

	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 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMR/T/107-01 Customer:	Batch No.: GF200501 Generic Health Care Pvt. Ltd.

BATCH MANUFACTURING RECORD COVER SHEET

PRODUCT NAME : Amloperin 5mg/5mg
GENERIC NAME : Amlodipine Besilate and Perindopril Erbumine Tablets
LABEL CLAIM : Each uncoated tablet contains:
 Amlodipine Besilate BP
 Equivalent to Amlodipine.....5 mg
 Perindopril Erbumine BP5 mg
 Excipients.....q.s
MFR No. / Reference Document No. : MFR/T/040-00
BMR No. : BMR/T/107-01
REVISION No. : 01
SUPERSEDES No. : BMR/T/107-00
BMR EFFECTIVE BATCH NUMBER/DATE : GF200501 | 22/05/2020
MFG. LIC No. : PON/DRUGS/19 13 4323
STORAGE : Store in cool and dry place. Protect from light
BMR ISSUED BY/DATE (QA) : *[Signature]* 21/05/2020
BMR CHECKED & RECEIVED BY/DATE (PRODUCTION) : L. Ke 21/05/2020
SHELF LIFE : 36 Months
BATCH SIZE : 6,00,000 Tablets (84.000 Kg)
MFG. DATE: 05/2020 **EXP. DATE:** 04/2023

RECOVERY ADDITION RECORD

BATCH NO	MFG	EXP	QUANTITY	REVISED BATCH SIZE
		ms		

ALLOTTED BY: *[Signature]* **COUNTER CHECKED BY:** *[Signature]*
QA SIGN/DATE: 21/05/2020 **QA SIGN/DATE:** 21/05/2020
DATE OF COMMENCEMENT: 21/05/2020 **DATE OF COMPLETION:** 22/05/2020
RELEASED QUANTITY OF TABLETS FOR PACKING : 591150 Tablets
RELEASE FOR PACKING STAGE
HEAD OF QA SIGN/DATE: *[Signature]* 21/05/2020

This BMR contains 33 Pages + 11 Additional Pages

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ke	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	21/05/2020	21/05/2020	22/05/2020	22/05/2020

UNCONTROLLED COPY

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.		Page 2 of 33
	BATCH MANUFACTURING RECORD	Product Code: A08	Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMR/T/107-01	Batch No.: GF200501
		Customer:	Generic Health Care Pvt. Ltd.

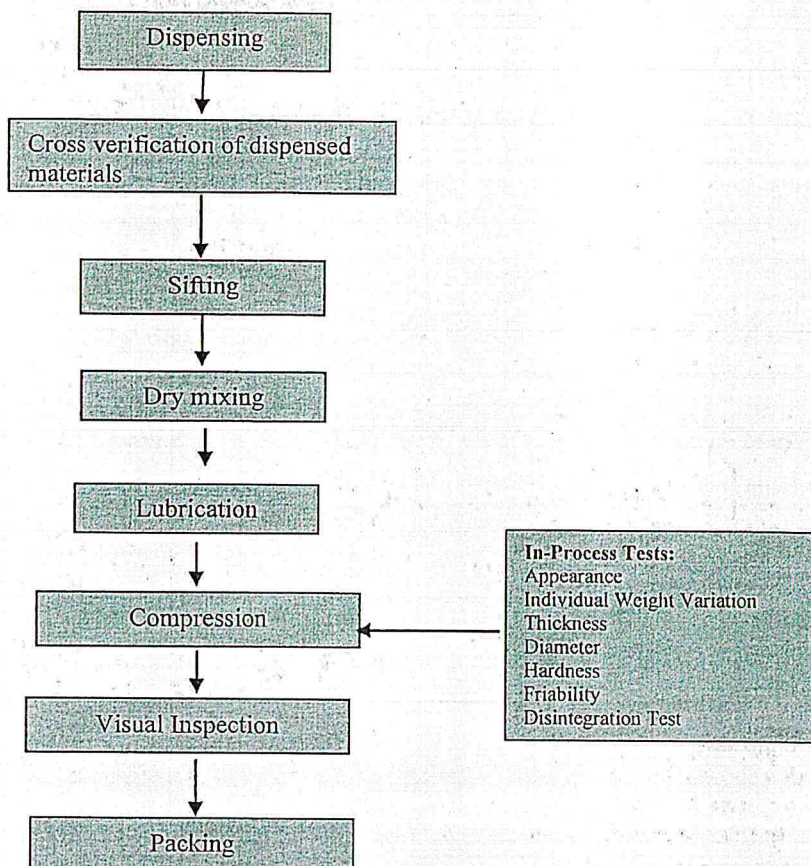
1.0 INDEX

Sr. No.	Content	Page No.
	Batch manufacturing cover sheet	1
1.0	Index	2
2.0	Flow Chart	3
3.0	Indent of active pharmaceutical ingredients & excipients	4
4.0	Calculation	5-6
5.0	Dispensing line clearance checks	7
6.0	Dispensing weighing sheet	8
7.0	Line clearance for Sifting and blending, Sieve integrity checks, Lubrication material sifting record, Blending and Lubrication instruction, Weight of final blend and Reconciliation	9-11
8.0	Release for Compression	11
9.0	Compression Line Clearance	12
10.0	Compression process instruction, granules receipt record, Compression specification and parameter, compression machine running status, Initial In-process checks, Compression specification and parameter, In-process checks (Production and IPQA), uniformity of weight checks (Production and IPQA), Weight record of compressed tablets, Reconciliation of compressed tablets	13-30
11.0	Release for Inspection	30
12.0	Inspection Line clearance	31
13.0	Inspection Process instruction, performance checks record for metal detector, tablets visual inspection record, weight record, Reconciliation of inspected tablets	32-33
14.0	Release for Packing	33
15.0	BMR Review details	33
16.0	Revision History	33

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	[Signature]	P. N. [Signature]	[Signature]
Date	21/05/2020	21/05/2020	21/05/2020	21/05/2020
UNCONTROLLED COPY		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.		Page 3 of 33
	BATCH MANUFACTURING RECORD	Product Code: A08	Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMR/T/107-01	Batch No.: <i>GF 200 501</i>
		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. Ke</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	21/05/2020	21/05/2020	22/05/2020	

UNCONTROLLED COPY

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.		Page 4 of 33
	BATCH MANUFACTURING RECORD	Product Code: A08	Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMR/T/107-01	Batch No.: <i>GF 200 501</i>
		Customer:	Generic Health Care Pvt. Ltd.

3.0 INDENT OF ACTIVE INGREDIENTS & EXCIPIENTS:

Sr. No.	Name of the Ingredient	Spec.	Item Code	Quantity/ Tablets (mg)	Standard quantity per 6,00,000 tablets (kg)	OA/ PL (%)	Required quantity per 6,00,000 tablets (kg)
Dry mixing							
1	Amlodipine Besilate*	BP	RAI/GH/A001	6.950	4.170	-	4.170
2	Perindopril Erbumine^	BP	RAI/GH/P001	5.000	3.000	-	3.000
3	Microcrystalline cellulose PH 102**^^	BP	REX/GH/M002	49.490	29.694	-	29.694
4	Microcrystalline cellulose PH 200	BP	REX/SP/M018	69.778	41.867	-	41.867
Lubrication:							
5	Colloidal silicon dioxide	BP	REX/GH/C001	0.484	0.290	-	0.290
6	Croscarmellose Sodium	BP	REX/GH/C002	3.425	2.055	-	2.055
7	Sodium Starch Glycolate	BP	REX/GH/S001	1.961	1.177	-	1.177
8	Magnesium stearate	BP	REX/GH/M001	5.882	3.529	-	3.529
Average wt. of core tablet				140.000	84.000	-	84.000

Note: *^API quantity shall be calculated based on potency.

OA: Overages, PL: Process loss

Potency calculation:

Theoretical Quantity of Amlodipine Besilate and Perindopril Erbumine required in Kg for a batch size of 6,00,000 Tablets are calculated.

* Excess Quantity shall be compensating from Microcrystalline cellulose PH-102**^^

Item losses 6% moisture.

Note: 1.39 mg of Amlodipine Besylate is equivalent to 1.0 mg of Amlodipine

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. Ka</i>	<i>S. S. S. S.</i>	<i>P. H. S.</i>	<i>S. S. S.</i>
Date	21/05/2020	21/05/2020	22/05/2020	21/05/2020

UNCONTROLLED COPY

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.

Page 5 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-01

Batch No.: GF 200 501

Customer:

Generic Health Care Pvt. Ltd.

4.0 ASSAY AND LOD CALCULATIONS FOR AMLODIPINE BESILATE:

Note: If assay of API is more than 100%, consider 100% at the time of calculation.

Standard quantity of Amlodipine Besilate: 4.170 Kg (A)

Calculation for Amlodipine Besilate:

$$\text{Theoretical Qty} = \frac{\text{Label Claim} \times \text{Std. Batch Size (in no's)}}{1000 \times 1000} \times \text{Equivalent factor} = \frac{5 \times 6,00,000}{1000 \times 1000} \times 1.39 = 4.170 \text{ kg}$$

1) Calculation for Single A. R. No. BMG/100011, Assay on dried basis: 99.94 w/w, LOD: 0.0234 w/w
Exp. Date...12.02.24

$$\text{Actual Quantity (Kg) (B)} = \frac{\text{Standard qty. required} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{4.17 \times 100 \times 100}{99.94 \times (100 - 0.0234)} = 4.173 \text{ Kg}$$

2) Calculation for Amlodipine Besilate Multiple A. R. No.:

Sr. No.	A. R. No.	Available Qty. (Kg) (C)	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 (D)					

Calculation for Remaining Quantity Required (E):

Theoretical Qty. - Actual Quantity (D) = N/A Kg

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

$$\text{Actual Remaining Quantity (Kg) (F)} = \frac{\text{Remaining qty. required (E)} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{N/A \times 100 \times 100}{N/A \times (100 -)} = N/A \text{ Kg.}$$

Total Qty. of Amlodipine Besilate to be dispensed (G) = (C) + (F) = N/A Kg

Done By/On (QA): [Signature]

Checked By/On (Production): [Signature]

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>21/05/2020</u>	<u>21/05/2020</u>	<u>21/05/2020</u>	<u>21/05/2020</u>

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.

Page 6 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-01

Batch No.: GF 200 501

Customer:

Generic Health Care Pvt. Ltd.

4.1 ASSAY AND LOD CALCULATIONS FOR PERINDOPRIL ERBUMINE:

Note: If assay of API is more than 100%, consider 100% at the time of calculation.

Standard quantity of Perindopril Erbumine: 3.000 Kg (A)

Standard quantity of Microcrystalline Cellulose PH 102 (B): 29.694 Kg

Calculation for Perindopril Erbumine BP:

- 1) Calculation for Single A. R. No. 2461/00012, Assay on dried basis: 97.63 w/w, LOD: 0.2835 w/w
Exp. Date: 18/05/2020

$$\text{Actual Quantity (Kg) (C)} = \frac{\text{Standard qty. required} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{3.000 \times 100 \times 100}{97.63 \times (100 - 0.2835)} = 3.019 \text{ Kg}$$

- 2) Calculation for Microcrystalline Cellulose PH 102 (B):

$$\begin{aligned} \text{Actual Quantity (Kg) (D)} &= \text{Standard quantity of Microcrystalline cellulose PH102} - (\text{Excess Calculated quantity of Amlodipine} \\ &\quad \text{Besilate} + \text{Excess Calculated quantity of Perindopril Erbumine}) \\ &= 29.694 \text{ Kg} - (0.003 \text{ Kg} + 0.01 \text{ Kg}) \\ &= 29.681 \text{ Kg} \end{aligned}$$

- 3) Calculation for Perindopril Erbumine 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):

$$\text{Theoretical Qty.} - \text{Actual Quantity (F)} = \text{---} \text{ Kg}$$

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

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

$$\text{Total Qty. of Perindopril Erbumine to be dispensed (I)} = (E) + (H) = \text{---} \text{ Kg}$$

- 4) Calculation for Microcrystalline Cellulose PH 102 (B):

$$\begin{aligned} \text{Actual Quantity (Kg) (J)} &= \text{Standard quantity of Microcrystalline cellulose PH102} - (\text{Excess Calculated quantity of Amlodipine} \\ &\quad \text{Besilate} + \text{Excess Calculated quantity of Perindopril Erbumine}) \\ &= 29.694 \text{ Kg} - (\text{---} \text{ Kg} + \text{---} \text{ Kg}) \\ &= \text{---} \text{ Kg} \end{aligned}$$

Done By/On (QA):

Checked By/On (Production):

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K.</u>	<u>P. N. S.</u>	<u>P. N. S.</u>	<u>S. M.</u>
Date	<u>21/05/2020</u>	<u>21/05/2020</u>	<u>22/05/2020</u>	<u>21/05/2020</u>

UNCONTROLLED COPY

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.		Page 7 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
	Product	Amloperin 5mg/5mg	BMR. No.: BMR/T/107-01 Customer:

5.0 DISPENSING LINE CLEARANCE CHECKS

Date: 22/05/2020 Time: 14:45

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/DPB/001	ST/BAL/005 ST/BAL/006	Dispensing Booth
Previous Product		Transmax	
B. No.		T09 0007E	
Cleaned by Sign/Date		Panganam / 22/05/2020	
Checked by Store Sign/Date		N. Arin / 22/05/2020	
Verified by IPQA Sign/Date		M. Arin / 22/05/2020	

ENVIRONMENTAL CONDITIONS: Date: 22/05/2020 Time: 14:50		Checked by Store Sign/Date	Verified by IPQA Sign/Date
(For Reference SOP No.: QAGN/011)			
Temperature (Limit: NMT 25°C)	23°C	N. Arin / 22/05/2020	M. Arin / 22/05/2020
Relative Humidity % (Limit: NMT 60%)	55%	N. Arin / 22/05/2020	M. Arin / 22/05/2020
Differential Pressure (NLT 10 Pascal)	10 cpa	N. Arin / 22/05/2020	M. Arin / 22/05/2020
Differential Pressure across the booth Limit: 5 to 20 mm Water	10 mm	N. Arin / 22/05/2020	M. Arin / 22/05/2020

APPROVAL FOR DISPENSING BY IPQA: Sign: M. Arin Date: 22/05/2020

Dispensing start Time: 15:20 End Time: 16:10

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	B. Arin	P. Arin	
Date	21/05/2020	21/05/2020	22/05/2020	

UNCONTROLLED CCPY



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 33

SAI PRIMUS
LIFE BIOTECH PVT LTD

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR No.: BMR/T/107-01

Batch No.: G1F 200501

Customer:

Generic Health Care Pvt. Ltd.

6.0 Dispensing Weighing Sheet:

Balance ID: 511 RA 4005 / 5113 RA 4006 Date: 22/05/2020 Shift: 6 Time: 15:20

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)
Dry Mixing:													
1	Amlodipine Besilate*	BP	RAI/GH/A001	Kg	4.170	4.173 4.185	RM 4 00011	4.237 4.265	6.080 4.173	N. Arj 22/05/2020	N. Arj 22/05/2020	N. Arj 22/05/2020	N. Arj 22/05/2020
2	Perindopril Erbumine^	BP	RAI/GH/P001	Kg	3.000	3.019	RM 4 00012	3.099 4.185	0.080 0.080	N. Arj 22/05/2020	N. Arj 22/05/2020	N. Arj 22/05/2020	N. Arj 22/05/2020
3	Microcrystalline cellulose PH 102***	BP	REX/GH/M002	Kg	29.694	29.165 29.683	RM 4 00003	29.700 4.774	0.200 0.080	N. Arj 22/05/2020	N. Arj 22/05/2020	N. Arj 22/05/2020	N. Arj 22/05/2020
4	Microcrystalline cellulose PH 200	BP	REX/SP/M018	Kg	41.867	41.867	RM 4 00040	29.700 17.067	0.200 0.200	N. Arj 22/05/2020	N. Arj 22/05/2020	N. Arj 22/05/2020	N. Arj 22/05/2020
Lubrication:													
5	Colloidal silicon dioxide	BP	REX/GH/C001	Kg	0.290	0.290	RM 4 00008	0.370	0.080	N. Arj 22/05/2020	N. Arj 22/05/2020	N. Arj 22/05/2020	N. Arj 22/05/2020
6	Croscarmellose Sodium	BP	REX/GH/C002	Kg	2.055	2.055	RM 4 00013	2.135	0.080	N. Arj 22/05/2020	N. Arj 22/05/2020	N. Arj 22/05/2020	N. Arj 22/05/2020
7	Sodium Starch Glycolate	BP	REX/GH/S001	Kg	1.177	1.177	RM 4 00009	1.211.56g	34.16g	N. Arj 22/05/2020	N. Arj 22/05/2020	N. Arj 22/05/2020	N. Arj 22/05/2020
8	Magnesium stearate	BP	REX/GH/M001	Kg	3.529	3.529	RM 4 00004	3.609	0.080	N. Arj 22/05/2020	N. Arj 22/05/2020	N. Arj 22/05/2020	N. Arj 22/05/2020

Prepared by:

Production

Checked by:

Quality Assurance

Approved By:

Head Quality Assurance

Dept.

Sign.

Date

Production

Production

Quality Assurance

Head Quality Assurance

COPY

* N. Arj
22/05/2020

* N. Arj
22/05/2020

* N. Arj
22/05/2020

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.		Page 9 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMR/T/107-01 Customer:	Batch No.: <u>GF 200501</u> Generic Health Care Pvt. Ltd.

7.0 SIFTING AND BLENDING LINE CLEARANCE CHECKS: Date/Shift: 22/05/2020, G / MA / MA

Sr. No.	Checks	Time:	*Observations					
			17-10		MA		MA	
			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)		✓	✓				
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	Blender	Area
EQP. ID No.	<u>PD/VBS/001</u>	<u>PD/DCB/001</u>	<u>48-01</u>
Previous Product	<u>Glimepiride - M2</u>		
Batch No.	<u>6020006E</u>		
Cleaned by	<u>Muthu Raju</u>		
Checked by	<u>22/05/2020</u>		
Verified by	<u>22/05/2020</u>		

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: <u>22/05/2020</u> Time: <u>17-12</u>			Date: <u>NA</u> Time: <u>NA</u>			Date: <u>NA</u> Time: <u>NA</u>		
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	<u>23.6</u>	<u>22</u>	<u>ES</u>						
RH % (NMT 60%)	<u>52.1</u>	<u>22</u>	<u>ES</u>						
DP (NLT 10 Pascal)	<u>1084</u>	<u>22</u>	<u>ES</u>						

APPROVAL FOR SIFTING AND BLENDING:

Production Sign/Date:	<u>22/05/2020</u>		
IPQA Sign/Date:	<u>22/05/2020</u>		
Start and End Time:	<u>17-15</u>	<u>18-53</u>	

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<u>21/05/2020</u>	<u>21/05/2020</u>	<u>22/05/2020</u>	<u>22/05/2020</u>	
Date	<u>21/05/2020</u>	<u>21/05/2020</u>	<u>22/05/2020</u>	<u>22/05/2020</u>	

UNCONTROLLED COPY

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.		Page 10 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMR/T/107-01	Batch No.: <i>GF 200 501</i>
		Customer:	Generic Health Care Pvt. Ltd.

7.1 Dry Microcrystalline Cellulose (PH 102) at NMT 105°C for 1 hour if the LOD of the lot used is more than 3%.

Excipients	LOD Found
Microcrystalline Cellulose (PH 102)	0.92%

7.2 LUBRICATION MATERIAL SIFTING RECORD: Date: *22/05/2020* Shift: *G*

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	Amlodipine Besilate*	<i>* 4.112</i> <i>4.185</i>	80#	<i>PD/30-80/01</i>	<i>OK/</i> <i>Not OK</i>	<i>17-15</i>	<i>17-30</i>	<i>OK/</i> <i>Not OK</i>	<i>pravin</i>	<i>h</i>
2	Perindopril Erbumine^	<i>3.010</i>	60#	<i>PD/30-60/01</i>	<i>OK/</i> <i>Not OK</i>	<i>17-31</i>	<i>17-42</i>	<i>OK/</i> <i>Not OK</i>	<i>Rajy</i>	<i>h</i>
3	Microcrystalline cellulose PH 102***	<i>* 29.664</i> <i>41.842</i> <i>29.182 29.681</i>	40#	<i>PD/30-40/01</i>	<i>OK/</i> <i>Not OK</i>	<i>17-43</i>	<i>17-53</i>	<i>OK/</i> <i>Not OK</i>	<i>pravin</i>	<i>h</i>
4	Microcrystalline cellulose PH 200	<i>* 41.867</i> <i>27.912</i>	30#	<i>PD/30-30/01</i>	<i>OK/</i> <i>Not OK</i>	<i>17-54</i>	<i>18-01</i>	<i>OK/</i> <i>Not OK</i>	<i>Rajy</i>	<i>h</i>
Lubrication:										
5	Colloidal silicon dioxide	<i>0.290</i>	30#	<i>PD/30-30/01</i>	<i>OK/</i> <i>Not OK</i>	<i>18-03</i>	<i>18-08</i>	<i>OK/</i> <i>Not OK</i>	<i>pravin</i>	<i>h</i>
6	Croscarmellose Sodium	<i>2.055</i>	40#	<i>PD/30-40/01</i>	<i>OK/</i> <i>Not OK</i>	<i>18-09</i>	<i>18-12</i>	<i>OK/</i> <i>Not OK</i>	<i>Rajy</i>	<i>h</i>
7	Sodium Starch Glycolate	<i>1.177</i>	40#			<i>18-13</i>	<i>18-14</i>			
8	Magnesium stearate	<i>3.529</i>	60#	<i>PD/30-60/01</i>	<i>OK/</i> <i>Not OK</i>	<i>18-20</i>	<i>18-25</i>	<i>OK/</i> <i>Not OK</i>	<i>Rajy</i>	<i>h</i>

7.3 BLENDING AND LUBRICATION INSTRUCTION AND RECORDS: Date: *22/05/2020* Shift: *G*

Step No.	Process Instructions	Time		Done by	Checked by Prod.
		Started	Completed		
1	Operate the Octagonal Blender as per the current version of the SOP: <i>PDOP/019</i>				
Pre-lubrication:					
1	Load the sifted Amlodipine Besilate, Perindopril Erbumine, Dried Microcrystalline cellulose PH 102, Microcrystalline cellulose PH 200, Colloidal silicon dioxide, Croscarmellose Sodium, Sodium Starch Glycolate in to the blender and blend for 10 minutes at 10 RPM (To be established).	<i>18-28</i> <i>18-35</i>	<i>18-32</i> <i>18-45</i>	<i>pravin</i> <i>Rajy</i>	<i>h</i>
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).	<i>18-48</i>	<i>18-53</i>	<i>pravin</i> <i>Rajy</i>	<i>h</i>

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<i>L. K.</i>	<i>S. S.</i>	<i>P. S.</i>	<i>J. S.</i>	
Date	<i>22/05/2020</i>	<i>22/05/2020</i>	<i>22/05/2020</i>	<i>22/05/2020</i>	



 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 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product Amloperin 5mg/5mg	BMR. No.: BMRT/107-01		Batch No.: <i>GF 200 501</i>
	Customer:		Generic Health Care Pvt. Ltd.

7.4 WEIGHING OF FINAL BLEND:

Balance I.D. No.: *22/05/2020*

Date: *22/05/2020* Shift: *6* Time: *20:10*

Cont No.	Gross Weight	Tare Weight	Net weight	Weighed by	Ckd by	Cont No.	Gross Weight	Tare Weight	Net weight	Weighed by	Ckd by
1	39.870	4.670	35.200	Kaun	h	4					
2	40.110	4.610	35.500	Rghy	h	5					
3	12.410	4.610	12.800	msm	h	6					

Theoretical weight of Blend: 84.000 Kg

Actual weight of Blend: *83.500* Kg

Verified by IPQA *22/05/2020*

7.5 RECONCILIATION:

1.0	Theoretical weight of blend	:	84.000 Kg
2.0	Actual Weight of blend	:	83.500 Kg
3.0	Manufacturing Loss (Blending stage) @	:	0.500 Kg
4.0	In-process samples		
	A IPQA Samples	:	0.020 Kg
	B QC Samples	:	0.080 Kg
	C Validation Samples	:	0.000 Kg
5.0	Total samples: (A + B + C)	:	0.100 Kg
6.0	Total: (2.0 + 5.0)	:	83.600 Kg
7.0	Yield {6.0 / 1.0 x 100}*	:	99.52 %

* Actually yield will be calculated after 3 validation batches.

@Total rejects destroyed: *0.500* 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: *ms* Checked By IPQA sign/Date: *22/05/2020*

Test request form raised by Prod Sign/Date: *22/05/2020*

Test request form received by IPQA Sign/Date: *22/05/2020*

8.0 RELEASED FOR COMPRESSION:

Reconciliation checked and blend is released for compression

IPQA Sign: *22/05/2020* Date: *22/05/2020*

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. Ka</i>	<i>22/05/2020</i>	<i>22/05/2020</i>	<i>22/05/2020</i>
Date	<i>22/05/2020</i>	<i>22/05/2020</i>	<i>22/05/2020</i>	<i>22/05/2020</i>

UNCONTROLLED COPY

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.

Page 12 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-01

Batch No.: GF 200 501

Customer:

Generic Health Care Pvt. Ltd.

9.0 COMPRESSION LINE CLEARANCE CHECKS: Date/Shift: 29/05/2020 / 19:20 / NA / NA

Sr. No.	Checks	Time:	*Observations					
			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.	19:20	✓	✓				
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/007	NA PD/DED/007, PD/DED/004	Compression - 02
Previous Product	Vetra Vitamin D		
Batch No.	VD 30048		
Cleaned by	Thiru. Vetri		
Checked by	N. Bal		
Verified by	29/05/2020		

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 29/05/2020 Time: 19:22		Date: Time:		Date: Time:		Date: Time:	
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by
Temperature °C (NMT 25°C)	23°C	N. Bal	✓					
RH % (NMT 60%)	52%	N. Bal	✓					
DP (NLT 10 Pascal)	10 Pascal	N. Bal	✓					

APPROVAL FOR COMPRESSION:

Production Sign/Date:	N. Bal 29/05/2020		
IPQA Sign/Date:	Prasanna 29/05/2020		
Start and End Time:	19:30	15:30	

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. K.	Prasanna	Prasanna		
Date	29/05/2020	29/05/2020	29/05/2020		

UNCONTROLLED COPY

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.		Page 13 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product Amloperin 5mg/5mg	BMR. No.: BMR/T/107-01		Batch No.: GF200 501
	Customer:		Generic Health Care Pvt. Ltd.

10.0 COMPRESSION

10.1 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: 6.80 mm Circular shaped standard concave with breakline punches. b. Lower punches: 6.80 mm Circular shaped standard concave plain punches. c. Dies: 6.80 mm suitable for above punches. d. Type of tooling - D.
	Punch Issued By: sign./Date: <i>22/05/2020</i> Checked and Received by Sign./Date: <i>22/05/2020</i> Verified by Sign./Date: <i>22/05/2020</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, diameter 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.

10.2 GRANULES RECEIPT RECORD:

Balance ID. No.: PD/BA/014 Date: 22/05/2020 Shift: B.....Time: 17:24

Sr. No.	Gross Weight in Kg	Issued By Production	Checked by Production
1	39.870	<i>PK</i>	<i>N. Bal</i>
2	40.110	<i>PK</i>	<i>N. Bal</i>
3	17.410	<i>PK</i>	<i>N. Bal</i>
4			
5			
6			

10.3 COMPRESSION SPECIFICATION / PARAMETERS:

Sr. No.	Parameter	Limits	No. of tablets to be checked from each side	Frequency	
				Production	IPQA
1.	Appearance	White to off white coloured, circular shaped, biconvex, uncoated tablet with breakline on one side and plain on other side	20	Every 30 min.	Every 2 Hr.
2.	Average weight(mg)	140.000 mg $\pm$ 3.0 % (135.800 mg – 144.200 mg)	20		
3.	Group Weight	2.800 g $\pm$ 3.0 % (2.716 gm to 2.884 gm)	20	Every 30 min.	Every 2 Hr.
4.	Uniformity of weight Tablets	140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)	20	Every 2 Hr.	Every 4 Hr.
6	Hardness (N)	NLT 4.0 Kg (To be established)	4	Every 30 min.	Every 2 Hr.
7.	Thickness (mm)	3.30 mm $\pm$ 0.2 (3.10 mm – 3.50 mm) (To be established)	4	Every 30 min.	Every 2 Hr.
8.	Friability	NMT 1% w/w	6 g	Every 2 Hr.	Every 4 Hr.
9.	Disintegration Time	NMT 15 Minutes	6	Every 2 Hr.	Every 4 Hr.

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<i>L. K.</i>	<i>S. Bal</i>	<i>P. K.</i>	<i>S. Bal</i>	
Date	22/05/2020	22/05/2020	22/05/2020	22/05/2020	



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 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-01

Batch No.: CF 200 501

Customer:

Generic Health Care Pvt. Ltd.

10.4 COMPRESSION MACHINE RUNNING STATUS:

Date	Shift	Start Time	End Time	M/C Speed	Tablets Output	Done By	Checked By
22/05/2020	B	19:10	15:30	20	591716	Vetri	N. Balasubramanian

10.5 INITIAL INPROCESS CHECKS: (Appearance, Uniformity of Weight, Thickness & Diameter):

Balance I.D. No.: PDIBAL/009

Date: 22/05/2020 Shift: B Time: 19:20

LHS					RHS				
Sr. No.	Appearance *	Weight (in mg)	Thickness (in mm)	Diameter (in mm)	Sr. No.	Appearance *	Weight (in mg)	Thickness (in mm)	Diameter (in mm)
1	OK	139	3.32	6.82	1	OK	141	3.31	6.81
2	OK	138	3.31	6.81	2	OK	140	3.32	6.80
3	OK	141	3.29	6.82	3	OK	141	3.33	6.80
4	OK	141	3.31	6.81	4	OK	140	3.29	6.81
5	OK	142	3.29	6.82	5	OK	139	3.28	6.80
6	OK	140	3.31	6.80	6	OK	139	3.32	6.82
7	OK	142	3.32	6.83	7	OK	139	3.31	6.81
8	OK	140	3.31	6.84	8	OK	140	3.30	6.81
9	OK	139	3.29	6.80	9	OK	142	3.31	6.82
10	OK	138	3.32	6.82	10	OK	144	3.32	6.84
11	OK	138	3.31	6.81	11	OK	140	3.31	6.80
12	OK	141	3.32	6.81	12	OK	139	3.32	6.81
13	OK	140	3.31	6.82	13	OK	139	3.31	6.80
14	OK	141	3.30	6.81	14	OK	140	3.32	6.81
15	OK	141	3.30	6.82	15	OK	139	3.31	6.81
16	OK	142	3.30	6.81	16	OK	141	3.32	6.81
17	OK	140	3.32	6.82	17	OK	142	3.31	6.81
18	OK	141	3.31	6.80	18	OK	141	3.31	6.84
19	OK	141	3.29	6.81	19	OK	142	3.32	6.81
20	OK	141	3.28	6.79	20	OK	141	3.31	6.81
21	OK	142	3.27	6.81	21	OK	140	3.31	6.81
22	OK	141	3.29	6.81	22	OK	140	3.30	6.84
23	OK	140	3.27	6.81	23	OK	141	3.29	6.83
24	OK	139	3.29	6.81	24	OK	141	3.32	6.84
25	OK	138	3.31	6.80	25	OK	142	3.34	6.81
26	OK	141	3.32	6.81	26	OK	142	3.31	6.84
27	OK	141	3.31	6.82	27	OK	141	3.31	6.83
28	OK	140	3.33	6.82	28	OK	141	3.32	6.81
29	OK	141	3.31	6.81	29	OK	142	3.31	6.82
30	OK	140	3.32	6.82	30	OK	141	3.34	6.81

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

Done by Production Sign/Date: P. Balasubramanian 22/05/2020

Checked by IPQA Sign/Date: P. Balasubramanian 22/05/2020

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. K. S.	P. Balasubramanian	P. Balasubramanian	P. Balasubramanian	
Date	22/05/2020	22/05/2020	22/05/2020	22/05/2020	

UNCONTROLLED COPY

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.		Page 15 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMR/T/107-01 Customer:	Batch No.: <u>G1F 200 501</u> Generic Health Care Pvt. Ltd.

10.6 COMPRESSION SPECIFICATION AND PARAMETERS: Date: 22/05/2020 Shift: General Time: 19:36

Parameters	Instrument used	Equip ID No.	Observations of LHS			Observations of RHS			Limits				
			Min		Max	Min		Max					
Appearance	Visual	NA	OK			OK			White to off white coloured, circular shaped, biconvex, uncoated tablet with breakline on one side and plain on other side				
Group Weight	Electronic Balance	PD/BAL/1009	2.805 gm			2.793 gm			2.800 g± 3.0 % (2.716 gm to 2.884 gm)				
Average weight	Electronic Balance		140.25 mg			139.6 mg			140.000 mg ± 3.0 % (135.800 mg – 144.200 mg)				
Individual weight	Electronic Balance		138 mg	142 mg	mg139	144 mg	140.00 mg ± 5.0 % (133.000 mg – 147.000 mg)						
Uniformity of weight	Electronic Balance		1.63 %	1.23 %	1.43 %	3.15 %							
Thickness	Vernier Caliper	BA/VE/1001	3.29 mm	3.32 mm	3.30 mm	3.32 mm	3.30 mm ±0.2 (3.10 mm – 3.50 mm) (To be established)						
Hardness	Hardness Tester	BA/HRT/1001	5	55	6	6	55	5	55	6	6	5	NLT 4.0 Kg (To be established)
Friability	Friabilator	SA/FR/1001	0.02 %			0.04 %			NMT 1% w/w				
DT	DT Apparatus	SA/DTA/1001	05 mins 12 sec			04 mins 43 sec			NMT 15 Minutes				

M/C set done by Operator Name: Netaji..... M/C set up Checked by Prod. Sign/Date: N. Bal 22/05/2020
 M/C Speed: 15 RPM (To be Established)

Compression Force: 7.0 kg.

Initial Setting Tablets Destroyed by: Sign: Thim..... Date: 22/05/2020 Quantity in Kg. : 0.022... Quantity in No... 14.1...

Approval for Batch Compression by IPQA: Sign : 24/05/2020..... Date: 22/05/2020..... Time: 19:45

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>22/05/2020</u>	<u>22/05/2020</u>	<u>22/05/2020</u>
Date	<u>22/05/2020</u>	<u>22/05/2020</u>	<u>22/05/2020</u>	<u>22/05/2020</u>

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.

Page 16 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMRT/107-01

Batch No.: GF 200 501

Customer:

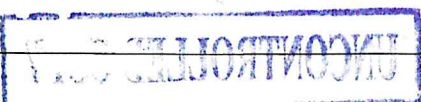
Generic Health Care Pvt. Ltd.

10.7 IN-PROCESS CHECKS: (For Production)

Date: 22.05.2020

Time	Appearance		Weight of 20 Tablets		Hardness				Thickness				Done by Production
	White to off white coloured, circular shaped, biconvex, uncoated tablet with breakline on one side and plain on other side		2.800 g± 3.0 % (2.716 gm to 2.884 gm)		NLT 4.0 Kg (To be established)				3.30 mm ±0.2 (3.10 mm – 3.50 mm) (To be established)				
	LHS	RHS	LHS	RHS	LHS	LHS	RHS	RHS	LHS	LHS	RHS	RHS	
19:55	OK	OK	2.727	2.787	5	5.5	6	6	3.32	3.31	3.32	3.31	N. Bal
20:10	OK	OK	2.781	2.793	5	5.5	6	6	3.32	3.29	3.30	3.34	N. Bal
20:35	OK	OK	2.749	2.783	5	5.5	6	5	3.31	3.29	3.30	3.32	N. Bal
21:15	OK	OK	2.787	2.793	5	5.5	6	5	3.31	3.29	3.32	3.34	N. Bal
21:38	OK	OK	2.781	2.796	5	6	6	5.5	3.32	3.30	3.29	3.28	N. Bal
22:10	OK	OK	2.792	2.779	6	6	5.5	6	3.32	3.30	3.24	3.27	N. Bal
22:34	OK	OK	2.794	2.786	6	6	5.5	6	3.31	3.30	3.29	3.29	N. Bal
23:15	OK	OK	2.783	2.791	6	6	5.5	6	3.32	3.39	3.31	3.32	N. Bal
23:38	OK	OK	2.787	2.796	6	6	5.5	6	3.31	3.32	3.32	3.31	N. Bal
04:13	OK	OK	2.783	2.794	6	5	5.5	6	3.32	3.39	3.32	3.34	N. Bal
05:38	OK	OK	2.796	2.787	6	6	5.5	6	3.31	3.32	3.31	3.34	N. Bal
10:15	OK	OK	2.786	2.749	6	6	5.5	6	3.32	3.31	3.29	3.38	N. Bal
10:39	OK	OK	2.798	2.801	6	6	6	5.5	3.39	3.31	3.29	3.31	N. Bal
11:10	OK	OK	2.796	2.812	6	6	6	5.5	3.31	3.32	3.29	3.31	N. Bal
11:35	OK	OK	2.787	2.779	6	6	6	5.5	3.30	3.30	3.29	3.27	N. Bal
12:15	OK	OK	2.797	2.783	6	6	6	6	3.32	3.29	3.27	3.26	N. Bal
12:38	OK	OK	2.798	2.793	6	6	6	5	3.31	3.28	3.29	3.31	N. Bal
13:15	OK	OK	2.753	2.812	6	6	5	6	3.32	3.34	3.31	3.32	N. Bal
13:35	OK	OK	2.784	2.801	6	6	6	5	3.28	3.31	3.32	3.33	N. Bal
14:17	OK	OK	2.773	2.753	5	6	6	5	3.34	3.32	3.31	3.32	N. Bal
14:30	OK	OK	2.798	2.784	6	6	6	5.5	3.34	3.32	3.32	3.31	N. Bal
15:10	OK	OK	2.793	2.791	6	6	5	5.5	3.21	3.24	3.30	3.32	N. Bal
15:30	OK	OK	2.791	2.782	6	6	5	5	3.21	3.24	3.29	3.32	N. Bal

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	R. S. S. S.	P. K. S. S.	J. M. S. S.
Date	21/05/2020	21/05/2020	22/05/2020	21/05/2020





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

Page 17 of 33

Batch Size: 6,00,000 Tablets

Batch No.: CF 200 501

Generic Health Care Pvt. Ltd.

Date:.....MA.....

[illegible]

23/05/20

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	<i>[Signature]</i>	P. H. <i>[Signature]</i>	<i>[Signature]</i>
Date	21/05/2020	21/05/2020	21/05/2020	21/05/2020

CONFIDENTIAL

UNCONTROLLED CITY



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

Page 18 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-01

Batch No.: G1F 200 501

Customer:

Generic Health Care Pvt. Ltd.

10.9 IN-PROCESS CHECKS: (For Production)

Date:.....

[illegible]

22/10/2017

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ke	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	21/01/2020	21/01/2020	21/01/2020	21/01/2020

UNCONTROLLED COPY

UNCONTROLLED COPY



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

Page 19 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-01

Batch No.: GF 200 501

Customer:

Generic Health Care Pvt. Ltd.

10.10 IN-PROCESS CHECKS: (For IPQA)

Date: 28.10.56 p.m.

[illegible]

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance ✓	Head Quality Assurance
Sign.	L. K.	<i>[Signature]</i>	P. H. <i>[Signature]</i>	<i>[Signature]</i>
Date	21/05/2020	21/05/2020	21/05/2020	22/05/2020

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.

Page 20 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-01

Batch No.: GF 200 501

Customer:

Generic Health Care Pvt. Ltd.

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

Date: 22/05/2020		Time: 20:10		Shift: 6	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	140	8	141	15	138
2	138	9	142	16	139
3	139	10	141	17	140
4	138	11	141	18	141
5	141	12	142	19	141
6	141	13	141	20	142
7	142	14	140		
Balance ID No.: PD/BAL/009			M/C Speed: 20 RPM		
Group weight of 20 Tablets: 2797.5 g. Avg. wt: 139.875 mg			Group weight of 20 Tablets: 2793.0 g. Avg. wt: 139.65 mg		
Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)			Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)		
Min weight: 138 mg Max. weight: 142 mg			Min weight: 137 mg Max. weight: 144 mg		
LHS		RHS			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.02%		0.01%	
Disintegration Time (Limit - NMT 15 minutes)		05 min 10 sec		05 min 20 sec	
Equipment ID No.: QA/FRT/001		Equipment ID No.: QA/DTA/002			
Done by: N. Bal 22/05/2020 (Production)					
Date: 22/05/2020		Time: 22:14		Shift: 6	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	138	8	140	15	141
2	138	9	141	16	142
3	138	10	140	17	141
4	140	11	141	18	140
5	139	12	142	19	141
6	139	13	142	20	140
7	140	14	140		
Balance ID No.: PD/BAL/009			M/C Speed: 20 RPM		
Group weight of 20 Tablets: 2726 g. Avg. wt: 136.3 mg			Group weight of 20 Tablets: 2790 g. Avg. wt: 139.5 mg		
Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)			Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)		
Min weight: 138 mg Max. weight: 142 mg			Min weight: 139 mg Max. weight: 143 mg		
LHS		RHS			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.03%		0.05%	
Disintegration Time (Limit - NMT 15 minutes)		05 min 32 sec		05 min 12 sec	
Equipment ID No.: QA/FRT/001		Equipment ID No.: QA/DTA/002			
Done by: N. Bal 22/05/2020 (Production)					

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka				
Date	21/05/2020	21/05/2020	21/05/2020		

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.		Page 21 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product Amloperin 5mg/5mg	BMR. No.: BMR/T/107-01		Batch No.: <i>GF 200 501</i>
	Customer:		Generic Health Care Pvt. Ltd.

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

Date: <i>23/05/2020</i>		Time: <i>09:30</i>		Shift: <i>6</i>							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	<i>138</i>	8	<i>141</i>	15	<i>140</i>	1	<i>140</i>	8	<i>142</i>	15	<i>141</i>
2	<i>140</i>	9	<i>141</i>	16	<i>140</i>	2	<i>140</i>	9	<i>142</i>	16	<i>140</i>
3	<i>141</i>	10	<i>141</i>	17	<i>141</i>	3	<i>143</i>	10	<i>140</i>	17	<i>141</i>
4	<i>140</i>	11	<i>140</i>	18	<i>140</i>	4	<i>141</i>	11	<i>143</i>	18	<i>140</i>
5	<i>141</i>	12	<i>141</i>	19	<i>141</i>	5	<i>143</i>	12	<i>143</i>	19	<i>142</i>
6	<i>141</i>	13	<i>142</i>	20	<i>140</i>	6	<i>140</i>	13	<i>141</i>	20	<i>140</i>
7	<i>142</i>	14	<i>142</i>			7	<i>141</i>	14	<i>142</i>		
Balance ID No.: <i>PD/BAL/009</i>						M/C Speed: <i>20</i> RPM					
Group weight of 20 Tablets: <i>2:781</i>g. Avg. wt: <i>139.05</i> .mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight. <i>138</i>mg Max. weight:.... <i>142</i>mg						Group weight of 20 Tablets: <i>2:804</i>g. Avg. wt: <i>140.2</i>mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight. <i>140</i>mg Max. weight:.... <i>143</i>mg					
LHS						RHS					
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						<i>0.04%</i>		<i>0.02%</i>		Equipment ID No.: QA/FRT/001	
Disintegration Time (Limit - NMT 15 minutes)						<i>05 min 32 sec</i>		<i>05 min 32 sec</i>		Equipment ID No.: QA/DTA/002	
Done by: <i>N. Bal</i> <i>23/05/2020</i> (Production)											
Date: <i>23/05/2020</i>		Time: <i>11:34</i>		Shift: <i>6</i>							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	<i>138</i>	8	<i>140</i>	15	<i>141</i>	1	<i>142</i>	8	<i>141</i>	15	<i>141</i>
2	<i>142</i>	9	<i>141</i>	16	<i>142</i>	2	<i>143</i>	9	<i>142</i>	16	<i>142</i>
3	<i>142</i>	10	<i>142</i>	17	<i>141</i>	3	<i>142</i>	10	<i>141</i>	17	<i>141</i>
4	<i>141</i>	11	<i>142</i>	18	<i>140</i>	4	<i>142</i>	11	<i>140</i>	18	<i>141</i>
5	<i>140</i>	12	<i>141</i>	19	<i>142</i>	5	<i>141</i>	12	<i>144</i>	19	<i>140</i>
6	<i>141</i>	13	<i>141</i>	20	<i>140</i>	6	<i>140</i>	13	<i>142</i>	20	<i>142</i>
7	<i>142</i>	14	<i>140</i>			7	<i>141</i>	14	<i>140</i>		
Balance ID No.: <i>PD/BAL/009</i>						M/C Speed: <i>20</i> RPM					
Group weight of 20 Tablets: <i>2:799</i>g. Avg. wt: <i>139.95</i> .mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight. <i>138</i>mg Max. weight:.... <i>142</i>mg						Group weight of 20 Tablets: <i>2:816</i>g. Avg. wt: <i>140.8</i>mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight. <i>140</i>mg Max. weight:.... <i>143</i>mg					
LHS						RHS					
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						<i>0.02%</i>		<i>0.04%</i>		Equipment ID No.: QA/FRT/001	
Disintegration Time (Limit - NMT 15 minutes)						<i>05 min 32 sec</i>		<i>05 min 12 sec</i>		Equipment ID No.: QA/DTA/002	
Done by: <i>N. Bal</i> <i>23/05/2020</i> (Production)											

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	<i>21/05/2020</i>	<i>21/05/2020</i>	<i>22/05/2020</i>	<i>21/05/2020</i>	

UNCONTROLLED COPY

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.		Page 22 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product Amloperin 5mg/5mg	BMR. No.: BMR/T/107-01		Batch No.: <i>CF 200 501</i>
	Customer:		Generic Health Care Pvt. Ltd.

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

Date: <i>23/05/2020</i>		Time: <i>13:30</i>		Shift: <i>01</i>							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	140	8	140	15	142	1	140	8	140	15	140
2	140	9	141	16	140	2	143	9	141	16	140
3	142	10	141	17	141	3	142	10	142	17	140
4	141	11	140	18	140	4	141	11	142	18	139
5	142	12	142	19	142	5	140	12	141	19	140
6	142	13	142	20	143	6	139	13	140	20	140
7	140	14	140			7	140	14	141		
Balance ID No.: <i>PD/BAC/009</i>				M/C Speed: <i>20</i> RPM							
Group weight of 20 Tablets: <i>2879.1</i> g. Avg. wt: <i>143.95</i> mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight: <i>140</i> mg Max. weight: <i>143</i> mg				Group weight of 20 Tablets: <i>2878</i> g. Avg. wt: <i>143.9</i> mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight: <i>139</i> mg Max. weight: <i>142</i> mg							
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				LHS		RHS		Equipment ID No.: QA/FRT/001			
Disintegration Time (Limit - NMT 15 minutes)				05 min		05 min		Equipment ID No.: QA/DTA/002			
Done by: <i>N. Bal</i> <i>23/05/2020</i> (Production)											
Date:		Time: <i>15:10</i>		Shift: <i>01</i>		Date:		Time: <i>15:10</i>		Shift: <i>01</i>	
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	142	8	143	15	139	1	140	8	141	15	140
2	140	9	141	16	140	2	141	9	140	16	142
3	141	10	140	17	141	3	141	10	141	17	141
4	140	11	141	18	141	4	142	11	140	18	141
5	141	12	140	19	140	5	140	12	141	19	141
6	142	13	141	20	141	6	141	13	142	20	142
7	140	14	140			7	142	14	140		
Balance ID No.: <i>PD/BAC/009</i>				M/C Speed: <i>20</i> RPM							
Group weight of 20 Tablets: <i>2880.3</i> g. Avg. wt: <i>144.02</i> mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight: <i>139</i> mg Max. weight: <i>143</i> mg				Group weight of 20 Tablets: <i>2881.2</i> g. Avg. wt: <i>144.06</i> mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight: <i>140</i> mg Max. weight: <i>144</i> mg							
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				LHS		RHS		Equipment ID No.: QA/FRT/001			
Disintegration Time (Limit - NMT 15 minutes)				05 min		05 min		Equipment ID No.: QA/DTA/002			
Done by: <i>N. Bal</i> <i>23/05/2020</i> (Production)											

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<i>L. K.</i>	<i>S. S.</i>	<i>P. S.</i>	<i>S. S.</i>	
Date	<i>21/05/2020</i>	<i>21/05/2020</i>	<i>21/05/2020</i>	<i>21/05/2020</i>	

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.

Page 23 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMRT/107-01

Batch No.: *GF 200 501*

Customer:

Generic Health Care Pvt. Ltd.

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

Date: *23/05/2020*

Time: *15:52*

Shift: *6*

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

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

1	139	8	140	15	140	1	140	8	140	15	141
2	140	9	141	16	140	2	141	9	141	16	140
3	140	10	140	17	141	3	142	10	140	17	142
4	141	11	141	18	141	4	140	11	141	18	140
5	142	12	142	19	140	5	139	12	140	19	141
6	140	13	140	20	141	6	140	13	141	20	140
7	141	14	141			7	141	14	140		

Balance ID No.: *PD 1BAC/009*

M/C Speed: *20* RPM

Group weight of 20 Tablets: *2782* g. Avg.
wt: *139.1* mg

Group weight of 20 Tablets: *2789* g. Avg.
wt: *139.4* mg

Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)

Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)

Min weight: *139* mg Max. weight: *142* mg

Min weight: *139* mg Max. weight: *143* mg

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

0.02%

0.04%

Equipment ID No.: QA/FRT/ *001*

Disintegration Time (Limit - NMT 15 minutes)

05 mins

05 mins

Equipment ID No.: QA/DTA/ *002*

Done by: *N. Bal* *23/05/2020* (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: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)

Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 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.	<i>L. K.</i>	<i>R. K.</i>	<i>P. K.</i>	<i>S. K.</i>	
Date	<i>21/05/2020</i>	<i>21/05/2020</i>	<i>22/05/2020</i>	<i>22/05/2020</i>	

UNCONTROLLED COPY

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-01

Batch No.: *GF 200 501*

Customer:

Generic Health Care Pvt. Ltd.

10.15 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 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: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)						Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 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: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)						Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 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)															

M. B. / 22/05/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>1. K.</i>	<i>Balabalan</i>	<i>P. K. S.</i>	<i>S. M.</i>
Date	<i>21/05/2020</i>	<i>21/05/2020</i>	<i>22/05/2020</i>	<i>21/05/2020</i>

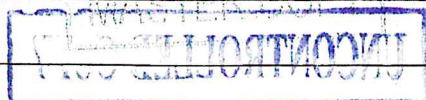
UNCONTROLLED COPY

 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.		Page 25 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMRT/107-01 Customer:	Batch No.: <i>GF 200 501</i> Generic Health Care Pvt. Ltd.

10.16 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 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		1	8	15	
2	9	16		2	9	16		2	9	16	
3	10	17		3	10	17		3	10	17	
4	11	18		4	11	18		4	11	18	
5	12	19		5	12	19		5	12	19	
6	13	20		6	13	20		6	13	20	
7	14			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: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)						Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 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		1	8	15	
2	9	16		2	9	16		2	9	16	
3	10	17		3	10	17		3	10	17	
4	11	18		4	11	18		4	11	18	
5	12	19		5	12	19		5	12	19	
6	13	20		6	13	20		6	13	20	
7	14			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: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)						Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 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.	<i>L.K.</i>	<i>P.K.</i>	<i>P.K.</i>	<i>P.K.</i>	
Date	21/05/2020	21/05/2020	22/05/2020	21/05/2020	



N.B.
22/07/20

 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 26 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product Amloperin 5mg/5mg	BMR. No.: BMR/T/107-01		Batch No.: GF 200 501
	Customer:		Generic Health Care Pvt. Ltd.

10.17 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours): Full he ppr

Date: * 22/05/2020 20/05/2020					Time: 20:00					Shift: 6:00-14:00									
LHS: Individual weight of 20 tablets (in mg).										RHS: Individual weight of 20 tablets (in mg).									
1	139	8	140	15	140	1	138	8	141	15	139								
2	140	9	141	16	141	2	141	9	140	16	140								
3	140	10	141	17	141	3	141	10	139	17	141								
4	141	11	140	18	140	4	140	11	141	18	140								
5	139	12	139	19	141	5	139	12	138	19	139								
6	141	13	140	20	139	6	141	13	141	20	140								
7	141	14	139			7	140	14	140										

Balance ID No.: QA/BAL/002	M/C Speed: 20 RPM
Group weight of 20 Tablets: 2850.5 g. Avg. wt: 142.5 mg	Group weight of 20 Tablets: 2879.9 g. Avg. wt: 144.0 mg
Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)	Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)
Min weight: 139 mg Max. weight: 141 mg	Min weight: 138 mg Max. weight: 141 mg

	LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	0.04 %	0.00 %	Equipment ID No.: QA/FRT/001
Disintegration Time (Limit - NMT 15 minutes)	05 Min 20 Sec	05 Min 29 Sec	Equipment ID No.: QA/DTA/002

Done by: R. Rajasekar (IPQA)

Date: 28/05/2025					Time: 09:30					Shift: Morning				
LHS: Individual weight of 20 tablets (in mg).							RHS: Individual weight of 20 tablets (in mg).							
1	142	8	139	15	139	1	138	8	141	15	139			
2	141	9	140	16	139	2	140	9	139	16	140			
3	139	10	141	17	140	3	141	10	138	17	141			
4	140	11	142	18	141	4	141	11	141	18	141			
5	139	12	140	19	140	5	139	12	142	19	142			
6	141	13	142	20	139	6	140	13	140	20	141			
7	142	14	141			7	140	14	139					

Balance ID No.: QA/BAL/002	M/C Speed: 10 RPM
Group weight of 20 Tablets: 2809 g. Avg. wt: 140.45 mg	Group weight of 20 Tablets: 2823 g. Avg. wt: 141.15 mg
Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)	Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)
Min weight: 139 mg Max. weight: 142 mg	Min weight: 138 mg Max. weight: 141 mg

	LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	0.04 %	0.04 %	Equipment ID No.: QA/FRT/001
Disintegration Time (Limit - NMT 15 minutes)	05 Min 21 Sec	05 Min 21 Sec	Equipment ID No.: QA/DTA/002

Done by: R. Rajasekar (IPQA)

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. K.	R. Rajasekar	P. N.	S. M.	
Date	21/05/2020	21/05/2020	22/05/2020	22/05/2020	





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 27 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMRT/107-01

Batch No.: *GF 200 501*

Customer:

Generic Health Care Pvt. Ltd.

10.18 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours): *High RPM: 25*

Date: 22/05/2020	Time: 11:25	Shift: General									
LHS: Individual weight of 20 tablets (in mg).						RHS: Individual weight of 20 tablets (in mg).					
1	141	8	139	15	140	1	142	8	140	15	141
2	140	9	139	16	141	2	140	9	141	16	139
3	139	10	140	17	141	3	129	10	140	17	140
4	141	11	141	18	139	4	140	11	129	18	140
5	140	12	141	19	139	5	141	12	140	19	129
6	140	13	140	20	140	6	140	13	141	20	140
7	141	14	141			7	141	14	140		

Balance ID No.: *GA/1242/100*

M/C Speed: *25* RPM

Group weight of 20 Tablets: *21.207* g. Avg. wt: *140* mg

Group weight of 20 Tablets: *21.202* g. Avg. wt: *140* mg

Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)

Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)

Min weight: *139* mg Max. weight: *141* mg

Min weight: *139* mg Max. weight: *142* mg

	LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	<i>0.03%</i>	<i>0.04%</i>	Equipment ID No.: QA/FRT/001
Disintegration Time (Limit - NMT 15 minutes)	<i>05 Min 12 sec</i>	<i>05 Min 12 sec</i>	Equipment ID No.: QA/DTA/002

Done by: *R. J. 23/05/2020* (IPQA)

Date:	22/05/2020	Time:	11:50	Shift:	General						
LHS: Individual weight of 20 tablets (in mg).					RHS: Individual weight of 20 tablets (in mg).						
1	140	8	139	15	139	1	140	8	140	15	140
2	141	9	140	16	139	2	141	9	141	16	141
3	141	10	129	17	141	3	140	10	141	17	141
4	140	11	140	18	140	4	140	11	140	18	141
5	129	12	141	19	141	5	139	12	141	19	140
6	140	13	140	20	140	6	139	13	141	20	129
7	140	14	141			7	141	14	140		

Balance ID No.: *GA/1242/100*

M/C Speed: *20* RPM

Group weight of 20 Tablets: *21.201* g. Avg. wt: *140* mg

Group weight of 20 Tablets: *21.202* g. Avg. wt: *141* mg

Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)

Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)

Min weight: *139* mg Max. weight: *141* mg

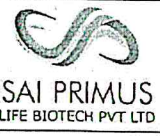
Min weight: *139* mg Max. weight: *142* mg

	LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	<i>0.00%</i>	<i>0.03%</i>	Equipment ID No.: QA/FRT/001
Disintegration Time (Limit - NMT 15 minutes)	<i>05 Min 52 sec</i>	<i>06 Min 04 sec</i>	Equipment ID No.: QA/DTA/002

Done by: *R. J. 23/05/2020* (IPQA)

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. K.</i>	<i>R. J.</i>	<i>R. J.</i>	<i>R. J.</i>
Date	<i>21/05/2020</i>	<i>21/05/2020</i>	<i>22/05/2020</i>	<i>22/05/2020</i>



	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 28 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMR/T/107-01 Customer:	Batch No.: <u>GF 200 501</u> Generic Health Care Pvt. Ltd.

10.19 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours): Mid hopper

Date: <u>22/05/2020</u>		Time: <u>10:10</u>		Shift: <u>6:00-14:00</u>	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	140	8	139	15	141
2	141	9	140	16	139
3	139	10	140	17	141
4	140	11	141	18	139
5	141	12	139	19	141
6	141	13	141	20	139
7	140	14	141		
Balance ID No.: <u>QA/13 DL 1002</u>			M/C Speed: <u>20</u> RPM		
Group weight of 20 Tablets: <u>2809</u> g. Avg. wt: <u>140.45</u> mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight: <u>139</u> mg Max. weight: <u>141</u> mg			Group weight of 20 Tablets: <u>2810</u> g. Avg. wt: <u>140.5</u> mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight: <u>139</u> mg Max. weight: <u>142</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)		05 Min	05 Min	Equipment ID No.: QA/DTA/002

Done by: RAJESH K (IPQA) 4 hrs hold by: 14:00

Date: <u>22/05/2020</u>		Time: <u>12:15</u>		Shift: <u>14:00-18:00</u>	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	140	8	140	15	140
2	141	9	141	16	139
3	141	10	142	17	140
4	139	11	141	18	141
5	141	12	140	19	140
6	140	13	139	20	140
7	139	14	138		
Balance ID No.: <u>QA/13 AL 1002</u>			M/C Speed: <u>20</u> RPM		
Group weight of 20 Tablets: <u>2800</u> g. Avg. wt: <u>140</u> mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight: <u>138</u> mg Max. weight: <u>142</u> mg			Group weight of 20 Tablets: <u>2803</u> g. Avg. wt: <u>140</u> mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight: <u>138</u> mg Max. weight: <u>142</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)		05 Min	05 Min	Equipment ID No.: QA/DTA/002

Done by: RAJESH K (IPQA)

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K.</u>	<u>RAJESH K</u>	<u>P. J. S.</u>	<u>J. S.</u>
Date	<u>22/05/2020</u>	<u>22/05/2020</u>	<u>22/05/2020</u>	<u>22/05/2020</u>





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 29 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-01

Batch No.: GF 200 501

Customer:

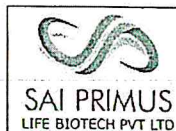
Generic Health Care Pvt. Ltd.

10.20 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours): End hopper

Date: 21/05/2020		Time: 15:10		Shift: Night	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	12.8	8	12.9	15	12.9
2	12.9	9	12.9	16	12.9
3	12.9	10	12.9	17	12.9
4	12.9	11	12.9	18	12.9
5	12.9	12	12.9	19	12.9
6	12.9	13	12.9	20	12.9
7	12.8	14	12.9		
Balance ID No.: QA/BAL/002			M/C Speed: 20 RPM		
Group weight of 20 Tablets: 21.127 g. Avg. wt: 1.056 mg			Group weight of 20 Tablets: 21.205 g. Avg. wt: 1.06 mg		
Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)			Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)		
Min weight: 12.8 mg Max. weight: 12.9 mg			Min weight: 12.9 mg Max. weight: 12.9 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		LHS	RHS	Equipment ID No.: QA/FRT/001	
Disintegration Time (Limit - NMT 15 minutes)		0.5 min	0.5 min	Equipment ID No.: QA/DTA/002	
Done by: KA. S. S. (IPQA)					
Date: 21/05/2020		Time: 15:10		Shift: Night	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	12.8	8	12.9	15	12.9
2	12.9	9	12.9	16	12.9
3	12.9	10	12.9	17	12.9
4	12.9	11	12.9	18	12.9
5	12.9	12	12.9	19	12.9
6	12.9	13	12.9	20	12.9
7	12.8	14	12.9		
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: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)			Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 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: (IPQA)					

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka	21/05/2020	21/05/2020	21/05/2020	
Date	21/05/2020	21/05/2020	21/05/2020	21/05/2020	

UNCONTROLLED COPY



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 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product Amloperin 5mg/5mg

BMR. No.: BMRT/107-01

Batch No.: GTF 200 501

Customer:

Generic Health Care Pvt. Ltd.

10.21 WEIGHING RECORD OF COMPRESSED TABLETS:

Cont. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Cont. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net Weight (Kg)	Cont. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)
1	23.670	2.300	21.370	5				9			
2	23.680	2.300	21.380	6				10			
3	20.290	2.300	17.990	7				11			
4	20.120	2.300	17.820	8				12			

17.820 *

Total Net Weight 83.580

Weighed by Vetai

Checked by Sign./ Date: N. Balashoo

Verified by IPQA Sign./ Date: 22/05/2020

10.22 RECONCILIATION (COMPRESSION STAGE):

Average weight of Uncoated Tablet: 141.25mg

1.0	Standard Batch size	:	84.000 Kg	6,00,000 Nos.
2.0	Actual weight of Lubricated granules	:	83.500Kg	591150 Nos.
3.0	Weight of compressed tablets	:	83.580 * 83.580Kg	591716 Nos.
4.0	Rejection during Compression@	:	0.080.Kg.	
5.0	In-process samples of all stages			
	A IPQA Samples	:	0.080.Kg.	
	B QC Samples	:	NA..Kg.	
	C Validation Samples	:	0.110.Kg.	
6.0	Total in process samples: (A + B+ C)	:	0.190.Kg.	
7.0	Total: (3.0 + 6.0)	:	83.770Kg.	593061 Nos.
8.0	Yield {7.0 / 1.0 x 100}*	:		98.84 %

* Actually yield will be calculated after 3 validation batches

@Total rejects destroyed: 0.080.....Kg. (Rejected materials shall be destroyed as per SOP No.: QAGN/048)

Done by Production Sign/Date: N. Balashoo 22/05/2020 Checked by IPQA Sign/Date: 22/05/2020

Test request form raised by Prod Sign/Date: 22/05/2020

Test request form received by IPQA Sign/Date: 22/05/2020

11.0 RELEASE FOR INSPECTION:

Reconciliation checked and Uncoated tablets released for inspection

IPQA Sign: 22/05/2020

Date: 22/05/2020

* W.F
N. Bal
23/05/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka			
Date	22/05/2020	21/05/2020	22/05/2020	22/05/2020

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.

Page 31 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-01

Batch No.: GF 200501

Customer:

Generic Health Care Pvt. Ltd.

12.0 INSPECTION LINE CLEARANCE:

Date/Shift/Time: 23/05/2020/12/09:25

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/INB/001	PD/INB/001	Inspection
Previous product	Glimiprime -M2		
Batch No.	G020006E		
Cleaned by	N.Bal		
Checked by Production Sign/Date:	N.Bal 23/05/2020		
Verified by IPQA Sign/Date:	R. 23/05/2020		

ENVIRONMENTAL CONDITIONS:			Date: 23/05/2020	Time: 09:40	Date:	Time:
(Refer to SOP No.: QAGN/011)	Temperature °C Limit: NMT 25 °C	Observation	Prod. Sign.	Verified by IPQA	Observation	Prod. Sign.
	Relative Humidity % Limit: NMT 60%	23°C	N.Bal	R.		
	Differential Pressure (NLT 10 Pascal)	52%	N.Bal	R.		
		NA	N.Bal	R.		

APPROVAL FOR INSPECTION:

Production Sign/Date: N.Bal 23/05/2020

Line Clearance IPQA Sign. / Date: R. 23/05/2020

Start Time/Date: 09:35/23/05/2020

End Time/Date: 12:00/23/05/2020

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka				
Date	21/05/2020	21/05/2020	22/05/2020		

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.		Page 32 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product Amloperin 5mg/5mg	BMR. No.: BMRT/107-01		Batch No.: <u>GF 200501</u>
	Customer:		Generic Health Care Pvt. Ltd.

13.0 INSPECTION PROCESS

13.1 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.

13.2 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								Checked by Production	Verified By IPQA	
		Ferrous (0.3 mm)		Stainless steel (0.5 mm)		Non-Ferrous (0.3 mm)		Non-metallic				Result
23/05/2020 09:20	1	✓	✗	✓	✗	✓	✗	✗	✗	PASS	N. Bal	OK
	2	✓	✗	✓	✗	✓	✗	✗	✗	PASS	N. Bal	OK
	3	✓	✗	✓	✗	✓	✗	✗	✗	PASS	N. Bal	OK
23/05/2020 12:10	1	✓	✗	✓	✗	✓	✗	✗	✗	PASS	N. Bal	OK
	2	✓	✗	✓	✗	✓	✗	✗	✗	PASS	N. Bal	OK
	3	✓	✗	✓	✗	✓	✗	✗	✗	PASS	N. Bal	OK
	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

13.3 TABLETS VISUAL INSPECTION RECORD:

Date	Container No		Time		Total Quantity Rejected	Tablet Inspection Done by/Date	Checked by/Date
	From	To	Started	Completed			
23/05/2020	01	04	09:40	12:35	0.080	Vinici, Devis	N. Bal 23/05/20

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	[Signature]	[Signature]	[Signature]
Date	21/05/2020	21/05/2020	21/05/2020	21/05/2020





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 33 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-01

Batch No.: GF-200501

Customer:

Generic Health Care Pvt. Ltd.

13.4 WEIGHING RECORD OF INSPECTED TABLETS:

Cont. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Cont. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net Weight (Kg)	Cont. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)
1	28.480	2.300	26.180	5				9			
2	28.440	2.300	26.140	6				10			
3	20.220	2.300	18.020	7				11			
4	20.460	2.300	18.160	8				12			

Total Net Weight 83.500

Weighed by: N. Bal

Checked by Sign./ Date: N. Bal 23/05/2020

Verified by IPQA Sign./ Date: [Signature] 23/05/2020

13.5 RECONCILIATION: (INSPECTION OF TABLETS)

1.0	Theoretical weight of Tablets	:	84.000 kg	6,00,000 No's
2.0	Tablets transferred for Inspection	:	83.580 kg	591716 No's
3.0	Rejected Tablets	:	0.080 kg	566 No's
4.0	Total weight of good Tablets	:	83.500 kg	591150 No's
5.0	*Yield = $\frac{4.0}{1.0} \times 100$	:		98.52 %

* Actually yield will be calculated after 3 validation batches

Total rejects destroyed: 0.080 Kg.

Rejected materials should be destroyed in the presence of QA.

Done by Packing sign/Date: N. Bal 23/05/2020

Checked by IPQA sign/Date: [Signature] 23/05/2020

14.0 RELEASE FOR PACKING:

BMR reviewed by IPQA Sign/Date : [Signature] 23/05/2020

BMR Released for packing by QA Head Sign/Date: [Signature] 23/05/2020

15.0 BMR REVIEW DETAILS:

Reviewed by	Name	Sign./Date
Production Executive	<u>Sathish Kumar</u>	<u>[Signature] 23/05/2020</u>
QA Executive	<u>Ram Kumar</u>	<u>[Signature] 23/05/2020</u>
Production Assistant Manager/ HOD	<u>BALASUBRAMANIAN</u>	<u>[Signature] 23/05/2020</u>
QA Manager/ HOD	<u>[Signature]</u>	<u>[Signature] 23/05/2020</u>

16.0 REVISION HISTORY:

Sr. No.	Document No.	Reason for Revision	Supersedes No.
1	BMR/T/107-00	New Document	Nil
2	BMR/T/107-01	Manufacturing Formula revised to improve the granules flow property. Change Control No. CC/20/006	BMR/T/107-00

Prepared by:	Checked by:	Approved By:
Dept. Production	Production Quality Assurance	Head Quality Assurance
Sign. <u>L. Ko</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date <u>21/05/2020</u>	<u>21/05/2020</u>	<u>22/05/2020</u>

MASTER COPY

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.		Page 1 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMRT/107-02 Customer:	Batch No.: <u>GF 200704</u> Generic Health Care Pvt. Ltd.

BATCH MANUFACTURING RECORD COVER SHEET

PRODUCT NAME	: Amloperin 5mg/5mg
GENERIC NAME	: Amlodipine Besilate and Perindopril Erbumine Tablets
LABEL CLAIM	Each uncoated tablet contains: Amlodipine Besilate BP Equivalent to Amlodipine.....5 mg Perindopril Erbumine BP5 mg Excipients.....q.s
MFR No. / Reference Document No.	: MFR/T/040-01
BMR No.	: BMRT/107-02
REVISION No.	: 02
SUPERSEDES No.	: BMRT/107-01
BMR EFFECTIVE BATCH NUMBER/DATE	: <u>GF 200704 / 27/07/2020</u>
MFG.LIC No.	: PON/DRUGS/19 13 4323
STORAGE	: Store in cool and dry place. Protect from light
BMR ISSUED BY/DATE (QA)	: <u>B. 27/07/2020</u>
BMR CHECKED & RECEIVED BY/DATE (PRODUCTION)	: <u>L.K. 29/07/2020</u>
SHELF LIFE	: 36 Months
BATCH SIZE	: 6,00,000 Tablets (84.000 Kg)
MFG. DATE: <u>07/2020</u>	: EXP. DATE: <u>06/2022</u>

RECOVERY ADDITION RECORD

BATCH NO	MFG	EXP	QUANTITY	REVISED BATCH SIZE
			NA	

ALLOTTED BY: QA SIGN/DATE: <u>B. 27/07/2020</u>	COUNTER CHECKED BY: <u>B. 27/07/2020</u> QA SIGN/DATE:
DATE OF COMMENCEMENT: <u>29/07/2020</u>	DATE OF COMPLETION: <u>31/07/2020</u>
RELEASED QUANTITY OF TABLETS FOR PACKING	: <u>599713 Tablets</u>
RELEASE FOR PACKING STAGE HEAD OF QA SIGN/DATE:	: <u>J. 31/07/2020</u>
This BMR contains 33 Pages + <u>Nil</u> Additional Pages	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L.K.</u>	<u>B.</u>	<u>B.</u>	<u>B.</u>
Date	<u>27/07/2020</u>	<u>27/07/2020</u>	<u>27/07/2020</u>	<u>27/07/2020</u>

MASTER COPY

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.		Page 2 of 33
	BATCH MANUFACTURING RECORD	Product Code: A08	Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMR/T/107-02	Batch No.: <i>GF 200 704</i>
		Customer:	Generic Health Care Pvt. Ltd.

1.0 INDEX

Sr. No.	Content	Page No.
	Batch manufacturing cover sheet	1
1.0	Index	2
2.0	Flow Chart	3
3.0	Indent of active pharmaceutical ingredients & excipients	4
4.0	Calculation	5-6
5.0	Dispensing line clearance checks	7
6.0	Dispensing weighing sheet	8
7.0	Line clearance for Sifting and blending, Sieve integrity checks, Lubrication material sifting record, Blending and Lubrication instruction, Weight of final blend and Reconciliation	9-11
8.0	Release for Compression	11
9.0	Compression Line Clearance	12
10.0	Compression process instruction, granules receipt record, Compression specification and parameter, compression machine running status, Initial In-process checks, Compression specification and parameter, In-process checks (Production and IPQA), uniformity of weight checks (Production and IPQA), Weight record of compressed tablets, Reconciliation of compressed tablets	13-30
11.0	Release for Inspection	30
12.0	Inspection Line clearance	31
13.0	Inspection Process instruction, performance checks record for metal detector, tablets visual inspection record, weight record, Reconciliation of inspected tablets	32-33
14.0	Release for Packing	33
15.0	BMR Review details	33
16.0	Revision History	33

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. Ka</i>	<i>Sm</i>	<i>24/07/2020</i>	<i>25/07/2020</i>
Date	<i>27/07/2020</i>	<i>24/07/2020</i>	<i>24/07/2020</i>	<i>25/07/2020</i>

MASTER COPY

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.

Page 3 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

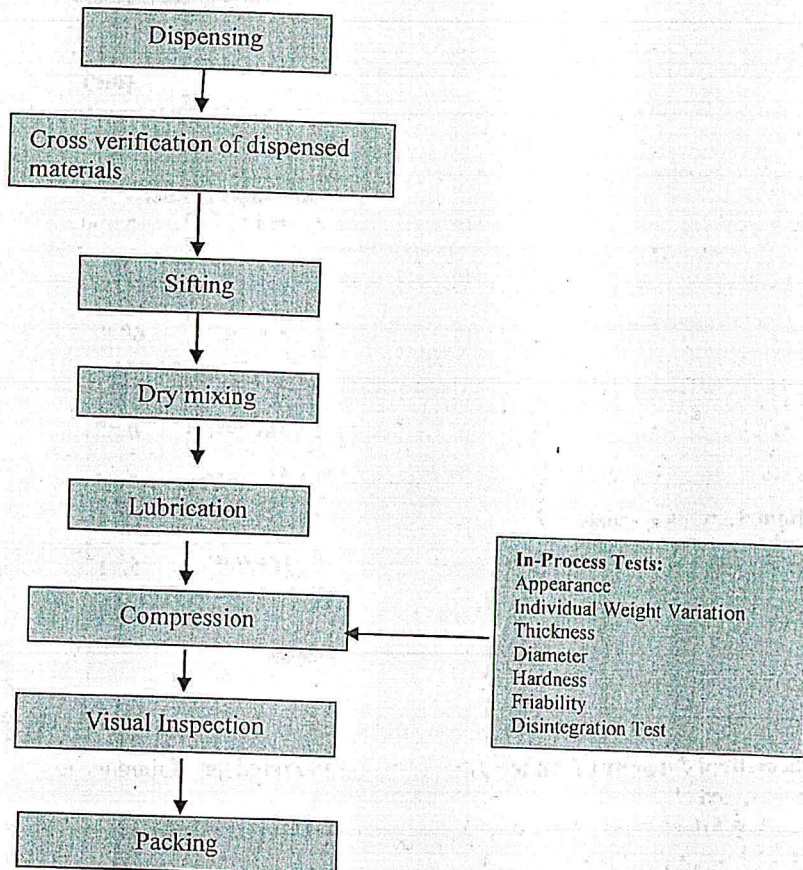
BMR. No.: BMR/T/107-02

Batch No.: GF200704

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.

Date

27/07/2020

27/07/2020

27/07/2020

27/07/2020

MASTER COPY

UNCONTROLLED

 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 33
	BATCH MANUFACTURING RECORD		Product Code: A08
Product	Amloperin 5mg/5mg	BMR. No.: BMR/T/107-02	Batch Size: 6,00,000 Tablets
		Customer:	Batch No.: GF200704
			Generic Health Care Pvt. Ltd.

3.0 INDENT OF ACTIVE INGREDIENTS & EXCIPIENTS:

Sr. No.	Name of the Ingredient	Spec.	Item Code	Quantity/ Tablets (mg)	Standard quantity per 6,00,000 tablets (kg)	OA/ PL (%)	Required quantity per 6,00,000 tablets (kg)
Dry mixing							
1	Amlodipine Besilate*	BP	RAI/GH/A001	6.950	4.170	-	4.170
2	Perindopril Erbumine^	BP	RAI/GH/P001	5.000	3.000	-	3.000
3	Microcrystalline cellulose PH 102**^^	BP	REX/GH/M002	49.490	29.694	-	29.694
4	Microcrystalline cellulose PH 200	BP	REX/SP/M018	69.778	41.867	-	41.867
Lubrication:							
5	Colloidal silicon dioxide	BP	REX/GH/C001	0.484	0.290	-	0.290
6	Croscarmellose Sodium	BP	REX/GH/C002	3.425	2.055	-	2.055
7	Sodium Starch Glycolate	BP	REX/GH/S001	1.961	1.177	-	1.177
8	Magnesium stearate	BP	REX/GH/M001	5.882	3.529	-	3.529
Average wt. of core tablet				140.000	84.000	-	84.000

Note: *^API quantity shall be calculated based on potency.

OA: Overages, PL: Process loss

Potency calculation:

Theoretical Quantity of Amlodipine Besilate and Perindopril Erbumine required in Kg for a batch size of 6,00,000 Tablets are calculated.

* Excess Quantity shall be compensating from Microcrystalline cellulose PH-102**^^

Item losses 6% moisture.

Note: 1.39 mg of Amlodipine Besylate is equivalent to 1.0 mg of Amlodipine

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K.	Dr.		
Date	27/07/2020	27/07/2020	27/07/2020	27/07/2020
MASTER COPY		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.

Page 5 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMRT/107-02

Batch No.: GF 200 704

Customer:

Generic Health Care Pvt. Ltd.

4.0 ASSAY AND LOD CALCULATIONS FOR AMLODIPINE BESILATE:

Note: If assay of API is more than 100%, consider 100% at the time of calculation.

Standard quantity of Amlodipine Besilate: 4.170 Kg (A)

Calculation for Amlodipine Besilate:

$$\text{Theoretical Qty} = \frac{\text{Label Claim} \times \text{Std. Batch Size (in no's)}}{1000 \times 1000} \times \text{Equivalent factor} = \frac{5 \times 6,00,000}{1000 \times 1000} \times 1.39 = 4.170 \text{ kg}$$

1) Calculation for Single A. R. No. Rev/0001, Assay on dried basis: 99.71 w/w, LOD: 0.08 w/w
Exp. Date: 11/24.

$$\text{Actual Quantity (Kg) (B)} = \frac{\text{Standard qty. required} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{4.170 \times 100 \times 100}{99.71 \times (100 - 0.08)} = 4.185 \text{ Kg}$$

2) Calculation for Amlodipine Besilate Multiple A. R. No.:

Sr. No.	A. R. No.	Available Qty. (Kg) (C)	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 (D)					

Calculation for Remaining Quantity Required (E): 22

Theoretical Qty. - Actual Quantity (D) = _____ Kg

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

$$\text{Actual Remaining Quantity (Kg) (F)} = \frac{\text{Remaining qty. required (E)} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{X \times 100 \times 100}{X(100 -)} = \text{_____ Kg.}$$

Total Qty. of Amlodipine Besilate to be dispensed (G) = (C) + (F) = _____ Kg

Done By/On (QA): JS

Checked By/On (Production): L. Ke 28/07/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ke</u>	<u>JS</u>	<u>JS</u>	<u>JS</u>
Date	<u>27/07/2020</u>	<u>28/07/2020</u>	<u>27/07/2020</u>	<u>28/07/2020</u>

MASTER COPY

UNCONTROLLED

 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 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMR/T/107-02 Customer:	Batch No.: <u>G1 F 200704</u> Generic Health Care Pvt. Ltd.

4.1 ASSAY AND LOD CALCULATIONS FOR PERINDOPRIL ERBUMINE:

Note: If assay of API is more than 100%, consider 100% at the time of calculation.

Standard quantity of Perindopril Erbumine: 3.000 Kg (A)

Standard quantity of Microcrystalline Cellulose PH 102 (B): 29.694 Kg

Calculation for Perindopril Erbumine BP:

1) Calculation for Single A. R. No. Rm/0007, Assay on dried basis: 100.00 w/w, LOD: 0.225 w/w
 Exp. Date: 28/07/20

$$\text{Actual Quantity (Kg) (C)} = \frac{\text{Standard qty. required} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{3.00 \times 100 \times 100}{100 \times (100 - 0.225)} = 2.010 \text{ Kg}$$

2) Calculation for Microcrystalline Cellulose PH 102 (B):

$$\begin{aligned} \text{Actual Quantity (Kg) (D)} &= \text{Standard quantity of Microcrystalline cellulose PH102} - (\text{Excess Calculated quantity of Amlodipine} \\ &\quad \text{Besilate} + \text{Excess Calculated quantity of Perindopril Erbumine}) \\ &= 29.694 \text{ Kg} - (0.015 \text{ Kg} + 0.010 \text{ Kg}) \\ &= 29.669 \text{ Kg} \end{aligned}$$

3) Calculation for Perindopril Erbumine 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: _____

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

Total Qty. of Perindopril Erbumine to be dispensed (I) = (E) + (H) = _____ Kg

4) Calculation for Microcrystalline Cellulose PH 102 (B):

$$\begin{aligned} \text{Actual Quantity (Kg) (J)} &= \text{Standard quantity of Microcrystalline cellulose PH102} - (\text{Excess Calculated quantity of Amlodipine} \\ &\quad \text{Besilate} + \text{Excess Calculated quantity of Perindopril Erbumine}) \\ &= 29.694 \text{ Kg} - (\text{_____ Kg} + \text{_____ Kg}) \\ &= \text{_____ Kg} \end{aligned}$$

Done By/On (QA): <u>[Signature]</u>		Checked By/On (Production): <u>L.Ka 28/07/2020</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>27/07/2020</u>	<u>28/07/2020</u>	<u>27/07/2020</u>	<u>28/07/2020</u>

MASTER COPY

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.		Page 7 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMR/T/107-02 Customer:	Batch No.: <u>G1 F 200 704</u> Generic Health Care Pvt. Ltd.

5.0 DISPENSING LINE CLEARANCE CHECKS

Date 28/07/2020 Time 18:25

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>SI/DPB/001</u>	<u>SI/Bal/004</u>	<u>SI/Bal/005</u>	<u>SI/Bal/006</u>
Previous Product	<u>Paracetamol - D</u>			
B. No.	<u>G1 F 200 704</u>			
Cleaned by Sign/Date	<u>Ranjitha / 28/07/2020</u>			
Checked by Store Sign/Date	<u>Self / 28/07/2020</u>			
Verified by IPQA Sign/Date	<u>Self / 28/07/2020</u>			

ENVIRONMENTAL CONDITIONS: Date: 28/07/2020 Time: 18: 30		Observation	Checked by	Verified by
(For Reference SOP No.: QAGN/011)			Store	IPQA
			Sign/Date	Sign/Date
Temperature (Limit: NMT 25°C)		23°C	Self 28/07/2020	Self 28/07/2020
Relative Humidity % (Limit: NMT 60%)		55%	Self 28/07/2020	Self 28/07/2020
Differential Pressure (NLT 10 Pascal)		11 Pa	Self 28/07/2020	Self 28/07/2020
Differential Pressure across the booth Limit: 5 to 20 mm Water		12 mm	Self 28/07/2020	Self 28/07/2020

APPROVAL FOR DISPENSING BY IPQA: Sign..... Self Date: 28/07/2020

Dispensing start Time 18:58 End Time 19:28

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>Self</u>	<u>Self</u>	<u>Self</u>
Date	<u>27/07/2020</u>	<u>27/07/2020</u>	<u>27/07/2020</u>	<u>27/07/2020</u>

MASTER COPY

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

Product

SAI PRIMUS LIFE BIOTECH PVT LTD

SAI KRIMUS LITE PROTECTA P. 22

605009.

BATCH MANUFACTURING RECORD

Product Code: A08

BMR No.: BMR/T/107-02

Amloperin 5mg/5mg

Batch Size: 6,000,000 Tablets

Batch No.: GF 200704

Generic Health Care Pvt. Ltd.

Page 8 of 33

6.0 Dispensing Weighing Sheet:

Date 28/11/22 Shift: 6 Time: 18:50

Date 28/11/22 Shift: 6 Time: 18:50

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	27/07/2020	<i>[Signature]</i>	27/07/2020	27/07/2020

MASTER COPY

UNCONTROLLED CITY

 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 9 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMRT/107-02 Customer:	Batch No.: <i>GF 200704</i> Generic Health Care Pvt. Ltd.

7.0 SIFTING AND BLENDING LINE CLEARANCE CHECKS: Date/Shift: *28/07/2020 / 18.00*

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.		✓	✓				
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	Blender	Area
EQP. ID No.	<i>P01 VBS 1001</i>	<i>P01 018 1001</i>	<i>Env-01</i>
Previous Product	<i>Promerich CZS</i>		
Batch No.	<i>FB 2 00016</i>		
Cleaned by	<i>Rajiv</i>		
Checked by	<i>[Signature]</i>		
Verified by	<i>[Signature]</i>		

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: <i>28/07/2020</i> Time: <i>18.05</i>			Date: Time:			Date: Time:		
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	<i>23°C</i>	<i>[Signature]</i>	<i>[Signature]</i>						
RH % (NMT 60%)	<i>50</i>	<i>[Signature]</i>	<i>[Signature]</i>						
DP (NLT 10 Pascal)	<i>10 pas</i>	<i>[Signature]</i>	<i>[Signature]</i>						

APPROVAL FOR SIFTING AND BLENDING:

Production Sign/Date:	<i>[Signature]</i> <i>28/07/2020</i>		
IPQA Sign/Date:	<i>[Signature]</i> <i>28/07/2020</i>		
Start and End Time:	<i>18.10</i>	<i>19.04</i>	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. Ko</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date:	<i>27/07/2020</i>	<i>28/07/2020</i>	<i>27/07/2020</i>	<i>29/07/2020</i>

MASTER COPY

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.		Page 10 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMR/T/107-02 Customer:	Batch No.: <u>GF 200 704</u> Generic Health Care Pvt. Ltd.

7.1 Dry Microcrystalline Cellulose (PH 102) at NMT 105°C for 1 hour if the LOD of the lot used is more than 3%.

Excipients	LOD Found
Microcrystalline Cellulose (PH 102)	2.91%

7.2 LUBRICATION MATERIAL SIFTING RECORD:

Date: 28/07/2022 Shift: General

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	Amlodipine Besilate*	4.185	80#	PD/308L-20/01	OK/Not OK	18.10	18.14	OK/Not OK	ANJITHA	2
2	Perindopril Erbumine^	3.010	60#	PD/308L-60/01	OK/Not OK	18.15	18.18	OK/Not OK	ANJITHA	2
3	Microcrystalline cellulose PH 102***	29.669	40#	PD/308L-40/01	OK/Not OK	18.19	18.24	OK/Not OK	ANJITHA	2
4	Microcrystalline cellulose PH 200	41.867	30#	PD/308L-30/01	OK/Not OK	18.25	18.32	OK/Not OK	ANJITHA	2
Lubrication:										
5	Colloidal silicon dioxide	0.290	30#	PD/308L-30/01	OK/Not OK	18.34	18.35	OK/Not OK	ANJITHA	2
6	Croscarmellose Sodium	2.055	40#	PD/308L-40/01	OK/Not OK	18.36	18.38	OK/Not OK	ANJITHA	2
7	Sodium Starch Glycolate	1.177	40#	01	OK/Not OK	18.39	18.41	OK/Not OK	ANJITHA	2
8	Magnesium stearate	3.529	60#	PD/308L-60/01	OK/Not OK	18.42	18.45	OK/Not OK	ANJITHA	2

7.3 BLENDING AND LUBRICATION INSTRUCTION AND RECORDS: Date: 28/07/2022 Shift: General

Step No.	Process Instructions	Time		Done by	Checked by Prod.
		Started	Completed		
1	Operate the Octagonal Blender as per the current version of the SOP: <u>POOP/009</u>				
Pre-lubrication:					
1	Load the sifted Amlodipine Besilate, Perindopril Erbumine, Dried Microcrystalline cellulose PH 102, Microcrystalline cellulose PH 200, Colloidal silicon dioxide, Croscarmellose Sodium, Sodium Starch Glycolate in to the blender and blend for 10 minutes at 10 RPM.	18.48	18.58	ANJITHA	2
Lubrication:					
2	Load the Sifted Magnesium Stearate into the above Pre-lubricated blend and mix for further 5 minutes at 10 RPM.	18.59	19.04	ANJITHA	2

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ko</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>27/07/2022</u>	<u>27/07/2022</u>	<u>27/07/2022</u>	<u>27/07/2022</u>

MASTER COPY

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.		Page 11 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMR/T/107-02 Customer:	Batch No.: <u>GF 200 704</u> Generic Health Care Pvt. Ltd.

7.4 WEIGHING OF FINAL BLEND:

Balance I.D. No.: PO. 101.1.0.2

Date: 28/07/2020 Shift: A Time: 19:08

Cont No.	Gross Weight	Tare Weight	Net weight	Weighed by	Ckd by	Cont No.	Gross Weight	Tare Weight	Net weight	Weighed by	Ckd by
1	41.820	4.600	37.220	Baran	2	4					
2	51.230	4.600	46.630	Baran	2	5					
3						6					
Theoretical weight of Blend:						84.000 Kg					
Actual weight of Blend:						83.850 Kg					
Verified by IPQA											

7.5 RECONCILIATION:

1.0	Theoretical weight of blend	:	84.000 Kg
2.0	Actual Weight of blend	:	83.850 Kg
3.0	Manufacturing Loss (Blending stage) @	:	0.150 Kg
4.0	In-process samples		
	A IPQA Samples	:	NA....Kg.
	B QC Samples	:	0.050...Kg.
	C Validation Samples	:	0.0126 0.000...Kg.
5.0	Total samples: (A + B + C)	:	0.0626 0.054...Kg
6.0	Total: (2.0 + 5.0)	:	83.919 Kg
7.0	Yield {6.0 / 1.0 x100}*	:	99.89 %

* Yield should not be less than 99.00%.

@Total rejects destroyed: 0.150 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: 28/07/2020 Checked By IPQA sign/Date: 28/07/2020

Test request form raised by Prod Sign/Date: 28/07/2020

Test request form received by IPQA Sign/Date: 28/07/2020

8.0 RELEASED FOR COMPRESSION:

Reconciliation checked and blend is released for compression

IPQA Sign: [Signature] Date: 28/07/2020

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>27/07/2020</u>	<u>27/07/2020</u>	<u>27/07/2020</u>	<u>27/07/2020</u>

MASTER COPY

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.

Page 12 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-02

Batch No.: GTF 200 704

Customer:

Generic Health Care Pvt. Ltd.

9.0 COMPRESSION LINE CLEARANCE CHECKS: Date/Shift: 29/07/2020 A-1

Sr. No.	Checks	Time:	*Observations					
			07:05					
			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/004		PD/DED/007 & PD/DED/008		Compression - IV	
Previous Product	Calced					
Batch No.	PC0500026					
Cleaned by	Piem					
Checked by	PD/29/07/2020					
Verified by	D. Balaji					
ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 29/07/2020	Time: 07:10	Date:	Time:	Date:	Time:
	Observation	Checked by	Verified by	Observation	Checked by	Verified by
	Temperature °C (NMT 25°C)	23°C	✓	NA		
	RH % (NMT 60%)	52%	✓			
	DP (NLT 10 Pascal)	12 Pascal	✓			
APPROVAL FOR COMPRESSION:						
Production Sign/Date:	29/07/2020					
IPQA Sign/Date:	29/07/2020					
Start and End Time:	08:00	16:10				

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	D. Balaji	29/07/2020	29/07/2020
Date	29/07/2020	29/07/2020	29/07/2020	29/07/2020

MASTER COPY

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.		Page 13 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMR/T/107-02 Customer:	Batch No.: GF 200704 Generic Health Care Pvt. Ltd.

10.0 COMPRESSION

10.1 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: 6.80 mm Circular shaped standard concave with breakline punches. b. Lower punches: 6.80 mm Circular shaped standard concave plain punches. c. Dies: 6.80 mm suitable for above punches. d. Type of tooling - D.
	Punch Issued by: sign./Date: <i>[Signature]</i> 29/07/2020 Checked and Received by Sign./Date: <i>[Signature]</i> 29/07/2020 Verified by Sign./Date: <i>[Signature]</i> 29/07/2020
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, diameter 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.

10.2 GRANULES RECEIPT RECORD:

Balance ID. No.: PD RAJ Date: 29/07/2020 Shift: A Time: 11:15

Sr. No.	Gross Weight in Kg	Issued By Production	Checked by Production
1	41.820	<i>[Signature]</i>	<i>[Signature]</i>
2	51.230	<i>[Signature]</i>	<i>[Signature]</i>
3			
4			
5			
6			

10.3 COMPRESSION SPECIFICATION / PARAMETERS:

Sr. No.	Parameter	Limits	No. of tablets to be checked from each side	Frequency	
				Production	IPQA
1.	Appearance	White to off white coloured, circular shaped, biconvex, uncoated tablet with breakline on one side and plain on other side	20	Every 30 min.	Every 2 Hr.
2.	Average weight(mg)	140.000 mg $\pm$ 3.0 % (135.800 mg – 144.200 mg)	20		
3.	Group Weight	2.800 g $\pm$ 3.0 % (2.716 gm to 2.884 gm)	20	Every 30 min.	Every 2 Hr.
4.	Uniformity of weight Tablets	140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)	20	Every 2 Hr.	Every 4 Hr.
6	Hardness (N)	NLT 3.0 Kg	4	Every 30 min.	Every 2 Hr.
7.	Thickness (mm)	3.30 mm $\pm$ 0.2 (3.10 mm – 3.50 mm)	4	Every 30 min.	Every 2 Hr.
8.	Friability	NMT 1% w/w	6 g	Every 2 Hr.	Every 4 Hr.
9.	Disintegration Time	NMT 15.Minutes	6	Every 2 Hr.	Every 4 Hr.

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	27/07/2020	27/07/2020	27/07/2020	27/07/2020

MASTER COPY

UNCONTROLLED

 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 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product Amloperin 5mg/5mg	BMR. No.: BMR/T/107-02 Customer:		Batch No.: <u>GF 200704</u> Generic Health Care Pvt. Ltd.

10.4 COMPRESSION MACHINE RUNNING STATUS:

Date	Shift	Start Time	End Time	M/C Speed	Tablets Output	Done By	Checked By
29/07/2020	A	08:00	16:10	25	600716	Prem	87

10.5 INITIAL INPROCESS CHECKS: (Appearance, Uniformity of Weight, Thickness & Diameter):

Balance I.D. No.: DD/BAL/027

Date: 29/07/2020 Shift: A Time: 07:19

LHS					RHS				
Sr. No.	Appearance *	Weight (in mg)	Thickness (in mm)	Diameter (in mm)	Sr. No.	Appearance *	Weight (in mg)	Thickness (in mm)	Diameter (in mm)
1	OK	140	3.40	6.80	1	OK	139	3.39	6.80
2	OK	139	3.37	6.81	2	OK	139	3.38	6.80
3	OK	141	3.41	6.80	3	OK	141	3.40	6.80
4	OK	138	3.38	6.80	4	OK	138	3.40	6.80
5	OK	139	3.43	6.80	5	OK	140	3.36	6.80
6	OK	140	3.42	6.80	6	OK	139	3.40	6.80
7	OK	141	3.39	6.80	7	OK	142	3.42	6.80
8	OK	139	3.38	6.80	8	OK	138	3.38	6.80
9	OK	138	3.43	6.80	9	OK	139	3.37	6.80
10	OK	139	3.42	6.80	10	OK	136	3.40	6.81
11	OK	137	3.40	6.80	11	OK	138	3.41	6.81
12	OK	140	3.41	6.80	12	OK	139	3.38	6.80
13	OK	141	3.43	6.81	13	OK	140	3.42	6.81
14	OK	139	3.42	6.80	14	OK	141	3.40	6.80
15	OK	142	3.41	6.80	15	OK	142	3.39	6.81
16	OK	139	3.39	6.81	16	OK	139	3.37	6.80
17	OK	144	3.40	6.80	17	OK	138	3.40	6.82
18	OK	139	3.42	6.81	18	OK	140	3.42	6.80
19	OK	136	3.43	6.80	19	OK	141	3.41	6.80
20	OK	139	3.44	6.80	20	OK	142	3.39	6.80
21	OK	138	3.43	6.81	21	OK	136	3.40	6.81
22	OK	139	3.45	6.80	22	OK	139	3.41	6.80
23	OK	140	3.32	6.81	23	OK	143	3.42	6.80
24	OK	141	3.39	6.80	24	OK	141	3.43	6.80
25	OK	139	3.36	6.80	25	OK	139	3.43	6.80
26	OK	140	3.34	6.80	26	OK	138	3.42	6.80
27	OK	138	3.30	6.80	27	OK	139	3.41	6.81
28	OK	139	3.41	6.79	28	OK	140	3.40	6.80
29	OK	140	3.42	6.80	29	OK	141	3.38	6.80
30	OK	141	3.43	6.80	30	OK	139	3.35	6.80

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

Done by Production Sign/Date: 87 29/07/2020

Checked by IPQA Sign/Date: 87 29/07/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K.</u>	<u>87</u>	<u>87</u>	<u>87</u>
Date	<u>29/07/2020</u>	<u>29/07/2020</u>	<u>29/07/2020</u>	<u>29/07/2020</u>

MASTER COPY

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.		Page 15 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMR/T/107-02 Customer:	Batch No.: <u>GF 200 704</u> Generic Health Care Pvt. Ltd.

10.6 COMPRESSION SPECIFICATION AND PARAMETERS: Date: 29/07/2020 Shift: A Time: 07:45

Parameters	Instrument used	Equip ID No.	Observations of LHS		Observations of RHS		Limits					
			Min	Max	Min	Max						
Appearance	Visual	NA	Ok		Ok		White to off white coloured, circular shaped, biconvex, uncoated tablet with breakline on one side and plain on other side					
Group Weight	Electronic Balance	9A/1002	2.790 gm		2.793 gm		2.800 g $\pm$ 3.0 % (2.716 gm to 2.884 gm)					
Average weight	Electronic Balance		139.50 mg		139.65 mg		140.000 mg $\pm$ 3.0 % (135.800 mg – 144.200 mg)					
Individual weight	Electronic Balance		136 mg	144 mg	mg 136	142 mg	140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)					
Uniformity of weight	Electronic Balance		-12.50 %	+13.22 %	-12.61 %	+1.68 %						
Thickness	Vernier Caliper	9A/1002	3.30 mm	3.45 mm	3.35 mm	3.43 mm	3.30 mm $\pm$ 0.2 (3.10 mm – 3.50 mm)					
Hardness	Hardness Tester	9A/1002	3.5	4.0	4.0	4.5	3.5	4.0	4.0	3.5	3.0	NLT 3.0 Kg
Friability	Friabilator	9A/1001	0.07 %		0.06 %		NMT 1% w/w					
DT	DT Apparatus	9A/1002	01 mint 26 sec		01 mint 30 sec		NMT 15 Minutes					

M/C set done by Operator Name: P. Prem M/C set up Checked by Prod. Sign/Date: 29/07/2020
 M/C Speed: 15 RPM (Not more than 30)

Compression Force: 70

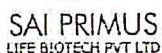
Initial Setting Tablets Destroyed by: Sign: 29/07/2020 Date: 29/07/2020 Quantity in Kg. : 0.030 Quantity in No. 214 ne-b

Approval for Batch Compression by IPQA: Sign: 29/07/2020 Date: 29/07/2020 Time: 07:54

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K.</u>	<u>29/07/2020</u>	<u>29/07/2020</u>	<u>29/07/2020</u>
Date	<u>29/07/2020</u>	<u>29/07/2020</u>	<u>29/07/2020</u>	<u>29/07/2020</u>

MASTER COPY

UNCONTROLLED



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

BATCH MANUFACTURING RECORD

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-02

Batch No.: G F 200 To 4

Customer:

Generic Health Care Pvt. Ltd.

Date: 29/07/2020

[illegible]

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ko	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	27/10/2020	27/10/2020	27/10/2020	27/10/2020

MASTER COPY

UNCONTROLLED COPY



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

Page 17 of 33

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amliperin 5mg/5mg

BMR. No.: BMR/T/107-02

Batch No.: G F 200 704

Customer:

Generic Health Care Pvt. Ltd.

10.8 IN-PROCESS CHECKS: (For Production)

Date:.....

[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	27/07/2020	27/07/2020	27/07/2020	27/07/2020

29/09/16

MASTER COPY

UNCONTROLLED COPY



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

Page 18 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-02

Batch No.: GF 200 704

Customer:

Generic Health Care Pvt. Ltd.

10.9 IN-PROCESS CHECKS: (For Production)

Date:.....

[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	27/07/2020	<i>[Signature]</i>	17/07/2020	<i>[Signature]</i>

MASTER COPY

UNCONTROLLED COPY



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

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-02

Batch No.: GF 200 704

Customer:

Generic Health Care Pvt. Ltd.

10.10

IN-PROCESS CHECKS: (For IPOA)

Date: 22/07/2020

[illegible]

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. Ke</i>	<i>Dr</i>	<i>B</i>	<i>Ami</i>
Date	27/07/2020	27/07/2020	27/07/2020	29/07/2020

MASTER COPY

UNCONTROLLED C

 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 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product: Amloperin 5mg/5mg	BMR. No.: BMR/T/107-02 Customer:		Batch No.: <i>G F 200 704</i> Generic Health Care Pvt. Ltd.

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

Date: <i>29/07/2020</i>		Time: <i>08:10</i>		Shift: <i>A</i>							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	140	8	142	15	141	1	139	8	140	15	139
2	139	9	144	16	139	2	140	9	139	16	140
3	141	10	139	17	140	3	139	10	141	17	139
4	138	11	139	18	140	4	138	11	139	18	140
5	137	12	140	19	139	5	140	12	140	19	138
6	139	13	141	20	138	6	141	13	141	20	139
7	140	14	138			7	139	14	138		
Balance ID No.: <i>PD/BA/1027</i>						M/C Speed: <i>25</i> RPM					
Group weight of 20 Tablets: <i>2794</i> g. Avg. wt: <i>139.70</i> mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight: <i>137</i> mg Max. weight: <i>144</i> mg						Group weight of 20 Tablets: <i>2789</i> g. Avg. wt: <i>139.45</i> mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight: <i>138</i> mg Max. weight: <i>141</i> mg					
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						LHS: <i>0.07%</i> RHS: <i>0.06%</i> Equipment ID No.: QA/FRT/ <i>002</i>					
Disintegration Time (Limit - NMT 15 minutes)						LHS: <i>01min20s</i> RHS: <i>01min20s</i> Equipment ID No.: QA/DTA/ <i>001</i>					
Done by: <i>[Signature]</i> <i>29/07/2020</i> (Production)											
Date: <i>29/07/2020</i>		Time: <i>10:15</i>		Shift: <i>A</i>							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	138	8	139	15	141	1	140	8	138	15	142
2	139	9	140	16	139	2	139	9	139	16	139
3	140	10	141	17	140	3	141	10	140	17	140
4	138	11	139	18	137	4	138	11	139	18	138
5	139	12	140	19	136	5	139	12	141	19	137
6	137	13	138	20	139	6	140	13	139	20	139
7	141	14	139			7	139	14	142		
Balance ID No.: <i>PD/BA/1027</i>						M/C Speed: <i>25</i> RPM					
Group weight of 20 Tablets: <i>2780</i> g. Avg. wt: <i>139.00</i> mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight: <i>136</i> mg Max. weight: <i>141</i> mg						Group weight of 20 Tablets: <i>2788</i> g. Avg. wt: <i>139.40</i> mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight: <i>137</i> mg Max. weight: <i>142</i> mg					
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						LHS: <i>0.05%</i> RHS: <i>0.06</i> Equipment ID No.: QA/FRT/ <i>002</i>					
Disintegration Time (Limit - NMT 15 minutes)						LHS: <i>01min20s</i> RHS: <i>01min20s</i> Equipment ID No.: QA/DTA/ <i>001</i>					
Done by: <i>[Signature]</i> <i>29/07/2020</i> (Production)											

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	<i>27/07/2020</i>	<i>28/07/2020</i>	<i>29/07/2020</i>	<i>29/07/2020</i>	

MASTER COPY

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.

Page 21 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMRT/107-02

Batch No.: GF 200704

Customer:

Generic Health Care Pvt. Ltd.

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

Date: 29/07/2020		Time: 12:180		Shift: A	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	138	8	140	15	141
2	139	9	139	16	143
3	140	10	140	17	139
4	139	11	138	18	140
5	138	12	139	19	139
6	141	13	140	20	138
7	139	14	139		
Balance ID No.: PD/BA/1004			M/C Speed: 25 RPM		
Group weight of 20 Tablets: 2789.9 g. Avg. wt: 139.45 mg			Group weight of 20 Tablets: 2795.5 g. Avg. wt: 139.75 mg		
Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)			Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)		
Min weight: 138.5 mg Max. weight: 143.5 mg			Min weight: 138.5 mg Max. weight: 142.5 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)		01 min 30 sec	01 min 41 sec	Equipment ID No.: QA/DTA/ 60-1	
Done by: J. J. (Production)					
Date: 29/07/2020		Time: 14:30		Shift: A	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	141	8	137	15	138
2	140	9	139	16	139
3	139	10	140	17	140
4	141	11	141	18	141
5	140	12	142	19	139
6	138	13	140	20	138
7	139	14	139		
Balance ID No.: PD/BA/1007			M/C Speed: 25 RPM		
Group weight of 20 Tablets: 2791.5 g. Avg. wt: 139.55 mg			Group weight of 20 Tablets: 2792.5 g. Avg. wt: 139.60 mg		
Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)			Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)		
Min weight: 138.5 mg Max. weight: 142.5 mg			Min weight: 137.5 mg Max. weight: 142.5 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)		01 min 31 sec	01 min 30 sec	Equipment ID No.: QA/DTA/ 001	
Done by: (Production)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.			
Date	29/07/2020	29/07/2020	29/07/2020	29/07/2020

MASTER COPY

UNCONTROLLED

 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 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product Amloperin 5mg/5mg	BMR. No.: BMR/T/107-02 Customer:		Batch No.: <u>GIF 200704</u> Generic Health Care Pvt. Ltd.

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

Date: <u>29/07/2020</u>		Time: <u>16:04</u>		Shift: <u>B</u>													
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).													
1	139	8	141	15	141	1	137	8	139	15	140						
2	140	9	140	16	139	2	139	9	140	16	141						
3	139	10	139	17	138	3	140	10	141	17	142						
4	138	11	138	18	137	4	138	11	138	18	139						
5	139	12	141	19	139	5	136	12	139	19	137						
6	140	13	139	20	136	6	141	13	136	20	134						
7	139	14	140			7	140	14	139								
Balance ID No.: <u>PD/BAL/097</u>						M/C Speed: <u>25</u> RPM											
Group weight of 20 Tablets: <u>2.782</u> ...g. Avg. wt: <u>139.10</u> ...mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight: <u>136</u> ...mg Max. weight: <u>141</u> ...mg						Group weight of 20 Tablets: <u>2.781</u> ...g. Avg. wt: <u>139.05</u> ...mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight: <u>136</u> ...mg Max. weight: <u>142</u> ...mg											
						<table border="1"> <tr> <td>LHS</td> <td>RHS</td> <td></td> </tr> <tr> <td>0.057</td> <td>0.077</td> <td>Equipment ID No.: QA/FRT/ 002</td> </tr> </table>						LHS	RHS		0.057	0.077	Equipment ID No.: QA/FRT/ 002
LHS	RHS																
0.057	0.077	Equipment ID No.: QA/FRT/ 002															
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						Equipment ID No.: QA/DTA/ 001											
Disintegration Time (Limit - NMT 15 minutes)						Equipment ID No.: QA/DTA/ 001											
Done by: <u>[Signature]</u> <u>29/07/2020</u> (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: <u> </u> RPM											
Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight:mg Max. weight:mg						Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight:mg Max. weight:mg											
						<table border="1"> <tr> <td>LHS</td> <td>RHS</td> <td></td> </tr> <tr> <td></td> <td></td> <td>Equipment ID No.: QA/FRT/</td> </tr> </table>						LHS	RHS				Equipment ID No.: QA/FRT/
LHS	RHS																
		Equipment ID No.: QA/FRT/															
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						Equipment ID No.: QA/DTA/											
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.	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	
Date	<u>29/07/2020</u>	<u>29/07/2020</u>	<u>29/07/2020</u>	<u>29/07/2020</u>	

MASTER COPY

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.

Page 23 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-02

Batch No.: GF 200704

Customer:

Generic Health Care Pvt. Ltd.

10.14 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 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: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)			Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 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: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)			Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 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	22/07/2020		27/07/2020	

MASTER COPY

UNCONTROLLED

 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 24 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product Amloperin 5mg/5mg	BMR. No.: BMR/T/107-02 Customer:		Batch No.: <i>GF 200704</i> Generic Health Care Pvt. Ltd.

10.15 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 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: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)								Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 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: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)								Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 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.	<i>L. K.</i>	<i>Da</i>	<i>27/07/2020</i>	<i>27/07/2020</i>	<i>27/07/2020</i>
Date	<i>27/07/2020</i>	<i>27/07/2020</i>	<i>27/07/2020</i>	<i>27/07/2020</i>	<i>27/07/2020</i>

MASTER COPY

UNCONTROLLED COPY

27/07/2020



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 25 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-02

Batch No.: G1F 200704

Customer:

Generic Health Care Pvt. Ltd.

10.16 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 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: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)				Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 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: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)				Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 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	21/07/2020				

MASTER COPY

UNCONTROLLED

 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 26 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMR/T/107-02 Customer:	Batch No.: G F 200 704 Generic Health Care Pvt. Ltd.

10.17 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours): FULL HOPPER

Date: <u>29/07/2020</u>		Time: <u>08:16</u>		Shift: <u>G</u>	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	141	8	141	15	139
2	142	9	138	16	140
3	140	10	142	17	141
4	142	11	139	18	142
5	138	12	139	19	141
6	139	13	136	20	139
7	140	14	138		
Balance ID No.: <u>QA/BGL/002</u>			M/C Speed: <u>25</u> RPM		
Group weight of 20 Tablets: <u>2796</u>g. Avg. wt: <u>139.8</u>mg			Group weight of 20 Tablets: <u>2807</u>g. Avg. wt: <u>140.35</u>mg		
Limit: 140.00 mg ± 5.0 % (133.000 mg – 147.000 mg)			Limit: 140.00 mg ± 5.0 % (133.000 mg – 147.000 mg)		
Min weight: <u>134</u>mg Max. weight: <u>144</u>mg			Min weight: <u>137</u>mg Max. weight: <u>144</u>mg		
		LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		<u>0.07%</u>	<u>0.09%</u>	Equipment ID No.: QA/FRT/001	
Disintegration Time (Limit - NMT 15 minutes)		<u>4 min 01 sec</u>	<u>4 min 04 sec</u>	Equipment ID No.: QA/DTA/002	
Done by: <u>AD</u>(IPQA)					
Date: <u>29/07/2020</u>		Time: <u>08:34</u>		Shift: <u>G</u>	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	141	8	139	15	138
2	140	9	140	16	139
3	141	10	139	17	142
4	139	11	139	18	141
5	138	12	138	19	139
6	141	13	141	20	140
7	141	14	139		
Balance ID No.: <u>QA/BGL/002</u>			M/C Speed: <u>10</u> RPM		
Group weight of 20 Tablets: <u>2796</u>g. Avg. wt: <u>139.8</u>mg			Group weight of 20 Tablets: <u>2792</u>g. Avg. wt: <u>139.6</u>mg		
Limit: 140.00 mg ± 5.0 % (133.000 mg – 147.000 mg)			Limit: 140.00 mg ± 5.0 % (133.000 mg – 147.000 mg)		
Min weight: <u>134</u>mg Max. weight: <u>144</u>mg			Min weight: <u>137</u>mg Max. weight: <u>144</u>mg		
		LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		<u>0.09%</u>	<u>0.06%</u>	Equipment ID No.: QA/FRT/001	
Disintegration Time (Limit - NMT 15 minutes)		<u>4 min 26 sec</u>	<u>4 min 25 sec</u>	Equipment ID No.: QA/DTA/002	
Done by: <u>AD</u>(IPQA)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K.</u>	<u>AD</u>	<u>AD</u>	<u>AD</u>
Date	<u>29/07/2020</u>	<u>29/07/2020</u>	<u>29/07/2020</u>	<u>29/07/2020</u>

MASTER COPY

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.		Page 27 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMRT/107-02	Batch No.: <u>G1 F 200 764</u>
		Customer:	Generic Health Care Pvt. Ltd.

10.18 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours): [Loc Hard/NGB]

Date: 29/07/2020 Time: 08:55 Shift: G1

LHS: Individual weight of 20 tablets (in mg).						RHS: Individual weight of 20 tablets (in mg).					
1	144	8	102	15	179	1	141	8	123	15	129
2	129	9	139	16	141	2	142	9	129	16	140
3	122	10	102	17	143	3	129	10	122	17	142
4	134	11	141	18	139	4	142	11	136	18	141
5	129	12	134	19	143	5	140	12	129	19	141
6	140	13	142	20	138	6	132	13	122	20	139
7	109	14	159			7	142	14	139		

Balance ID No.: QA/B01/002 M/C Speed: 25 RPM

Group weight of 20 Tablets: <u>2791</u> g. Avg. wt.: <u>139.55</u> mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight: <u>122</u> mg Max. weight: <u>144</u> mg	Group weight of 20 Tablets: <u>2803</u> g. Avg. wt.: <u>140.15</u> mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight: <u>136</u> mg Max. weight: <u>142</u> mg
---	---

LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	0 min 0 sec	Equipment ID No.: QA/FRT/ 001
Disintegration Time (Limit - NMT 15 minutes)	04 min 25 sec	Equipment ID No.: QA/DTA/ 002

Done by: [Signature] (IPQA)

Date: 29/07/2020 Time: 10:16 Shift: G1

LHS: Individual weight of 20 tablets (in mg).						RHS: Individual weight of 20 tablets (in mg).					
1	142	8	122	15	142	1	121	8	142	15	142
2	129	9	141	16	140	2	129	9	129	16	140
3	136	10	140	17	139	3	132	10	132	17	140
4	129	11	141	18	138	4	142	11	132	18	141
5	134	12	139	19	138	5	141	12	142	19	142
6	141	13	138	20	141	6	129	13	142	20	142
7	140	14	136			7	132	14	144		

Balance ID No.: QA/B41/002 M/C Speed: 25 RPM

Group weight of 20 Tablets: <u>2781</u> g. Avg. wt.: <u>139.05</u> mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight: <u>136</u> mg Max. weight: <u>147</u> mg	Group weight of 20 Tablets: <u>2807</u> g. Avg. wt.: <u>140.35</u> mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight: <u>134</u> mg Max. weight: <u>144</u> mg
---	---

LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	0 min 0 sec	Equipment ID No.: QA/FRT/ 001
Disintegration Time (Limit - NMT 15 minutes)	04 min 20 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.	<u>L.R.</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>29/07/2020</u>	<u>29/07/2020</u>	<u>29/07/2020</u>	<u>29/07/2020</u>

MASTER COPY

UNCONTROLLED



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 28 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-02

Batch No.: G1F 200704

Customer:

Generic Health Care Pvt. Ltd.

10.19 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours): [HIGH RPM]

Date: 29/07/2020		Time: 10:54		Shift: G7	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	141	8	134	15	136
2	142	9	141	16	139
3	140	10	140	17	136
4	139	11	139	18	138
5	138	12	142	19	141
6	143	13	138	20	139
7	138	14	136		
Balance ID No.: QH/B9L/002			M/C Speed: 30 RPM		
Group weight of 20 Tablets: 2.783 g. Avg. wt: 139.15 mg			Group weight of 20 Tablets: 2.775 g. Avg. wt: 139.15 mg		
Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)			Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)		
Min weight: 136 mg Max. weight: 143 mg			Min weight: 136 mg Max. weight: 144 mg		
			LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			0.10%	0.08%	Equipment ID No.: QA/FRT/001
Disintegration Time (Limit - NMT 15 minutes)			04 min 32 sec	04 min 32 sec	Equipment ID No.: QA/DTA/002
Done by: [Signature] (IPQA)					
Date: 29/07/2020		Time: 12:32		Shift: G7	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	142	8	139	15	140
2	139	9	136	16	139
3	138	10	138	17	140
4	139	11	140	18	144
5	140	12	142	19	139
6	142	13	139	20	142
7	144	14	142		
Balance ID No.: QH/B9L/002			M/C Speed: 25 RPM		
Group weight of 20 Tablets: 2.811 g. Avg. wt: 140.55 mg			Group weight of 20 Tablets: 2.818 g. Avg. wt: 140.9 mg		
Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)			Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)		
Min weight: 136 mg Max. weight: 144 mg			Min weight: 136 mg Max. weight: 144 mg		
			LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			0.10%	0.12%	Equipment ID No.: QA/FRT/001
Disintegration Time (Limit - NMT 15 minutes)			4 min 12 sec	4 min 02 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	[Signature]	[Signature]	[Signature]
Date	29/07/2020	29/07/2020	29/07/2020	29/07/2020

MASTER COPY

UNCONTROLLED C. 1



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 29 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-02

Batch No.: G1F 200 704

Customer:

Generic Health Care Pvt. Ltd.

10.20 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours): [END HOPPER]

Date: 29/07/2020

Time: 13:24

Shift: G1

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

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

1	132	8	132	15	134	1	131	8	139	15	138
2	139	9	139	16	139	2	139	9	139	16	141
3	140	10	142	17	138	3	132	10	141	17	142
4	136	11	146	18	134	4	132	11	144	18	139
5	132	12	139	19	139	5	132	12	139	19	141
6	139	13	142	20	136	6	139	13	142	20	139
7	144	14	142			7	141	14	146		

Balance ID No.: QA/BAL/002

M/C Speed: 25 RPM

Group weight of 20 Tablets: 2.805 g. Avg.
wt: 140.25 mg

Group weight of 20 Tablets: 2.802 g. Avg.
wt: 140.1 mg

Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)

Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)

Min weight: 136 mg Max. weight: 144 mg

Min weight: 134 mg Max. weight: 144 mg

	LHS	RHS	
--	-----	-----	--

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

0.10% 0.09% Equipment ID No.: QA/FRT/001

Disintegration Time (Limit - NMT 15 minutes)

04 min 04 min Equipment ID No.: QA/DTA/002

Done by: IPQA

Date: 29/07/2020

Time: 15:25

Shift: G1

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

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

1	134	8	142	15	139	1	143	8	146	15	142
2	137	9	137	16	137	2	139	9	139	16	140
3	136	10	144	17	134	3	141	10	142	17	137
4	139	11	146	18	136	4	137	11	142	18	135
5	134	12	139	19	133	5	136	12	136	19	144
6	141	13	141	20	142	6	139	13	139	20	137
7	139	14	137			7	144	14	142		

Balance ID No.: QA/BAL/002

M/C Speed: 20 RPM

Group weight of 20 Tablets: 2.767 g. Avg.
wt: 138.35 mg

Group weight of 20 Tablets: 2.802 g. Avg.
wt: 140.1 mg

Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)

Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)

Min weight: 133 mg Max. weight: 146 mg

Min weight: 135 mg Max. weight: 146 mg

	LHS	RHS	
--	-----	-----	--

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

0.07% 0.09% Equipment ID No.: QA/FRT/001

Disintegration Time (Limit - NMT 15 minutes)

04 min 04 min Equipment ID No.: QA/DTA/002

Done by: IPQA

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign:	<u>L K</u>	<u>Dr</u>	<u>Dr</u>	<u>Dr</u>
Date:	<u>29/07/2020</u>	<u>29/07/2020</u>	<u>29/07/2020</u>	<u>29/07/2020</u>

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.		Page 30 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg		BMR. No.: BMRT/107-02 Batch No.: <u>GIF 200704</u> Customer: Generic Health Care Pvt. Ltd.

10.21 WEIGHING RECORD OF COMPRESSED TABLETS:

Cont. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Cont. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net Weight (Kg)	Cont. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)
1	26.670	2.300	24.370	5	9.210	2.300	6.910	9			
2	24.680	2.300	22.380	6	8.930	2.300	6.630	10			
3	14.970	2.300	12.670	7	6.400		4.100	11			
4	15.890	2.300	13.590	8				12			
										Total Net Weight	83.750
Weighed by <u>Saxena</u>				Checked by Sign./ Date: <u>21/07/2020</u>				Verified by IPQA Sign./ Date: <u>21/07/2020</u>			

10.22 RECONCILIATION (COMPRESSION STAGE):

Average weight of Uncoated Tablet: 137.57mg

1.0	Standard Batch size	:	84.000 Kg	6,00,000 Nos.
2.0	Actual weight of Lubricated granules	:	83.850 Kg	601615 Nos.
3.0	Weight of compressed tablets	:	83.750 Kg	600358 Nos.
4.0	Rejection during Compression@	:	0.050 Kg.	
5.0	In-process samples of all stages			
	A IPQA Samples	:	0.030 Kg.	
	B QC Samples	:	0.030 Kg.	
	C Validation Samples	:	NA..Kg.	
6.0	Total in process samples: (A + B + C)	:	0.050 Kg.	
7.0	Total: (3.0 + 6.0)	:	83.800 Kg.	600716 Nos.
8.0	Yield {7.0 / 1.0 x 100}*	:		100.1 %

* Yield should not be less than 99.00%.

@Total rejects destroyed:0.050 Kg. (Rejected materials shall be destroyed as per SOP No.: QAGN/048)

Done by Production Sign/Date: 21/07/2020 Checked by IPQA Sign/Date: 21/07/2020

Test request form raised by Prod Sign/Date: 21/07/2020

Test request form received by IPQA Sign/Date: 21/07/2020

11.0 RELEASE FOR INSPECTION:

Reconciliation checked and Uncoated tablets released for inspection

IPQA Sign: [Signature] Date: 21/07/2020

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>21/07/2020</u>	<u>21/07/2020</u>	<u>21/07/2020</u>	<u>21/07/2020</u>

MASTER COPY

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.

Page 31 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-02

Batch No.: G1F 200 To 4

Customer:

Generic Health Care Pvt. Ltd.

12.0 INSPECTION LINE CLEARANCE:

Date/Shift/Time: 31/07/2020 / 4 /

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.	✓	✓		
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/INS/002	PD/MED/002	Inspection - 2
Previous product	Infoto		
Batch No.	F1010002G		
Cleaned by	Nehru		
Checked by Production Sign/Date:	[Signature] 31/07/2020		
Verified by IPQA Sign/Date:	[Signature] 31/07/2020		

ENVIRONMENTAL CONDITIONS:		Date: 31/07/2020 Time: 06.10			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	23°C					
	Relative Humidity % Limit: NMT 60%	52%					
	Differential Pressure (NLT 10 Pascal)	11 pascal.					

APPROVAL FOR INSPECTION:

Production Sign/Date: [Signature] 31/07/2020

Line Clearance IPQA Sign. / Date: [Signature] 31/07/2020

Start Time/Date: 06.39 / 31/07/2020

End Time/Date: 08.50 / 31/07/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ka	[Signature]	[Signature]	[Signature]
Date:	31/07/2020	31/07/2020	31/07/2020	31/07/2020

MASTER COPY

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.		Page 32 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMR/T/107-02 Customer:	Batch No.: GF 200 704 Generic Health Care Pvt. Ltd.

13.0 INSPECTION PROCESS

13.1 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.

13.2 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/.....&PD/MED/..002.								Checked by Production	Verified By IPQA	
		Ferrous (0.3 mm)		Stainless steel (0.5 mm)		Non-Ferrous (0.3 mm)		Non-metallic				Result
31/07/2020 06:39	1	NA	✓	NA	✓	NA	✓	NA	✓	Pass		
	2	NA	✓	NA	✓	NA	✓	NA	✓	Pass		
	3	NA	✓	NA	✓	NA	✓	NA	✓	Pass		
31/07/2020 08:50	1	NA	✓	NA	✓	NA	✓	NA	✓	Pass		
	2	NA	✓	NA	✓	NA	✓	NA	✓	Pass		
	3	NA	✓	NA	✓	NA	✓	NA	✓	Pass		
	1											
	2											
	3											
	1											
	2											
	3											
	1										NA	
	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

13.3 TABLETS VISUAL INSPECTION RECORD:

Date	Container No		Time		Total Quantity Rejected	Tablet Inspection Done by/Date	Checked by/Date
	From	To	Started	Completed			
31/07/2020	01	06	06:40	08:52	0.090	Saxena, Devi	31/07/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign:	L. Ka			
Date	27/07/2020			

MASTER COPY

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.		Page 33 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMRT/107-02 Customer:	Batch No.: GF 200 704 Generic Health Care Pvt. Ltd.

13.4 WEIGHING RECORD OF INSPECTED TABLETS:

Cont. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Cont. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net Weight (Kg)	Cont. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)
1	26.690	2.300	24.390	5	9.210	2.300	6.910	9			
2	24.680	2.300	22.380	6	6.250	2.300	3.950	10			
3	14.490	2.300	12.190	7				11			
4	15.880	2.300	13.580	8				12			
										Total Net Weight	83.660

Weighed by: Nehru

Checked by Sign./ Date: 31/07/2020

Verified by IPQA Sign./ Date: 31/07/2020

13.5 RECONCILIATION: (INSPECTION OF TABLETS)

1.0	Theoretical weight of Tablets	:	84.000 kg	6,00,000 No's
2.0	Tablets transferred for Inspection	:	83.750 [*] 83.85 kg	600 358 No's
3.0	Rejected Tablets	:	0.090 kg	6 45 No's
4.0	Total weight of good Tablets	:	83.660 kg	599 713 No's
5.0	*Yield = $\frac{4.0}{1.0} \times 100$	:		99.95 %

* Yield should not be less than 99.00%.

Total rejects destroyed: ...0.090.....Kg.

Rejected materials should be destroyed in the presence of QA.

Done by Packing sign/Date: 31/07/2020

Checked by IPQA sign/Date: 31/07/2020

14.0 RELEASE FOR PACKING:

BMR reviewed by IPQA Sign/Date : 31/07/2020

BMR Released for packing by QA Head Sign/Date: 31/07/2020

15.0 BMR REVIEW DETAILS:

Reviewed by	Name	Sign./Date
Production Executive	R. Arthi Kuman	31/07/2020
QA Executive	R. Arthi Kuman	31/07/2020
Production Assistant Manager/ HOD	BALASUBRAMANIAN B	31/07/2020
QA Manager/ HOD	K. J. BALASUBRAMANIAN	31/07/2020

16.0 REVISION HISTORY:

Sr. No.	Document No.	Reason for Revision	Supersedes No.
1	BMRT/107-00	New Document	Nil
2	BMRT/107-01	Manufacturing Formula revised to improve the granules flow property. Change Control No. CC/20/006	BMRT/107-00
3	BMRT/107-02	Revision after three validation batches	BMRT/107-01

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.			
Date	22/07/2020			

MASTER COPY

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.		Page 1 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMR/T/107-01	Batch No.: GF 200 502
		Customer:	Generic Health Care Pvt. Ltd.

BATCH MANUFACTURING RECORD COVER SHEET

PRODUCT NAME : Amloperin 5mg/5mg
GENERIC NAME : Amlodipine Besilate and Perindopril Erbumine Tablets
LABEL CLAIM : Each uncoated tablet contains:
 Amlodipine Besilate BP
 Equivalent to Amlodipine.....5 mg
 Perindopril Erbumine BP5 mg
 Excipients.....q.s
MFR No. / Reference Document No. : MFR/T/040-00
BMR No. : BMR/T/107-01
REVISION No. : 01
SUPERSEDES No. : BMR/T/107-00
BMR EFFECTIVE BATCH NUMBER/DATE : GF 200501 | 22/05/2020
MFG.LIC No. : PON/DRUGS/19 13 4323
STORAGE : Store in cool and dry place. Protect from light
BMR ISSUED BY/DATE (QA) : *[Signature]* 21/05/2020
BMR CHECKED & RECEIVED BY/DATE (PRODUCTION) : *[Signature]* 21/05/2020
SHELF LIFE : 36 Months
BATCH SIZE : 6,00,000 Tablets (84.000 Kg)
MFG. DATE: 05/2020 **EXP. DATE:** 05/2023

RECOVERY ADDITION RECORD

BATCH NO	MFG	EXP	QUANTITY	REVISED BATCH SIZE
		MP		

ALLOTTED BY: *[Signature]* 21/05/2020
QA SIGN/DATE: *[Signature]* 21/05/2020
COUNTER CHECKED BY: *[Signature]* 21/05/2020
QA SIGN/DATE: *[Signature]* 21/05/2020
DATE OF COMMENCEMENT: 22/05/2020
DATE OF COMPLETION: 26/05/2020
RELEASED QUANTITY OF TABLETS FOR PACKING : 596349 Tablets
RELEASE FOR PACKING STAGE
HEAD OF QA SIGN/DATE: *[Signature]* 22/05/2020

This BMR contains 33 Pages + 21 Additional Pages

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	21/05/2020	21/05/2020	22/05/2020	22/05/2020

UNCONTROLLED COPY

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.		Page 2 of 33
	BATCH MANUFACTURING RECORD	Product Code: A08	Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMRT/107-01	Batch No.: GF 200502
		Customer:	Generic Health Care Pvt. Ltd.

1.0 INDEX

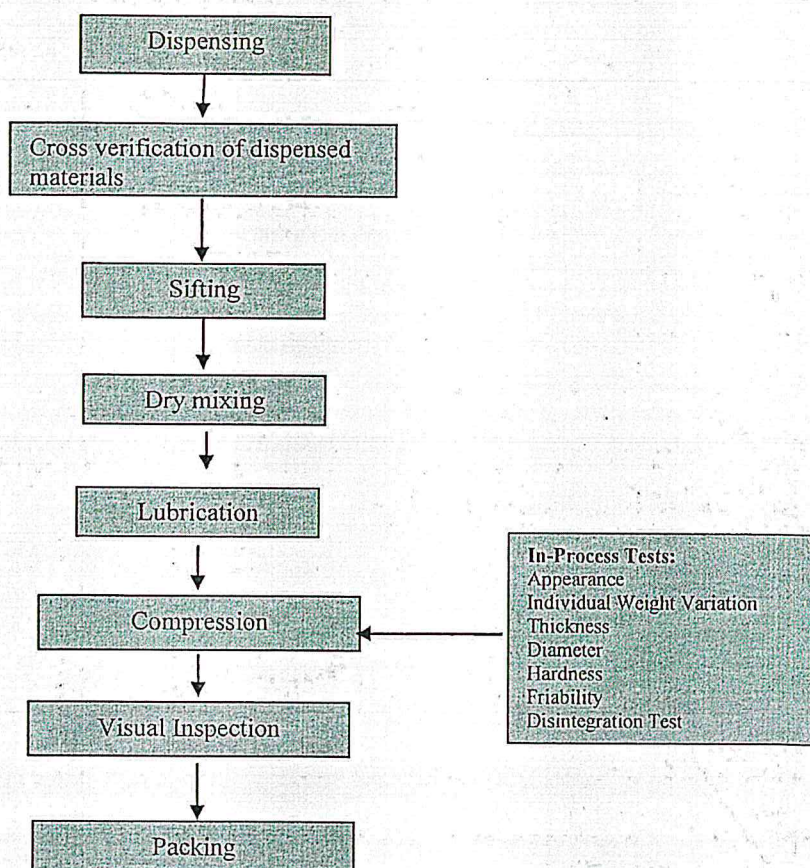
Sr. No.	Content	Page No.
	Batch manufacturing cover sheet	1
1.0	Index	2
2.0	Flow Chart	3
3.0	Indent of active pharmaceutical ingredients & excipients	4
4.0	Calculation	5-6
5.0	Dispensing line clearance checks	7
6.0	Dispensing weighing sheet	8
7.0	Line clearance for Sifting and blending, Sieve integrity checks, Lubrication material sifting record, Blending and Lubrication instruction, Weight of final blend and Reconciliation	9-11
8.0	Release for Compression	11
9.0	Compression Line Clearance	12
10.0	Compression process instruction, granules receipt record, Compression specification and parameter, compression machine running status, Initial In-process checks, Compression specification and parameter, In-process checks (Production and IPQA), uniformity of weight checks (Production and IPQA), Weight record of compressed tablets, Reconciliation of compressed tablets	13-30
11.0	Release for Inspection	30
12.0	Inspection Line clearance	31
13.0	Inspection Process instruction, performance checks record for metal detector, tablets visual inspection record, weight record, Reconciliation of inspected tablets	32-33
14.0	Release for Packing	33
15.0	BMR Review details	33
16.0	Revision History	33

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	S. K. S.	P. N. S.	J. P. S.
Date	21/05/2020	21/05/2020	22/05/2020	22/05/2020



 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 33
	BATCH MANUFACTURING RECORD	Product Code: A08	Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMR/T/107-01	Batch No.: GF 200 502
		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. Ka	[Signature]	[Signature]	[Signature]
Date	21/05/2020	21/05/2020	22/05/2020	22/05/2020

MASTER COPY
UNCONTROLLED COPY

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.		Page 4 of 33
	BATCH MANUFACTURING RECORD	Product Code: A08	Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMRT/107-01	Batch No.: GF 200502
		Customer:	Generic Health Care Pvt. Ltd.

3.0 INDENT OF ACTIVE INGREDIENTS & EXCIPIENTS:

Sr. No.	Name of the Ingredient	Spec.	Item Code	Quantity/ Tablets (mg)	Standard quantity per 6,00,000 tablets (kg)	OA/ PL (%)	Required quantity per 6,00,000 tablets (kg)
Dry mixing							
1	Amlodipine Besilate*	BP	RAI/GH/A001	6.950	4.170	-	4.170
2	Perindopril Erbumine^	BP	RAI/GH/P001	5.000	3.000	-	3.000
3	Microcrystalline cellulose PH 102***^	BP	REX/GH/M002	49.490	29.694	-	29.694
4	Microcrystalline cellulose PH 200	BP	REX/SP/M018	69.778	41.867	-	41.867
Lubrication:							
5	Colloidal silicon dioxide	BP	REX/GH/C001	0.484	0.290	-	0.290
6	Croscarmellose Sodium	BP	REX/GH/C002	3.425	2.055	-	2.055
7	Sodium Starch Glycolate	BP	REX/GH/S001	1.961	1.177	-	1.177
8	Magnesium stearate	BP	REX/GH/M001	5.882	3.529	-	3.529
Average wt. of core tablet				140.000	84.000	-	84.000

Note: *^API quantity shall be calculated based on potency.

OA: Overages, PL: Process loss

Potency calculation:

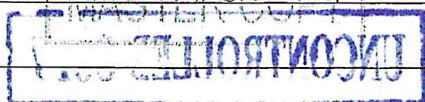
Theoretical Quantity of Amlodipine Besilate and Perindopril Erbumine required in Kg for a batch size of 6,00,000 Tablets are calculated.

* Excess Quantity shall be compensating from Microcrystalline cellulose PH-102***^

Item losses 6% moisture.

Note: 1.39 mg of Amlodipine Besylate is equivalent to 1.0 mg of Amlodipine

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	[Signature]	P. N. [Signature]	[Signature]
Date	21/05/2020	21/05/2020	22/05/2020	22/05/2020





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 5 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-01

Batch No.: GHF 200 502

Customer:

Generic Health Care Pvt. Ltd.

4.0 ASSAY AND LOD CALCULATIONS FOR AMLODIPINE BESILATE:

Note: If assay of API is more than 100%, consider 100% at the time of calculation.

Standard quantity of Amlodipine Besilate: 4.170 Kg (A)

Calculation for Amlodipine Besilate:

$$\text{Theoretical Qty} = \frac{\text{Label Claim} \times \text{Std. Batch Size (in no's)}}{1000 \times 1000} \times \text{Equivalent factor} = \frac{5 \times 6,00,000}{1000 \times 1000} \times 1.39 = 4.170 \text{ kg}$$

1) Calculation for Single A. R. No. RW6/00011, Assay on dried basis: 99.94 w/w, LOD: 0.0234 w/w
Exp. Date: 11/10/2020

$$\text{Actual Quantity (Kg) (B)} = \frac{\text{Standard qty. required} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{4.17 \times 100 \times 100}{99.94 \times (100 - 0.0234)} = 4.173 \text{ Kg}$$

2) Calculation for Amlodipine Besilate Multiple A. R. No.:

Sr. No.	A. R. No.	Available Qty. (Kg) (C)	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 (D)					<u>2110512020</u>

Calculation for Remaining Quantity Required (E):

$$\text{Theoretical Qty.} - \text{Actual Quantity (D)} = \text{NA} \text{ Kg}$$

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

$$\text{Actual Remaining Quantity (Kg) (F)} = \frac{\text{Remaining qty. required (E)} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{X \times 100 \times 100}{X(100 -)} = \text{NA} \text{ Kg.}$$

$$\text{Total Qty. of Amlodipine Besilate to be dispensed (G)} = (C) + (F) = \text{NA} \text{ Kg}$$

Done By/On (QA): [Signature]

Checked By/On (Production): [Signature]

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>21/05/2020</u>	<u>21/05/2020</u>	<u>21/05/2020</u>	<u>21/05/2020</u>



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 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMRT/107-01

Batch No.: GF 200502

Customer:

Generic Health Care Pvt. Ltd.

4.1 ASSAY AND LOD CALCULATIONS FOR PERINDOPRIL ERBUMINE:

Note: If assay of API is more than 100%, consider 100% at the time of calculation.

Standard quantity of Perindopril Erbumine: 3.000 Kg (A)

Standard quantity of Microcrystalline Cellulose PH 102 (B): 29.694 Kg

Calculation for Perindopril Erbumine BP:

- 1) Calculation for Single A. R. No. Bmr/00012, Assay on dried basis: 99.62 w/w, LOD: 0.2835 w/w
Exp. Date: 10/2024.

$$\text{Actual Quantity (Kg) (C)} = \frac{\text{Standard qty. required} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{3.0 \times 100 \times 100}{99.62 \times (100 - 0.2835)} = \underline{2.010} \text{ Kg}$$

- 2) Calculation for Microcrystalline Cellulose PH 102 (B):

$$\begin{aligned} \text{Actual Quantity (Kg) (D)} &= \text{Standard quantity of Microcrystalline cellulose PH102} - (\text{Excess Calculated quantity of Amlodipine} \\ &\quad \text{Besilate} + \text{Excess Calculated quantity of Perindopril Erbumine}) \\ &= 29.694 \text{ Kg} - (\underline{0.03} \text{ Kg} + \underline{0.01} \text{ Kg}) \\ &= \underline{29.654} \text{ Kg.} \end{aligned}$$

- 3) Calculation for Perindopril Erbumine 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)					<u>21051200</u>

Calculation for Remaining Quantity Required (G):

$$\text{Theoretical Qty.} - \text{Actual Quantity (F)} = \underline{\text{NA}} \text{ Kg}$$

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

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

$$\text{Total Qty. of Perindopril Erbumine to be dispensed (I)} = (\text{E}) + (\text{H}) = \underline{\text{NA}} \text{ Kg}$$

- 4) Calculation for Microcrystalline Cellulose PH 102 (B):

$$\begin{aligned} \text{Actual Quantity (Kg) (J)} &= \text{Standard quantity of Microcrystalline cellulose PH102} - (\text{Excess Calculated quantity of Amlodipine} \\ &\quad \text{Besilate} + \text{Excess Calculated quantity of Perindopril Erbumine}) \\ &= 29.694 \text{ Kg} - (\underline{\text{NA}} \text{ Kg} + \underline{\text{NA}} \text{ Kg}) \\ &= \underline{\text{NA}} \text{ Kg.} \end{aligned}$$

Done By/On (QA): 21/05/2020Checked By/On (Production): 21/05/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K.</u>	<u>[Signature]</u>	<u>P. N. [Signature]</u>	<u>[Signature]</u>
Date	<u>21/05/2020</u>	<u>21/05/2020</u>	<u>21/05/2020</u>	<u>21/05/2020</u>

UNCONTROLLED COPY

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.

Page 7 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-01

Batch No.: GF200502

Customer:

Generic Health Care Pvt. Ltd.

5.0 DISPENSING LINE CLEARANCE CHECKS

Date: 22/05/2020 Time: 11:45

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/DPB/001	ST/BAL/005 ST/BAL/006	Dispensing booth
Previous Product	Transver		
B. No.	Tag 0003E		
Cleaned by Sign/Date	Rajivani / 22/05/2020		
Checked by Store Sign/Date	N. Arjun / 22/05/2020		
Verified by IPQA Sign/Date	N. Arjun / 22/05/2020		

ENVIRONMENTAL CONDITIONS: Date: 22/05/2020 Time: 11:45		Observation	Checked by Store Sign/Date	Verified by IPQA Sign/Date
(For Reference SOP No.: QAGN/011)				
Temperature (Limit: NMT 25°C)		23°C	N. Arjun / 22/05/2020	N. Arjun / 22/05/2020
Relative Humidity % (Limit: NMT 60%)		55%	N. Arjun / 22/05/2020	N. Arjun / 22/05/2020
Differential Pressure (NLT 10 Pascal)		10 (pasc)	N. Arjun / 22/05/2020	N. Arjun / 22/05/2020
Differential Pressure across the booth Limit: 5 to 20 mm Water		10mm	N. Arjun / 22/05/2020	N. Arjun / 22/05/2020

APPROVAL FOR DISPENSING BY IPQA: Sign: N. Arjun Date: 22/05/2020

Dispensing start Time 15:20 End Time 16:10

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	3. Balakrishnan	P. K. Reddy	
Date	21/05/2020	21/05/2020	22/05/2020	

UNCONTROLLED COPY

 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 33	
	BATCH MANUFACTURING RECORD		Product Code: A08	
Product	Amloperin 5mg/5mg		Batch Size: 6,00,000 Tablets	
	BMR. No.: BMR/T/107-01		Batch No.: GTF-200502	
Customer:		Generic Health Care Pvt. Ltd.		

6.0 Dispensing Weighing Sheet:

Balance ID: 571344/005, 571344/006 Date: 22/05/2020 Shift: 04 Time: 15:30

Sl. 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)
Dry Mixing:													
	Amlodipine Besilate *	BP	RAI/GH/A001	Kg	4.170	4.173 4.185	RMG/00011	4.253 4.265	4.173 4.185	N. Arghy 22/05/2020	N. Arghy 22/05/2020	22/05/2020	22/05/2020
2	Perindopril Erbumine^	BP	RAI/GH/P001	Kg	3.000	3.019	RMG/00012	3.059	3.019	N. Arghy 22/05/2020	N. Arghy 22/05/2020	22/05/2020	22/05/2020
3	Microcrystalline cellulose PH 102***	BP	REX/GH/M002	Kg	29.694	29.681	RMG/00003	25.000 4.761 4.743	25.000 4.881 4.863	N. Arghy 22/05/2020	N. Arghy 22/05/2020	22/05/2020	22/05/2020
4	Microcrystalline cellulose PH 200	BP	REX/SP/M018	Kg	41.867	41.867	RMG/00040	25.000 17.067	25.000 16.867	N. Arghy 22/05/2020	N. Arghy 22/05/2020	22/05/2020	22/05/2020
Lubrication:													
5	Colloidal silicon dioxide	BP	REX/GH/C001	Kg	0.290	0.290	RMG/00008	0.370	0.080	N. Arghy 22/05/2020	N. Arghy 22/05/2020	22/05/2020	22/05/2020
6	Croscarmellose Sodium	BP	REX/GH/C002	Kg	2.055	2.055	RMG/00013	2.135	0.080	N. Arghy 22/05/2020	N. Arghy 22/05/2020	22/05/2020	22/05/2020
7	Sodium Starch Glycolate	BP	REX/GH/S001	Kg	1.177	1.177	RMG/00009	12.115	24.500	N. Arghy 22/05/2020	N. Arghy 22/05/2020	22/05/2020	22/05/2020
8	Magnesium stearate	BP	REX/GH/M001	Kg	3.529	3.529	RMG/00004	3.609	0.080	N. Arghy 22/05/2020	N. Arghy 22/05/2020	22/05/2020	22/05/2020

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Quality Assurance	Quality Assurance	Head Quality Assurance	
Sign.	L. Ko	N. Arghy	N. Arghy		
Date	22/05/2020	22/05/2020	22/05/2020		

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.		Page 9 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMR/T/107-01 Customer:	Batch No.: GF 200 502 Generic Health Care Pvt. Ltd.

7.0 SIFTING AND BLENDING LINE CLEARANCE CHECKS: Date/Shift: 23/05/2020 / NB / SWB

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.	09-10	✓	✓				
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.

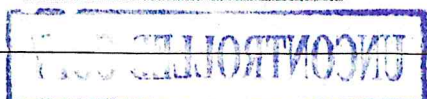
Equipment	Sifter	Blender	Area
EQP. ID No.	PD/VBS/001	PD/OCB/001	Gr-01
Previous Product	Amloperin 5mg/5mg		
Batch No.	GF200501		
Cleaned by	Karthi, Venu		
Checked by	23/05/2020		
Verified by	23/05/2020		

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 23/05/2020 Time: 09-10			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	23/05/2020	23/05/2020						
RH % (NMT 60%)	52%	23/05/2020	23/05/2020						
DP (NLT 10 Pascal)	10 pa	23/05/2020	23/05/2020						

APPROVAL FOR SIFTING AND BLENDING:

Production Sign/Date:	23/05/2020		
IPQA Sign/Date:	23/05/2020		
Start and End Time:	09-25	11-15	

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	MASTH...	...	...	...	
Date	21/05/2020	21/05/2020	22/05/2020		



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 33

BATCH MANUFACTURING RECORD		Product Code: A08	Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMRT/107-01	Batch No.: <u>GF 200 502</u>
		Customer:	Generic Health Care Pvt. Ltd.

7.1 Dry Microcrystalline Cellulose (PH 102) at NMT 105°C for 1 hour if the LOD of the lot used is more than 3%.

Excipients	LOD Found
Microcrystalline Cellulose (PH 102)	2.22 %

7.2 LUBRICATION MATERIAL SIFTING RECORD:

Date: 23/05/2020 Shift: G

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	Amlodipine Besilate*	4.185 4.173	80#	PD/30-se-80/01	OK/ Not OK	09-29	09-35	OK/ Not OK	Muthu	R
2	Perindopril Erbumine^	3.010	60#	PD/30-se-60/01	OK/ Not OK	09-40	09-46	OK/ Not OK	Rajh	R
3	Microcrystalline cellulose PH 102***	4. 35.00 41.842 4.682	40#	PD/30-se-40/01	OK/ Not OK	09-47	09-57	OK/ Not OK	mishu	R
4	Microcrystalline cellulose PH 200	25.00 27.942 10.867	30#	PD/30-se-30/01	OK/ Not OK	10-01	10-20	OK/ Not OK	Rajh	R
Lubrication:										
5	Colloidal silicon dioxide	0.290	30#	PD/30-se-30/01	OK/ Not OK	10-21	10-28	OK/ Not OK	mishu	R
6	Croscarmellose Sodium	2.055	40#	PD/30-se-40/01	OK/ Not OK	10-29	10-32	OK/ Not OK	Rajh	R
7	Sodium Starch Glycolate	1.177	40#			10-33	10-46		mishu	R
8	Magnesium stearate	3.529	60#	PD/30-se-60/01	OK/ Not OK	10-41	10-46	OK/ Not OK	Rajh	R

7.3 BLENDING AND LUBRICATION INSTRUCTION AND RECORDS: Date: 23/05/2020 Shift: G

Step No.	Process Instructions	Time		Done by	Checked by Prod.
		Started	Completed		
1	Operate the Octagonal Blender as per the current version of the SOP: <u>PD0P/009</u>				
Pre-lubrication:					
1	Load the sifted Amlodipine Besilate, Perindopril Erbumine, Dried Microcrystalline cellulose PH 102, Microcrystalline cellulose PH 200, Colloidal silicon dioxide, Croscarmellose Sodium, Sodium Starch Glycolate in to the blender and blend for 10 minutes at 10 RPM (To be established).	<u>10-48</u> <u>10-55</u>	<u>10-53</u> <u>11-05</u>	<u>Muthu</u>	<u>R</u>
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).	<u>11-10</u>	<u>11-15</u>	<u>Rajh</u>	<u>R</u>

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<u>L. K.</u>	<u>S. S. S.</u>	<u>P. S. S.</u>	<u>S. S. S.</u>	
Date	<u>21/05/2020</u>	<u>21/05/2020</u>	<u>22/05/2020</u>	<u>22/05/2020</u>	

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.		Page 11 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product Amloperin 5mg/5mg	BMR. No.: BMR/T/107-01		Batch No.: GF200502
	Customer:		Generic Health Care Pvt. Ltd.

7.4 WEIGHING OF FINAL BLEND:

Balance I.D. No.: ... 25/05/2020

Date: 25/05/2020 Shift: C Time: 11-16

Cont No.	Gross Weight	Tare Weight	Net weight	Weighed by	Ckd by	Cont No.	Gross Weight	Tare Weight	Net weight	Weighed by	Ckd by
1	47.660	4.660	43.000	kam	ke	4					
2	45.320	4.620	40.700	viswa	ke	5					
3					me	6					
Theoretical weight of Blend:						84.000 Kg					
Actual weight of Blend:						83.700 Kg					
Verified by IPQA						25/05/2020					

7.5 RECONCILIATION:

1.0	Theoretical weight of blend	:	84.000 Kg
2.0	Actual Weight of blend	:	83.700 Kg
3.0	Manufacturing Loss (Blending stage) @	:	0.300 Kg
4.0	In-process samples		
	A IPQA Samples	:	0.020 Kg
	B QC Samples	:	0.080 Kg
	C Validation Samples	:	0.000 Kg
5.0	Total samples: (A + B + C)	:	0.100 Kg
6.0	Total: (2.0 + 5.0)	:	83.800 Kg
7.0	Yield {6.0 / 1.0 x 100}*	:	99.76 %

* 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: 0.00 (Recovery addition materials shall be as per SOP: QAGN/047).

Done by Production sign/Date: 23/05/2020 Checked By IPQA sign/Date: 23/05/2020

Test request form raised by Prod Sign/Date: 23/05/2020

Test request form received by IPQA Sign/Date: 23/05/2020

8.0 RELEASED FOR COMPRESSION:

Reconciliation checked and blend is released for compression	
IPQA Sign: 23/05/2020	Date: 23/05/2020

Prepared by:	Checked by:	Approved By:
Dept. Production	Production Quality Assurance	Head Quality Assurance
Sign. L. Ka	23/05/2020	23/05/2020
Date 23/05/2020		

UNCONTROLLED COPY

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.

Page 12 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMRT/107-01

Batch No.: GF 200 502

Customer:

Generic Health Care Pvt. Ltd.

9.0 COMPRESSION LINE CLEARANCE CHECKS: Date/Shift: 23/05/2020 17:00

Sr. No.	Checks	Time:	*Observations					
			NA		NA		NA	
			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.	<u>PD/10M/1002</u>	<u>NA PD/DED/003, PD/DED/004</u>	<u>Compression-02</u>
Previous Product	<u>Amloperin 5mg/5mg</u>		
Batch No.	<u>GF 200 501</u>		
Cleaned by	<u>Vetxi</u>		
Checked by	<u>N. Bal 23/05/2020</u>		
Verified by	<u>R. Lakshmi</u>		

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: <u>23/05/2020</u> Time: <u>17:00</u>			Date: <u>23/05/2020</u> Time: <u>17:00</u>			Date: <u>23/05/2020</u> Time: <u>17:00</u>		
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	<u>23°C</u>	<u>N. Bal</u>	<u>NA</u>						
RH % (NMT 60%)	<u>52%</u>	<u>N. Bal</u>	<u>NA</u>						
DP (NLT 10 Pascal)	<u>10 Pascal</u>	<u>N. Bal</u>	<u>NA</u>						

APPROVAL FOR COMPRESSION:

Production Sign/Date:	<u>N. Bal 23/05/2020</u>		
IPQA Sign/Date:	<u>NA</u>		
Start and End Time:	<u>17:12</u>	<u>21:23</u>	

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	
Date	<u>23/05/2020</u>	<u>23/05/2020</u>	<u>23/05/2020</u>	<u>23/05/2020</u>	

UNCONTROLLED COPY

UNCONTROLLED COPY

*W
N. Bal
23/05/2020

23/05/2020

 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 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product Amloperin 5mg/5mg	BMR. No.: BMR/T/107-01		Batch No.: 67F200502
	Customer:		Generic Health Care Pvt. Ltd.

10.0 COMPRESSION

10.1 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: 6.80 mm Circular shaped standard concave with breakline punches. b. Lower punches: 6.80 mm Circular shaped standard concave plain punches. c. Dies: 6.80 mm suitable for above punches. d. Type of tooling - D. Punch Issued by: sign./Date: _____ Checked and Received by Sign./Date: _____ Verified by Sign./ Date: _____
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, diameter 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.

10.2 GRANULES RECEIPT RECORD:

Balance ID. No.: PD/BA/0114 Date: 21/05/2020 Shift: B Time: 17:10

Sr. No.	Gross Weight in Kg	Issued By Production	Checked by Production
1	47.660	POJ	N. Bal
2	45.320	POJ	N. Bal
3			
4			
5			
6			

10.3 COMPRESSION SPECIFICATION / PARAMETERS:

Sr. No.	Parameter	Limits	No. of tablets to be checked from each side	Frequency	
				Production	IPQA
1.	Appearance	White to off white coloured, circular shaped, biconvex, uncoated tablet with breakline on one side and plain on other side	20	Every 30 min.	Every 2 Hr.
2.	Average weight(mg)	140.000 mg $\pm$ 3.0 % (135.800 mg – 144.200 mg)	20		
3.	Group Weight	2.800 g $\pm$ 3.0 % (2.716 gm to 2.884 gm)	20	Every 30 min.	Every 2 Hr.
4.	Uniformity of weight Tablets	140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)	20	Every 2 Hr.	Every 4 Hr.
6	Hardness (N)	NLT 4.0 Kg (To be established)	4	Every 30 min.	Every 2 Hr.
7.	Thickness (mm)	3.30 mm $\pm$ 0.2 (3.10 mm – 3.50 mm) (To be established)	4	Every 30 min.	Every 2 Hr.
8.	Friability	NMT 1% w/w	6 g	Every 2 Hr.	Every 4 Hr.
9.	Disintegration Time	NMT 15 Minutes	6	Every 2 Hr.	Every 4 Hr.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	3a. [Signature]	P. H. [Signature]	[Signature]
Date	21/05/2020	21/05/2020	22/05/2020	22/05/2020





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 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMRT/107-01

Batch No.: GF 200502

Customer:

Generic Health Care Pvt. Ltd.

10.4 COMPRESSION MACHINE RUNNING STATUS:

Date	Shift	Start Time	End Time	M/C Speed	Tablets Output	Done By	Checked By
23/05/2020	G	17:12	23:22	25	598640	Thum	PQ

10.5 INITIAL INPROCESS CHECKS: (Appearance, Uniformity of Weight, Thickness & Diameter):

Balance I.D. No.: PIPAL009

Date: 23/05/2020 Shift: G Time: 17:12

LHS					RHS				
Sr. No.	Appearance *	Weight (in mg)	Thickness (in mm)	Diameter (in mm)	Sr. No.	Appearance *	Weight (in mg)	Thickness (in mm)	Diameter (in mm)
1	OK	139	3.32	6.81	1	OK	141	3.28	6.80
2	OK	139	3.31	6.82	2	OK	140	3.28	6.81
3	OK	140	3.32	6.83	3	OK	139	3.29	6.84
4	OK	139	3.34	6.81	4	OK	138	3.31	6.83
5	OK	141	3.32	6.82	5	OK	141	3.32	6.82
6	OK	142	3.33	6.81	6	OK	142	3.31	6.81
7	OK	141	3.29	6.82	7	OK	141	3.29	6.82
8	OK	138	3.32	6.81	8	OK	139	3.32	6.81
9	OK	138	3.39	6.83	9	OK	139	3.29	6.82
10	OK	141	3.31	6.81	10	OK	144	3.27	6.81
11	OK	142	3.32	6.84	11	OK	143	3.31	6.81
12	OK	141	3.32	6.82	12	OK	142	3.30	6.84
13	OK	139	3.31	6.84	13	OK	141	3.32	6.84
14	OK	141	3.32	6.81	14	OK	143	3.31	6.84
15	OK	139	3.28	6.82	15	OK	143	3.31	6.81
16	OK	138	3.29	6.81	16	OK	141	3.31	6.82
17	OK	141	3.29	6.81	17	OK	142	3.32	6.81
18	OK	142	3.29	6.84	18	OK	141	3.32	6.81
19	OK	141	3.31	6.81	19	OK	143	3.31	6.84
20	OK	140	3.31	6.82	20	OK	142	3.32	6.82
21	OK	143	3.32	6.81	21	OK	139	3.29	6.84
22	OK	142	3.32	6.81	22	OK	141	3.27	6.81
23	OK	139	3.29	6.84	23	OK	142	3.28	6.82
24	OK	138	3.21	6.83	24	OK	141	3.29	6.84
25	OK	138	3.29	6.84	25	OK	139	3.27	6.81
26	OK	141	3.31	6.82	26	OK	138	3.29	6.84
27	OK	142	3.29	6.81	27	OK	141	3.31	6.81
28	OK	141	3.29	6.82	28	OK	142	3.22	6.82
29	OK	140	3.31	6.81	29	OK	141	3.31	6.81
30	OK	141	3.32	6.84	30	OK	140	3.29	6.84

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

Done by Production Sign/Date: N. Bal 23/05/2020

Checked by IPQA Sign/Date: N. Bal 23/05/2020

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka	N. Bal	P. Bal		
Date	21/05/2020	21/05/2020	22/05/2020		

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.		Page 15 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg		BMR. No.: BMR/T/107-01 Batch No.: GF 200502 Customer: Generic Health Care Pvt. Ltd.

10.6 COMPRESSION SPECIFICATION AND PARAMETERS: Date: 21/05/2020 Shift: 6 Time: 17:22

Parameters	Instrument used	Equip ID No.	Observations of LHS		Observations of RHS		Limits
			Min	Max	Min	Max	
Appearance	Visual	NA	OK		OK		White to off white coloured, circular shaped, biconvex, uncoated tablet with breakline on one side and plain on other side
Group Weight	Electronic Balance	QA/BAL/009	2.797 gm		2.809 gm		2.800 g ± 3.0 % (2.716 gm to 2.884 gm)
Average weight	Electronic Balance		139.85 mg		140 mg		140.000 mg ± 3.0 % (135.800 mg – 144.200 mg)
Individual weight	Electronic Balance		138 mg	142 mg	mg 139	142 mg	140.00 mg ± 5.0 % (133.000 mg – 147.000 mg)
Uniformity of weight	Electronic Balance		-1.30 %	1.54 %	0.71 %	1.40 %	
Thickness	Vernier Caliper	QA/VEE/001	3.29 mm	3.32 mm	3.27 mm	3.34 mm	3.30 mm ± 0.2 (3.10 mm – 3.50 mm) (To be established)
Hardness	Hardness Tester	QA/HRT/001	4	4.5	5	5	NLT 4.0 Kg (To be established)
Friability	Friabilator	QA/FRT/001	0.02%		0.03%		NMT 1% w/w
DT	DT Apparatus	QA/DTA/004	03 mins 47 secs		03 mins 39 secs		NMT 15 Minutes

M/C set done by Operator Name: Vetrin..... M/C set up Checked by Prod. Sign/Date: N. Bal 23/05/2020
 M/C Speed: 2.0 RPM (To be Established)

Compression Force: 7.0 kg

Initial Setting Tablets Destroyed by: Sign: P. K. Date: 21/05/2020 Quantity in Kg.: 0.040 Quantity in No.: 285.....

Approval for Batch Compression by IPQA: Sign: P. K. Date: 21/05/2020 Time: 17:35

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	P. K.	P. K.	J. K.
Date	21/05/2020	21/05/2020	22/05/2020	22/05/2020





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

Page 16 of 33

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-01

Batch No.: GTF 200 502

Customer:

Generic Health Care Pvt. Ltd.

Date: 23/05/2020

[illegible]

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	[Signature]	P. H. [Signature]	[Signature]
Date	21/05/2022	21/05/2022	21/05/2022	21/05/2022

UNCONTROLLED COPY



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

Page 17 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg.

BMR. No.: BMR/T/107-01

Batch No.: G7F 200502

Customer:

Generic Health Care Pvt. Ltd.

10.8 IN-PROCESS CHECKS: (For Production)

Date:.....*NA*.....

[illegible]

~~N. Bay~~
23 Jan 1900

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	21/05/2020	21/05/2020	21/05/2020	21/05/2020

UNCONTROLLED

UNCONTROLLED COPY



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

Page 18 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-01

Batch No.: GF200 502

Customer:

Generic Health Care Pvt. Ltd.

10.9 IN-PROCESS CHECKS: (For Production)

Date:.....NA.....

[illegible]

u Bal
23/01/20

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ke			
Date	21/05/2020	21/05/2020	21/05/2020	

UNCONTROLLED COPY



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

Page 19 of 33

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-01

Batch No.: GF 200 502

Customer:

Generic Health Care Pvt. Ltd.

10.10 IN-PROCESS CHECKS: (For IPQA)

Date: 24/05/2020

[illegible]

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ke	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	21/05/2020	21/05/2020	21/05/2020	21/05/2020

UNCONTROLLED

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.		Page 20 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMR/T/107-01 Customer:	Batch No.: GF 200 502 Generic Health Care Pvt. Ltd.

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

Date: 23/05/2020		Time: 17:25		Shift: 6							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	140	8	138	15	141	1	139	8	141	15	141
2	141	9	139	16	140	2	142	9	142	16	142
3	140	10	139	17	141	3	141	10	140	17	140
4	141	11	141	18	140	4	140	11	141	18	141
5	140	12	142	19	139	5	141	12	140	19	140
6	140	13	140	20	139	6	140	13	142	20	140
7	141	14	141			7	141	14	140		
Balance ID No.: PD/BAL/009				M/C Speed: 25 RPM							
Group weight of 20 Tablets: 2786 g. Avg. wt: 139.3 mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight: 138 mg Max. weight: 142 mg				Group weight of 20 Tablets: 2782 g. Avg. wt: 139.1 mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight: 139 mg Max. weight: 142 mg							
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)				03min 37sec		03min 17sec		Equipment ID No.: QA/DTA/ 002			
Done by: N. Bal 23/05/2020 (Production)											
Date: 23/05/2020		Time: 19:25		Shift: 6							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	141	8	142	15	142	1	139	8	140	15	142
2	141	9	143	16	140	2	140	9	141	16	140
3	140	10	142	17	141	3	141	10	140	17	142
4	142	11	141	18	141	4	142	11	141	18	140
5	141	12	140	19	140	5	140	12	140	19	140
6	140	13	141	20	142	6	141	13	141	20	142
7	140	14	142			7	142	14	142		
Balance ID No.: PD/BAL/009				M/C Speed: 25 RPM							
Group weight of 20 Tablets: 2810 g. Avg. wt: 140.5 mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight: 140 mg Max. weight: 143 mg				Group weight of 20 Tablets: 2807 g. Avg. wt: 140.3 mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight: 139 mg Max. weight: 142 mg							
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				0.00%		0.02%		Equipment ID No.: QA/FRT/ 001			
Disintegration Time (Limit - NMT 15 minutes)				03min 17sec		04min 07sec		Equipment ID No.: QA/DTA/ 002			
Done by: N. Bal 23/05/2020 (Production)											

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka	[Signature]	[Signature]	[Signature]	
Date	21/05/2020	21/05/2020	21/05/2020	21/05/2020	

UNCONTROLLED COPY

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.

Page 21 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-01

Batch No.: GF 200 502

Customer:

Generic Health Care Pvt. Ltd.

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

Date: 23/05/2020		Time: 20:25		Shift: A	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	140	8	139	15	140
2	141	9	140	16	142
3	140	10	141	17	140
4	140	11	142	18	139
5	141	12	140	19	140
6	142	13	141	20	142
7	140	14	142		
Balance ID No.: PD/BAL/009			M/C Speed: 25 RPM		
Group weight of 20 Tablets: 2.793 g. Avg. wt: 139.8 mg			Group weight of 20 Tablets: 2.798 g. Avg. wt: 140 mg		
Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)			Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)		
Min weight: 139 mg Max. weight: 142 mg			Min weight: 140 mg Max. weight: 142 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		LHS	RHS	Equipment ID No.: QA/FRT/001	
Disintegration Time (Limit - NMT 15 minutes)		03 min 37 sec	03 min 47 sec	Equipment ID No.: QA/DTA/002	
Done by: N. Bal (Production)					
Date: 23/05/2020		Time: 22:20		Shift: B	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	140	8	140	15	142
2	141	9	142	16	140
3	141	10	140	17	140
4	140	11	141	18	141
5	142	12	141	19	142
6	140	13	140	20	140
7	142	14	142		
Balance ID No.: PD/BAL/009			M/C Speed: 25 RPM		
Group weight of 20 Tablets: 2.811 g. Avg. wt: 140.55 mg			Group weight of 20 Tablets: 2.796 g. Avg. wt: 139.83 mg		
Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)			Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)		
Min weight: 140 mg Max. weight: 142 mg			Min weight: 139 mg Max. weight: 142 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		LHS	RHS	Equipment ID No.: QA/FRT/001	
Disintegration Time (Limit - NMT 15 minutes)		07 min 29 sec	8 min 52 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.			
Date	21/05/2020	21/05/2020	22/05/2020	21/05/2020



 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 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product Amloperin 5mg/5mg	BMR. No.: BMR/T/107-01		Batch No.: GF 200502
	Customer:		Generic Health Care Pvt. Ltd.

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

Date: 23/05/2020		Time: 23:20		Shift: G							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	139	8	140	15	141	1	139	8	141	15	140
2	139	9	140	16	142	2	140	9	141	16	141
3	141	10	141	17	140	3	141	10	142	17	141
4	142	11	141	18	141	4	141	11	140	18	142
5	142	12	142	19	141	5	142	12	140	19	140
6	140	13	141	20	142	6	140	13	141	20	143
7	140	14	141			7	141	14	142		
Balance ID No.: 991BAL1009				M/C Speed: 25 RPM							
Group weight of 20 Tablets: 2787 g. Avg. wt: 139.35 mg				Group weight of 20 Tablets: 2793 g. Avg. wt: 139.65 mg							
Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)				Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)							
Min weight: 141 mg Max. weight: 142 mg				Min weight: 139 mg Max. weight: 143 mg							
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.02%		0.04%		Equipment ID No.: QA/FRT/ 001					
Disintegration Time (Limit - NMT 15 minutes)		02 min 30 sec		03 min 12 sec		Equipment ID No.: QA/DTA/ 002					
Done by: N. Bal (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: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)				Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)							
Min weight: mg Max. weight: mg				Min weight: mg Max. weight: mg							
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	21/05/2020	21/05/2020	22/05/2020	22/05/2020	





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 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-01

Batch No.: *GF 200502*

Customer:

Generic Health Care Pvt. Ltd.

10.14 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 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: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)				Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 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: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)				Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 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.	<i>L. Ka</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	21/05/2020	21/05/2020	22/05/2020	22/05/2020





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 24 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMRT/107-01

Batch No.: GF 200502

Customer:

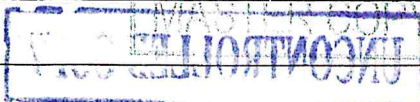
Generic Health Care Pvt. Ltd.

10.15 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 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: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)				Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 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: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)				Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 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)							

10/12/20
23/10/20

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	1. Ka	Rabul	23/10/20	J. M
Date	21/05/2020	21/05/2020		21/5/20



 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 25 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product Amloperin 5mg/5mg	BMR. No.: BMR/T/107-01		Batch No.: <i>CTF 200502</i>
	Customer:		Generic Health Care Pvt. Ltd.

10.16 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 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: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight. :..... mg Max. weight:.....mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 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: RRM			
Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight. :..... mg Max. weight:.....mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 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.	<i>L. Ka</i>	<i>P. K. S. S. S. S.</i>	<i>P. K. S. S. S. S.</i>	<i>P. K. S. S. S. S.</i>	
Date	21/05/2020	21/05/2020	22/05/2020	22/05/2020	

UNCONTROLLED COPY

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.		Page 26 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product Amloperin 5mg/5mg	BMR. No.: BMR/T/107-01		Batch No.: GF200502
	Customer:		Generic Health Care Pvt. Ltd.

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

Date:	23/05/2020	Time:	14:15	Shift:	Morning						
LHS: Individual weight of 20 tablets (in mg).					RHS: Individual weight of 20 tablets (in mg).						
1	141	8	140	15	140	1	141	8	139	15	141
2	141	9	140	16	139	2	141	9	139	16	140
3	140	10	141	17	139	3	139	10	139	17	139
4	139	11	139	18	140	4	140	11	141	18	138
5	139	12	139	19	141	5	139	12	140	19	138
6	140	13	140	20	141	6	141	13	140	20	139
7	141	14	141			7	140	14	139		

Balance ID No.: QA/MA/1002	M/C Speed: 25 RPM
Group weight of 20 Tablets: 2850.00 g. Avg. wt: 142.50 mg	Group weight of 20 Tablets: 2795.00 g. Avg. wt: 139.75 mg
Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)	Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)
Min weight: 139.00 mg Max. weight: 141.00 mg	Min weight: 139.00 mg Max. weight: 141.00 mg

	LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	0.00%	0.01%	Equipment ID No.: QA/FRT/001
Disintegration Time (Limit - NMT 15 minutes)	03 Min 34 Sec	03 Min 45 Sec	Equipment ID No.: QA/DTA/002

Done by: K. Anil Kumar (IPQA) 100 RPM 10'

Date: 24/05/2020					Time: 13:05					Shift: Morning									
LHS: Individual weight of 20 tablets (in mg).										RHS: Individual weight of 20 tablets (in mg).									
1	139	8	139	15	140	1	139	8	140	15	139								
2	138	9	139	16	139	2	138	9	140	16	140								
3	140	10	140	17	138	3	140	10	139	17	141								
4	139	11	140	18	140	4	140	11	139	18	139								
5	140	12	138	19	139	5	139	12	140	19	139								
6	140	13	139	20	140	6	139	13	141	20	140								
7	139	14	140			7	138	14	140										

Balance ID No.: QA/MA/1002	M/C Speed: 10 RPM
Group weight of 20 Tablets: 2785.00 g. Avg. wt: 139.25 mg	Group weight of 20 Tablets: 2795.00 g. Avg. wt: 139.75 mg
Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)	Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)
Min weight: 138.00 mg Max. weight: 140.00 mg	Min weight: 138.00 mg Max. weight: 141.00 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)	03 Min 49 Sec	03 Min 51 Sec	Equipment ID No.: QA/DTA/002

Done by: K. Anil Kumar (IPQA)

Prepared by:	Checked by:	Approved By:
Dept. Production	Production Quality Assurance	Head Quality Assurance
Sign. L. K.	P. N. S.	J. M.
Date 21/05/2020	21/05/2020	21/05/2020

SAI PRIMUS LIFE BIOTECH PVT LTD

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.

Page 27 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-01

Batch No.: 07F-200-502

Customer:

Generic Health Care Pvt. Ltd.

10.18 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours): High RPM: 25

Date:	24/05/2020	Time:	20:25	Shift:	(Morning)						
LHS: Individual weight of 20 tablets (in mg).						RHS: Individual weight of 20 tablets (in mg).					
1	140	8	140	15	139	1	141	8	141	15	141
2	138	9	139	16	140	2	140	9	141	16	140
3	138	10	139	17	139	3	139	10	140	17	139
4	139	11	140	18	140	4	140	11	139	18	140
5	140	12	140	19	139	5	139	12	138	19	139
6	139	13	139	20	140	6	140	13	139	20	141
7	140	14	140			7	139	14	140		

Balance ID No.: QA/BAZ/002

M/C Speed: 25 RPM

Group weight of 20 Tablets:.....21.128...g. Avg.
wt:.....139.1...mg

Group weight of 20 Tablets:.....21.195...g. Avg.
wt:.....139.7...mg

Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)

Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)

Min weight:138... mg Max. weight:140.....mg

Min weight:139... mg Max. weight:141.... mg

	LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	0.01%	0.00%	Equipment ID No.: QA/FRT/001
Disintegration Time (Limit - NMT 15 minutes)	03 Min 14 Sec	03 Min 56 Sec	Equipment ID No.: QA/DTA/002

Done by:K. Jayalalitha.....(IPQA)

Date: 24/05/2020					Time: 20:45					Shift: (Morning)				
LHS: Individual weight of 20 tablets (in mg).						RHS: Individual weight of 20 tablets (in mg).								
1	141	8	139	15	141	1	140	8	138	15	139			
2	141	9	141	16	141	2	141	9	139	16	142			
3	140	10	140	17	140	3	141	10	140	17	140			
4	139	11	141	18	141	4	140	11	139	18	141			
5	141	12	140	19	139	5	139	12	141	19	140			
6	141	13	141	20	138	6	139	13	140	20	140			
7	140	14	139			7	141	14	141					

Balance ID No.: QA/BAZ/002

M/C Speed: 25 RPM

Group weight of 20 Tablets:.....21.204...g. Avg.
wt:.....140.....mg

Group weight of 20 Tablets:.....21.205...g. Avg.
wt:.....140.....mg

Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)

Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)

Min weight:138... mg Max. weight:141.....mg

Min weight:139.... mg Max. weight:141.... mg

	LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	0.02%	0.00%	Equipment ID No.: QA/FRT/001
Disintegration Time (Limit - NMT 15 minutes)	03 Min 55 Sec	04 Min 04 Sec	Equipment ID No.: QA/DTA/002

Done by:K. Jayalalitha.....(IPQA)

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka	K. Jayalalitha	P. A. Jayalalitha	S. Anand	
Date	21/05/2020	21/05/2020	22/05/2020	22/05/2020	

UNCONTROLLED COPY

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.		Page 28 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg		BMR. No.: BMR/T/107-01 Batch No.: 61F200502 Customer: Generic Health Care Pvt. Ltd.

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

Date: 22/05/2020		Time: 11:45		Shift: General	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	128	8	141	15	141
2	129	9	140	16	140
3	140	10	142	17	140
4	141	11	143	18	141
5	141	12	140	19	140
6	129	13	143	20	129
7	140	14	141		
Balance ID No.: QA/18A2/1002			M/C Speed: 25 RPM		
Group weight of 20 Tablets: ... 2800 ... g. Avg. wt: ... 140 ... mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight: ... 138 ... mg Max. weight: ... 142 ... mg			Group weight of 20 Tablets: ... 2818 ... g. Avg. wt: ... 140 ... mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight: ... 138 ... mg Max. weight: ... 141 ... mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			LHS	RHS	Equipment ID No.: QA/FRT/004
Disintegration Time (Limit - NMT 15 minutes)			03 Min 46 Sec	03 Min 52 Sec	Equipment ID No.: QA/DTA/002
Done by: P. J. 22/05/2020 (IPQA)					
Date: 22/05/2020		Time: 12:25		Shift: General	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	129	8	141	15	140
2	140	9	140	16	141
3	141	10	141	17	140
4	129	11	139	18	138
5	141	12	141	19	129
6	140	13	138	20	140
7	142	14	138		
Balance ID No.: QA/18A2/1002			M/C Speed: 25 RPM		
Group weight of 20 Tablets: ... 2819 ... g. Avg. wt: ... 140 ... mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight: ... 139 ... mg Max. weight: ... 142 ... mg			Group weight of 20 Tablets: ... 2806 ... g. Avg. wt: ... 140 ... mg Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg) Min weight: ... 139 ... mg Max. weight: ... 142 ... mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			LHS	RHS	Equipment ID No.: QA/FRT/004
Disintegration Time (Limit - NMT 15 minutes)			03 Min 32 Sec	03 Min 42 Sec	Equipment ID No.: QA/DTA/002
Done by: P. J. 22/05/2020 (IPQA)					

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. K.	3a. [Signature]	P. J. [Signature]	[Signature]	
Date	21/05/2020	21/05/2020	22/05/2020	22/05/2020	

UNCONTROLLED COPY

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.		Page 29 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product Amloperin 5mg/5mg	BMR. No.: BMR/T/107-01		Batch No.: GTF-200 508
	Customer:		Generic Health Care Pvt. Ltd.

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

Date: 22/05/2020					Time: 20:50					Shift: 6:00-4:30				
LHS: Individual weight of 20 tablets (in mg).					RHS: Individual weight of 20 tablets (in mg).									
1	140	8	139	15	139	1	139	8	141	15	140			
2	141	9	139	16	140	2	140	9	141	16	139			
3	141	10	140	17	139	3	141	10	141	17	141			
4	141	11	141	18	141	4	139	11	139	18	141			
5	140	12	141	19	139	5	139	12	141	19	139			
6	139	13	141	20	140	6	140	13	140	20	140			
7	141	14	139			7	141	14	140					

Balance ID No.: QA 1701/100	M/C Speed: 25 RPM
Group weight of 20 Tablets:.....g. Avg. wt:.....mg	Group weight of 20 Tablets:.....g. Avg. wt:.....mg
Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)	Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)
Min weight:mg Max. weight:mg	Min weight:mg Max. weight:mg

	LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	0.02%	0.01%	Equipment ID No.: QA/FRT/004
Disintegration Time (Limit - NMT 15 minutes)	03 Min 49 Sec	03 Min 54 Sec	Equipment ID No.: QA/DTA/003

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: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)	Limit: 140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 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. Ka				
Date	21/05/2020	21/05/2020	22/05/2020		

UNCONTROLLED COPY

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.		Page 30 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg		BMR. No.: BMRT/107-01 Batch No.: <u>GIF 200 502</u> Customer: Generic Health Care Pvt. Ltd.

10.21 WEIGHING RECORD OF COMPRESSED TABLETS:

Cont. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Cont. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net Weight (Kg)	Cont. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)
1	17.500	2.300	15.200	5				9			
2	17.530	2.300	15.230	6				10			
3	29.020	2.300	26.720	7				11			
4	*28.830	2.300	*26.530	8				12			
28.620			26.320								
										Total Net Weight	
Weighed by Vetri				Checked by Sign./ Date: P. 23/05/2020				Verified by IPQA Sign./ Date: P. 23/05/2020			

10.22 RECONCILIATION (COMPRESSION STAGE):

Average weight of Uncoated Tablet: 139.77 mg

1.0	Standard Batch size	:	84.000 Kg	6,00,000 Nos.
2.0	Actual weight of Lubricated granules	:	...83.700Kg	599141 Nos.
3.0	Weight of compressed tablets	:	83.470Kg	597495 Nos.
4.0	Rejection during Compression@	:	0.070.Kg.	
5.0	In-process samples of all stages			
	A IPQA Samples	:	0.045.Kg.	
	B QC Samples	:	0.05.Kg.	
	C Validation Samples	:	0.100.Kg.	
6.0	Total in process samples: (A + B + C)	:	0.160...Kg.	
7.0	Total: (3.0 + 6.0)	:	83.630...Kg.	*58598640 Nos.
8.0	Yield {7.0 / 1.0 x 100}*	:		99.77 %

* 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: ...P. 23/05/2020 Checked by IPQA Sign/Date: ...P. 23/05/2020

Test request form raised by Prod Sign/Date: ...P. 23/05/2020

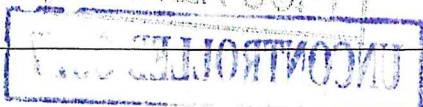
Test request form received by IPQA Sign/Date: ...P. 23/05/2020

11.0 RELEASE FOR INSPECTION:

Reconciliation checked and Uncoated tablets released for inspection

IPQA Sign.....P. 23/05/2020 Date:.....24/05/2020.....

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance?	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>P. 23/05/2020</u>	<u>P. 23/05/2020</u>	<u>P. 23/05/2020</u>
Date	<u>24/05/2020</u>	<u>21/05/2020</u>	<u>22/05/2020</u>	<u>22/05/2020</u>





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 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-01

Batch No.: GTF 200 50 2

Customer:

Generic Health Care Pvt. Ltd.

12.0 INSPECTION LINE CLEARANCE:

Date/Shift/Time: 26/05/2020/14:00 108

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 INB/001	PD IMED/001	Inspection - 01
Previous product	Obigocarefortect		
Batch No.	763 SPL 2004F		
Cleaned by	Nehru		
Checked by Production Sign/Date:	N. Bal 26/05/2020		
Verified by IPQA Sign/Date:	R. 26/05/2020		

ENVIRONMENTAL CONDITIONS:		Date: 26/05/2020 Time: 14:02			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	23 °C	N. Bal	RA			
	Relative Humidity % Limit: NMT 60%	52%	N. Bal	RA			
	Differential Pressure (NLT 10 Pascal)	NA	N. Bal	RA			4.5

APPROVAL FOR INSPECTION:

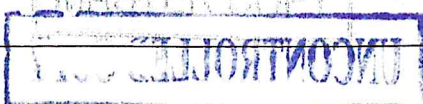
Production Sign/Date: N. Bal 26/05/2020

Line Clearance IPQA Sign. / Date: R. 26/05/2020

Start Time/Date: 14:05 / 26/05/2020

End Time/Date: 17:10 / 26/05/2020

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka	3a	P. 26/05/2020	P. 26/05/2020	
Date	21/05/2020	21/05/2020	21/05/2020	21/05/2020	



 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 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product Amloperin 5mg/5mg	BMR. No.: BMR/T/107-01		Batch No.: GTF 200 502
	Customer:		Generic Health Care Pvt. Ltd.

13.0 INSPECTION PROCESS

13.1 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.

13.2 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/...NA...								Checked by Production	Verified By IPQA	
		Ferrous (0.3 mm)		Stainless steel (0.5 mm)		Non-Ferrous (0.3 mm)		Non-metallic				Result
26/05/2020 14:06	1	✓	N/A	✓	N/A	✓	N/A	✓	N/A	Pass	Pass	Pass
	2	✓	N/A	✓	N/A	✓	N/A	✓	N/A	Pass	Pass	Pass
	3	✓	N/A	✓	N/A	✓	N/A	✓	N/A	Pass	Pass	Pass
26/05/2020 17:00	1	✓	N/A	✓	N/A	✓	N/A	✓	N/A	Pass	Pass	Pass
	2	✓	N/A	✓	N/A	✓	N/A	✓	N/A	Pass	Pass	Pass
	3	✓	N/A	✓	N/A	✓	N/A	✓	N/A	Pass	Pass	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.

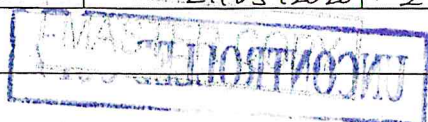
..... (To be filled by Production)

Note: Take QA Approval before proceeding to next stage

13.3 TABLETS VISUAL INSPECTION RECORD:

Date	Container No		Time		Total Quantity Rejected	Tablet Inspection Done by/Date	Checked by/Date
	From	To	Started	Completed			
26/05/2020	01	04	14:05	17:10	1146	Sathy, Santhi	26/05/2020

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka				
Date	21/05/2020	21/05/2020	21/05/2020		



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 33 of 33

BATCH MANUFACTURING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BMR. No.: BMR/T/107-01

Batch No.: 61 F 200508

Customer:

Generic Health Care Pvt. Ltd.

13.4 WEIGHING RECORD OF INSPECTED TABLETS:

Cont. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Cont. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net Weight (Kg)	Cont. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)
1	17.480	2.300	15.180	5	17.480	2.300	15.180	9	17.480	2.300	15.180
2	17.460	2.300	15.160	6	17.460	2.300	15.160	10	17.460	2.300	15.160
3	29.000	2.300	26.700	7	29.000	2.300	26.700	11	29.000	2.300	26.700
4	28.600	2.300	26.300	8	28.600	2.300	26.300	12	28.600	2.300	26.300
Total Net Weight										83.310	

Weighed by: *me* Checked by Sign./ Date: *26/05/2020* Verified by IPQA Sign./ Date: *27/05/2020*

13.5 RECONCILIATION: (INSPECTION OF TABLETS)

1.0	Theoretical weight of Tablets	:	84.000 kg	6,00,000 No's
2.0	Tablets transferred for Inspection	:	83.470 kg	597495 No's
3.0	Rejected Tablets	:	* 83.30.160 kg	1146 No's
4.0	Total weight of good Tablets	:	83.310 kg	596349 No's
5.0	*Yield = $\frac{4.0}{1.0} \times 100$	:		99.39 %

* Actually yield will be calculated after 3 validation batches

Total rejects destroyed: 6.160 Kg.

Rejected materials should be destroyed in the presence of QA.

Done by Packing sign/Date: *26/05/2020*Checked by IPQA sign/Date: *27/05/2020*

14.0 RELEASE FOR PACKING:

BMR reviewed by IPQA Sign/Date : *26/05/2020*BMR Released for packing by QA Head Sign/Date: *27/05/2020*

15.0 BMR REVIEW DETAILS:

Reviewed by	Name	Sign./Date
Production Executive	<i>Sathishkumar P</i>	<i>26/05/2020</i>
QA Executive	<i>Ram Kumar</i>	<i>26/05/2020</i>
Production Assistant Manager/ HOD	<i>BALASUBRAMANIAN B</i>	<i>26/05/2020</i>
QA Manager/ HOD	<i>Stephen A</i>	<i>27/05/2020</i>

16.0 REVISION HISTORY:

Sr. No.	Document No.	Reason for Revision	Supersedes No.
1	BMR/T/107-00	New Document	Nil
2	BMR/T/107-01	Manufacturing Formula revised to improve the granules flow property. Change Control No. CC/20/006	BMR/T/107-00

Prepared by:	Checked by:	Approved By:
Dept. Production	Production Quality Assurance	Head Quality Assurance
Sign. <i>L. Ko</i>	<i>21/05/2020</i>	<i>21/05/2020</i>
Date <i>21/05/2020</i>	<i>21/05/2020</i>	<i>21/05/2020</i>

MASTER COPY

UNCONTROLLED COPY