21 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date: 03/01/2021		Time: 10:25		Shift: 01 Full Hopper	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	112	8	119	15	120
2	117	9	118	16	119
3	116	10	120	17	117
4	115	11	122	18	114
5	119	12	114	19	116
6	117	13	112	20	117
7	120	14	119		
Balance ID No.: QA/BAL/002			M/C Speed: 22 RPM		
Group weight of 20 Tablets: 2.361.....g. Avg. wt.: 112.05.....mg			Group weight of 20 Tablets: 2.381.....g. Avg. wt.: 119.05.....mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight: 115.....mg Max. weight: 120.....mg			Min weight: 117.....mg Max. weight: 122.....mg		
			LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			0.20%	0.18%	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)			2min 50sec	2min 45sec	Equipment ID No.: QA/DTA/001
Done by: SP 03/01/2021 (IPQA)					
Date: 03/01/2021		Time: 14:10		Shift: 02	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	117	8	117	15	117
2	119	9	119	16	119
3	122	10	112	17	117
4	120	11	122	18	112
5	117	12	124	19	120
6	116	13	120	20	121
7	112	14	121		
Balance ID No.: QA/BAL/002			M/C Speed: 22 RPM		
Group weight of 20 Tablets: 2.322.....g. Avg. wt.: 119.1.....mg			Group weight of 20 Tablets: 2.375.....g. Avg. wt.: 112.15.....mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight: 115.....mg Max. weight: 124.....mg			Min weight: 117.....mg Max. weight: 124.....mg		
			LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			0.17%	0.19%	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)			2min 37sec	2min 45sec	Equipment ID No.: QA/DTA/001
Done by: SP 03/01/2021 (IPQA)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K	SP	SP	SP
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 21 01 01

Customer:

Generic Health Care Pvt. Ltd.

11.22 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date: 03/01/2021						Time: 18:30						Shift: 6																																																																							
LHS: Individual weight of 20 tablets (in mg).												RHS: Individual weight of 20 tablets (in mg).																																																																							
1	117	8	117	15	117	1	115	8	117	15	114	2	117	9	115	16	114	2	114	9	116	16	117	3	117	10	114	17	117	3	117	10	117	17	116	4	112	11	117	18	114	4	119	11	115	18	119	5	119	12	119	19	119	5	112	12	114	19	114	6	117	13	117	20	117	6	119	13	117	20	115	7	119	14	119			7	117	14	112		
Balance ID No.: GA/BA1/002												M/C Speed: 22 RPM																																																																							
Group weight of 20 Tablets: 2.332 g. Avg. wt: 116.6 mg												Group weight of 20 Tablets: 2.328 g. Avg. wt: 116.4 mg																																																																							
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)												Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)																																																																							
Min weight: 113 mg Max. weight: 119 mg												Min weight: 114 mg Max. weight: 119 mg																																																																							
Friability (Limit: NMT 1% after 4 minutes/100 rotations): 0.16												Equipment ID No.: QA/FRT/002																																																																							
Disintegration Time (Limit - NMT 15 minutes) 2min 30sec												Equipment ID No.: QA/DTA/001																																																																							
Done by: SP 03/01/2021 (IPQA)																																																																																			
Date: 03/01/2021						Time: 22:35						Shift: 6																																																																							
LHS: Individual weight of 20 tablets (in mg).												RHS: Individual weight of 20 tablets (in mg).																																																																							
1	117	8	117	15	119	1	117	8	119	15	117	2	120	9	119	16	114	2	116	9	116	16	119	3	119	10	114	17	116	3	116	10	117	17	114	4	112	11	116	18	117	4	114	11	117	18	119	5	116	12	119	19	114	5	117	12	119	19	114	6	117	13	120	20	119	6	114	13	116	20	117	7	116	14	116			7	117	14	117		
Balance ID No.: GA/BA2/002												M/C Speed: RPM																																																																							
Group weight of 20 Tablets: 2.327 g. Avg. wt: 116.35 mg												Group weight of 20 Tablets: 2.325 g. Avg. wt: 116.25 mg																																																																							
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)												Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)																																																																							
Min weight: 112 mg Max. weight: 120 mg												Min weight: 112 mg Max. weight: 119 mg																																																																							
Friability (Limit: NMT 1% after 4 minutes/100 rotations): 0.19%												Equipment ID No.: QA/FRT/002																																																																							
Disintegration Time (Limit - NMT 15 minutes) 2min 40sec												Equipment ID No.: QA/DTA/001																																																																							
Done by: SP 03/01/2021 (IPQA)																																																																																			

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	POB	31/12/2020	31/12/2020
Date	31/12/2020			

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

BMR. No.: BMR/T/195-00

Batch No.: GF 210101

Product

GENSET

Customer:

Generic Health Care Pvt. Ltd.

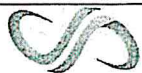
11.23 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours): Mid Happen

Date: 04/01/2021		Time: 02:40		Shift: A	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	116	8	117	15	117
2	112	9	117	16	117
3	113	10	121	17	112
4	117	11	112	18	117
5	122	12	117	19	112
6	117	13	121	20	117
7	117	14	121		
Balance ID No.: 04/BAL/002			M/C Speed: 22 RPM		
Group weight of 20 Tablets: 2.362 g. Avg. wt: 118.1 mg			Group weight of 20 Tablets: 2.322 g. Avg. wt: 116.1 mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight: 113 mg Max. weight: 122 mg			Min weight: 112 mg Max. weight: 122 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		LHS		RHS	
Disintegration Time (Limit - NMT 15 minutes)		0.17%		0.18%	
		2min 45sec		2min 45sec	
		Equipment ID No.: QA/FRT/002		Equipment ID No.: QA/DTA/001	

Done by: [Signature] (IPQA)					
Date: 04/01/2021					
Time: 06:50					
Shift: A					
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	116	8	117	15	117
2	117	9	119	16	113
3	117	10	117	17	114
4	117	11	112	18	119
5	117	12	117	19	114
6	121	13	117	20	117
7	120	14	114		
Balance ID No.: 04/BAL/001			M/C Speed: RPM		
Group weight of 20 Tablets: 2.343 g. Avg. wt: 117.15 mg			Group weight of 20 Tablets: 2.342 g. Avg. wt: 117.1 mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight: 113 mg Max. weight: 121 mg			Min weight: mg Max. weight: mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		LHS		RHS	
Disintegration Time (Limit - NMT 15 minutes)		0.17%		0.21%	
		2min 15sec		2min 25sec	
		Equipment ID No.: QA/FRT/002		Equipment ID No.: QA/DTA/001	
Done by: [Signature] (IPQA)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	[Signature]	[Signature]	[Signature]
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210101

Customer:

Generic Health Care Pvt. Ltd.

11.24 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date: 09/01/2021		Time: 10:50		Shift: G	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	116	8	112	15	119
2	119	9	119	16	116
3	120	10	117	17	119
4	112	11	120	18	112
5	119	12	113	19	116
6	115	13	119	20	117
7	114	14	117		
Balance ID No.: QA/BAL/002			M/C Speed: 22 RPM		
Group weight of 20 Tablets: 2.363 g. Avg. wt: 118.15 mg			Group weight of 20 Tablets: 2.362 g. Avg. wt: 118.1 mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight: 116 mg Max. weight: 117 mg			Min weight: 116 mg Max. weight: 120 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		LHS	RHS	Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)		2 min 31 sec	2 min 40 sec	Equipment ID No.: QA/DTA/001	
Done by: S. Sathish (IPQA)					
Date: 09/01/2021		Time: 14:45		Shift: G	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	117	8	119	15	117
2	113	9	113	16	119
3	115	10	113	17	119
4	114	11	110	18	117
5	117	12	117	19	114
6	116	13	115	20	116
7	112	14	116		
Balance ID No.: QA/BAL/002			M/C Speed: 22 RPM		
Group weight of 20 Tablets: 2.325 g. Avg. wt: 116.25 mg			Group weight of 20 Tablets: 2.327 g. Avg. wt: 116.35 mg		
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)			Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)		
Min weight: 114 mg Max. weight: 117 mg			Min weight: 114 mg Max. weight: 117 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		LHS	RHS	Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)		2 min 45 sec	2 min 50 sec	Equipment ID No.: QA/DTA/001	
Done by: S. Sathish (IPQA)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	P. Ka	S. Sathish	S. Sathish
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 41 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 BMR. No.: BMR/T/195-00 Customer:
Product	GENSET		Batch Size: 30,00,000 Tablets Batch No.: G1F210101 Generic Health Care Pvt. Ltd.

11.25 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours): End Hopper

Date: 04/01/2021		Time: 16:40		Shift: 6							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	117	8	112	15	119	1	119	8	119	15	121
2	112	9	117	16	118	2	119	9	119	16	119
3	113	10	119	17	120	3	120	10	119	17	112
4	116	11	122	18	117	4	120	11	112	18	119
5	112	12	121	19	119	5	117	12	119	19	120
6	116	13	119	20	120	6	119	13	119	20	119
7	117	14	120			7	119	14	122		
Balance ID No.: QA/BA/L/002						M/C Speed: 22 RPM					
Group weight of 20 Tablets: 2.371 g. Avg. wt.: 118.55 mg Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg) Min weight: 116 mg Max. weight: 122 mg						Group weight of 20 Tablets: 2.341 g. Avg. wt.: 119.05 mg Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg) Min weight: 116 mg Max. weight: 121 mg					
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						LHS		RHS		Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)						2min 44 sec		2min 37 sec		Equipment ID No.: QA/DTA/001	
Done by: 04/01/2021 (IPQA)											
Date: 04/01/2021		Time: 16:50		Shift: 6							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	116	8	116	15	116	1	112	8	116	15	116
2	114	9	112	16	119	2	119	9	119	16	119
3	119	10	119	17	112	3	116	10	117	17	116
4	114	11	112	18	119	4	117	11	112	18	117
5	116	12	117	19	112	5	119	12	120	19	112
6	112	13	119	20	117	6	120	13	119	20	116
7	119	14	116			7	119	14	117		
Balance ID No.: QA/BA/L/002						M/C Speed: 20 RPM					
Group weight of 20 Tablets: 2.352 g. Avg. wt.: 117.6 mg Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg) Min weight: 116 mg Max. weight: 119 mg						Group weight of 20 Tablets: 2.356 g. Avg. wt.: 117.8 mg Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg) Min weight: 116 mg Max. weight: 120 mg					
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						LHS		RHS		Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)						2min 46 sec		2min 26 sec		Equipment ID No.: QA/DTA/001	
Done by: 04/01/2021 (IPQA)											

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka				
Date	31/12/2020	31/12/2020	31/12/2020		

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 42 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET		BMR. No.: BMR/T/195-00 Batch No.: G1F-210101
		Customer:	Generic Health Care Pvt. Ltd.

11.26 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours): H.Rpm

Date: 04/01/2021		Time: 16:55		Shift: G	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	116	8	117	15	116
2	117	9	119	16	112
3	112	10	112	17	120
4	116	11	112	18	117
5	116	12	117	19	116
6	114	13	116	20	112
7	115	14	117		
Balance ID No.: QA/BAL/002			M/C Speed: 30 RPM		
Group weight of 20 Tablets: 2.342 g. Avg. wt: 117.1 mg Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg) Min weight: 115 mg Max. weight: 120 mg			Group weight of 20 Tablets: 2.352 g. Avg. wt: 117.6 mg Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg) Min weight: 115 mg Max. weight: 120 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			LHS	RHS	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)			2 min 43 sec	02 min 44 sec	Equipment ID No.: QA/DTA/001
Done by: L. Handaru (IPQA)			Date: 04/01/2021		
Date: 04/01/2021		Time: 17:05		Shift: G	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	114	8	116	15	116
2	118	9	114	16	117
3	119	10	116	17	119
4	114	11	119	18	117
5	120	12	118	19	120
6	121	13	121	20	121
7	117	14	116		
Balance ID No.: QA/BAL/002			M/C Speed: 20 RPM		
Group weight of 20 Tablets: 2.365 g. Avg. wt: 118.25 mg Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg) Min weight: 115 mg Max. weight: 121 mg			Group weight of 20 Tablets: 2.360 g. Avg. wt: 118.1 mg Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg) Min weight: 115 mg Max. weight: 122 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			LHS	RHS	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)			1 min 58 sec	1 min 58 sec	Equipment ID No.: QA/DTA/001
Done by: L. Handaru (IPQA)			Date: 04/01/2021		

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	J. K.	J. K.	J. K.
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

BMR. No.: BMR/T/195-00

Batch No.: GF 210101

Customer:

Generic Health Care Pvt. Ltd.

Product: GENSET

11.27 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

H. Handan

Date: 04/01/2021						Time: 14:15						Shift: G1					
LHS: Individual weight of 20 tablets (in mg).						RHS: Individual weight of 20 tablets (in mg).											
1	117	8	115	15	121	1	115	8	117	15	119						
2	119	9	116	16	119	2	119	9	115	16	112						
3	116	10	117	17	114	3	114	10	116	17	119						
4	117	11	116	18	116	4	116	11	117	18	114						
5	112	12	120	19	116	5	115	12	115	19	116						
6	119	13	113	20	112	6	117	13	117	20	117						
7	117	14	117			7	115	14	112								

Balance ID No.: QA/BA/002	M/C Speed: 22 RPM
Group weight of 20 Tablets: 2346 g. Avg. wt: 117.3 mg	Group weight of 20 Tablets: 2323 g. Avg. wt: 116.15 mg
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)	Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)
Min weight: 115 mg Max. weight: 121 mg	Min weight: 114 mg Max. weight: 119 mg

	LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	0.05%	0.06%	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)	3min 45sec	3min 24sec	Equipment ID No.: QA/DTA/001

Done by: QA/BA/002 (IPQA)

Done by: _____

Date:	04/01/2021	Time:	14:30	Shift:	G1 composite						
LHS: Individual weight of 20 tablets (in mg).					RHS: Individual weight of 20 tablets (in mg).						
1	116	8	116	15	116	1	112	8	116	15	116
2	117	9	112	16	119	2	119	9	117	16	119
3	119	10	119	17	118	3	116	10	117	17	116
4	117	11	112	18	119	4	117	11	112	18	117
5	116	12	116	19	112	5	112	12	126	19	112
6	112	13	117	20	117	6	120	13	119	20	116
7	119	14	117			7	119	14	117		

Balance ID No.: QA/BA/002	M/C Speed: 22 RPM
Group weight of 20 Tablets: 2252 g. Avg. wt: 112.6 mg	Group weight of 20 Tablets: 2356 g. Avg. wt: 117.8 mg
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)	Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)
Min weight: 116 mg Max. weight: 119 mg	Min weight: 116 mg Max. weight: 126 mg

	LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	0.03%	0.02%	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)	2min 55sec	2min 37sec	Equipment ID No.: QA/DTA/001

Done by: QA/BA/002 (IPQA)

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	1.12	31/12/2020	31/12/2020	31/12/2020
Date	31/12/2020			

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 44 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMR/T/195-00 Customer:	Batch No.: GF 210101 Generic Health Care Pvt. Ltd.

11.28 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date:				Time:				Shift:							
LHS: Individual weight of 20 tablets (in mg).								RHS: Individual weight of 20 tablets (in mg).							
1		8		15				1		8		15			
2		9		16				2		9		16			
3		10		17				3		10		17			
4		11		18				4		11		18			
5		12		19				5		12		19			
6		13		20				6		13		20			
7		14						7		14					
Balance ID No.: _____								M/C Speed: _____ RPM							
Group weight of 20 Tablets:.....g. Avg. wt:.....mg								Group weight of 20 Tablets:.....g. Avg. wt:.....mg							
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)								Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)							
Min weight. :..... mg Max. weight.: mg								Min weight. :..... mg Max. weight.: mg							
								LHS		RHS					
Friability (Limit: NMT 1% after 4 minutes/100 rotations):												Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)												Equipment ID No.: QA/DTA/			
Done by:(IPQA)															
Date:				Time:				Shift:							
LHS: Individual weight of 20 tablets (in mg).								RHS: Individual weight of 20 tablets (in mg).							
1		8		15				1		8		15			
2		9		16				2		9		16			
3		10		17				3		10		17			
4		11		18				4		11		18			
5		12		19				5		12		19			
6		13		20				6		13		20			
7		14						7		14					
Balance ID No.: _____								M/C Speed: _____ RPM							
Group weight of 20 Tablets:.....g. Avg. wt:.....mg								Group weight of 20 Tablets:.....g. Avg. wt:.....mg							
Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)								Limit: 118.000 mg $\pm$ 7.5 % (109.150 mg – 126.850 mg)							
Min weight. :..... mg Max. weight.: mg								Min weight. :..... mg Max. weight.: mg							
								LHS		RHS					
Friability (Limit: NMT 1% after 4 minutes/100 rotations):												Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)												Equipment ID No.: QA/DTA/			
Done by:(IPQA)															

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. K.				
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020	

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF210101

Customer:

Generic Health Care Pvt. Ltd.

11.29 WEIGHING RECORD OF COMPRESSED TABLETS:

S. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Weighed by	Checked by Prod.	Verified by IPQA
1	25.900	2.300	23.600	Bala	N. Bal	R
2	25.800	2.300	23.500	Bala	N. Bal	R
3	25.820	2.300	23.520	Bala	N. Bal	R
4	26.250	2.300	23.950	Arshgu	N. Bal	R
5	26.180	2.300	23.880	Arshgu	N. Bal	R
6	26.230	2.300	24.030	Arshgu	N. Bal	R
7	25.650	2.300	23.350	Arshgu	N. Bal	R
8	25.730	2.300	23.430	Arshgu	N. Bal	R
9	25.850	2.300	23.550	Bala	N. Bal	R
10	26.320	2.300	24.020	Bala	N. Bal	R
11	25.930	2.300	23.630	Bala	N. Bal	R
12	25.900	2.300	23.600	Bala	N. Bal	R
13	26.880	2.300	24.680	Bala	N. Bal	R
14	28.770	2.200	26.570	Bala	N. Bal	R
15	18.150	2.200	15.950	Arshgu	N. Bal	R
16						
17						
18						
19						
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27						
28						
29						
30						

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	Raf	21/12/2020	21/12/2020
Date	31/12/2020	31/12/2020		

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 46 of 58
	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMR/T/195-00 Customer:	Batch No.: GF 210101 Generic Health Care Pvt. Ltd.

11.30 RECONCILIATION (COMPRESSION STAGE):

Average weight of Uncoated Tablet: ...118...mg

1.0	Standard Batch size	:	354.000 Kg.	30,00,000 No.
2.0	Actual weight of Lubricated granules	:	352.220 Kg	29 85 000 Nos.
3.0	Weight of compressed tablets	:	351.210 Kg	29 76 355 Nos.
4.0	Rejection during Compression @	:	...0.860 Kg.	
5.0	In-process samples of all stages			
	A	IPQC Samples	: 0.090 Kg.	
	B	QC Samples	: 0.030 Kg.	
	C	Validation Samples	: 0.040 Kg.	
6.0	Total in process samples: (A + B + C)	:	...0.160 Kg.	
7.0	Total: (3.0 + 6.0)	:	351.270 Kg.	29 77 771 Nos.
8.0	Yield {7.0 / 1.0 x 100}*	:		99.25 %

* Actually yield will be calculated after 3 validation batches

@Total rejects destroyed:0.860 Kg. (Rejected materials shall be destroyed as per SOP No.: QAGN/048)

Done by Production Sign/Date: N. Bal 04/01/2021 Checked by IPQA Sign/Date: ...04/01/2021.....

Test request form raised by Prod Sign/Date: N. Bal 04/01/2021

Test request form received by IPQA Sign/Date: ...04/01/2021.....

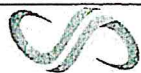
12.0 RELEASED FOR COATING:

Reconciliation checked and compressed tablets released for coating:

IPQA Sign..... Date: 04/01/2021.....

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	[Signature]	[Signature]	[Signature]
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMRT/195-00

Batch No.: GF210101

Customer:

Generic Health Care Pvt. Ltd.

13.0 LINE CLEARANCE FOR COATING SOLUTION PREPARATION:

Date/Shift/Time: 04/01/2021/16:20

Sr. No.	Checks	*Observation			
		Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty containers, polythene bags, Tags and documents of previous batch/product are removed.	✓	✓		
2	Check and ensure that absence of previous batch/product from area below machine and inside machine.	✓	✓		
3	Check and ensure that machine body, machine parts and control panel are clean.	✓	✓		
4	Check and ensure that absence of previous batch/product below container weighing balance.	✓	✓		
5	Check and ensure that working desk, analytical balance and other accessories are clean.	✓	✓		
6	Check and ensure that Tube light fixture, supply grills, riser grills and filters, electrical fixtures and Drain point are clean.	✓	✓		
7	Check and ensure that instruments to be used are within calibration due date.	✓	✓		
8	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.	✓	✓		
9	Check and ensure that environmental conditions are recorded in the BMR.	✓	✓		
10	Check and ensure that rinse water is released from QC and attached the test request from (TRF) in BMR	✓	✓		
11	Equipment status is updated for Cleaned, Qualification and Preventive maintenance.	✓	✓		

Note: *Tick mark (✓) if Complies and (X) if does not comply.

Equipment	Solution preparation vessel and stirrer	Colloidal Mill	Area
Equipment ID No.	NA	pd/cm/001	Soln preparation Area
Previous product	Ultra vitamin D3 tablets		
Batch No.	UP201028		
Cleaned by	magesh		
Checked by Production Sign/Date:	[Signature]		
Verified by IPQA Sign/Date:	[Signature]		

ENVIRONMENTAL CONDITIONS:		Date: 04/01/2021 Time: 16:22		Date:		Time:	
		Observation	Prod. Sign.	Verified by IPQA	Observation	Prod. Sign.	Verified by IPQA
(Refer to SOP No.: QAGN/011)	Temperature °C Limit: NMT 25 °C	22°C	✓	✓			
	Relative Humidity % Limit: NMT 60%	50%	✓	✓			

APPROVAL FOR COATING SOLUTION PREPARATION:

Production Sign/Date: [Signature] 04/01/2021

Line Clearance IPQA Sign. / Date: [Signature]

Start Time/Date: 16:24/04/01/2021

End Time/Date: 18:25/04/01/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	[Signature]	[Signature]	[Signature]
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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	BATCH MANUFACTURING RECORD	Product Code: G13	Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMRT/195-00	Batch No.: GF210101
		Customer:	Generic Health Care Pvt. Ltd.

14.0 Coating Procedure:

14.1 General Instructions:

1. Prepare the coating solution lot wise.
2. Do not use synthetic containers for storage/ transfer of coating solution
3. Do not use high speed stirrer for preparing coating solution. Avoid direct contact of body with Solvent & coating solution. Solvent based coating should be done in spark proof area.

14.2 TABLETS RECEIPT RECORD OF UNCOATED TABLETS FOR COATING:

Balance ID. No.: 001BA4014

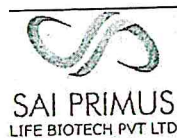
Sr. No.	Description	Observations	Checked By (Production)	Verified By (IPQA)
1.	Total Quantity (Net Qty.in Kg)	351.210	N. BL/04/01/2021	B. Subhakar
2.	Number of Containers	15	N. BL/04/01/2021	B. Subhakar

14.3 COATING SOLUTION PREPARATION

Sr. No.		General Instructions		Balance ID.:		
1.		Check the cleanliness of the Solution Preparation area and operation as per current version of SOP.				
2.		Use hand gloves while handling the materials				
3.		Transfer the verified coating materials to Coating solution preparation area.				
Step No.	Name of Ingredient & Operation	Time		Done by	Checked by Prod.	Verified by IPQA
		Start	Finish			
1	LOT I Charge Purified water and Instacoat White (IC-U-3849) in a ss container slowly under continuous stirring. Continue stirring until uniform solution is obtained. If required mill the solution in colloidal mill until uniform solution is obtained. If required filter the solution through 100 nylon mesh if necessary	16:25	16:42	magadh	N. BL	✓
2	LOT II Charge Purified water and Instacoat White (IC-U-3849) in a ss container slowly under continuous stirring. Continue stirring until uniform solution is obtained. If required mill the solution in colloidal mill until uniform solution is obtained. If required filter the solution through 100 nylon mesh if necessary	17:15	18:25	magadh	N. BL	✓
3	Sieve integrity of 100 nylon mesh before Use	OK #	Not OK #	Checked by	Verified by	Remarks
		OK	NA	N. BL	✓	NA
		OK	NA	N. BL	✓	NA
4	Sieve integrity of 100 nylon mesh after Use	OK	NA	N. BL	✓	NA
		OK	NA	N. BL	✓	NA

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	✓	✓	✓
Date	31/12/2020	21/12/2020	31/12/2020	31/12/2020

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

BMR. No.: BMR/T/195-00

Batch No.: GF 210101

Customer:

Generic Health Care Pvt. Ltd.

15.0 COATING AREA:

15.1 LINE CLEARANCE CHECKS: Date/Shift/Time: 04/01/2021/16:55

Sr. No.	Checks	*Observation					
		Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty containers, polythene bags, Tags and documents of previous batch/product are removed.	✓	✓	✓			
2	Check and ensure that absence of previous batch/product from area below machine and inside machine.	✓	✓				
3	Check and ensure that machine body, machine parts and control panel are clean.	✓	✓				
4	Check and ensure that absence of previous batch/product below container weighing balance.	✓	✓				
5	Check and ensure that working desk, analytical balance and other accessories are clean.	✓	✓				
6	Check and ensure that Tube light fixture, supply grills, riser grills and filters, electrical fixtures and Drain point are clean.	✓	✓				
7	Check and ensure that instruments to be used are within calibration due date.	✓	✓				
8	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.	✓	✓				
9	Check and ensure that environmental conditions are recorded in the BMR.	✓	✓				
10	Check and ensure that rinse water is released from QC and attached the test request from (TRF)	✓	✓				
11	Equipment status is updated for Cleaned, Qualification and Preventive maintenance.	✓	✓				

Note: *Tick mark (✓) if Complies and (X) if does not comply.

Equipment	Coating Machine	Area
Equipment ID No.	PD/NEC/001	Coating area
Previous product	Ultra vitamin D3 tablets	
Batch No.	UD201028	
Cleaned by	maresh	
Checked by Production Sign/Date:	04/01/2021	
Verified by IPQA Sign/Date:		

ENVIRONMENTAL CONDITIONS:		Date: 04/01/2021	Time: 16:55	Date:	Time:	Date:	Time:
		Observation	Checked by	Verified by	Observation	Checked by	Verified by
(Refer to SOP No.: QAGN/011)	Temperature °C Limit: NMT 25 °C	23°C	✓	✓			
	Relative Humidity % Limit: NMT 60%	52%	✓	✓			
	Differential Pressure (NLT 10 Pascal)	12 pascals	✓	✓			

APPROVAL FOR COATING:

Production Sign/Date: 04/01/2021

Line Clearance IPQA Sign. / Date: 04/01/2021

Start Time/Date: 17:12/04/01/2021

End Time/Date: 21:26/04/01/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	✓	✓	✓
Date	31/12/2020	21/12/2020	31/12/2020	21/12/2020

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

GENSET

BMR. No.: BMRT/195-00

Batch No.: GF 210101

Customer:

Generic Health Care Pvt. Ltd.

COATING

I INSTRUCTION FOR FILM COATING:

Transfer the compressed tablets to coating area.

Load the tablets in coater.

Pre-warm the tablets with inlet temp. 55 °C - 60 °C and exhaust temp. 50 °C - 55 °C.

Set the spray gun connected to peristaltic pump by silicon tubing and start coating.

Carry out in process check after every 30 min. and record.

After completion of coating, dry the film coated tablets in the coating pan for about 10 min. with inlet temp. 55 °C - 60 °C.

The film coating suspension need to be stirred slowly during the coating process to prevent suspended solids from setting.

II COATING PROCESS:

Process Steps

Name of Ingredient & Operation	Time		Done by	Checked by Prod.	Verified by IPQA
	Start	Finish			
Transfer the compressed tablets in to the coating Area	17:15	17:36	magah	N. Bel	10
Pre-warm the tablet with inlet temp. 55°C - 60°C and exhaust temp. 50°C - 55°C.	17:49	18:59	magah	N. Bel	10
Arrange the spray gun in such a way that the spray droplets just touch the tablet bed on upper rim. The spray should not fall on the wall of the pan. Weight gain obtained: 2.07% (Approx. 2.0%)	19:00	19:09	magah	N. Bel	10
When the spraying is complete, dry the tablets perfectly, in the pan by hot air at NMT 45°C with intermittently flipping the tablets, until no more solvent odour is observed. Caution: Ensure the tablet bed temperature does not rise excessively.	19:05	19:07	magah	N. Bel	10
Found Disintegration Time: 03mins (Limit: NMT 30 minutes).	19:08	19:14	magah	N. Bel	10
Unload the film coated tablets in a HDPE container lined with double polybag.			magah	N. Bel	10

T II

Transfer the compressed tablets in to the coating Area	19:20	19:25	magah	N. Bel	10
Pre-warm the tablet with inlet temp. 55°C - 60°C and exhaust temp. 50°C - 55°C.	19:30	20:59	magah	N. Bel	10
Arrange the spray gun in such a way that the spray droplets just touch the tablet bed on upper rim. The spray should not fall on the wall of the pan. Weight gain obtained: 2.12% (Approx. 2.0%)	21:00	21:20	magah	N. Bel	10
When the spraying is complete, dry the tablets perfectly, in the pan by hot air at NMT 45°C with intermittently flipping the tablets, until no more solvent odour is observed. Caution: Ensure the tablet bed temperature does not rise excessively.	21:21	21:36	magah	N. Bel	10
Found Disintegration Time: 03mins (Limit: NMT 30 minutes).	21:37	21:40	magah	N. Bel	10
Unload the film coated tablets in a HDPE container lined with double polybag.			magah	N. Bel	10

16. INITIAL CHECKS OF COATING PARAMETERS:

S. No	Parameter	Set	Observed	
			LOT I	LOT II
1	Inlet Temp.	55 °C - 60 °C (To be established)	54 °C	55 °C
2	Exhaust air Temp.	50 °C - 55 °C (To be established)	45 °C	41 °C
3	Tablet Bed temp.	50 °C - 55 °C (To be established)	42 °C	42 °C
4	Atomization air pressure	1.5 - 3 Kg/cm ² (To be established)	3.0 kg/cm ²	3.0 kg/cm ²
5	Pan speed	2.0 - 4.0 RPM (To be established)	3.0 RPM	3.0 RPM
6	Spray rate	50 ml/min - 100 ml/min (To be established)	89 ml/min	89 ml/min
Checked by Production/ Date			N. Bel 04/10/2021	N. Bel 04/10/2021
Verified by IPQA/ Date			04/10/2021	04/10/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	POB	21/12/2020	8. 10/12/2020
Date	31/12/2020	31/12/2020		

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LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

BMR. No.: BMR/T/195-00

Batch No.: GF210101

Product

GENSET

Customer:

Generic Health Care Pvt. Ltd.

16.6 FINAL COATING PARAMETERS CHECKS: (PRODUCTION)

Parameters	Limits	Observed	
		LOT I	LOT II
Description	White coloured capsule shaped film coated tablets with breakline on one side and plain on other side	OK	OK
Theoretical weight per tablet	120.800 mg $\pm$ 3 % (117.176 mg – 124.424 mg)	120 mg	120.041
Weight of 20 tablets	2.416 g $\pm$ 3 % (2.344 g – 2.488 g)	2.401 g	2.397 g
Uniformity of weight	120.800 mg $\pm$ 5 % (114.760 mg – 126.840 mg)		100.62%
Length (mm)	10.20 mm $\pm$ 0.1 mm (10.10 mm – 10.30 mm) (To be established)	10.12 mm	10.13 mm
Width (mm)	4.10 mm $\pm$ 0.1 mm (4.00 mm – 4.20 mm) (To be established)	4.07 mm	4.09
Thickness	(2.50 mm – 3.10 mm) (To be established)	2.80 mm	2.82 mm
Disintegration test	NMT 30 min	08 min 16 sec	03 min 19 sec
Checked by Production/ Date		N.B.L. 04/01/2021	N.B.L. 04/01/2021

16.7 FINAL COATING PARAMETERS CHECKS: (IPQA)

Parameters	Limits	Observed	
		LOT I	LOT II
Description	White coloured capsule shaped film coated tablets with breakline on one side and plain on other side	OK	OK
Theoretical weight per tablet	120.800 mg $\pm$ 3 % (117.176 mg – 124.424 mg)	120 mg	119 mg
Weight of 20 tablets	2.416 g $\pm$ 3 % (2.344 g – 2.488 g)	2.400 g	2.389
Uniformity of weight	120.800 mg $\pm$ 5 % (114.760 mg – 126.840 mg)	-2.5% / 0.83%	-1.5%
Length (mm)	10.20 mm $\pm$ 0.1 mm (10.10 mm – 10.30 mm) (To be established)	10.11 mm	10.11 mm
Width (mm)	4.10 mm $\pm$ 0.1 mm (4.00 mm – 4.20 mm) (To be established)	4.08 mm	4.08 mm
Thickness	(2.50 mm – 3.10 mm) (To be established)	2.81 mm	2.80 mm
Disintegration test	NMT 30 min	03 min 12 sec	03 min 39 sec
Checked by IPQA/ Date		N.B.L. 04/01/2021	N.B.L. 04/01/2021

16.8 UNIFORMITY CHECKS FOR COATED TABLETS (PRODUCTION)

Sample No.	1	2	3	4	5	6	7	8	9	10
Weight	119	119	121	122	123	122	120	121	120	121
Sample No.	11	12	13	14	15	16	17	18	19	20
Weight	120	118	119	120	121	120	121	122	120	122
Thickness	2.74	2.79	2.81	2.82	2.83					
Group Weight of 20 tablets: 2.414g										
Checked by Production: N.B.L. Date: 04/01/2021										

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K.	N.B.L.	N.B.L.	N.B.L.
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

BMR. No.: BMR/T/195-00

Batch No.: GF210101

Product: GENSET

Customer:

Generic Health Care Pvt. Ltd.

16.9 UNIFORMITY CHECKS FOR COATED TABLETS (IPQA)

Sample No.	1	2	3	4	5	6	7	8	9	10
Weight	11.9	12.1	11.9	12.0	12.3	12.1	12.0	11.9	11.8	12.0
Sample No.	11	12	13	14	15	16	17	18	19	20
Weight	11.9	12.0	11.8	11.9	12.1	11.8	11.9	12.1	12.2	12.1
Thickness	2.71	2.71	2.81	2.76	2.79					

Group Weight of 20 tablets: 239.6

Checked by Production: 0.11.12.2021

Date: 01.12.2021

16.10 ACTUAL AVERAGE WEIGHT OF COATED TABLETS:

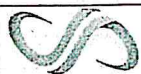
Weight of 100 coated tablet = 120.130 mg
100

16.11 WEIGHT OF FILM COATED TABLETS:

Container No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Weighed by	Checked by Production	Verified by IPQA
1	34.460	2.200	32.260	magesh	N. Bal	Q
2	38.280	2.200	36.080	magesh	N. Bal	Q
3	32.830	2.200	30.630	magesh	N. Bal	Q
4	33.790	2.200	31.590	magesh	N. Bal	Q
5	26.210	2.200	24.010	magesh	N. Bal	Q
6	27.400	2.200	25.200	magesh	N. Bal	Q
7	31.240	2.200	29.040	magesh	N. Bal	Q
8	24.950	2.200	22.750	magesh	N. Bal	Q
9	31.400	2.200	29.200	magesh	N. Bal	Q
10	26.200	2.200	24.000	magesh	N. Bal	Q
11	27.170	2.200	24.970	magesh	N. Bal	Q
12	26.840	2.200	24.640	magesh	N. Bal	Q
13	25.120	2.200	22.920	magesh	N. Bal	Q
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						
25						
26						
27						
28						
29						
30						
TOTAL			357.240			

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	208	31/12/2021	8. 31/12/2021
Date	31/12/2021	31/12/2021	31/12/2021	31/12/2021

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210101

Customer:

Generic Health Care Pvt. Ltd.

16.12 RECONCILIATION (COATING STAGE):

Average weight of coated Tablet: ...120.13mg

1.0	Batch size	:	362.400 Kg.	30,00,000 Nos.
2.0	Weight of coated tablets	:	357.240 Kg.	2973478 Nos.
3.0	Coating loss@	:	0.070 Kg.	
4.0	In-process samples of all stages			
	A	IPQC Samples	:	0.010 Kg.
	B	QC Samples	:	0.090 Kg.
	C	Validation Samples	:	NA. Kg.
5.0	Total in process samples: (A + B + C)	:	0.100 Kg.	
6.0	Total: (2.0 + 5.0)	:	357.340 Kg.	2974610 Nos.
7.0	Yield {6.0 x 100 / 1.0} *	:		99.15 %

* Actually yield will be calculated after 3 validation batches

@Total rejects destroyed:0.070 Kg. (Rejected materials shall be destroyed as per SOP No.: QAGN/048)

Done by Production Sign/Date: ...N. B. Loga/01/12/2021 Checked by IPQA Sign/Date: ...S. A. /01/2021

Test request form raised by Prod Sign/Date: ...N. B. Loga/01/2021

Test request form received by IPQA Sign/Date: ...S. A. /01/2021

16.13 RELEASE FOR INSPECTION:

Reconciliation checked and Coated tablets released for inspection

IPQA Sign: ...S. A. /01/2021 Date: ...01/12/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. R.	[Signature]	[Signature]	[Signature]
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF 210101

Customer:

Generic Health Care Pvt. Ltd.

17.0 INSPECTION LINE CLEARANCE:

Date/Shift/Time: 05/01/2024 / A / 06:27

Sr. No.	Checks	*Observation			
		Prod	IPQA	Prod	IPQA
1	Check and ensure that empty containers, polythene bags, Tags and documents of previous batch/product are removed.	✓	✓		
2	Check and ensure that absence of previous batch/product from area below machine and inside machine.	✓	✓		
3	Check and ensure that machine body, machine parts and control panel are clean.	✓	✓		
4	Check and ensure that absence of previous batch/product below container weighing balance.	✓	✓		
5	Check and ensure that working desk, analytical balance and other accessories are clean.	✓	✓		
6	Check and ensure that Tube light fixture, supply grills, riser grills and filters, electrical fixtures and Drain point are clean.	✓	✓		
7	Check and ensure that instruments to be used are within calibration due date.	✓	✓		
8	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.	✓	✓		
9	Check and ensure that environmental conditions are recorded in the BMR.	✓	✓		
10	Check and ensure that rinse water is released from QC and attached the test request from (TRF) in BMR	✓	✓		
11	Equipment status is updated for Cleaned, Qualification and Preventive maintenance.	✓	✓		

Note: *Tick mark (✓) if Complies and (X) if does not comply.

Equipment	Inspection Belt	Metal Detector	Area
Equipment ID No.	PD1TNB/001	PD1MED/001	Inspection-01
Previous product	Ascorbic Acid		
Batch No.	ST014120		
Cleaned by	Jegan		
Checked by Production Sign/Date:	N. Bal 05/01/2024		
Verified by IPQA Sign/Date:	[Signature] 05/01/2024		

ENVIRONMENTAL CONDITIONS:		Date: 05/01/2024 Time: 06:25		Date: Time:		
		Observation	Prod. Sign.	Verified by IPQA	Observation	Prod. Sign.
(Refer to SOP No.: QAGN/011)	Temperature °C Limit: NMT 25 °C	23 °C	N. Bal	[Signature]		
	Relative Humidity % Limit: NMT 60%	52%	N. Bal	[Signature]		

APPROVAL FOR INSPECTION:

Production Sign/Date: N. Bal 05/01/2024

Line Clearance IPQA Sign. / Date: [Signature] 05/01/2024

Start Time/Date: 06:30 / 05/01/2024

End Time/Date: 12:50 / 05/01/2024

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	[Signature]	[Signature]	[Signature]
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMR/T/195-00 Customer:	Batch No.: GF210101 Generic Health Care Pvt. Ltd.

18.0 INSPECTION PROCESS

18.1 INSTRUCTIONS

S. No.	Process Instructions
1	Carry out visual inspection of tablets on inspection belt area as per the SOP No. PDOP/019.
2	Collect inspected tablets in containers lined with polythene bags. Weigh the containers and record the weight.
3	Intimate In-process Quality Assurance.

18.2 PERFORMANCE CHECKS RECORD FOR METAL DETECTOR:

Sr. No	Process instructions
1.	At the start of the activity, after each break and at the end of operation/shift) as per SOP No. PDGN/022.
2.	Testing frequency: Startup, End of the activity and after every break time.
3.	Acceptance Criteria: 1. Ferrous, Stainless steel & Non-Ferrous shall be detected & rejected. 2. Nonmetallic shall not be detected.

Date & Time	Trial No.	Metal Detector ID No.: PD/MED/021 & PD/MED/022...				Result	Checked by Production	Verified By IPQA
		Ferrous (0.3 mm)	Stainless steel (0.5 mm)	Non-Ferrous (0.3 mm)	Non-metallic			
05/01/2021 06:40	1	✓	✓	✓	α	pass	N. Bal	✓
	2	✓	✓	✓	α	pass	N. Bal	✓
	3	✓	✓	✓	α	pass	N. Bal	✓
05/01/2021 10:32	1	✓	✓	✓	α	pass	N. Bal	✓
	2	✓	✓	✓	α	pass	N. Bal	✓
	3	✓	✓	✓	α	pass	N. Bal	✓
05/01/2021 12:26	1	✓	✓	✓	α	pass	N. Bal	✓
	2	✓	✓	✓	α	pass	N. Bal	✓
	3	✓	✓	✓	α	pass	N. Bal	✓
	1							
	2							
	3							
	1							
	2							
	3							

Note: Put ✓ mark for detection and x mark for non-detection
 If during the test Metal Detector fails to reject any of the Standard chips then mention the corrective action taken.
 (To be filled by Production)
 Note: Take QA Approval before proceeding to next stage

18.3 TABLETS VISUAL INSPECTION RECORD:

Date	Container No		Time		Total Quantity Rejected	Tablet Inspection Done by/Date	Checked by/Date
	From	To	Started	Completed			
05/01/2021	01	13	06:22	12:46	0.060	Flow, Youngma	N. Bal 05/01/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	P. A	S. K	S. K
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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BATCH MANUFACTURING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

BMR. No.: BMR/T/195-00

Batch No.: GF210101

Customer:

Generic Health Care Pvt. Ltd.

18.4 WEIGHING RECORD OF INSPECTED TABLETS:

Container No	Gross weight Kg	Tare weight Kg	Net. weight Kg	Container No	Gross weight Kg	Tare weight Kg	Net. weight Kg
1	34.400	2.200	32.200	16			
2	38.210	2.200	36.010	17			
3	32.800	2.200	30.600	18			
4	33.700	2.200	31.500	19			
5	26.210	2.200	24.010	20			
6	27.390	2.200	25.190	21			
7	31.220	2.200	29.020	22			
8	24.900	2.200	22.700	23			
9	31.370	2.200	29.170	24			
10	26.200	2.200	24.000	25			
11	27.120	2.200	24.920	26			
12	26.820	2.200	24.620	27			
13	25.440	2.200	23.240	28			
14				29			
15				30			
Total			357.180 Kg	Total			NA Kg
				Grand Total			357.180 Kg

Weighing Done By: Jagan... Checked By Prod./ Date: N. B. 05/01/2021 Verified by IPQA Sign./Date: J. Jagan...

18.5 RECONCILIATION: (INSPECTION OF TABLETS)

1.0	Theoretical weight of Tablets	:	362.400 Kg	30,00,000 No's
2.0	Tablets transferred for Inspection	:	357.240 kg	2973778 No's
3.0	Total weight of good Tablets	:	357.180 kg	2973278 No's
4.0	Rejected Tablets	:	0.060 kg	500 No's
5.0	*Yield = $\frac{3.0}{1.0} \times 100$	:		99.10 %

*Actually yield will be calculated after 3 validation batches.

Total rejects destroyed: 0.060 Kg.

Rejected materials should be destroyed in the presence of QA.

Done by Production sign/Date: N. B. 05/01/2021

Checked by IPQA sign/Date: J. Jagan...

18.6 RELEASE FOR PACKING:

BMR reviewed by IPQA Sign/Date : J. Jagan...

BMR Released for packing by QA Head Sign/Date: J. Jagan...

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	1. Ka	J. Jagan	J. Jagan	J. Jagan
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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	BATCH MANUFACTURING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BMR. No.: BMR/T/195-00 Customer:	Batch No.: GF210101 Generic Health Care Pvt. Ltd.

19.0 BMR REVIEW DETAILS:

Reviewed by	Name	Sign./Date
Production Executive	Jal. Raman. k.	05/01/2021
QA Executive	Ran Kumar	05/01/2021
Production Assistant Manager/ HOD	BALASUBRAMANIAM. R	07/01/2021
QA Manager/ HOD	STEPHEN. R	07/01/2021

20.0 REVISION HISTORY:

Sr. No.	Document No.	Reason for Revision	Supersedes No.
1	BMRT/195-00	New Document	Nil

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	J. R.	S. R.	S. R.
Date	31/12/2020	31/12/2020	31/12/2020	31/12/2020

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