

STABILITY BATCH

VALIDATION BATCH

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 37
SAI PRIMUS LIFE BIOTECH PVT LTD	BATCH MANUFACTURING RECORD	Product Code: B05
Product	BONCIPRO 500	Batch Size: 3,00,000 Tablets
		BMR. No.: BMR/T/305-00
		Batch No.: <u>G1822068</u>
		Customer: Generic Health Care Pvt. Ltd.

BATCH MANUFACTURING RECORD COVER SHEET

PRODUCT NAME : BONCIPRO 500

GENERIC NAME : Ciprofloxacin Tablets BP 500 mg

LABEL CLAIM : Each film coated tablet contains:
Ciprofloxacin Hydrochloride BP
Equivalent to Ciprofloxacin 500 mg
Colour: Approved Colour used.

MFR No. / Reference Document No. : MFR/T/177-00

BMR No. : BMR/T/305-00

REVISION No. : 00

SUPERSEDES No. : NIL

BMR EFFECTIVE BATCH NUMBER/DATE : G1822068 / 01/04/2022

MFG. LIC No. : PON/DRUGS/21 14 4376

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

BMR ISSUED BY/DATE (QA) : [Signature] 01/04/22

BMR CHECKED & RECEIVED BY/DATE (PRODUCTION) : L. Ka 01/04/2022

SHELF LIFE : 36 Months

BATCH SIZE : 3,00,000 Tablets (220.800 Kg)

MFG. DATE: 04/02/22 : EXP. DATE: 03/2025

RECOVERY ADDITION RECORD

BATCH NO	MFG	EXP	QUANTITY	REVISED BATCH SIZE
		<u>NA</u>		

ALLOTTED BY: [Signature] 01/04/22 : COUNTER CHECKED BY: [Signature] 01/04/22

QA SIGN/DATE: : QA SIGN/DATE:

DATE OF COMMENCEMENT: 04/04/22 : DATE OF COMPLETION: 12/04/2022

RELEASED QUANTITY OF TABLETS FOR PACKING : 292707 Nos

RELEASE FOR PACKING STAGE : [Signature] 12/04/22

HEAD OF QA SIGN/DATE:

This BMR contains 37 Pages + 05 Additional Pages

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>P. Anand</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>

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	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: <u>01822068</u> Generic Health Care Pvt. Ltd.

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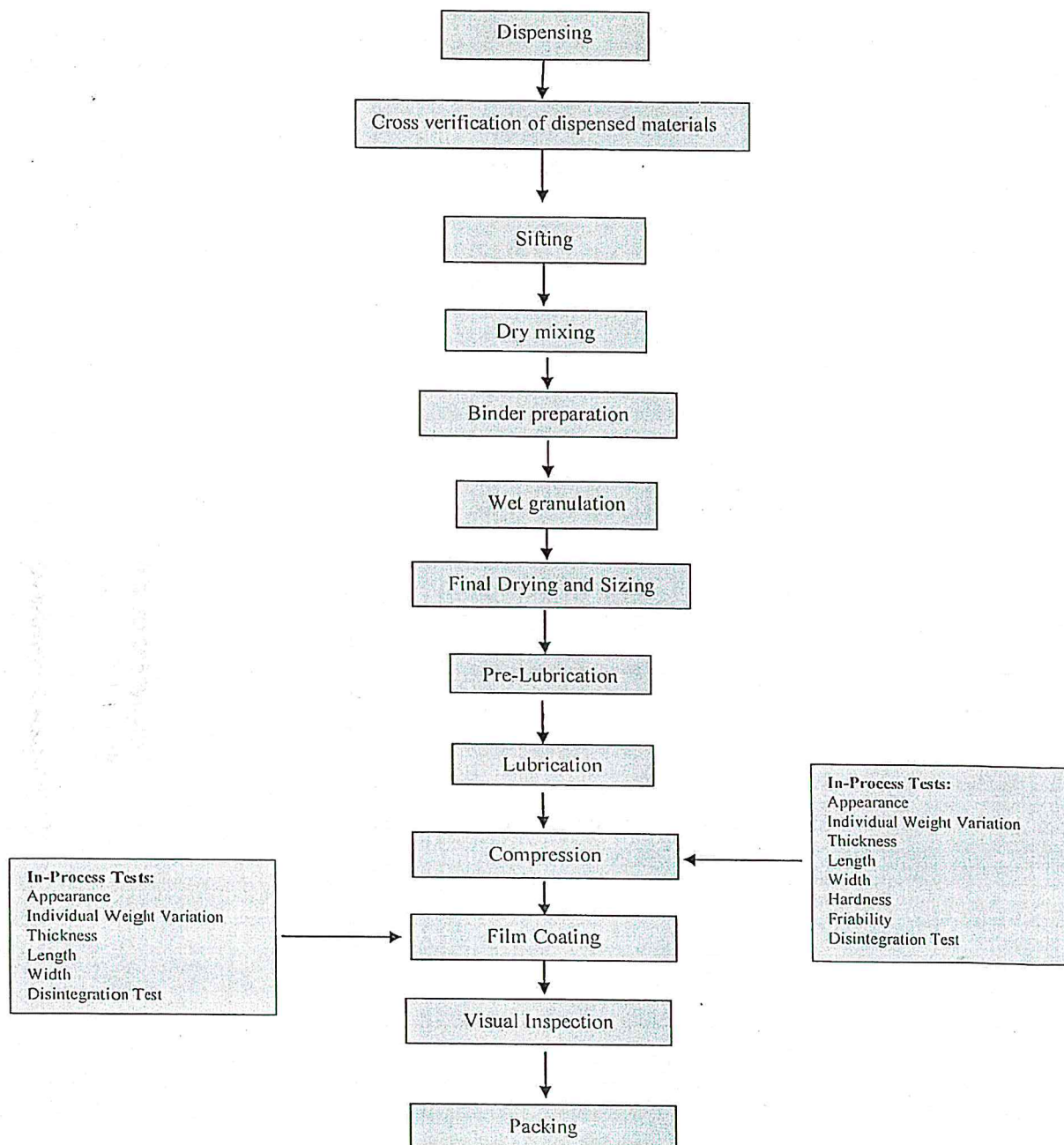
Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>P. Anand</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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	BATCH MANUFACTURING RECORD	Product Code: B05	Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00	Batch No.: 61822068
		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	P. Anub	V. Anub	V. Anub
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
	Product BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: 618 22068 Generic Health Care Pvt. Ltd.

3.0 INDENT OF ACTIVE PHARMACEUTICAL INGREDIENTS & EXCIPIENTS:

Sr. No.	Name of the Ingredient	Spec.	Item Code	Quantity/ Tablets (mg)	Std. quantity per 3,00,000 tablets (kg)	OA/ PL (%)	Req. quantity per 3,00,000 tablets (kg)
Dry mixing material:							
1	Ciprofloxacin Hydrochloride*	BP	RAI/SP/C015	582.200	174.660	-	174.660
2	Microcrystalline cellulose PH102 **	BP	REX/SP/M010	108.050	32.415	-	32.415
Binder Material:							
3	Purified Water	BP	NA	q.s.	83.000	-	83.000
Theoretical Weight of Dried Granules				690.250	207.075	-	207.075
Lubrication Material:							
4	Sodium Stach Glycollate	BP	REX/SP/S004	21.000	6.300	-	6.300
5	Colloidal Silicon Dioxide	BP	REX/SP/C022	1.750	0.525	-	0.525
6	Magnesium Stearate	BP	REX/SP/M011	7.000	2.100	-	2.100
Theoretical Weight of the Lubricated granules				720.000	216.000	-	216.000
Theoretical weight of Compressed tablet				720.000	216.000	-	216.000
Coating Material:							
7	Hydroxy Propyl Methyl Cellulose (6 cps)	BP	REX/SP/H016	10.800	3.240	25	4.050
8	Titanium Dioxide	BP	REX/SP/T002	1.200	0.360	25	0.450
9	Ponceau 4R Lake	IHS	REX/SP/P006	0.600	0.180	25	0.225
10	Purified Talc	BP	REX/SP/P017	1.000	0.300	25	0.375
11	Polyethylene Glycol 6000	BP	REX/SP/P003	2.400	0.720	25	0.900
12	Purified Water	BP	NA	q.s.	42.500	-	42.500
Theoretical weight of Coated tablet^s				736.000	220.800	-	220.800

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

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

\$ Average weight rounded off.

OA: Overages, PL: Process loss

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	P. Anil	V. Anil	V. Anil
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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SAI PRIMUS
LIFE BIOTECH PVT LTD

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

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BATCH MANUFACTURING RECORD

Product Code: B05

Batch Size: 3,00,000 Tablets

Product

BONCIPRO 500

BMR. No.: BMR/T/305-00

Batch No.: 41202062

Customer:

Generic Health Care Pvt. Ltd.

4.0 ASSAY AND LOD CALCULATIONS FOR CIPROFLOXACIN HYDROCHLORIDE:

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

Standard quantity of Ciprofloxacin Hydrochloride (A): 174.660 Kg

Standard quantity of Microcrystalline Cellulose PH 102 (B): 32.415 Kg

Calculation for Ciprofloxacin Hydrochloride:

1) Calculation for Single A. R. No. _____, Assay on dried basis: _____ w/w, LOD: _____ w/w
Exp. Date: _____

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

LOT I: _____ Kg, LOT II: _____ Kg

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

Actual Quantity (Kg) (D) = Standard quantity of Microcrystalline Cellulose PH 102 - Excess Calculated quantity of Ciprofloxacin Hydrochloride

= 32.415 Kg - _____ Kg

= _____ Kg/2. LOT I: _____ Kg, LOT II: _____ Kg

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

Sr. No.	A. R. No.	Available Qty. (Kg) (E)	Assay % w/w	LOD % w/w	Actual Qty. = $\frac{\text{Available Qty.} \times \text{Assay} \times (100 - \text{LOD})}{100 \times 100}$
1.	100/00044	50.000	99.24	5.205	46.789
Total Actual Quantity (F)					46.789

Calculation for Remaining Quantity Required (G):

Theoretical Qty. - Actual Quantity (F) = 127.871 Kg

AR. No.: 100/00045, Assay on dried basis: 100.24 w/w, LOD: 6.239 %w/w, Exp. Date: 09/02

Actual Quantity (Kg) (H) = $\frac{\text{Remaining qty. required (G)} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{127.871 \times 100 \times 100}{100 \times (100 - 6.239)} = 136.525 \text{ Kg.}$

Total Qty. of Ciprofloxacin Hydrochloride to be dispensed (I) = (E) + (H) = 186.525 Kg/2

LOT I: 93.262 Kg, LOT II: 93.262 Kg

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

Actual Quantity (Kg) (D) = Standard quantity of Microcrystalline Cellulose PH 102 - Excess Calculated quantity of Ciprofloxacin Hydrochloride

= 32.415 Kg - 11.865 Kg

= 20.550 Kg/2. LOT I: 10.275 Kg, LOT II: 10.275 Kg

Done By/On (QA):

Checked By/On (Production):

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	P. Arun		
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 6 of 37
	BATCH MANUFACTURING RECORD	Product Code: B05 BMR. No.: BMR/T/305-00 Customer:	Batch Size: 3,00,000 Tablets Batch No.: <u>G1822068</u> Generic Health Care Pvt. Ltd.
Product	BONCIPRO 500		

5.0 DISPENSING LINE CLEARANCE CHECKS

Date: 02/04/22 Time: 14:15

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

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

Equipment	Dispensing Booth	Weighing Balance	Area
ID No.	<u>ST 1DPB1002</u>	<u>ST 1BAC1008</u> <u>ST 1BAC1009</u>	<u>Dispensing Booth B</u>
Previous Product	<u>BONCIPRO - 250 mg</u>		
B. No.	<u>G18 22069</u>		
Cleaned by Sign/Date	<u>BHAVAN 02/04/22</u>		
Checked by Store Sign/Date	<u>S. Balu 02/04/22</u>		
Verified by IPQA Sign/Date	<u>R. 02/04/22</u>		

ENVIRONMENTAL CONDITIONS: Date: 02/04/22 Time: 14:25		Observation	Checked by Store Sign/Date	Verified by IPQA Sign/Date
(For Reference SOP No.: QAGN/011)				
Temperature (Limit: NMT 25°C)		23°C	MS 02/04/22	AK 02/04/22
Relative Humidity % (Limit: NMT 60%)		58%	MS 02/04/22	AK 02/04/22
Differential Pressure (NLT 10 Pascal)		11 Pascal	MS 02/04/22	AK 02/04/22
Differential Pressure across the booth Limit: 5 to 20 mm Water		12 mm	MS 02/04/22	AK 02/04/22

APPROVAL FOR DISPENSING BY IPQA: Sign: R Date: 02/04/2022

Dispensing start Time 14:35 End Time 15:35

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K</u>	<u>T. Anand</u>	<u>V. K</u>	<u>V. K</u>
Date	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>

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

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SAI PRIMUS
LIFE BIOTECH PVT LTD

BATCH MANUFACTURING RECORD

Product Code: B05

Batch Size: 3,00,000 Tablets

Product

BONCIPRO 500

BMR. No.: BMR/T/305-00

Batch No.: G1822068

Customer: Generic Health Care Pvt. Ltd.

5.1 Dispensing Weighing Sheet:

Balance ID: 2013AC1008

Date: 02/04/2022 Shift: C Time: 14:25

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 Checked by Production (Sign & Date)	Verified by IPQA (Sign & Date)
								Gross Wt.	Net Wt.				

LOT - I

Dry mixing material:

1	Ciprofloxacin Hydrochloride	BP	RAI/SP/C015	Kg	87.330	21.660	100044	25.260	0.260	25.000	02/04/22	02/04/22	02/04/22
2	Microcrystalline cellulose PH102	BP	REX/SP/M010	Kg	16.208	10.115	100044	10.115	0.200	10.215	02/04/22	02/04/22	02/04/22

Binder Material:

3	Purified Water	BP	NA	Kg	41.500	41.500	RA/20/0012	NA	NA	41.50	02/04/22	02/04/22	02/04/22
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LOT - II

Dry mixing material:

4	Ciprofloxacin Hydrochloride	BP	RAI/SP/C015	Kg	87.330	21.660	100045	25.260	0.260	25.000	02/04/22	02/04/22	02/04/22
5	Microcrystalline cellulose PH102	BP	REX/SP/M010	Kg	16.208	10.115	100045	10.115	0.200	10.215	02/04/22	02/04/22	02/04/22

Binder Material:

6	Purified Water	BP	NA	Kg	41.500	41.500	RA/20/0012	NA	NA	41.50	02/04/22	02/04/22	02/04/22
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Lubrication Material:

7	Sodium Stach Glycolate	BP	REX/SP/S004	Kg	6.300	6.300	RA/20/0012	6.300	0.060	6.300	02/04/22	02/04/22	02/04/22
8	Colloidal Silicon Dioxide	BP	REX/SP/C022	Kg	0.525	0.525	RA/20/0012	0.525	0.050	0.575	02/04/22	02/04/22	02/04/22
9	Magnesium Stearate	BP	REX/SP/M011	Kg	2.100	2.100	RA/20/0012	2.100	0.060	2.160	02/04/22	02/04/22	02/04/22

Prepared by:

Production

L. Ka

30/03/2022

Checked by:

Quality Assurance

Well

30/03/2022

Approved By:

Head Quality Assurance

VCA

30/03/2022

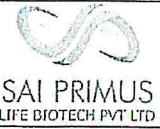
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	BATCH MANUFACTURING RECORD		Product Code: B05	
BONCIPRO 500		BMR. No.: BMR/T/305-00		Batch Size: 3,00,000 Tablets
Product		Customer:		Batch No.: G18 @ 2068
		Generic Health Care Pvt. Ltd.		

Sr. No.	Ingredients	Spec.	Item code	UOM	Std. Qty.	Req. Qty.	A.R No.	Issued Qty.		Weighed By Store (Sign & Date)	Checked By (IPQA) (Sign & Date)	Cross Checked by	
								Gross Wt.	Net Wt.			Checked by Production (Sign & Date)	Verified by IPQA(Sign & Date)
Coating Material:													
10	Hydroxy Propyl Methyl Cellulose (6 cps)	BP	REX/SP/H016	Kg	4.050	4.050	Rm4/6002	4.110	0.060	4.050	02/04/22	09/04/22	02/04/22
11	Titanium Dioxide	BP	REX/SP/T002	Kg	0.450	0.450	Rm4/600392	489.05	39.05	450.05	02/04/22	09/04/22	02/04/22
12	Ponceau 4R Lake	IHS	REX/SP/P006	Kg	0.225	0.225	Rm4/01251	265.05	10.05	275.05	02/04/22	09/04/22	02/04/22
13	Purified Talc	BP	REX/SP/P017	Kg	0.375	0.375	Rm4/600740	415.05	40.05	375.05	02/04/22	09/04/22	02/04/22
14	Polyethylene Glycol 6000	BP	REX/SP/P003	Kg	0.900	0.900	Rm4/600869	410.05	40.05	370.05	02/04/22	09/04/22	02/04/22
15	Purified Water	BP	NA	Kg	42.500	42.500	PW/22/60038	NA	NA	42.500	02/04/22	09/04/22	02/04/22

Prepared by:		Checked by:		Approved By:	
Dept.	Production		Quality Assurance		Head Quality Assurance
Sign.	L. Ka		Neel		
Date	30/03/2022		30/03/2022		30/03/2022

 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 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: <u>G1822068</u> Generic Health Care Pvt. Ltd.

6.0 GRANULATION LINE CLEARANCE CHECKS: Date/Shift: 04/04/2022 / 1 / II, 05/04/2022

Sr. No.	Checks	Time:	*Observations					
			17:20		07:00			
			Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty SS containers, polythene bags, Tags and documents of previous batch/product are removed.		✓	✓	✓	✓		
2	Check and ensure that Scrap from waste bin is removed and new polythene bag is put into it.		✓	✓	✓	✓		
3	Check and ensure that display, display stand, weighing balance are clean.		✓	✓	✓	✓		
4	Check and ensure that SS storage Cabinet and Drain point are clean.		✓	✓	✓	✓		
5	Check and ensure that absence of previous batch/product from area below machine		✓	✓	✓	✓		
6	Check and ensure that all equipment body and inside the vessel are clean		✓	✓	✓	✓		
7	Check and ensure that Tube light fixture, supply grills, riser grills and filters and electrical fixtures are clean		✓	✓	✓	✓		
8	Check and ensure that instruments to be used are within calibration due date and earthing connection.		✓	✓	✓	✓		
9	Check and ensure that daily records (Logbook, Balance, Temp. & RH) are updated and signed.		✓	✓	✓	✓		
10	Check and ensure that environment condition and record on BMR		✓	✓	✓	✓		
11	Check and ensure that rinse water is released from QC and attached the test request from (TRF)		NA	NA	NA	NA		
12	Equipment status is updated for Cleaned and Preventive maintenance.		✓	✓	✓	✓		

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

Equipment	Sifter	Multimill	RMG/Mass Mixer	FBD/Tray Drier	Area
EQP. ID No.	<u>Ppl VBS/002</u>	<u>Ppl MLM/002</u>	<u>Ppl RMG/001</u>	<u>Ppl FBD/001</u>	<u>Granulation-II</u>
Previous Product	<u>Boncipro-250</u>				
Batch No.	<u>G1822069</u>				
Cleaned by	<u>Jay Kumar</u>				
Checked by	<u>NA</u>				
Verified by	<u>NA</u>				

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: <u>04/04/22</u> Time: <u>17:21</u>			Date: <u>05/04/22</u> Time: <u>07:00</u>			Date: _____ Time: _____		
	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>NA</u>	<u>NA</u>	<u>23°C</u>	<u>NA</u>	<u>NA</u>			
RH % (NMT 60%)	<u>52%</u>	<u>NA</u>	<u>NA</u>	<u>52%</u>	<u>NA</u>	<u>NA</u>			
DP (NLT 10 Pascal)	<u>6 Pascal</u>	<u>NA</u>	<u>NA</u>	<u>10</u>	<u>NA</u>	<u>NA</u>			

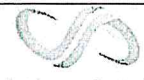
APPROVAL FOR SIFTING AND GRANULATION:

Production Sign/Date:	<u>NA</u>	<u>NA</u>	<u>NA</u>	<u>NA</u>
IPQA Sign/Date:	<u>NA</u>	<u>NA</u>	<u>NA</u>	<u>NA</u>
Start and End Time:	<u>17:23</u>	<u>22:00</u>	<u>07:25</u>	<u>08:20</u>

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>P. Anand</u>	<u>NA</u>	<u>NA</u>
Date	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 10 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
	Product: BONCIPRO 500	BMR. No.: BMRT/305-00 Customer:	Batch No.: 51822068 Generic Health Care Pvt. Ltd.

7.0 LOT - I: GRANULATION SIFTING INSTRUCTIONS AND SIFTING RECORD: Date: 04/04/2022 Shift: II

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	Vfd by
						From	To				
Dry mixing:											
1	Ciprofloxacin Hydrochloride	98.263	40#	P230-SE-40/07	OK Not OK	17:23	17:33	OK Not OK	Jaya	MS	Q
2	Microcrystalline cellulose PH102	10.275	40#	P230-SE-40/07		17:33	17:35		Jaya	MS	Q
Binder Material:											
3	Purified Water	—	NA	—	NA	—	—	NA	—	—	—

7.1 MANUFACTURING PROCESS:

Step No.	Process Instructions	Date: <u>04/04/22</u>		Done by	Checked by	Verified by
		Time				
		Started	Completed			
1	Dry mixing: Transfer the sifted material from step 7.0 (1-2) into the RMG/Mass Mixer. Mix for 10 minute with impeller at slow speed and chopper 'off'. Impeller Speed: <u>45</u> RPM	17:40 17:50 17:54	17:48 17:52 17:56	Jaya	MS	Q
2	Wet Granulation: Binder Addition: Add Purified water into the contents of RMG take 2 - 5 min for water addition with impeller slow speed and Chopper OFF. Impeller Speed: <u>45</u> RPM, Chopper: <u>NA</u> RPM	17:58	18:00	Jaya	MS	Q
3	After Water addition allow mixing to form a coherent mass. If required allow mixing for 1 min or till required consistency of granules obtained with impeller at slow speed and chopper at slow speed. Impeller Speed: <u>45</u> RPM, Chopper Speed: <u>2800</u> RPM Additional quantity of Purified Water <u>4.2</u> Kg	18:00	18:01	Jaya	MS	Q
4	Note the Ampere at granulation end point .. <u>30</u> ... AMP.				MS	Q
5	Discharge the wet mass to FBD bowl or Tray drier operating slow speed of Impeller and slow speed of Chopper. Impeller Speed: <u>45</u> RPM, Chopper Speed <u>2800</u> RPM	18:02	18:05	Jaya	MS	Q

7.2 DRYING:

Step No	Process Instructions	Date : 04/04/2022		Done by	Checked by	Verified by
		Time				
		Started	Completed			
1	Load the wet mass into the FBD bowl and air dry the wet mass.					
2	Load the wet mass into the cleaned FBD bowl Dry at inlet temperature 60-65°C till the LOD reached up to 1.5 – 3.0% w/w.	18:06	20:15	Jaya	MS	P
3	LOD checking temperature at 105°C (Auto mode). LOD should be 1.5% - 3.0% w/w.	Observed LOD in %		Jaya	MS	P
		1.89				

7.3 FBD Finger bag Integrity checks:

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

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<u>I. K.</u>	<u>P. Arundh</u>	<u>Veel</u>	<u>[Signature]</u>	
Date	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 11 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00	Batch Size: 3,00,000 Tablets
		Customer:	Batch No.: 71822068
			Generic Health Care Pvt. Ltd.

7.4 SET PARAMETERS:

Sr. No.	Operation	Started at	Inlet Temp. (60-65°C)	Outlet Temp.	Product Temp.	Completed at	Total Time (mins)	LOD Observed	Done by	Checked By
1.	Air-Drying-I	18:06	NA	NA	NA	18:16	10 mins	NA	Jaya	NA
2.	Raking-I	18:17	NA	NA	NA	18:20	03 mins	NA	Jaya	NA
3.	Drying-I	18:21	65°C	40°C	40°C	19:21	60 mins	3.86	Jaya	NA
4.	Raking-II	19:25	NA	NA	NA	19:29	04 mins	NA	Jaya	NA
5.	Drying-II	19:30	65°C	40°C	40°C	20:15	45 mins	1.89	Jaya	NA
6.	Raking-III		NA	NA	NA			NA		
7.	Drying-III									

Total Drying Time (Exclude Raking & Air-Drying time): 105 min

Total Drying time: 128 min

LOD Verified By IPQA: 

7.5 SIFTING AND MILLING:

S. No.	Process Instructions	Date: 04/04/2022	Time	Done by	Checked by	Verified by
		Started	Completed			
1.	Sift the dried granules through 20 # sieve. Record the observation.	20:20	20:30	vignesh	NA	P
2.	Mill the oversized granules through 2.0 mm multi mill screen fitted with (knives forward medium speed) followed by sifting through 20# sieve on vibrating sifter and collect the sifted granules in double polythene lined cleaned HDPE containers, record the weights.	20:32	20:38	vignesh	NA	P
3.	Unload the granules in to cleaned HDPE containers in double polythene bag.	20:39	20:43	vignesh	NA	P

7.6 SIZING RECORD:

Mesh and screen size	Sieve ID No	Integrity checked before use	Date: 04/04/2022	Time	Integrity checked After use	Done by	Checked by	Verified by
			Started	Completed				
20#	PP/30-SE-20/04	OK/Not OK	20:19	20:31	OK/Not OK	vignesh	NA	P
2.0 mm	PP/30-SE-20/02	OK/Not OK	20:32	20:39	OK/Not OK	vignesh	NA	P

8.0 LOT - II: GRANULATION SIFTING INSTRUCTIONS AND SIFTING RECORD: Date: 04/04/2022 Shift: ...

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	Vfd by
						From	To			
Dry mixing:										
1	Ciprofloxacin Hydrochloride	93.263	40#	PP/30-SE-40/07	OK/Not OK	18:10	18:20	OK/Not OK	vignesh	NA
2	Microcrystalline cellulose PH102	10.275	40#	PP/30-SE-40/07	OK/Not OK	18:20	18:23	OK/Not OK	vignesh	NA
Binder Material:										
3	Purified Water	NA	NA		NA			NA		
Lubrication Material:										
4	Sodium Stach Glycollate	6.300	60#	PP/30-SE-60/00	OK/Not OK	14:10	14:15	OK/Not OK	bala	NA
5	Colloidal Silicon Dioxide	0.525	60#		OK/Not OK	14:15	14:18	OK/Not OK	bala	NA
6	Magnesium Stearate	2.150	60#		OK/Not OK	14:20	14:25	OK/Not OK	bala	NA
Prepared by:										
Dept.	Production	Checked by:				Approved By:				
Sign.	L. Ka	P. Asunt				Head Quality Assurance				
Date	30/03/2022	30/03/2022				30/03/2022				

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 12 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:		Batch No.: 741822068 Generic Health Care Pvt. Ltd.

8.1 MANUFACTURING PROCESS:

Step No.	Process Instructions	Date: 04/04/2022		Done by	Checked by	Verified by
		Time				
		Started	Completed			
1	Dry mixing: Transfer the sifted material from step 8.0 (1-2) into the RMG/Mass Mixer. Mix for 10 minute with impeller at slow speed and chopper 'off'. Impeller Speed: <u>145</u> RPM	18:35 18:45 18:49	18:43 18:47 18:51	Jaya	NI	Q
2	Wet Granulation: Binder Addition: Add Purified water into the contents of RMG take 2 - 5 min for water addition with impeller slow speed and Chopper OFF. Impeller Speed: <u>45</u> RPM, Chopper: <u>NI</u> RPM	18:52	18:54	Jaya	NI	Q
3	After Water addition allow mixing to form a coherent mass. If required allow mixing for 1 min or till required consistency of granules obtained with impeller at slow speed and chopper at slow speed. Impeller Speed: <u>45</u> RPM, Chopper Speed: <u>2800</u> RPM Additional quantity of Purified Water <u>40.00</u> Kg	18:54	18:55	Jaya	NI	Q
4	Note the Ampere at granulation end point <u>30.0</u> AMP.				NI	Q
5	Discharge the wet mass to FBD bowl or Tray drier operating slow speed of Impeller and slow speed of Chopper. Impeller Speed: <u>45</u> RPM, Chopper Speed: <u>2800</u> RPM	18:56	19:00	Jaya	NI	Q

8.2 DRYING:

Step No	Process Instructions	Date: 04/04/2022		Done by	Checked by	Verified by
		Time				
		Started	Completed			
1	Load the wet mass into the FBD bowl and air dry the wet mass.					
2	Load the wet mass into the cleaned FBD bowl Dry at inlet temperature 60-65°C till the LOD reached up to 1.5 – 3.0% w/w.	20:15	22:00	Jaya	NI	Q
3	LOD checking temperature at 105°C (Auto mode). LOD should be 1.5% - 3.0% w/w.	Observed LOD in %		Jaya	NI	Q
		2.26 %				

8.3 FBD Finger bag Integrity checks:

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

8.4 SET PARAMETERS:

Sr. No.	Operation	Started at	Inlet Temp. (60-65°C)	Outlet Temp.	Product Temp.	Completed at	Total Time (mins)	LOD Observed	Done by	Checked By
1.	Air-Drying-I	20:15	NI	NI	NI	20:20	05 min	NI	Jaya	NI
2.	Raking-I	20:21	NA	NA	NA	20:25	04 min	NA	Jaya	NI
3.	Drying-I	20:26	65°C	40°C	40°C	21:26	60 min	3.53	Jaya	NI
4.	Raking-II	21:30	NA	NA	NA	21:35	05 min	NA	Jaya	NI
5.	Drying-II	21:35	65°C	40°C	40°C	22:00	25 min	3.26	Jaya	NI
6.	Raking-III	07:25	NA	NA	NA	07:30	05 min	NA	mani	Q
7.	Drying-III	07:31	60°C	16°C	12°C	08:01	30 min	2.20%	mani	Q

Total Drying Time (Exclude Raking & Air-Drying time): 115 min

Total Drying time: 1A 1A min

LOD Verified By IPQA: Q

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. V.	P. Anub	V. S.	V. S.	
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 13 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: 61829068 Generic Health Care Pvt. Ltd.

8.5 SIFTING AND MILLING:

S. No	Process Instructions	Date: 09/04/2022		Done by	Checked by	Verified by
		Time				
		Started	Completed			
1.	Sift the dried granules through 20 # sieve. Record the observation.	08:05	08:10	Karmi	P-	Sw.
2.	Mill the oversized granules through 2.0 mm multi mill screen fitted with (knives forward medium speed) followed by sifting through 20# sieve on vibrating sifter and collect the sifted granules in double polythene lined cleaned HDPE containers, record the weights.	08:11	08:16	Karmi	P-	Sw
3.	Unload the granules in to cleaned HDPE containers in double polythene bag.	08:17	08:20	Karmi	P-	Sw

8.6 SIZING RECORD:

Mesh and screen size	Sieve ID No	Integrity checked before use	Date : 09/04/2022		Integrity checked After use	Done by	Checked by	Verified by
			Time					
			Started	Completed				
20#	pp130-sc-20/b4	OK/ Not OK	08:05	08:10	OK/ Not OK	Karmi	P-	Sw
2.0 mm	pp1mm-sc-2/c2	OK/ Not OK	08:11	08:16	OK/ Not OK	Karmi	P-	Sw

8.7 WEIGHING OF DRIED GRANULES:

S. No.	Tare Weight (Kg)	Gross Weight (Kg)	Net Weight (Kg)	Weighed By	Checked By
1	1.850	28.250	26.400	Karmi	P-
2	2.230	32.020	29.790	Karmi	P-
3	1.850	28.210	26.360	Karmi	P-
4	2.850	31.210	28.360	Karmi	P-
5	2.700	32.750	30.050	Karmi	P-
6	2.300	30.980	28.680	Karmi	P-
7	2.000	17.670	15.670	Karmi	P-
8	2.700	31.780	29.080	Karmi	P-
9					
10					
Total			206.090		

Theoretical Weight: 207.075 Kg

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

Actual Yield (Weight): 206.090 Kg % Yield: 99.52 %

Date: 05/04/2022

Production Executive Sign. /Date:

Verified By IPQA:

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	P. Aravind	V. S.	V. S.
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 14 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: <u>G1822068</u> Generic Health Care Pvt. Ltd.

9.0 BLENDING LINE CLEARANCE CHECKS: Date/Shift: 05/03/22 T / 14:00 / 1

Sr. No.	Checks	Time	*Observations					
			14:03					
			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	Blender	Area
EQP. ID No.	<u>P010CA/002</u>	<u>Blending - II</u>
Previous Product	<u>Lita Cold FLO</u>	
Batch No.	<u>G1822071</u>	
Cleaned by	<u>Marthi</u>	
Checked by	<u>P. Anand</u>	
Verified by	<u>P. Anand</u>	

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: <u>05/03/22</u> Time: <u>14:05</u>			Date:			Date:		
	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>P. Anand</u>	<u>P. Anand</u>						
RH % (NMT 60%)	<u>22%</u>	<u>P. Anand</u>	<u>P. Anand</u>						
DP (NLT 10 Pascal)	<u>11</u>	<u>P. Anand</u>	<u>P. Anand</u>						

APPROVAL FOR SIFTING AND BLENDING:

Production Sign/Date:	<u>P. Anand</u> <u>05/03/22</u>	
IPQA Sign/Date:	<u>P. Anand</u> <u>05/03/22</u>	
Start and End Time:	<u>14:10</u>	<u>17:18</u>

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K.</u>	<u>P. Anand</u>	<u>P. Anand</u>	<u>P. Anand</u>
Date	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 15 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00	Batch Size: 3,00,000 Tablets
		Customer:	Batch No.: 31822068
			Generic Health Care Pvt. Ltd.

9.1 BLENDING AND LUBRICATION PROCESS:

Date: 05/04/2022 Shift: D

Step No.	Process Instructions	Time		Done by	Checked by Prod.	Verified by IPQA
		Started	Completed			
1	Use hand gloves and goggles while handling the materials.					
2	Operate the Octagonal Blender as per the current version of the SOP No. PDOP/009.					
Pre-lubrication:						
1	Load the dried and sifted granules from step 8.7, sifted Material from step 8.0 (4,5) in to the blender and mix at 10 RPM for 10 minutes.	16:35	16:45	bala	DR	Q
Lubrication:						
2	Load the Sifted Magnesium Stearate into the above Pre-lubricated blend and mix for further at 10 RPM for 3 minutes.	16:51	16:54	bala	DR	Q
3	Unload the lubricated blend in HDPE container having double lined	17:05	17:18	bala	DR	Q

9.2 WEIGHING OF FINAL BLEND: Balance I.D. No.: P/BAL/005

Date: 05/04/2022 Shift: D Time: 17:25

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	40.700	2.630	38.070	bala	DR	6	32.230	2.330	29.900	bala	DR
2	36.220	2.210	34.010	bala	DR	7	32.270	2.100	30.170	bala	DR
3	28.900	1.900	27.000	bala	DR	8					
4	29.590	1.800	27.790	bala	DR	9					
5	29.270	1.880	27.390	bala	DR	10					
Theoretical weight of Blend:						216.000 Kg					
Actual weight of Blend:						214.330 Kg					
Verified by IPQA						Q/05/04/2022					

9.3 RECONCILIATION:

1.0	Theoretical weight of blend	:	216.000 Kg
2.0	Actual Weight of blend	:	214.330 Kg
3.0	Manufacturing Loss (Blending stage) @	:	1.530 Kg
4.0	In-process samples		
	A IPQA Samples	:	0.030 Kg
	B QC Samples	:	0.150 Kg
	C Validation Samples	:	0.090 Kg
5.0	Total samples: (A + B + C)	:	0.140 Kg
6.0	Total: (2.0 + 5.0)	:	214.470 Kg
7.0	Yield {6.0 / 1.0 x 100}*	:	99.29 %

* Actually yield will be calculated after 3 validation batches.

@Total rejects destroyed: 1.530 Kg. (Rejected materials shall be destroyed as per SOP: QAGN/048).

Recovery Addition Quantity in Kg: 1.530 (Recovery addition materials shall be as per SOP: QAGN/047).

Done by Production sign/Date: DR 05/04/2022 Checked By IPQA sign/Date: Q/05/04/2022

Test request form raised by Prod Sign/Date: DR 05/04/2022

Test request form received by IPQA Sign/Date: Q/05/04/2022

9.4 RELEASED FOR COMPRESSION:

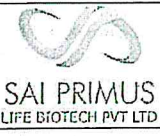
Reconciliation checked and blend is released for compression

IPQA Sign: P Date: 05/04/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	P. Arunt	Q/05/04/2022	Q/05/04/2022
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 16 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05
	Product: BONCIPRO 500		Batch Size: 3,00,000 Tablets
		BMR. No.: BMR/T/305-00	Batch No.: G118 22068
		Customer:	Generic Health Care Pvt. Ltd.

10.0 COMPRESSION LINE CLEARANCE CHECKS: Date: 05/04/2022 / 07/04/2022 / 08/04/2022

Sr. No.	Checks	Time:	*Observations					
			18-45		18-45		06-40	
			Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty SS containers/ containers polythene bags, Tags, and documents of previous batch/product are removed.		/	/	/	/	/	/
2	Check and ensure that absence of tablets of previous batch/product from area below machine and inside machine by opening the guard of machine.		/	/	/	/	/	/
3	Check and ensure that the machine body and machine parts like hoppers, feed frame, dust collection chute, hosepipe and ejection chute and control panel are clean.		/	/	/	/	/	/
4	Check and ensure that absence of tablet of previous batch/product below the weighing balance, check the cleanliness of area and equipment.		/	/	/	/	/	/
5	Check and ensure that working desk, analytical balance and other accessories are clean.		/	/	/	/	/	/
6	Check and ensure that Deduster and hosepipe are clean.		/	/	/	/	/	/
7	Check and ensure that Tube light fixture, supply grills, riser grills and filters and electrical fixtures are clean.		/	/	/	/	/	/
8	Check and ensure that instruments to be used are within calibration due date, and Punch inspection record		/	/	/	/	/	/
9	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.		/	/	/	/	/	/
10	Check and ensure that environmental conditions are recorded in the BMR.		/	/	/	/	/	/
11	Area, equipment and preventive maintenance status board is updated.		/	/	/	/	/	/
12	Check and ensure that rinse water is released from QC and attached the test request from (TRF) in BMR		/	/	/	NA	NA	NA
13	Equipment status is updated for Cleaned and Preventive Maintenance label.		/	/	/	/	/	/

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

Equipment	Compression Machine	Deduster	Area
EQP ID No.	PD/COM/001	PD/DEF/005, 006	Compression-01
Previous Product	Glimiprim H1		
Batch No.	G0222042		
Cleaned by	K. S. S. S.		
Checked by	L		
Verified by	L		

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 05/04/2022 Time: 17.50			Date: 07/04/2022 Time: 19.00			Date: 08/04/2022 Time: 06.45		
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	23°C	L	R	23°C	L	R	23°C	R	R
RH % (NMT 60%)	52%	L	R	52%	L	R	52%	R	R
DP (NLT 10 Pascal)	10 pascal	L	R	12 pascal	L	R	11 pascal	R	R

APPROVAL FOR COMPRESSION:

Production Sign/Date:	L. K. S. S. S.	L. K. S. S. S.	L. K. S. S. S.
IPQA Sign/Date:	R. S. S. S.	R. S. S. S.	R. S. S. S.
Start and End Time:	18.45	18.50	13.00

Prepared by:	Checked by:	Approved By:
Dept. Production	Production Quality Assurance	Head Quality Assurance
Sign. L. K. S. S. S.	P. A. S. S. S.	R. S. S. S.
Date 30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 17 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00	Batch Size: 3,00,000 Tablets
		Customer:	Batch No.: G1822068
			Generic Health Care Pvt. Ltd.

11.0 COMPRESSION

11.1 PROCESS INSTRUCTIONS:

Sr. No.	Process Instructions
1	Check the cleanliness of area and equipment.
2	Ensure that the correct punch set are issued as per the Punch issue record.
3	Set the Double Rotary Compression Machine with a. Upper punches: 17.20 x 7.50 mm Caplet shaped with breakline on punches. b. Lower punches: 17.20 x 7.50 mm Caplet shaped plain punches. c. Dies: 17.20 x 7.50 mm suitable for above punches. d. Type of tooling - D.
4	Punch Issued by: sign./Date: <u>05/04/2022</u> Checked and Received by Sign./Date: <u>05/04/2022</u> Verified by Sign./Date: <u>05/04/2022</u>
5	Transfer the blend to compression cubicle. Load the blend into hopper manually.
6	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.
7	Collect the tablets of one complete rotation and carry out In-process checks for thickness, weight and appearance, record the observations in the BMR. Verify the tablets for uniformity of weight and hardness and record in the BMR.
8	Collect the compressed tablets in double polythene bag lined and labelled cleaned HDPE containers/SS container.
9	Check and record the weight of the compressed tablets.

11.2 GRANULES RECEIPT RECORD:

Balance ID. No.: DD/BAU018 Date: 05/04/2022 Shift: B Time: 12:52

Sr. No.	Gross Weight in Kg	Issued By Production	Checked by Production
1	40.700	<u>L</u>	<u>L</u>
2	36.220	<u>M</u>	<u>L</u>
3	28.900	<u>M</u>	<u>L</u>
4	29.590	<u>M</u>	<u>L</u>
5	29.270	<u>M</u>	<u>L</u>
6	32.230	<u>M</u>	<u>L</u>
7	32.270	<u>M</u>	<u>L</u>
8			
9			
10			

11.3 COMPRESSION SPECIFICATION / PARAMETERS:

Sr. No.	Parameter	Limits	No. of tablets to be checked from each side	Frequency	
				Production	IPQA
1.	Appearance	White coloured caplet shaped uncoated tablet with breakline on one side and plain on other side.	20	Every 30 min.	Every 2 Hr.
2.	Average weight (mg)	720.000 mg $\pm$ 3.0 % (698.400 mg – 741.600 mg)	20		
3.	Group Weight	14.400 g $\pm$ 3.0 % (13.968 g to 14.832 g)	20	Every 30 min.	Every 2 Hr.
4.	Uniformity of weight Tablets	720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)	20	Every 2 Hr.	Every 4 Hr.
5.	Hardness	NLT 3.0 Kg (To be Established)	4	Every 30 min.	Every 2 Hr.
6.	Thickness (mm)	5.20 mm $\pm$ 0.2 (5.00 mm – 5.40 mm) (To be Established)	4	Every 30 min.	Every 2 Hr.
7.	Friability	NMT 1% w/w	6 g	Every 2 Hr.	Every 4 Hr.
8.	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.	<u>L. K.</u>	<u>P. Anand</u>	<u>Shel</u>	<u>V. R.</u>	
Date	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 18 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:		Batch No.: 61822068 Generic Health Care Pvt. Ltd.

11.4 COMPRESSION MACHINE RUNNING STATUS:

Date	Shift	Start Time	End Time	Total Hour	M/C Speed	Tablets Output	Done By	Checked
08/04/2022	A	13.00	21.36	08.30	13	293175	pram	By 

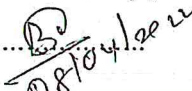
11.5 INITIAL INPROCESS CHECKS: (Appearance, Uniformity of Weight, Thickness & Diameter):

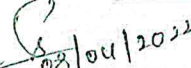
Balance I.D. No.: DD/BAC/1008

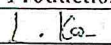
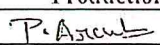
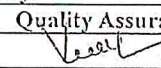
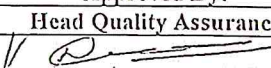
Date: 08/04/2022 Shift: A Time: 12.35

LHS						RHS					
Sr. No.	Appearance*	Weight (in mg)	Thickness (in mm)	Length (in mm)	Width (in mm)	Sr. No.	Appearance*	Weight (in mg)	Thickness (in mm)	Length (in mm)	Width (in mm)
1	OK	722	5.32	17.25	7.60	1	OK	733	5.37	17.29	7.58
2	OK	706	5.35	17.28	7.56	2	OK	720	5.40	17.27	7.52
3	OK	710	5.31	17.26	7.55	3	OK	718	5.38	17.25	7.55
4	OK	706	5.34	17.21	7.58	4	OK	722	5.39	17.24	7.58
5	OK	714	5.35	17.25	7.54	5	OK	727	5.36	17.22	7.54
6	OK	720	5.33	17.22	7.59	6	OK	724	5.40	17.30	7.55
7	OK	700	5.37	17.24	7.54	7	OK	727	5.38	17.26	7.52
8	OK	712	5.34	17.25	7.56	8	OK	721	5.39	17.24	7.54
9	OK	719	5.32	17.24	7.55	9	OK	723	5.37	17.25	7.54
10	OK	728	5.36	17.22	7.60	10	OK	723	5.40	17.26	7.53
11	OK	711	5.35	17.25	7.56	11	OK	727	5.38	17.24	7.55
12	OK	715	5.32	17.23	7.54	12	OK	724	5.40	17.25	7.54
13	OK	706	5.34	17.24	7.58	13	OK	726	5.38	17.26	7.51
14	OK	712	5.32	17.21	7.56	14	OK	721	5.40	17.30	7.54
15	OK	710	5.26	17.24	7.54	15	OK	730	5.37	17.22	7.55
16	OK	719	5.35	17.25	7.52	16	OK	724	5.39	17.24	7.52
17	OK	714	5.32	17.23	7.54	17	OK	725	5.27	17.25	7.56
18	OK	726	5.31	17.26	7.55	18	OK	725	5.36	17.24	7.55
19	OK	716	5.32	17.28	7.56	19	OK	725	5.40	17.23	7.54
20	OK	712	5.36	17.24	7.51	20	OK	729	5.38	17.26	7.55
21	OK	716	5.32	17.30	7.58	21	OK	720	5.40	17.25	7.58
22	OK	713	5.32	17.28	7.55	22	OK	728	5.39	17.24	7.55
23	OK	724	5.31	17.25	7.56	23	OK	722	5.40	17.22	7.54
24	OK	718	5.37	17.22	7.52	24	OK	724	5.38	17.24	7.51
25	OK	709	5.36	17.26	7.54	25	OK	721	5.40	17.28	7.56
26	OK	705	5.33	17.28	7.55	26	OK	719	5.39	17.25	7.54
27	OK	706	5.35	17.28	7.52	27	OK	721	5.40	17.29	7.53
28	OK	714	5.34	17.23	7.54	28	OK	716	5.37	17.30	7.55
29	OK	718	5.32	17.24	7.53	29	OK	722	5.40	17.25	7.53
30	OK	720	5.31	17.26	7.55	30	OK	719	5.37	17.28	7.56

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

Done by Production Sign/Date:  08/04/2022

Checked by IPQA Sign/Date:  08/04/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 19 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00	Batch Size: 3,00,000 Tablets
		Customer:	Batch No.: 51822068
			Generic Health Care Pvt. Ltd.

11.6 COMPRESSION SPECIFICATION AND PARAMETERS: Date: 08/04/2022 Shift: A Time: 12:50

Parameters	Instrument used	Equip ID No.	Observations of LHS		Observations of RHS		Limits
			Min	Max	Min	Max	
Appearance	Visual	NA	OK		OK		White coloured caplet shaped uncoated tablet with breakline on one side and plain on other side.
Group Weight	Electronic Balance	PD/BAL/008	14.202 g		14.492 g		14.400 g $\pm$ 3.0 % (13.968 g to 14.832 g)
Average weight	Electronic Balance		713.1 mg		724.6 mg		720.000 mg $\pm$ 3.0 % (698.400 mg – 741.600 mg)
Individual weight	Electronic Balance		706 mg	728 mg	718 mg	733 mg	720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)
Uniformity of weight	Electronic Balance		-1.00 %	2.04 %	-0.91 %	1.14 %	
Thickness	Vernier Caliper	BA/VE/001	5.31 mm	5.37 mm	5.36 mm	5.44 mm	5.20 mm $\pm$ 0.2 (5.00 mm – 5.40 mm) (To be Established)
Hardness	Hardness Tester	BA/HRT/000	15 ⁰	15 ⁰	15 ⁰	15 ⁰	NLT 3.0 Kg (To be Established)
Friability	Friabilator	QA/FRT/002	0.20%		0.18%		NMT 1% w/w
DT	DT Apparatus	QA/DTA/001	01m 35s		01m 42s		NMT 15 Minutes

M/C set done by Operator Name: Rajitha M/C set up Checked by Prod. Sign/Date: 08/04/2022

M/C Speed: 08 RPM Initial Setting Tablets Destroyed by: Sign: Quantity in Kg: 0.078 Quantity in No: 97

Approval for Batch Compression by IPQA: Sign: Date: 08/04/2022 Time: 13:00

* Thickness Limit: 5.20 to 5.40 mm (BMR)
 Observed parameter is 5.2 to 5.47 mm, next time
 BMR Revision we change the parameter.
 M
 08/04/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ke	P. Arun	V. Arun	V. Arun
Date	20/03/2022	30/03/2022	30/03/2022	30/03/2022

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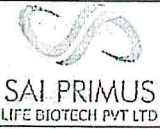
Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Generic Health Care Pvt. Ltd.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ko	P. Arant	Vauvi	P. Arant
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 21 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:		Batch No.: 671822068 Generic Health Care Pvt. Ltd.

11.8 IN-PROCESS CHECKS: (For IPQA)

Date & Time	Appearance		Weight of 20 Tablets		Hardness				Thickness				Done by IPQA
	White coloured caplet shaped uncoated tablet with breakline on one side and plain on other side.		14.400 g $\pm$ 3.0 % (13.968 g to 14.832 g)		NLT 3.0 Kg (To be Established)				5.20 mm $\pm$ 0.2 (5.00 mm – 5.40 mm) (To be Established)				
	LHS	RHS	LHS	RHS	LHS	LHS	RHS	RHS	LHS	LHS	RHS	RHS	
07/04/2022	OK	OK	14.397	14.417	12.0	12.5	12.5	13.0	5.40	5.52	5.47	5.52	CS
08/04/2022	OK	OK	14.402	14.387	12.5	13.0	13.0	13.0	5.46	5.47	5.50	5.51	CS
13:06	OK	OK	14.393	14.402	12.5	12.5	13.0	13.0	5.48	5.47	5.46	5.43	CS
13:10	OK	OK	14.386	14.399	12.0	12.0	12.0	12.0	5.52	5.55	5.56	5.53	CS
13:15	OK	OK	14.367	14.392	15.0	15.0	15.0	14.5	5.35	5.34	5.33	5.36	CS
13:20	OK	OK	14.412	14.422	12.5	13.0	13.0	13.5	5.45	5.46	5.42	5.38	CS
15:30	OK	OK	14.077	14.012	12.5	13.0	13.5	13.0	5.38	5.42	5.40	5.42	CS
17:30	OK	OK	14.069	14.014	12.5	13.0	13.5	13.0	5.43	5.50	5.46	5.43	CS
19:30	OK	OK	14.077	14.014	12.5	13.0	13.5	13.5	5.42	5.46	5.43	5.41	AI
21:30	OK	OK	14.069	14.041	13.0	13.0	12.5	12.5	5.42	5.44	5.49	5.46	AI
21:30	OK	OK	14.179	14.188	12.0	13.0	12.5	13.0	5.47	5.52	5.50	5.48	AI
/													

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. G.	P. Arun	V. Arun	P. Arun
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 22 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: 518 22068 Generic Health Care Pvt. Ltd.

11.9 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION:

Date: 08/04/2022		Time: 13.40		Shift: A	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	718	8	720	15	721
2	711	9	716	16	718
3	715	10	718	17	713
4	720	11	715	18	716
5	716	12	714	19	717
6	719	13	711	20	720
7	714	14	720		
Balance ID No.: PD1BA4008			M/C Speed: 13 RPM		
Group weight of 20 Tablets: 14.332g. Avg. wt: 716.6mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 711mg Max. weight: 721mg			Group weight of 20 Tablets: 14.428g. Avg. wt: 721.4mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 715mg Max. weight: 726mg		
			LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			0.19%	0.22%	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)			01.55 min	01.45 min	Equipment ID No.: QA/DTA/001
Done by: (Signature) (Production)					
Date: 08/04/2022		Time: 15.20		Shift: B	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	710	8	719	15	710
2	715	9	720	16	715
3	719	10	717	17	721
4	718	11	715	18	725
5	719	12	695	19	726
6	720	13	699	20	720
7	719	14	699		
Balance ID No.: PD1BA4008			M/C Speed: 13 RPM		
Group weight of 20 Tablets: 14.311g. Avg. wt: 715.55mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 695mg Max. weight: 720mg			Group weight of 20 Tablets: 14.201g. Avg. wt: 710.05mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 690mg Max. weight: 731mg		
			LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			0.21%	0.17%	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)			01min 40sec	01min 20sec	Equipment ID No.: QA/DTA/001
Done by: (Signature) (Production)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	P. Arcub	V. S.	(Signature)
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 23 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00	Batch Size: 3,00,000 Tablets
		Customer:	Batch No.: 41822068
			Generic Health Care Pvt. Ltd.

11.10 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION:

Date: 08/04/2022		Time: 17.20		Shift: B							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	710	8	690	15	715	1	699	8	700	15	699
2	715	9	697	16	716	2	697	9	702	16	690
3	712	10	699	17	710	3	699	10	700	17	697
4	710	11	701	18	716	4	699	11	707	18	697
5	709	12	700	19	717	5	705	12	699	19	699
6	699	13	709	20	710	6	700	13	697	20	697
7	695	14	710			7	701	14	699		
Balance ID No.: PD/BAU/008				M/C Speed: 13 RPM							
Group weight of 20 Tablets: 14.140 g. Avg. wt.: 710.5 mg 701				Group weight of 20 Tablets: 13.979 g. Avg. wt.: 698.95 mg 698.95							
Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)				Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)							
Min weight: 690 mg Max. weight: 716 mg				Min weight: 670 mg Max. weight: 705 mg							
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		LHS		RHS		Equipment ID No.: QA/FRT/002					
Disintegration Time (Limit - NMT 15 minutes)		01 min		01 min		Equipment ID No.: QA/DTA/007					
Done by: (Production)											
Date: 08/04/2022		Time: 19.20		Shift: B							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	740	8	697	15	710	1	675	8	741	15	690
2	720	9	699	16	715	2	690	9	740	16	697
3	719	10	697	17	716	3	770	10	731	17	700
4	700	11	690	18	720	4	721	11	735	18	706
5	715	12	715	19	735	5	740	12	740	19	710
6	720	13	716	20	740	6	731	13	736	20	740
7	699	14	717			7	735	14	706		
Balance ID No.: PD/BAU/008				M/C Speed: 13 RPM							
Group weight of 20 Tablets: 14.210 g. Avg. wt.: 710.5 mg				Group weight of 20 Tablets: 14.215 g. Avg. wt.: 710.75 mg							
Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)				Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)							
Min weight: 690 mg Max. weight: 740 mg				Min weight: 690 mg Max. weight: 740 mg							
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		LHS		RHS		Equipment ID No.: QA/FRT/002					
Disintegration Time (Limit - NMT 15 minutes)		01 min		01 min		Equipment ID No.: QA/DTA/007					
Done by: (Production)											

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. K.	P. Arun	Ver	P. Arun	
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 24 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500		BMR. No.: BMR/T/305-00 Batch No.: <u>G18 Q2068</u> Customer: Generic Health Care Pvt. Ltd.

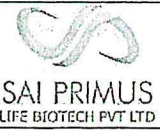
11.11 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION:

Date: <u>07/04/2022</u>		Time: <u>21:20</u>		Shift: <u>B</u>											
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).											
1	710	8	690	15	697	1	710	8	699	15	715				
2	712	9	712	16	699	2	740	9	709	16	716				
3	700	10	715	17	697	3	716	10	706	17	710				
4	699	11	710	18	702	4	712	11	700	18	712				
5	692	12	715	19	716	5	716	12	710	19	770				
6	692	13	716	20	717	6	710	13	712	20	715				
7	699	14	712			7	715	14	715						
Balance ID No.: <u>PD/RP1/007</u>						M/C Speed: <u>13</u> RPM									
Group weight of 20 Tablets: <u>14112</u> g. Avg. wt: <u>705.6</u> mg						Group weight of 20 Tablets: <u>14323</u> g. Avg. wt: <u>716.15</u> mg									
Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)						Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)									
Min weight: <u>699</u> mg Max. weight: <u>717</u> mg						Min weight: <u>699</u> mg Max. weight: <u>716</u> mg									
						<table border="1"> <tr> <td>LHS</td> <td>RHS</td> </tr> <tr> <td>0.26%</td> <td>0.20%</td> </tr> </table>						LHS	RHS	0.26%	0.20%
LHS	RHS														
0.26%	0.20%														
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						Equipment ID No.: QA/FRT/ <u>00</u>									
Disintegration Time (Limit - NMT 15 minutes)						Equipment ID No.: QA/DTA/ <u>00</u>									
Done by: <u>L</u> (Production)															
Date:		Time:		Shift:		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.: <u>Wb</u>						M/C Speed: <u>13</u> RPM									
Group weight of 20 Tablets: <u>14112</u> g. Avg. wt: <u>705.6</u> mg						Group weight of 20 Tablets: <u>14323</u> g. Avg. wt: <u>716.15</u> mg									
Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)						Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)									
Min weight: <u>699</u> mg Max. weight: <u>717</u> mg						Min weight: <u>699</u> mg Max. weight: <u>716</u> mg									
						<table border="1"> <tr> <td>LHS</td> <td>RHS</td> </tr> <tr> <td></td> <td></td> </tr> </table>						LHS	RHS		
LHS	RHS														
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						Equipment ID No.: QA/FRT/ <u>00</u>									
Disintegration Time (Limit - NMT 15 minutes)						Equipment ID No.: QA/DTA/ <u>00</u>									
Done by: <u>L</u> (Production)															

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<u>L. K</u>	<u>P. Anand</u>	<u>[Signature]</u>	<u>[Signature]</u>	
Date	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Pudukcherry-605009.		Page 25 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:		Batch No.: <u>G18 22068</u> Generic Health Care Pvt. Ltd.

11.12 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA:

Pre-compression

Date:	08/04/2022	Time:	21:30	Shift:	B						
LHS: Individual weight of 20 tablets (in mg).					RHS: Individual weight of 20 tablets (in mg).						
1	715	8	735	15	745	1	726	8	704	15	712
2	744	9	732	16	710	2	746	9	703	16	702
3	710	10	723	17	726	3	711	10	726	17	703
4	726	11	706	18	718	4	744	11	741	18	732
5	710	12	710	19	744	5	716	12	705	19	716
6	710	13	706	20	730	6	732	13	731	20	722
7	726	14	746			7	705	14	734		

Balance ID No.: R21/BAL/002

M/C Speed: 18 RPM

Group weight of 20 Tablets: 14.675 g. Avg.
wt: 723.5 mg

Group weight of 20 Tablets: 14.611 g. Avg.
wt: 720.55 mg

Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)

Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)

Min weight: 706 mg Max. weight: 747 mg

Min weight: 702 mg Max. weight: 746 mg

	LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	<u>0.21%</u>	<u>0.17%</u>	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)	<u>01 min 37 sec</u>	<u>01 min 41 sec</u>	Equipment ID No.: QA/DTA/001

Done by: Arunoj/09/1022 (IPQA)

L. RPM

Date:	08/04/2022	Time:	13:05	Shift:	A						
LHS: Individual weight of 20 tablets (in mg).					RHS: Individual weight of 20 tablets (in mg).						
1	735	8	722	15	726	1	705	8	719	15	761
2	727	9	719	16	732	2	744	9	731	16	710
3	732	10	727	17	716	3	732	10	720	17	726
4	712	11	720	18	718	4	718	11	712	18	744
5	716	12	718	19	727	5	720	12	722	19	705
6	730	13	702	20	732	6	703	13	716	20	718
7	704	14	709			7	722	14	766		

Balance ID No.: Q21/BAL/002

M/C Speed: 10 RPM

Group weight of 20 Tablets: 14.645 g. Avg.
wt: 723.25 mg

Group weight of 20 Tablets: 14.670 g. Avg.
wt: 723.5 mg

Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)

Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)

Min weight: 703 mg Max. weight: 735 mg

Min weight: 703 mg Max. weight: 746 mg

	LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	<u>0.16%</u>	<u>0.18%</u>	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)	<u>01 min 42 sec</u>	<u>01 min 46 sec</u>	Equipment ID No.: QA/DTA/001

Done by: Arunoj/09/1022 (IPQA)

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K.</u>	<u>P. Anand</u>	<u>V. S.</u>	<u>V. S.</u>
Date	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 26 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500		BMR. No.: BMR/T/305-00 Batch No.: 61822068 Customer: Generic Health Care Pvt. Ltd.

11.13 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA:

Date: 08/04/2022		Time: 13:12		Shift: A		H.RPM	
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	712	8	732	15	733	1	727
2	720	9	720	16	727	2	707
3	709	10	727	17	712	3	731
4	720	11	706	18	709	4	732
5	712	12	702	19	710	5	704
6	714	13	733	20	714	6	698
7	713	14	738			7	702
Balance ID No.: QA/BAL/001				M/C Speed: 20 RPM			
Group weight of 20 Tablets: 14348 g. Avg. wt: 718.9 mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 702 mg Max. weight: 738 mg				Group weight of 20 Tablets: 14336 g. Avg. wt: 716.8 mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 698 mg Max. weight: 740 mg			
				LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				0.16%	0.14%	Equipment ID No.: QA/FRT/001	
Disintegration Time (Limit - NMT 15 minutes)				01 min 10 sec	01 min 37 sec	Equipment ID No.: QA/DTA/001	
Done by: 608/04/2022 (IPQA)							
Date: 08/04/2022		Time: 13:13		Shift: A		L. Handness	
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	714	8	714	15	724	1	727
2	709	9	712	16	725	2	709
3	712	10	709	17	731	3	712
4	727	11	727	18	732	4	709
5	733	12	731	19	740	5	722
6	732	13	733	20	727	6	730
7	730	14	740			7	734
Balance ID No.: QA/BAL/002				M/C Speed: 18 RPM			
Group weight of 20 Tablets: 14503 g. Avg. wt: 725.15 mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 709 mg Max. weight: 740 mg				Group weight of 20 Tablets: 14498 g. Avg. wt: 724.9 mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 709 mg Max. weight: 736 mg			
				LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				0.18%	0.16%	Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)				01 min 10 sec	01 min 08 sec	Equipment ID No.: QA/DTA/001	
Done by: 608/04/2022 (IPQA)							

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	P. Anand	V. K.	V. K.
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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

Generic Health Care Pvt. Ltd.

H. Howard

Done by: A. C. S. / 04/10/2022 (IPQA)

Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Fe	P. A. 		
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 28 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMRT/305-00 Customer:	Batch No.: G118 22068 Generic Health Care Pvt. Ltd.

11.15 WEIGHING RECORD OF COMPRESSED TABLETS:

S. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Weighed by	Checked by Production	Verified by IPQA
1	32.900	2.500	30.400	Ajit	R	P
2	29.480	2.300	27.180	Ajit	B	P
3	28.120	3.000	25.120	Ajit	B	P
4	24.050	2.300	21.750	Pram	L	P
5	29.240	2.200	27.040	Pram	L	P
6	31.480	2.400	29.080	Pram	L	P
7	26.260	3.000	23.260	muthu	B	P
8	29.070	2.400	26.670	muthu	B	P
9						
10						

11.16 RECONCILIATION (COMPRESSION STAGE):

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

1.0	Standard Batch size	:	216.000 Kg.	3,00,000 No.
2.0	Actual weight of Lubricated granules	:	214.330 Kg.	298509 Nos.
3.0	Weight of compressed tablets	:	240.500 Kg.	293175 Nos.
4.0	Rejection during Compression @	:	0.070 Kg.	
5.0	In-process samples of all stages			
	A	IPQC Samples	: 0.400 Kg.	
	B	QC Samples	: 0.090 Kg.	
	C	Validation Samples	: 0.110 Kg.	
6.0	Total in process samples: (A + B + C)	:	0.600 Kg.	
7.0	Total: (3.0 + 6.0)	:	211.100 Kg.	294011 Nos.
8.0	Yield {7.0 / 1.0 x 100}*	:		98.00 %

* Actually yield will be calculated after 3 validation batches

@Total rejects destroyed: ...3.030 Kg. (Rejected materials shall be destroyed as per SOP No.: QAGN/048)

Done by Production Sign/Date: 09/04/2022 Checked by IPQA Sign/Date: 09/04/2022

Test request form raised by Prod Sign/Date: 09/04/2022

Test request form received by IPQA Sign/Date: 09/04/2022

12.0 RELEASED FOR COATING:

Reconciliation checked and compressed tablets released for coating:

IPQA Sign: [Signature]

Date: 09/04/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	P. Anand	[Signature]	[Signature]
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 27 of 37
	BATCH-MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500		BMR. No.: BMR/T/305-00 Batch No.: G1822068(A) Customer: Generic Health Care Pvt. Ltd.

11.14 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA:

Date: 08/04/2022		Time: 17:40		Shift: A		Mid Hopper	
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	709	8	710	15	734	1	712
2	712	9	717	16	727	2	721
3	730	10	712	17	724	3	733
4	737	11	727	18	717	4	709
5	727	12	745	19	733	5	712
6	712	13	734	20	732	6	717
7	709	14	733			7	714
Balance ID No.: QA/BAL/002				M/C Speed: 12 RPM			
Group weight of 20 Tablets: 14.465 g. Avg. wt: 722.25 mg				Group weight of 20 Tablets: 14.367 g. Avg. wt: 718.35 mg			
Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)				Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)			
Min weight: 709 mg Max. weight: 745 mg				Min weight: 709 mg Max. weight: 732 mg			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.14%		0.14%		Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)		01 min 40 sec		01 min 30 sec		Equipment ID No.: QA/DTA/001	
Done by: 08/04/2022 (IPQA)							
Date: 08/04/2022		Time: 21:25		Shift: B		End Hopper	
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	706	8	732	15	732	1	709
2	712	9	730	16	712	2	712
3	710	10	737	17	710	3	710
4	724	11	709	18	712	4	712
5	712	12	712	19	709	5	734
6	710	13	710	20	733	6	713
7	727	14	709			7	727
Balance ID No.: QA/BAL/002				M/C Speed: 13 RPM			
Group weight of 20 Tablets: 14.352 g. Avg. wt: 717.6 mg				Group weight of 20 Tablets: 14.625 g. Avg. wt: 731.25 mg			
Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)				Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)			
Min weight: 706 mg Max. weight: 737 mg				Min weight: 709 mg Max. weight: 737 mg			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.14%		0.14%		Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)		01 min 20 sec		01 min 30 sec		Equipment ID No.: QA/DTA/001	
Done by: 08/04/2022 (IPQA)							

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka	P. Arun	V. Arun	V. Arun	
Date	30/03/2022	30/03/2022	20/03/2022	20/03/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 27 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500		BMR. No.: BMR/T/305-00 Batch No.: G1822068(B) Customer: Generic Health Care Pvt. Ltd.

11.14 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA:

Date: 08/01/2022		Time: 21:40		Shift: B		Composite	
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	712	8	722	15	731	1	712
2	714	9	714	16	732	2	709
3	709	10	709	17	712	3	720
4	722	11	712	18	714	4	731
5	731	12	731	19	715	5	722
6	732	13	732	20	709	6	730
7	720	14	727			7	739
Balance ID No.: QA/BAC/002				M/C Speed: 17 RPM			
Group weight of 20 Tablets: 14240 g. Avg. wt: 712.0 mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 709 mg Max. weight: 732 mg				Group weight of 20 Tablets: 14236 g. Avg. wt: 711.8 mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 708 mg Max. weight: 740 mg			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.14%		0.19%		Equipment ID No.: QA/FRT/001	
Disintegration Time (Limit - NMT 15 minutes)		01 min 29 sec		01 min 41 sec		Equipment ID No.: QA/DTA/001	
Done by: AS/04/22 (IPQA)							
Date:		Time:		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1		8		15		1	
2		9		16		2	
3		10		17		3	
4		11		18		4	
5		12		19		5	
6		13		20		6	
7		14				7	
Balance ID No.:				M/C Speed: RPM			
Group weight of 20 Tablets: g. Avg. wt: mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: mg Max. weight: mg				Group weight of 20 Tablets: g. Avg. wt: mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 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: (IPQA)							

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. K.	P. Aravind			
Date	30/03/2022	30/03/2022	20/03/2022	30/03/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 29 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: <u>G1822068</u> Generic Health Care Pvt. Ltd.

13.0 LINE CLEARANCE FOR COATING SOLUTION PREPARATION:

Date/Shift/Time: 09/04/2022 8A 10.40

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

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

Equipment	Solution preparation vessel and stirrer	Colloidal Mill	Area
Equipment ID No.	<u>NA</u>	<u>DD1 c/m/01</u>	<u>Sol-prop</u>
Previous product	<u>Prasidol 40mg</u>		
Batch No.	<u>G1822068</u>		
Cleaned by	<u>1 carth</u>		
Checked by Production Sign/Date:	<u>B</u> <u>09/04/2022</u>		
Verified by IPQA Sign/Date:		<u>Postman</u>	

ENVIRONMENTAL CONDITIONS:		Date: <u>09/04/2022</u> Time: <u>10.45</u>		Date: _____ Time: _____	
(Refer to SOP No.: QAGN/011)	Temperature °C Limit: NMT 25 °C	Observation	Prod. Sign.	Verified by IPQA	Prod. Sign.
	Relative Humidity % Limit: NMT 60%	<u>23°C</u>	<u>B</u>	<u>10</u>	<u>✓</u>

APPROVAL FOR COATING SOLUTION PREPARATION:	
Production Sign/Date:..... <u>B</u> <u>09/04/2022</u>	
Line Clearance IPQA Sign. / Date:..... <u>Postman</u>	
Start Time/Date..... <u>11:20</u> <u>09/04/2022</u>	End Time/Date..... <u>11:41</u> <u>09/04/2022</u>

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>P. Anant</u>	<u>Yash</u>	<u>P. Anant</u>
Date	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 30 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: <u>G18 22068</u> Generic Health Care Pvt. Ltd.

14.0 Coating Procedure:

14.1 General Instructions:

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

14.2 TABLETS RECEIPT RECORD OF UNCOATED TABLETS FOR COATING:

Balance ID. No.: DD1BAL015

Date/Shift/Time: 09/09/2022 4th

Sr. No.	Description	Observations	Checked By (Production)	Verified By (IPQA)
1.	Total Quantity (Net Qty.in Kg)	<u>210.400</u>	<u>B</u>	<u>P</u>
2.	Number of Containers	<u>08</u>	<u>B</u>	<u>P</u>

14.3 COATING SOLUTION PREPARATION

Sr. No.	General Instructions	Balance ID.: DD1BAL015				
1.	Check the cleanliness of the Solution Preparation area and operation as per current version of SOP.					
2.	Use hand gloves while handling the materials					
3.	Transfer the verified coating materials to Coating solution preparation area. (Lot D)					
Step No.	Name of Ingredient & Operation	Time		Done by	Checked by Prod.	Verified by IPQA
		Start	Finish			
1	Take Purified water in a SS Vessel. Slowly disperse HPMC 6 cps, Titanium dioxide, Ponceau 4R Lake, Purified Talc and Polyethylene Glycol 6000 and stir well to disperse completely.	11.20	11.30	mogah	B	C
2	If required mill the solution through colloidal mill.	11.31	11.40	mogah	B	C

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K</u>	<u>P. Anand</u>	<u>V. Anand</u>	<u>V. Anand</u>
Date	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 30 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: 51829068 Generic Health Care Pvt. Ltd.

14.0 Coating Procedure:

14.1 General Instructions:

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

14.2 TABLETS RECEIPT RECORD OF UNCOATED TABLETS FOR COATING:

Balance ID. No.: NT

Date/Shift/Time: 09/04/2022 / 12 / 15-15

Sr. No.	Description	Observations	Checked By (Production)	Verified By (IPQA)
1.	Total Quantity (Net Qty.in Kg)			
2.	Number of Containers			

14.3 COATING SOLUTION PREPARATION

Sr. No.	General Instructions	Balance ID.: PD / BAL / 015				
1.	Check the cleanliness of the Solution Preparation area and operation as per current version of SOP.					
2.	Use hand gloves while handling the materials					
3.	Transfer the verified coating materials to Coating solution preparation area. (Wt / g)					
Step No.	Name of Ingredient & Operation	Time		Done by	Checked by Prod.	Verified by IPQA
		Start	Finish			
1	Take Purified water in a SS Vessel. Slowly disperse HPMC 6 cps, Titanium dioxide, Ponceau 4R Lake, Purified Talc and Polyethylene Glycol 6000 and stir well to disperse completely.	15-00	15-10	Abi	L	S
2	If required mill the solution through colloidal mill.	15-11	15-20	Abi	L	S

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>P. Anand</u>	<u>Thang</u>	<u>V. R</u>
Date	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 31 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product: BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:		Batch No.: 61822068 Generic Health Care Pvt. Ltd.

15.0 COATING AREA:
LINE CLEARANCE CHECKS:

 Date/Shift/Time: 09/04/2022 / 11:18:32

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

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

Equipment		Coating Machine			Area					
Equipment ID No.		PD/NEC/001			Coating area <u>Scrap</u>					
Previous product		<u>Pranitol 40mg</u>								
Batch No.		<u>071822068</u>								
Cleaned by		<u>partu</u>								
Checked by Production Sign/Date:		<u>09/04/2022</u>								
Verified by IPQA Sign/Date:		<u>09/04/2022</u>								
ENVIRONMENTAL CONDITIONS:		Date: <u>09/04/2022</u> Time: <u>10:55</u>			Date: _____ Time: _____			Date: _____ Time: _____		
		Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
(Refer to SOP No.: QAGN/011)	Temperature °C Limit: NMT 25 °C	<u>23 °C</u>	<u>B</u>	<u>B</u>						
	Relative Humidity % Limit: NMT 60%	<u>52%</u>	<u>B</u>	<u>B</u>						
	Differential Pressure (NLT 10 Pascal)	<u>11 Pa</u>	<u>B</u>	<u>B</u>						

APPROVAL FOR COATING:

 Production Sign/Date: 09/04/2022

 Line Clearance IPQA Sign. / Date: 09/04/2022

 Start Time/Date: 14:00 / 09/04/2022

 End Time/Date: 22:15 / 09/04/2022

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<u>L. K</u>	<u>P. Anand</u>	<u>Val</u>	<u>VP</u>	
Date	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 32 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: 71822068 Generic Health Care Pvt. Ltd.

15.1 COATING PROCESS:

(Lot 7)

Process Steps					
Step No.	Name of Ingredient & Operation	Time Start	Time Finish	Done by	Ckd by Prod.
1	Transfer the compressed tablets in to the coating Area	12:00	12:05	Abi	Abi
2	Pre-warm the tablet with inlet temp. 45°C to 55°C.	14:06	14:11	Abi	Abi
3	Arrange the spray gun in such a way that the spray droplets just touch the tablet bed on upper rim. The spray should not fall on the wall of the pan. Weight gain obtained: 2.50 2.50 % (2.0 - 3.0%)	14:12	20:00	Abi	L
4	When the spraying is complete, dry the tablets perfectly, in the pan by keeping inlet temp. 55°C-75 °C with intermittently flipping the tablets, until no more solvent odour is observed. Caution: Ensure the tablet bed temperature does not rise excessively.	20:01	20:06	Abi	L
5	Monitor DT: Limit: NMT 30 minutes. Found Disintegration Time: 02min 45sec	20:07	20:10	Abi	L
6	Unload the film coated tablets in a HDPE container lined with double polybag.			Abi	L

15.2 INITIAL CHECKS OF COATING PARAMETERS:

S. No	Parameter	Set	Observed
1	Inlet air Temp.	55°C to 75°C (To be established)	58.5°C
2	Exhaust air Temp.	50 ± 5 °C (To be established)	48.9°C
3	Tablet Bed temp.	50°C-60 °C (To be established)	35.6°C
4	Atomization air pressure	1.0 - 4.0 Kg/cm ² (To be established)	3.1kg
5	Pan speed	1.0 - 10.0 RPM (To be established)	2.5 RPM
6	Spray rate	30 to 70 ml/min (To be established)	5.18 ml/min
Checked by Production/ Date			Abi 09/04/2022
Verified by IPQA/ Date			Abi 09/04/2022

15.3 INDIVIDUAL WEIGHT CHECKING OF PRE-WARMED TABLETS:

Sr. No.	Weight (mg)	Sr. No.	Weight (mg)
1	711	11	714
2	714	12	716
3	713	13	715
4	715	14	713
5	712	15	718
6	714	16	711
7	716	17	716
8	715	18	715
9	714	19	714
10	718	20	713
Total		14.290	
Avg. Weight		714.5	

15.4 FINAL COATING PARAMETERS CHECKS: (PRODUCTION)

Parameters	Limits	Observed
Description	Pink coloured caplet shaped film coated tablet with breakline on one side and plain on other side	OK
Theoretical weight per tablet	736.000 mg ± 3 % (713.920 mg - 758.080 mg)	734.10
Weight of 20 tablets	14.720 g ± 3 % (14.278 g - 15.162 g)	14.682
Uniformity of weight	736.000 mg ± 5 % (699.200 mg - 772.800 mg)	-0.25
Thickness	5.50 mm ± 0.2 mm (5.30 mm to 5.70 mm)	5.40 - 5.57
Disintegration test	NMT 30 min	02min 45sec
Checked by Production/ Date		Abi 09/04/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	P. Arul	V. Arul	V. Arul
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 32 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: (11822068A) Generic Health Care Pvt. Ltd.

15.1 COATING PROCESS:

(L 11)

Process Steps					
Step No.	Name of Ingredient & Operation	Time		Done by	Ckd by Prod.
		Start	Finish		
1	Transfer the compressed tablets in to the coating Area	20.15	20.20	Abi	L
2	Pre-warm the tablet with inlet temp. 45°C to 55°C.	20.21	20.30	Abi	L
3	Arrange the spray gun in such a way that the spray droplets just touch the tablet bed on upper rim. The spray should not fall on the wall of the pan. Weight gain obtained: 3.3 % (2.0 – 3.0%)	20.35	23.10	Abi	L
4	When the spraying is complete, dry the tablets perfectly, in the pan by keeping inlet temp. 55°C-75 °C with intermittently flipping the tablets, until no more solvent odour is observed. <u>Caution:</u> Ensure the tablet bed temperature does not rise excessively.	23.11	23.15	Abi	L
5	Monitor DT: Limit: NMT 30 minutes. Found Disintegration Time: 02 min 45 sec	23.16	23.19	Abi	L
6	Unload the film coated tablets in a HDPE container lined with double polybag.			Abi	L

15.2 INITIAL CHECKS OF COATING PARAMETERS:

S. No	Parameter	Set	Observed
1	Inlet air Temp.	55°C to 75°C (To be established)	58° 5"
2	Exhaust air Temp.	50 ± 5 °C (To be established)	47.9 °C
3	Tablet Bed temp.	50°C-60 °C (To be established)	35.6 °C
4	Atomization air pressure	1.0 - 4.0 Kg/cm ² (To be established)	3 kg/cm ²
5	Pan speed	1.0 - 10.0 RPM (To be established)	2.5 RPM
6	Spray rate	30 to 70 ml/min (To be established)	18 ml/min
Checked by Production/ Date			09/04/2022
Verified by IPQA/ Date			09/04/2022

15.3 INDIVIDUAL WEIGHT CHECKING OF PRE-WARMED TABLETS:

Sr. No.	Weight (mg)	Sr. No.	Weight (mg)
1	710	11	712
2	710	12	715
3	709	13	710
4	708	14	711
5	707	15	712
6	707	16	710
7	710	17	715
8	712	18	716
9	710	19	710
10	715	20	712
Total		14.640 14.223	
Avg. Weight		734.5 711.5	

L
09/04/22

15.4 FINAL COATING PARAMETERS CHECKS: (PRODUCTION)

Parameters	Limits	Observed
Description	Pink coloured caplet shaped film coated tablet with breakline on one side and plain on other side	OK
Theoretical weight per tablet	736.000 mg ± 3 % (713.920 mg – 758.080 mg)	735.10
Weight of 20 tablets	14.720 g ± 3 % (14.278 g – 15.162 g)	14.702
Uniformity of weight	736.000 mg ± 5 % (699.200 mg – 772.800 mg)	- 0.24
Thickness	5.50 mm ± 0.2 mm (5.30 mm to 5.70 mm)	5.40 - 5.57
Disintegration test	NMT 30 min	02 min 40 sec
Checked by Production/ Date		09/04/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K...	T. An...	V...	V...
Date	30/03/2022	30/03/2022	30/03/2022	20/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 33 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: <u>1822068</u> Generic Health Care Pvt. Ltd.

15.5 FINAL COATING PARAMETERS CHECKS: (IPQA) (Lot 11)

Parameters	Limits	Observed
Description	Pink coloured caplet shaped film coated tablet with breakline on one side and plain on other side	OK
Theoretical weight per tablet	736.000 mg $\pm$ 3 % (713.920 mg – 758.080 mg)	738.84
Weight of 20 tablets	14.720 g $\pm$ 3 % (14.278 g – 15.162 g)	14.710
Uniformity of weight	736.000 mg $\pm$ 5 % (699.200 mg – 772.800 mg)	-1.24% +2.91%
Thickness	5.50 mm $\pm$ 0.2 mm (5.30 mm to 5.70 mm)	5.45 – 5.55
Disintegration test	NMT 30 min	02min 50sec
Checked by IPQA/ Date		11/09/2022

15.6 FILM COATING WEIGHT GAIN PARAMETER CHECKS:

S. No.	Start time	End time	Inlet temp.	Outlet temp.	Bed temp.	Pan RPM	Atomizing air pressure	Initial weight gain (A)	Final weight gain (B)	Difference C = B - A	Percentage weight gain	Ckd by	Verified by
1	14.15	20.00	58°C	42.7°C	35.6°C	2.5 rpm	3kg	720	724	14	2.22%	L	C

15.7 WEIGHT CHECK FOR 20 TABLETS:

S. NO.	INITIAL WEIGHT	FINAL WEIGHT	S. NO.	INITIAL WEIGHT	FINAL WEIGHT
1	720	735	1	722	736
2	710	740	2	716	759
3	715	772	3	732	733
4	720	741	4	731	739
5	717	720	5	727	726
6	710	729	6	722	743
7	720	730	7	730	749
8	715	715	8	737	748
9	710	710	9	714	730
10	679	715	10	727	728
11	715	770	11	730	724
12	717	775	12	724	743
13	719	760	13	731	730
14	725	735	14	729	701
15	726	745	15	730	725
16	730	750	16	724	765
17	710	732	17	732	722
18	707	730	18	722	766
19	705	716	19	731	720
20	700	719	20	732	732
TOTAL	14.300	14.400	TOTAL	14.536	14.710
Checked by Production:		11/09/2022	Checked by IPQA:		11/09/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Kar	P. Anand	V. Kar	V. Kar
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 34 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:		Batch No.: <u>G18 22068</u> Generic Health Care Pvt. Ltd.

15.8 PERCENTAGE OF COATING WEIGHT BUILDS UP:

$$\% \text{ of Weight buildup} = \frac{\text{Avg. wt. of coated tablets} - \text{Avg. wt. of core tablet (Pre-warmed)} \times 100}{\text{Avg. wt. of core tablets (Pre-warmed)}}$$

$$= 2.36\%$$

15.9 ACTUAL AVERAGE WEIGHT OF COATED TABLETS:

$$\frac{\text{Weight of 100 coated tablet}}{100} = 735 \text{ mg}$$

15.10 WEIGHT OF FILM COATED TABLETS:

Container No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Weighed by	Checked by Production	Verified by-IPQA
1	31.550	2.500	29.050	Abi	L	Abi
2	28.680	2.400	26.280	Abi	L	Abi
3	30.240	2.400	27.840	Abi	L	Abi
4	27.990	2.400	25.590	Abi	L	Abi
5	36.230	3.000	33.230	Abi	L	Abi
6	37.240	3.000	30.240	Abi	L	Abi
7	21.950	2.300	19.650	Abi	L	Abi
8	26.390	2.400	23.990	Abi	L	Abi
9				Abi		
10						
TOTAL			215.870			

15.11 RECONCILIATION (COATING STAGE):

Average weight of coated Tablet: 735.....mg

1.0	Batch size	:	220.800 Kg.	3,00,000 Nos.
2.0	Weight of coated tablets	:	215.870 Kg.	293700 Nos.
3.0	Coating loss@	:	0.010 Kg.	
4.0	In-process samples of all stages			
	A	IPQC Samples	: 0.040 Kg.	
	B	QC Samples	: 0.080 Kg.	
	C	Validation Samples	: N/A Kg.	
5.0	Total in process samples: (A + B + C)	:	0.120 Kg.	
6.0	Total: (2.0 + 5.0)	:	215.990 Kg.	293863 Nos.
7.0	Yield {(6.0 x 100 / 1.0)*}	:		97.95 %

* Actually yield will be calculated after 3 validation batches

@Total rejects destroyed: 0.010.....Kg. (Rejected materials shall be destroyed as per SOP No.: QAGN/048)

Done by Production Sign/Date: L. K. 30/03/2022 Checked by IPQA Sign/Date: S. A. 30/03/2022

Test request form raised by Prod Sign/Date: L. K. 30/03/2022

Test request form received by IPQA Sign/Date: S. A. 30/03/2022

15.12 RELEASE FOR INSPECTION:

Reconciliation checked and Coated tablets released for inspection

IPQA Sign: S. A. Date: 30/03/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K.</u>	<u>P. Anand</u>	<u>V. S.</u>	<u>V. S.</u>
Date	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>

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Page 33 of 37

Product

Product Code: B05

Batch Size: 3,00,000 Tablets

BONCIPRO 500

BMR. No.: BMR/T/305-00

Batch No.: 61822068(A)

Customer:

Generic Health Care Pvt. Ltd.

(Lat I)

Parameters	Limits	Observed
Description	Pink coloured caplet shaped film coated tablet with breakline on one side and plain on other side	ok
Theoretical weight per tablet	736.000 mg $\pm$ 3 % (713.920 mg – 758.080 mg)	735.85 mg
Weight of 20 tablets	14.720 g $\pm$ 3 % (14.278 g – 15.162 g)	14.7249 g
Uniformity of weight	736.000 mg $\pm$ 5 % (699.200 mg – 772.800 mg)	-1.61% / +0.56%
Thickness	5.50 mm $\pm$ 0.2 mm (5.30 mm to 5.70 mm)	5.46 – 5.61 mm
Disintegration test	NMT 30 min	0 min, 56 sec
Checked by IPQA/ Date		18/09/2022

15.6 FILM COATING WEIGHT GAIN PARAMETER CHECKS:

S. No.	Start time	End time	Inlet temp.	Outlet temp.	Bed temp.	Pan RPM	Atomizing air pressure	Initial weight gain (A)	Final weight gain (B)	Difference C = B-A	Percentage weight gain	Ckd by	Verified by
1	20.40	22.00	58°C	48°C	35.6°C	2.5rpm	3kg/cm ²	720	735	15	2.5%	L	AP
NIP													

15.7 WEIGHT CHECK FOR 20 TABLETS:

S. NO.	INITIAL WEIGHT	FINAL WEIGHT	S. NO.	INITIAL WEIGHT	FINAL WEIGHT
1	715	725	1	718	726
2	716	740	2	723	732
3	717	741	3	725	724
4	710	725	4	722	729
5	715	726	5	720	721
6	710	721	6	719	722
7	712	725	7	712	724
8	710	726	8	715	726
9	712	740	9	714	725
10	715	721	10	712	732
11	710	720	11	714	724
12	715	725	12	715	732
13	716	720	13	716	727
14	717	729	14	712	721
15	719	725	15	718	727
16	715	720	16	720	724
17	716	720	17	716	729
18	717	721	18	712	739
19	719	722	19	716	740
20	718	722	20	718	724
TOTAL	14,250	14,710	TOTAL	14,249 gm	14,629 gm

Checked by Production:

Checked by IPQA:

Prepared by:

Checked by:

Approved By:

Dept.

Production

Production

Quality Assurance

Head Quality Assurance

Sign.

1. Ka

P. Anand

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Date _____

30/07/2022

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2010/04/27

30/03/2022

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	BATCH MANUFACTURING RECORD		Product Code: B05	Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500		BMR. No.: BMR/T/305-00	Batch No.: <u>G1822068</u>
			Customer:	Generic Health Care Pvt. Ltd.

16.0 INSPECTION LINE CLEARANCE:

Date/Shift/Time: 11/04/2022 / G1 / 09:12

12/04/2022 / G1 / 09:39

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 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.	<u>PD/INB/002</u>	<u>PD/MED/002</u>	<u>Inspection - II</u>
Previous product	<u>Boncipro 250</u>		
Batch No.	<u>G1822069</u>		
Cleaned by	<u>Shamini</u>		
Checked by Production Sign/Date:	<u>M. Kalu</u> <u>11/04/2022</u>		
Verified by IPQA Sign/Date:	<u>S</u> <u>11/04/2022</u>		

ENVIRONMENTAL CONDITIONS:		Date: <u>11/04/2022</u> Time: <u>09:44</u>		Date: <u>12/04/2022</u> Time: <u>09:41</u>			
		Observation	Prod. Sign.	Verified by IPQA	Observation	Prod. Sign.	Verified by IPQA
(Refer to SOP No.: QAGN/011)	Temperature °C Limit: NMT 25 °C	<u>23°C</u>	<u>M. Kalu</u>	<u>S</u>	<u>23°C</u>	<u>M. Kalu</u>	<u>S</u>
	Relative Humidity % Limit: NMT 60%	<u>52%</u>	<u>M. Kalu</u>	<u>S</u>	<u>52%</u>	<u>M. Kalu</u>	<u>S</u>

APPROVAL FOR INSPECTION:

Production Sign/Date: M. Kalu / 11/04/2022

Line Clearance IPQA Sign. / Date: S / 11/04/2022

Start Time/Date: 09:48 / 11/04/2022 End Time/Date: 12:05 / 12/04/2022

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<u>L. Vasa</u>	<u>P. Arun</u>	<u>V. Suresh</u>	<u>P. Arun</u>	
Date	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 36 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: G18 2 2068 Generic Health Care Pvt. Ltd.

17.0 INSPECTION PROCESS

17.1 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.

17.2 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/002 & PD/MED/007....					Checked by Production	Verified By IPQA
		Ferrous (0.3 mm)	Stainless steel (0.5 mm)	Non-Ferrous (0.4 mm)	Non-metallic	Result		
09/04/2022 09:51	1	✓	✓	✓	x	Pass	M. Kalp	G
	2	✓	✓	✓	x	Pass	M. Kalp	G
	3	✓	✓	✓	x	Pass	M. Kalp	G
12/04/2022 09:50	1	✓	✓	✓	x	Pass	M. Kalp	G
	2	✓	✓	✓	x	Pass	M. Kalp	G
	3	✓	✓	✓	x	Pass	M. Kalp	G
12/04/2022 12:02	1	✓	✓	✓	x	Pass	M. Kalp	G
	2	✓	✓	✓	x	Pass	M. Kalp	G
	3	✓	✓	✓	x	Pass	M. Kalp	G

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

17.3 TABLETS VISUAL INSPECTION RECORD:

Date	Container No		Time		Total Quantity Rejected	Tablet Inspection Done by/Date	Checked by/Date
	From	To	Started	Completed			
09/04/2022	01	04	09:48	13:09	0.310	Shreeam 11/04/2022	M. Kalp 11/04/2022
12/04/2022	05	08	09:47	12:05	0.480	Shreeam 12/04/2022	M. Kalp 12/04/2022

17.4 WEIGHING RECORD OF INSPECTED TABLETS:

Container No	Gross weight Kg	Tare weight Kg	Net. weight Kg	Container No	Gross weight Kg	Tare weight Kg	Net. weight Kg
1	28.810	2.590	26.220	6	26.370	2.270	24.100
2	30.010	2.430	27.580	7	32.530	2.410	30.120
3	31.290	2.410	28.880	8	35.670	2.730	32.940
4	28.970	2.550	26.420	9	22.640	3.060	19.580
5				10			
Total			108.400 Kg	Total			106.740 Kg
				Grand Total			215.140 Kg

Weighing Done By: Shreeam..... Checked By Prod./ Date: M. Kalp 12/04/2022 Verified by IPQA Sign./Date: G 12/04/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	P. Aravind	Shreeam	V. R.
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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	BATCH MANUFACTURING RECORD		Product Code: B05
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00	Batch Size: 3,00,000 Tablets
		Customer:	Batch No.: 61822068
			Generic Health Care Pvt. Ltd.

17.5 RECONCILIATION: (INSPECTION OF TABLETS)

1.0	Theoretical weight of Tablets	:	220.800 kg	3,00,000 No's
2.0	Tablets transferred for Inspection	:	215.870 kg	293700 No's
3.0	Total weight of good Tablets	:	215.140 kg	292707 No's
4.0	Rejected Tablets	:	0.730 kg	993 No's
5.0	*Yield = $\frac{3.0}{1.0} \times 100$	:		97.56 %

*Actually yield will be calculated after 3 validation batches.

Total rejects destroyed:0.730.....Kg.

Rejected materials should be destroyed in the presence of QA.

Done by Production sign/Date: *M. K. S.* 12/04/2022.

Checked by IPQA sign/Date: *S.* 12/04/2022.

17.6 RELEASE FOR PACKING:

BMR reviewed by IPQA Sign/Date : *P. N. N.* 12/04/2022

BMR Released for packing by QA Head Sign/Date: *S.* 12/04/2022

18.0 BMR REVIEW DETAILS:

Reviewed by	Name	Sign./Date
Production Executive	<i>Vignesh</i>	<i>Vignesh</i> 12/04/2022
QA Executive	<i>Ram Kumar</i>	<i>Ram Kumar</i> 12/04/2022
Production Assistant Manager/ HOD	<i>P. N. N.</i>	<i>P. N. N.</i> 12/04/2022
QA Manager/ HOD	<i>Stephen R</i>	<i>Stephen R</i> 12/04/2022

19.0 REVISION HISTORY:

Sr. No.	Document No.	Reason for Revision	Supersedes No.
1	BMR/T/305-00	New Document	Nil

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. K.</i>	<i>P. N. N.</i>	<i>Vignesh</i>	<i>Vignesh</i>
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villanur Commune, Puducherry-605009.		VALIDATION BATCH Page 1 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: 41822116 Generic Health Care Pvt. Ltd.

BATCH MANUFACTURING RECORD COVER SHEET

PRODUCT NAME : BONCIPRO 500
 GENERIC NAME : Ciprofloxacin Tablets BP 500 mg
 LABEL CLAIM : Each film coated tablet contains:
 Ciprofloxacin Hydrochloride BP
 Equivalent to Ciprofloxacin 500 mg
 Colour: Approved Colour used.
 MFR No. / Reference Document No. : MFR/T/177-00
 BMR No. : BMR/T/305-00
 REVISION No. : 00
 SUPERSEDES No. : NIL
 BMR EFFECTIVE BATCH NUMBER/DATE : 41822068 / 01/04/2022
 MFG.LIC No. : PON/DRUGS/21 14 4376
 STORAGE : Store in cool and dry place. Protect from light and moisture.
 BMR ISSUED BY/DATE (QA) : S. S. 05/09/2022
 BMR CHECKED & RECEIVED BY/DATE (PRODUCTION) : P. Anand 05/09/2022
 SHELF LIFE : 36 Months
 BATCH SIZE : 3,00,000 Tablets (220.800 Kg)
 MFG. DATE: 09/2022 : EXP. DATE: 08/2025

RECOVERY ADDITION RECORD				
BATCH NO	MFG	EXP	QUANTITY	REVISED BATCH SIZE

ALLOTTED BY: S. S. 05/09/2022 : COUNTER CHECKED BY: [Signature] 05/09/2022
 QA SIGN/DATE: : QA SIGN/DATE: :
 DATE OF COMMENCEMENT: 05/09/2022 : DATE OF COMPLETION: 10/09/2022
 RELEASED QUANTITY OF TABLETS FOR PACKING : 291989 Nos
 RELEASE FOR PACKING STAGE : [Signature] 10/09/2022
 HEAD OF QA SIGN/DATE:

This BMR contains 37 Pages + Nil Additional Pages

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	P. Anand	[Signature]	[Signature]
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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	BATCH MANUFACTURING RECORD	Product Code: B05	Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00	Batch No.: 61822116
		Customer:	Generic Health Care Pvt. Ltd.

1.0 INDEX

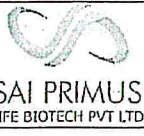
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Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	P. Anand	[Signature]	[Signature]
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

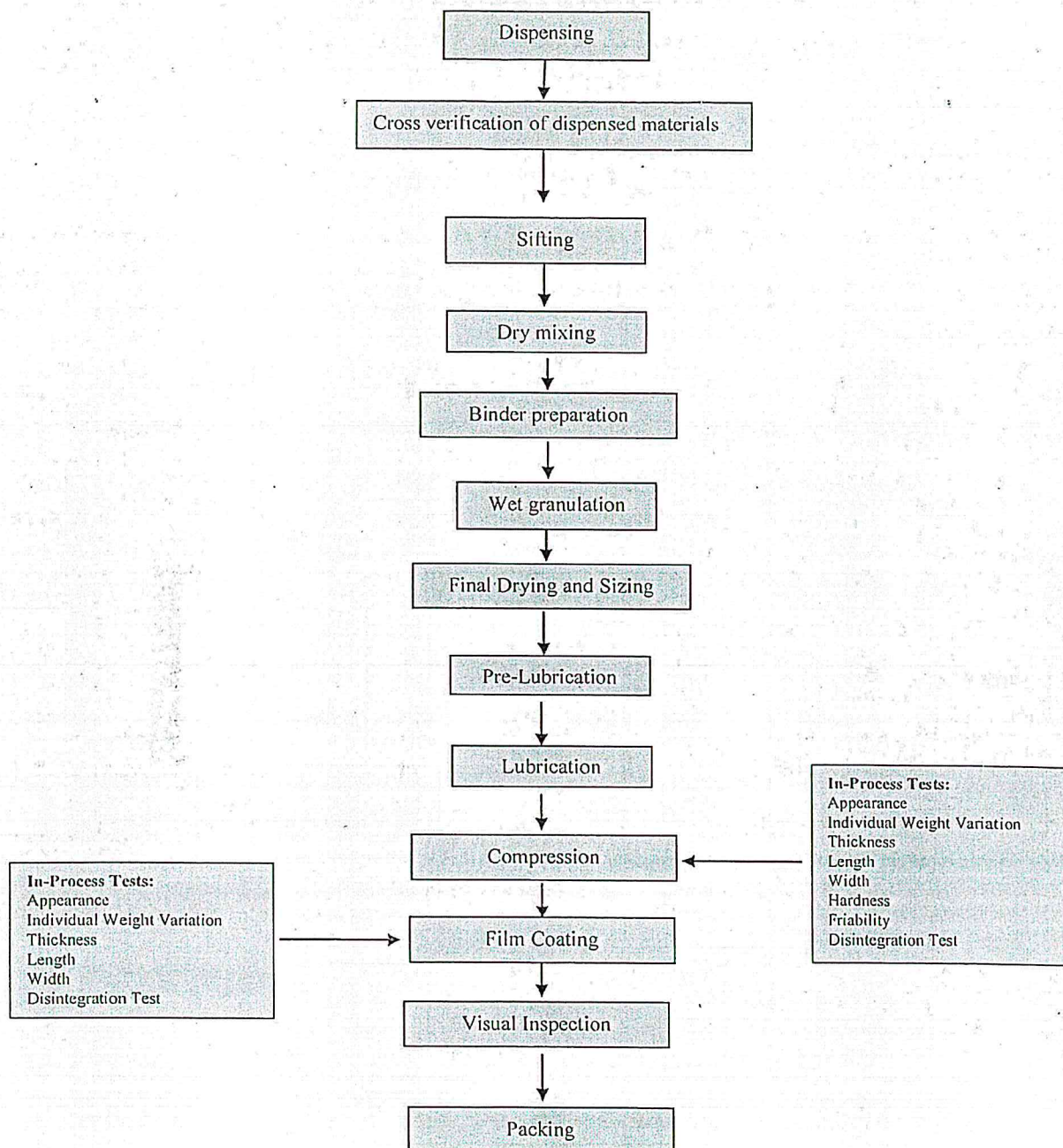
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	BATCH MANUFACTURING RECORD	Product Code: B05	Batch Size: 3,00,000 Tablets
	Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:
			Batch No.: 61822116 Generic Health Care Pvt. Ltd.

2.0 PROCESS FLOW CHART

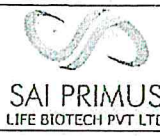


Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	P. Anub	V. S.	V. S.
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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	BATCH MANUFACTURING RECORD		Product Code: B05
	Product: BONCIPRO 500		Batch Size: 3,00,000 Tablets
		BMR. No.: BMR/T/305-00	Batch No.: 618 22 116
		Customer:	Generic Health Care Pvt. Ltd.

3.0 INDENT OF ACTIVE PHARMACEUTICAL INGREDIENTS & EXCIPIENTS:

Sr. No.	Name of the Ingredient	Spec.	Item Code	Quantity/ Tablets (mg)	Std. quantity per 3,00,000 tablets (kg)	OA/ PL (%)	Req. quantity per 3,00,000 tablets (kg)
Dry mixing material:							
1	Ciprofloxacin Hydrochloride*	BP	RAI/SP/C015	582.200	174.660	-	174.660
2	Microcrystalline cellulose PH102 **	BP	REX/SP/M010	108.050	32.415	-	32.415
Binder Material:							
3	Purified Water	BP	NA	q.s.	83.000	-	83.000
Theoretical Weight of Dried Granules				690.250	207.075	-	207.075
Lubrication Material:							
4	Sodium Stach Glycollate	BP	REX/SP/S004	21.000	6.300	-	6.300
5	Colloidal Silicon Dioxide	BP	REX/SP/C022	1.750	0.525	-	0.525
6	Magnesium Stearate	BP	REX/SP/M011	7.000	2.100	-	2.100
Theoretical Weight of the Lubricated granules				720.000	216.000	-	216.000
Theoretical weight of Compressed tablet				720.000	216.000	-	216.000
Coating Material:							
7	Hydroxy Propyl Methyl Cellulose (6 cps)	BP	REX/SP/H016	10.800	3.240	25	4.050
8	Titanium Dioxide	BP	REX/SP/T002	1.200	0.360	25	0.450
9	Ponceau 4R Lake	IHS	REX/SP/P006	0.600	0.180	25	0.225
10	Purified Talc	BP	REX/SP/P017	1.000	0.300	25	0.375
11	Polyethylene Glycol 6000	BP	REX/SP/P003	2.400	0.720	25	0.900
12	Purified Water	BP	NA	q.s.	42.500	-	42.500
Theoretical weight of Coated tablet ^s				736.000	220.800	-	220.800

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

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

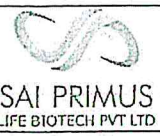
\$ Average weight rounded off.

OA: Overages, PL: Process loss

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	P. Arul	[Signature]	[Signature]
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 5 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: 41822116 Generic Health Care Pvt. Ltd.

4.0 ASSAY AND LOD CALCULATIONS FOR CIPROFLOXACIN HYDROCHLORIDE:

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

Standard quantity of Ciprofloxacin Hydrochloride (A): 174.660 Kg

Standard quantity of Microcrystalline Cellulose PH 102 (B): 32.415 Kg

Calculation for Ciprofloxacin Hydrochloride:

1) Calculation for Single A. R. No. Rm1/00046, Assay on dried basis: 100.50 w/w, LOD: 5.855 w/w
 Exp. Date: 10.02.22

$$\text{Actual Quantity (Kg) (C)} = \frac{\text{Standard qty. required} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{174.660 \times 100 \times 100}{100 \times (100 - 5.855)} = 185.522 \text{ Kg/2}$$

LOT I: 92.761 Kg, LOT II: 92.761 Kg

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

Actual Quantity (Kg) (D) = Standard quantity of Microcrystalline Cellulose PH 102 - Excess Calculated quantity of Ciprofloxacin Hydrochloride

$$= 32.415 \text{ Kg} - 10.862 \text{ Kg}$$

$$= 21.553 \text{ Kg/2. LOT I: } 10.776 \text{ Kg, LOT II: } 10.776 \text{ Kg}$$

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

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

Calculation for Remaining Quantity Required (G):

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

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

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

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

LOT I: _____ Kg, LOT II: _____ Kg

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

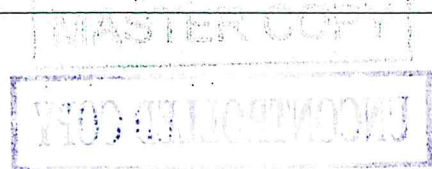
Actual Quantity (Kg) (D) = Standard quantity of Microcrystalline Cellulose PH 102 - Excess Calculated quantity of Ciprofloxacin Hydrochloride

$$= 32.415 \text{ Kg} - \text{_____ Kg}$$

$$= \text{_____ Kg/2. LOT I: _____ Kg, LOT II: _____ Kg}$$

Done By/On (QA): [Signature] 30/03/2022 Checked By/On (Production): P. Anant 30/03/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K.</u>	<u>P. Anant</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>



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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

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

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BATCH MANUFACTURING RECORD

Product Code: B05

Batch Size: 3,00,000 Tablets

Product

BONCIPRO 500

BMR. No.: BMR/T/305-00

Batch No.: 51822116

Customer:

Generic Health Care Pvt. Ltd.

5.0 DISPENSING LINE CLEARANCE CHECKS

Date: 05/09/2022 Time: 15:00

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.	ST10101	ST101004	ST101005	ST101006	Dispensing booth
Previous Product	Alendronate Sodium 70mg				
B. No.	ST026 H2A				
Cleaned by Sign/Date	Penmal / 05/09/2022				
Checked by Store Sign/Date	Pb / 05/09/2022				
Verified by IPQA Sign/Date	P05/09/2022				

ENVIRONMENTAL CONDITIONS: Date: 05/09/2022 Time: 15:10

(For Reference SOP No.: QAGN/011)

	Observation	Checked by Store Sign/Date	Verified by IPQA Sign/Date
Temperature (Limit: NMT 25°C)	23°C	Pb 05/09/2022	P05/09/2022
Relative Humidity % (Limit: NMT 60%)	55%	Pb 05/09/2022	P05/09/2022
Differential Pressure (NLT 10 Pascal)	11 Pascal	Pb 05/09/2022	P05/09/2022
Differential Pressure across the booth Limit: 5 to 20 mm Water	11 mm	Pb 05/09/2022	P05/09/2022

APPROVAL FOR DISPENSING BY IPQA: Sign: [Signature] Date: 05/09/2022

Dispensing start Time: 15:18 End Time: 16:00

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. K.	T. Anand	[Signature]	[Signature]	
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022	

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SAI PRIMUS
LIFE BIOTECH PVT LTD

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

SAI PRIMUS LIFE BIOTECH PVT LTD

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Product

BONCIPRO 500

BATCH MANUFACTURING RECORD

Product Code: B05

Batch Size: 3,00,000 Tablets

BMR. No.: BMR/T/305-00

Batch No.: G1822116

Customer: Generic Health Care Pvt. Ltd.

5.1 Dispensing Weighing Sheet:

Balance ID: SAI 2024 004 Date: 30/03/2022 Shift: Day Time: 15:18

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 Checked by Production (Sign & Date)	Verified by IPQA (Sign & Date)
								Gross Wt.	Tare Wt.	Net Wt.				

LOT - I

Dry mixing material:

1	Ciprofloxacin Hydrochloride	BP	RAI/SP/C015	Kg	87.330	92.761	Rm 9/22/0692	34.260	0.260	34.000	05/09/22	05/09/22	05/09/22	05/09/22
2	Microcrystalline cellulose PH102	BP	REX/SP/M010	Kg	16.208	10.776	Rm 9/22/0692	10.976	0.200	10.776	05/09/22	05/09/22	05/09/22	05/09/22

Binder Material:

3	Purified Water	BP	NA	Kg	41.500	41.500	PW/22/0692	44.500	3.000	41.500	05/09/22	05/09/22	05/09/22	05/09/22
---	----------------	----	----	----	--------	--------	------------	--------	-------	--------	----------	----------	----------	----------

LOT - II

Dry mixing material:

4	Ciprofloxacin Hydrochloride	BP	RAI/SP/C015	Kg	87.330	92.761	Rm 9/22/0692	34.260	0.260	34.000	05/09/22	05/09/22	05/09/22	05/09/22
5	Microcrystalline cellulose PH102	BP	REX/SP/M010	Kg	16.208	10.776	Rm 9/22/0692	10.976	0.200	10.776	05/09/22	05/09/22	05/09/22	05/09/22

Binder Material:

6	Purified Water	BP	NA	Kg	41.500	41.500	PW/22/0692	44.500	3.000	41.500	05/09/22	05/09/22	05/09/22	05/09/22
---	----------------	----	----	----	--------	--------	------------	--------	-------	--------	----------	----------	----------	----------

Lubrication Material:

7	Sodium Stach Glycolate	BP	REX/SP/S004	Kg	6.300	6.300	Rm 9/22/0692	6.380	0.080	6.300	05/09/22	05/09/22	05/09/22	05/09/22
8	Colloidal Silicon Dioxide	BP	REX/SP/C022	Kg	0.525	0.525	Rm 9/22/0692	0.598	0.070	0.528	05/09/22	05/09/22	05/09/22	05/09/22
9	Magnesium Stearate	BP	REX/SP/M011	Kg	2.100	2.100	Rm 9/22/0692	2.180	0.080	2.100	05/09/22	05/09/22	05/09/22	05/09/22

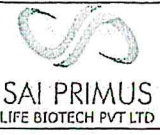
Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka	SP. Arul	N. Sub	V. Ka	
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 8 of 37
	BATCH MANUFACTURING RECORD Product Code: B05		Batch Size: 3,00,000 Tablets
	BONCIPRO 500 Customer:		Batch No.: 61822116 BMR. No.: BMR/T/305-00 Generic Health Care Pvt. Ltd.

Sr. No.	Ingredients	Spec.	Item code	UOM	Std. Qty.	Req. Qty.	A.R No.	Issued Qty.		Weighed By Store (Sign & Date)	Checked By (IPQA) (Sign & Date)	Cross Checked by	
								Gross Wt.	Net Wt.			Checked by Production (Sign & Date)	Verified by IPQA(Sign & Date)
Coating Material:													
10	Hydroxy Propyl Methyl Cellulose (6 cps)	BP	REX/SP/H016	Kg	4.050	4.050	RM4161202	4.120	4.050	08/08/2022	08/08/2022	R-822	08/08/2022
11	Titanium Dioxide	BP	REX/SP/T002	Kg	0.450	0.450	RM4161181	490.05	480.05	08/08/2022	08/08/2022	R-822	08/08/2022
12	Ponceau 4R Lake	IHS	REX/SP/P006	Kg	0.225	0.225	RM4160298	205.05	205.05	08/08/2022	08/08/2022	R-822	08/08/2022
13	Purified Talc	BP	REX/SP/P017	Kg	0.375	0.375	RM4160440	415.05	375.05	08/08/2022	08/08/2022	R-822	08/08/2022
14	Polyethylene Glycol 6000	BP	REX/SP/P003	Kg	0.900	0.900	RM4160806	940.05	900.05	08/08/2022	08/08/2022	R-822	08/08/2022
15	Purified Water	BP	NA	Kg	42.500	42.500	RM41610702	45.50	40.50	08/08/2022	08/08/2022	R-822	08/08/2022

Prepared by:		Checked by:		Approved By:	
Dept. Production		Production		Head Quality Assurance	
Sign. L. Ka		Quality Assurance			
Date 30/03/2022		30/03/2022		20/03/2022	

 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 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: 41822116 Generic Health Care Pvt. Ltd.

6.0 GRANULATION LINE CLEARANCE CHECKS: Date/Shift: 05/09/22 / 17:20 / 06/09/22 / 09:25

Sr. No.	Checks	Time:	*Observations					
			17:20		09:25			
			Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty SS containers, polythene bags, Tags and documents of previous batch/product are removed.		✓	✓	✓	✓		
2	Check and ensure that Scrap from waste bin is removed and new polythene bag is put into it.		✓	✓	✓	✓		
3	Check and ensure that display, display stand, weighing balance are clean.		✓	✓	✓	✓		
4	Check and ensure that SS storage Cabinet and Drain point are clean.		✓	✓	✓	✓		
5	Check and ensure that absence of previous batch/product from area below machine		✓	✓	✓	✓		
6	Check and ensure that all equipment body and inside the vessel are clean		✓	✓	✓	✓		
7	Check and ensure that Tube light fixture, supply grills, riser grills and filters and electrical fixtures are clean		✓	✓	✓	✓		
8	Check and ensure that instruments to be used are within calibration due date and earthing connection.		✓	✓	✓	✓		
9	Check and ensure that daily records (Logbook, Balance, Temp. & RH) are updated and signed.		✓	✓	✓	✓		
10	Check and ensure that environment condition and record on BMR		✓	✓	✓	✓		
11	Check and ensure that rinse water is released from QC and attached the test request from (TRF)		✓	✓	NA	NA		
12	Equipment status is updated for Cleaned and Preventive maintenance.		✓	✓	✓	✓		

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

Equipment	Sifter	Multimill	RMG/Mass Mixer	FBD/Tray Drier	Area
EQP. ID No.	PD14BS/002	PD14mm/002	PD14mm/001	PD14BD/001	Granulation Room
Previous Product	Actihealth - OD				
Batch No.	PA0622014				
Cleaned by	Karthi				
Checked by	M				
Verified by	R				

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 05/09/22 Time: 17:22			Date: 06/09/22 Time: 09:25			Date: Time:		
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	23°C	M	R	22°C	M	R			
RH % (NMT 60%)	52%	M	R	50%	M	R			
DP (NLT 10 Pascal)	11	M	R	12	M	R			

APPROVAL FOR SIFTING AND GRANULATION:

Production Sign/Date:	M 05/09/22	M 06/09/22	
IPQA Sign/Date:	R 05/09/22	R 06/09/22	
Start and End Time:	NA	NA	09:32 14:55

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka	P. Anand	V. Senthil	R. D.	
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 10 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:		Batch No.: 41822116 Generic Health Care Pvt. Ltd.

7.0 LOT - I: GRANULATION SIFTING INSTRUCTIONS AND SIFTING RECORD: Date: 06/09/22 Shift:h.....

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	Vfd by
						From	To				
Dry mixing:											
1	Ciprofloxacin Hydrochloride	92.761 87.8	40#	Pa130-26-40/09	OK	09:32	09:55	OK	From	NY	G.P
2	Microcrystalline cellulose PH102	10.776	40#	Pa130-26-40/09	Not OK	09:56	10:00	Not OK	From	NY	G.P
Binder Material:											
3	Purified Water	41.500	NA	—	NA	—	—	NA	—	—	—

7.1 MANUFACTURING PROCESS:

Step No.	Process Instructions	Date: 06/09/22		Done by	Checked by	Verified by
		Time				
		Started	Completed			
1	Dry mixing: Transfer the sifted material from step 7.0 (1-2) into the RMG/Mass Mixer. Mix for 10 minute with impeller at slow speed and chopper 'off'. Impeller Speed: <u>45</u> RPM	10:03	10:13	Rajin	NE	G.P
2	Wet Granulation: Binder Addition: Add Purified water into the contents of RMG take 2 - 5 min for water addition with impeller slow speed and Chopper OFF. Impeller Speed: <u>45</u> RPM, Chopper: <u>1800</u> RPM	10:14	10:19	Rajin	NE	G.P
3	After Water addition allow mixing to form a coherent mass. If required allow mixing for 1 min or till required consistency of granules obtained with impeller at slow speed and chopper at slow speed. Impeller Speed: <u>55</u> RPM, Chopper Speed: <u>1800</u> RPM Additional quantity of Purified Water <u>NA</u> Kg	10:20	10:21	Rajin	NE	G.P
4	Note the Ampere at granulation end point .. <u>3.1</u> AMP.		no		NE	G.P
5	Discharge the wet mass to FBD bowl or Tray drier operating slow speed of Impeller and slow speed of Chopper. Impeller Speed: .. <u>55</u>RPM, Chopper Speed.. <u>1800</u> RPM	10:22	10:26	Rajin	NE	G.P

7.2 DRYING:

Step No	Process Instructions	Date : 06/09/22		Done by	Checked by	Verified by
		Time				
		Started	Completed			
1	Load the wet mass into the FBD bowl and air dry the wet mass.					
2	Load the wet mass into the cleaned FBD bowl Dry at inlet temperature 60-65°C till the LOD reached up to 1.5 – 3.0% w/w.	10:28	12:25	Rajin	ny	G.P
3	LOD checking temperature at 105°C (Auto mode). LOD should be 1.5% - 3.0% w/w.	Observed LOD in %		Rajin	ny	G.P
		1.56 %				

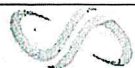
7.3 FBD Finger bag Integrity checks:

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

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	I. K.	P. Arun	V. Arun	V. Arun	
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022	

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SAI PRIMUS
LIFE BIOTECH PVT LTD

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

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BATCH MANUFACTURING RECORD

Product Code: B05

Batch Size: 3,00,000 Tablets

Product

BONCIPRO 500

BMR. No.: BMR/T/305-00

Batch No.: 41822116

Customer:

Generic Health Care Pvt. Ltd.

7.4 SET PARAMETERS:

Sr. No.	Operation	Started at	Inlet Temp. (60-65°C)	Outlet Temp.	Product Temp.	Completed at	Total Time (mins)	LOD Observed	Done by	Checked By
1.	Air-Drying-I	10:28		NA		10:33	05	NA	Rajh	MS
2.	Raking-I	10:34	NA	NA	NA	10:39	05	NA	Rajh	MS
3.	Drying-I	10:40	65°C	42°C	40°C	11:15	35	7.54	Rajh	MS
4.	Raking-II	11:16	NA	NA	NA	11:20	04	NA	Rajh	MS
5.	Drying-II	11:21	65°C	40°C	37°C	11:50	29	4.49	Rajh	MS
6.	Raking-III	11:51	NA	NA	NA	11:55	04	NA	Rajh	MS
7.	Drying-III	11:56	65°C	42°C	39°C	12:25	29	1.56	Rajh	MS
Total Drying Time (Exclude Raking & Air-Drying time): 93 min							LOD Verified By IPQA: G.P			
Total Drying time: 111 min										

7.5 SIFTING AND MILLING:

S. No	Process Instructions	Date : 06/09/22		Done by	Checked by	Verified by
		Time				
		Started	Completed			
1.	Sift the dried granules through 20 # sieve. Record the observation.	12 : 31	12 : 48	Rishik	M	G.P
2.	Mill the oversized granules through 2.0 mm multi mill screen fitted with (knives forward medium speed) followed by sifting through 20# sieve on vibrating sifter and collect the sifted granules in double polythene lined cleaned HDPE containers, record the weights.	12 : 49	12 : 55	Rishik	M	G.P
3.	Unload the granules in to cleaned HDPE containers in double polythene bag.	12 : 56	13 : 00	Rishik	M	G.P

7.6 SIZING RECORD:

Mesh and screen size	Sieve ID No	Integrity checked before use	Date : 06/09/22		Integrity checked After use	Done by	Checked by	Verified by
			Time					
			Started	Completed				
20#	PP130-SE-20/02	OK/Not OK	12:30	12:49	OK/Not OK	Rishik	MS	G.P
2.0 mm	PP130-SE-20/02	OK/Not OK	12:49	12:56	OK/Not OK	Rishik	MS	G.P

8.0 LOT - II: GRANULATION SIFTING INSTRUCTIONS AND SIFTING RECORD: Date: 06/09/22 Shift: 2nd

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	Vfd by
						From	To				
Dry mixing:											
1	Ciprofloxacin Hydrochloride	92.761	40#	PP130-SE-40/09	OK/ Not OK	10:03	10:30	OK/ Not OK	Rishik	MS	G.P
2	Microcrystalline cellulose PH102	10.776	40#	PP130-SE-40/09		10:31	10:35		Rishik	MS	G.P
Binder Material:											
3	Purified Water	41.500	NA	—————	NA	—————	—————	NA	—————	—————	—————
Lubrication Material:											
4	Sodium Stach Glycollate	6.300	60#	PP130-SE-60/06	OK/ Not OK	14:35	14:38	OK/ Not OK	Premn	MS	G.P
5	Colloidal Silicon Dioxide	0.525	60#			14:39	14:42		Premn	MS	G.P
6	Magnesium Stearate	2.100	60#			14:44	14:46		Premn	MS	G.P

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. G.	P. Anub	V. V.	V. V.	
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 12 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: G1822116 Generic Health Care Pvt. Ltd.

8.1 MANUFACTURING PROCESS:

Step No.	Process Instructions	Date: 06/09/22		Done by	Checked by	Verified by
		Time				
		Started	Completed			
1	Dry mixing: Transfer the sifted material from step 8.0 (1-2) into the RMG/Mass Mixer. Mix for 10 minute with impeller at slow speed and chopper 'off'. Impeller Speed: <u>45</u> RPM	10:45	10:55	Refn	ny	G.P
2	Wet Granulation: Binder Addition: Add Purified water into the contents of RMG take 2 - 5 min for water addition with impeller slow speed and Chopper OFF. Impeller Speed: <u>45</u> RPM, Chopper: <u>1800</u> RPM	10:56	11:01	Refn	ny	G.P
3	After Water addition allow mixing to form a coherent mass. If required allow mixing for 1 min or till required consistency of granules obtained with impeller at slow speed and chopper at slow speed. Impeller Speed: <u>55</u> RPM, Chopper Speed: <u>1800</u> RPM Additional quantity of Purified Water <u>NA</u> Kg	11:02	11:03	Refn	ny	G.P
4	Note the Ampere at granulation end point ... <u>3.4</u> ... AMP.				ny	G.P
5	Discharge the wet mass to FBD bowl or Tray drier operating slow speed of Impeller and slow speed of Chopper. Impeller Speed: ... <u>55</u> ...RPM, Chopper Speed... <u>1800</u> ... RPM	11:04	11:10	Refn	ny	

8.2 DRYING:

Step No	Process Instructions	Date : 06/09/22		Done by	Checked by	Verified by
		Time				
		Started	Completed			
1	Load the wet mass into the FBD bowl and air dry the wet mass.					
2	Load the wet mass into the cleaned FBD bowl Dry at inlet temperature 60-65°C till the LOD reached up to 1.5 – 3.0% w/w.	12:30	14:25	Refn	ny	G.P
3	LOD checking temperature at 105°C (Auto mode). LOD should be 1.5% - 3.0% w/w.	Observed LOD in %		Refn	ny	G.P
		1.78 %				

8.3 FBD Finger bag Integrity checks:

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

8.4 SET PARAMETERS:

Sr. No.	Operation	Started at	Inlet Temp. (60-65°C)	Outlet Temp.	Product Temp.	Completed at	Total Time (mins)	LOD Observed	Done by	Checked By
1.	Air-Drying-I	12:30		NA		12:35	05	NA	Refn	ny
2.	Raking-I	12:36	NA	NA	NA	12:40	04	NA	Refn	ny
3.	Drying-I	12:41	65°C	41°C	38°C	12:50	09	7.33	Refn	ny
4.	Raking-II	12:51	NA	NA	NA	13:05	04	NA	Refn	ny
5.	Drying-II	13:06	65°C	40°C	37°C	13:50	34	3.94	Refn	ny
6.	Raking-III	13:51	NA	NA	NA	13:55	04	NA	Refn	ny
7.	Drying-III	13:56	65°C	40°C	38°C	14:25	29	1.78	Refn	ny
Total Drying Time (Exclude Raking & Air-Drying time):							LOD Verified By IPQA: G.P			
Total Drying time:										

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka	P. Anub	V. S	V. S	
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 13 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: 61822116 Generic Health Care Pvt. Ltd.

8.5 SIFTING AND MILLING:

S. No	Process Instructions	Date: 06/09/22		Done by	Checked by	Verified by
		Time				
		Started	Completed			
1.	Sift the dried granules through 20 # sieve. Record the observation.	14:29	14:43	Pithir	M	G.P.
2.	Mill the oversized granules through 2.0 mm multi mill screen fitted with (knives forward medium speed) followed by sifting through 20# sieve on vibrating sifter and collect the sifted granules in double polythene lined cleaned HDPE containers, record the weights.	14:44	14:50	Pithir	M	G.P.
3.	Unload the granules in to cleaned HDPE containers in double polythene bag.	14:51	14:55	Pithir	M	G.P.

8.6 SIZING RECORD:

Mesh and screen size	Sieve ID No	Integrity checked before use	Date : 06/09/22		Integrity checked After use	Done by	Checked by	Verified by
			Time					
			Started	Completed				
20#	P312-562-06	OK/ Not OK	14:28	14:44	OK/ Not OK	Pithir	M	G.P.
2.0 mm	P312-562-06	OK/ Not OK	14:44	14:51	OK/ Not OK	Pithir	M	G.P.

8.7 WEIGHING OF DRIED GRANULES:

S. No.	Tare Weight (Kg)	Gross Weight (Kg)	Net Weight (Kg)	Weighed By	Checked By
1	1.940	18.780	16.840	Reyh	M
2	2.500	32.280	29.780	Reyh	M
3	2.200	28.040	25.840	Reyh	M
4	1.800	30.920	29.120	Reyh	M
5	2.140	30.600	28.460	Reyh	M
6	2.200	34.300	32.100	Reyh	M
7	2.500	32.940	30.440	Reyh	M
8	1.810	15.000	13.190	Reyh	M
9					
10					
Total			205.770		

Theoretical Weight: 207.075 Kg

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

Actual Yield (Weight): 205.770 Kg % Yield: 99.36 %

Date: 06/09/22

Production Executive Sign. / Date: 06/09/22

Verified By IPQA: G.P. 06/09/22

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K.	P. Arun	V. S. S.	G.P.
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 14 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
	Product BONCIPRO 500	BMR. No.: BMRT/305-00 Customer:	Batch No.: 318 22116 Generic Health Care Pvt. Ltd.

9.0 BLENDING LINE CLEARANCE CHECKS: Date/Shift: **06/09/2022 09 / 1**

Sr. No.	Checks	Time	*Observations					
			1A129					
			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	Blender	Area
EQP. ID No.	P01DCB1002	Blender - B
Previous Product	Perfexin	
Batch No.	632001221AF	
Cleaned by	Praveen	
Checked by	At 06/09/2022	
Verified by	G.P.	

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 06/09/2022 Time: 14:32			Date: Time:			Date: Time:		
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	22°C	At	G.P.						
RH % (NMT 60%)	50%	At	G.P.						
DP (NLT 10 Pascal)	10	At	G.P.						

APPROVAL FOR SIFTING AND BLENDING:

Production Sign/Date:	At 06/09/2022		
IPQA Sign/Date:	G.P. 06/09/2022		
Start and End Time:	14:35	16:40	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	P. Aravind	At	At
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 15 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:		Batch No.: 61822116 Generic Health Care Pvt. Ltd.

9.1 BLENDING AND LUBRICATION PROCESS:

Date: 06/09/22 Shift: 1st

Step No.	Process Instructions	Time		Done by	Checked by Prod.	Verified by IPQA
		Started	Completed			
1	Use hand gloves and goggles while handling the materials.					
2	Operate the Octagonal Blender as per the current version of the SOP No. PDOP/009.					
Pre-lubrication:						
1	Load the dried and sifted granules from step 8.7, sifted Material from step 8.0 (4,5) in to the blender and mix at 10 RPM for 10 minutes.	15:48	15:58	praveen	mg	mg
Lubrication:						
2	Load the Sifted Magnesium Stearate into the above Pre-lubricated blend and mix for further at 10 RPM for 3 minutes.	16:01 16:05 16:09	16:02 16:06 16:10	praveen	mg	mg
3	Unload the lubricated blend in HDPE container having double lined	16:25	16:36	praveen	mg	mg

9.2 WEIGHING OF FINAL BLEND: Balance I.D. No.: PD/RAL/005

Date: 06/09/22 Shift: 1st Time: 16:40

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	30.820	1.850	28.970	praveen	mg	6	32.120	1.800	30.320	praveen	mg
2	37.160	2.500	34.660	praveen	mg	7	26.160	2.500	23.660	praveen	mg
3	39.840	2.400	37.440	praveen	mg	8					
4	31.660	2.200	29.460	praveen	mg	9					
5	31.540	1.940	29.600	praveen	mg	10					
Theoretical weight of Blend:						216.000 Kg					
Actual weight of Blend:						214.110 Kg					
Verified by IPQA						06/09/22					

9.3 RECONCILIATION:

1.0	Theoretical weight of blend	:	216.000 Kg
2.0	Actual Weight of blend	:	214.110 Kg
3.0	Manufacturing Loss (Blending stage) @	:	1.688 Kg
4.0	In-process samples		
	A	IPQA Samples	0.030 Kg
	B	QC Samples	0.150 Kg
	C	Validation Samples	0.022 Kg
5.0	Total samples: (A + B + C)	:	0.202 Kg
6.0	Total: (2.0 + 5.0)	:	214.312 Kg
7.0	Yield {6.0 / 1.0 x 100}*	:	99.21 %

* Actually yield will be calculated after 3 validation batches.

@Total rejects destroyed: 1.688 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: 06/09/22 Checked By IPQA sign/Date: 06/09/22

Test request form raised by Prod Sign/Date: 06/09/22

Test request form received by IPQA Sign/Date: 06/09/22

9.4 RELEASED FOR COMPRESSION:

Reconciliation checked and blend is released for compression

IPQA Sign: mg		Date: 06/09/22	
Prepared by:		Checked by:	
Dept.	Production	Production	Quality Assurance
Sign.	L. Ka	P. Arun	mg
Date	30/03/2022	30/03/2022	30/03/2022
Approved By:		Head Quality Assurance	
Sign.		mg	
Date		30/03/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 16 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: 51822116 Generic Health Care Pvt. Ltd.

10.0 COMPRESSION LINE CLEARANCE CHECKS:

Date: 06/09/2022 / 07/09/2022 /

Sr. No.	Checks	Time:	*Observations					
			16:50		09:22			
			Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty SS containers/ containers polythene bags, Tags, and documents of previous batch/product are removed.		/	/	/	/		
2	Check and ensure that absence of tablets of previous batch/product from area below machine and inside machine by opening the guard of machine.		/	/	/	/		
3	Check and ensure that the machine body and machine parts like hoppers, feed frame, dust collection chute, hosepipe and ejection chute and control panel are clean.		/	/	/	/		
4	Check and ensure that absence of tablet of previous batch/product below the weighing balance, check the cleanliness of area and equipment.		/	/	/	/		
5	Check and ensure that working desk, analytical balance and other accessories are clean.		/	/	/	/		
6	Check and ensure that Deduster and hosepipe are clean.		/	/	/	/		
7	Check and ensure that Tube light fixture, supply grills, riser grills and filters and electrical fixtures are clean.		/	/	/	/		
8	Check and ensure that instruments to be used are within calibration due date, and Punch inspection record		/	/	/	/		
9	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.		/	/	/	/		
10	Check and ensure that environmental conditions are recorded in the BMR.		/	/	/	/		
11	Area, equipment and preventive maintenance status board is updated.		/	/	/	/		
12	Check and ensure that rinse water is released from QC and attached the test request from (TRF) in BMR		/	/	NA	NA		
13	Equipment status is updated for Cleaned and Preventive Maintenance label.		/	/	/	/		

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

Equipment	Compression Machine	Deduster	Area
EQP ID No.	PD/COM/001	PD/DED/001, PD/DED/002	Compression
Previous Product	Actihealth - OD		
Batch No.	FA0622014		
Cleaned by	Keshavan		
Checked by	R. S. 06/09/2022		
Verified by	06/09/2022		

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 06/09/22 Time: 16:55			Date: 07/09/22 Time: 09:25			Date: Time:		
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	23°C	R. S.	G.	24°C	R. S.	G.			
RH % (NMT 60%)	52%	R. S.	G.	53%	R. S.	G.			
DP (NLT 10 Pascal)	11 pascal	R. S.	G.	12 pascal	R. S.	G.			

APPROVAL FOR COMPRESSION:

Production Sign/Date:	R. S. 06/09/2022	R. S. 07/09/2022
IPQA Sign/Date:	G. 06/09/2022	G. 07/09/2022
Start and End Time:	19:30 20:00	09:30 17:35

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	P. Arundh	V. S.	R.
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 17 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00	Batch Size: 3,00,000 Tablets
		Customer:	Batch No.: 51822116
			Generic Health Care Pvt. Ltd.

11.0 COMPRESSION

11.1 PROCESS INSTRUCTIONS:

Sr. No.	Process Instructions
1	Check the cleanliness of area and equipment.
2	Ensure that the correct punch set are issued as per the Punch issue record.
3	Set the Double Rotary Compression Machine with a. Upper punches: 17.20 x 7.50 mm Caplet shaped with breakline on punches. b. Lower punches: 17.20 x 7.50 mm Caplet shaped plain punches. c. Dies: 17.20 x 7.50 mm suitable for above punches. d. Type of tooling - D.
4	Transfer the blend to compression cubicle. Load the blend into hopper manually.
5	Operate the Double Rotary Compression machine as per the current version of SOP: PDOP/010 and reject tablets of the first three round which shall be destroyed as per SOP: QAGN/048.
6	Collect the tablets of one complete rotation and carry out In-process checks for thickness, weight and appearance, record the observations in the BMR. Verify the tablets for uniformity of weight and hardness and record in the BMR.
7	Collect the compressed tablets in double polythene bag lined and labelled cleaned HDPE containers/SS container.
8	Check and record the weight of the compressed tablets.

11.2 GRANULES RECEIPT RECORD:

Balance ID. No.: PD/BAL/015 Date: 06/09/2022 Shift: G1.....Time: 17:01

Sr. No.	Gross Weight in Kg	Issued By Production	Checked by Production
1	46.660	AK	R. ell
2	22.280	AK	R. ell
3	23.740	AK	R. ell
4	19.060	AK	R. ell
5	25.650	AK	R. ell
6	26.960	AK	R. ell
7	24.280	AK	R. ell
8			
9			
10			

11.3 COMPRESSION SPECIFICATION / PARAMETERS:

Sr. No.	Parameter	Limits	No. of tablets to be checked from each side	Frequency	
				Production	IPQA
1.	Appearance	White coloured caplet shaped uncoated tablet with breakline on one side and plain on other side.	20	Every 30 min.	Every 2 Hr.
2.	Average weight (mg)	720.000 mg $\pm$ 3.0 % (698.400 mg – 741.600 mg)	20		
3.	Group Weight	14.400 g $\pm$ 3.0 % (13.968 g to 14.832 g)	20	Every 30 min.	Every 2 Hr.
4.	Uniformity of weight Tablets	720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)	20	Every 2 Hr.	Every 4 Hr.
5.	Hardness	NLT 3.0 Kg (To be Established)	4	Every 30 min.	Every 2 Hr.
6.	Thickness (mm)	5.20 mm $\pm$ 0.2 (5.00 mm – 5.40 mm) (To be Established)	4	Every 30 min.	Every 2 Hr.
7.	Friability	NMT 1% w/w	6 g	Every 2 Hr.	Every 4 Hr.
8.	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. Ka	P. Anand	V. S. S.	V. S. S.
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 18 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500		BMR. No.: BMR/T/305-00 Batch No.: G 18 22 116 Customer: Generic Health Care Pvt. Ltd.

11.4 COMPRESSION MACHINE RUNNING STATUS:

Date	Shift	Start Time	End Time	Total Hour	M/C Speed	Tablets Output	Done By	Checked By
06/09/2022	G1	19:30	20:00	30 min	12	200	Veeri	R. ell
07/09/2022	G2	09:30	17:35	08:00	12	292.925	Korawan	22
						mg		

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

Balance I.D. No.: PD/BAL/015

Date: 06/09/2022 Shift: G1 Time: 19:10...

LHS						RHS					
Sr. No.	Appearance*	Weight (in mg)	Thickness (in mm)	Length (in mm)	Width (in mm)	Sr. No.	Appearance*	Weight (in mg)	Thickness (in mm)	Length (in mm)	Width (in mm)
1	OK	725	5.33	17.23	7.54	1	OK	713	5.36	17.25	7.55
2	OK	723	5.32	17.20	7.56	2	OK	721	5.35	17.24	7.52
3	OK	723	5.36	17.24	7.55	3	OK	718	5.32	17.21	7.56
4	OK	717	5.35	17.25	7.53	4	OK	717	5.31	17.25	7.55
5	OK	717	5.36	17.27	7.54	5	OK	723	5.32	17.24	7.53
6	OK	726	5.37	17.26	7.56	6	OK	718	5.31	17.21	7.52
7	OK	721	5.36	17.25	7.55	7	OK	723	5.36	17.25	7.55
8	OK	716	5.37	17.26	7.54	8	OK	724	5.35	17.24	7.52
9	OK	723	5.39	17.25	7.56	9	OK	723	5.36	17.21	7.55
10	OK	713	5.36	17.21	7.55	10	OK	724	5.37	17.22	7.53
11	OK	724	5.37	17.22	7.56	11	OK	713	5.36	17.25	7.52
12	OK	722	5.36	17.24	7.52	12	OK	722	5.37	17.24	7.51
13	OK	711	5.35	17.25	7.51	13	OK	727	5.36	17.23	7.53
14	OK	711	5.32	17.21	7.53	14	OK	724	5.33	17.25	7.51
15	OK	722	5.36	17.26	7.51	15	OK	721	5.36	17.26	7.54
16	OK	721	5.37	17.25	7.54	16	OK	721	5.39	17.24	7.53
17	OK	722	5.38	17.21	7.53	17	OK	724	5.37	17.23	7.52
18	OK	723	5.39	17.26	7.52	18	OK	726	5.36	17.25	7.51
19	OK	724	5.37	17.23	7.53	19	OK	712	5.35	17.24	7.53
20	OK	713	5.36	17.24	7.51	20	OK	725	5.36	17.25	7.52
21	OK	726	5.35	17.23	7.54	21	OK	725	5.37	17.24	7.51
22	OK	717	5.34	17.24	7.53	22	OK	723	5.35	17.21	7.53
23	OK	721	5.32	17.26	7.52	23	OK	719	5.34	17.20	7.54
24	OK	711	5.34	17.25	7.51	24	OK	719	5.36	17.25	7.53
25	OK	724	5.36	17.26	7.53	25	OK	716	5.35	17.21	7.54
26	OK	723	5.35	17.25	7.54	26	OK	721	5.37	17.25	7.52
27	OK	714	5.36	17.26	7.53	27	OK	722	5.36	17.22	7.51
28	OK	722	5.37	17.23	7.52	28	OK	722	5.35	17.21	7.53
29	OK	722	5.38	17.22	7.55	29	OK	711	5.36	17.24	7.52
30	OK	721	5.37	17.25	7.51	30	OK	722	5.35	17.25	7.50

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

Done by Production Sign/Date: R. ell 06/09/2022

Checked by IPQA Sign/Date: G. ob 06/09/2022

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ke	P. Asub	Veeri		
Date	30/03/2022	30/03/2022	30/03/2022		30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 19 of 37	
	BATCH MANUFACTURING RECORD		Product Code: B05	
Product	BONCIPRO 500		Batch Size: 3,00,000 Tablets	
			Batch No.: 5182216	
			Customer:	
			Generic Health Care Pvt. Ltd.	

11.6 COMPRESSION SPECIFICATION AND PARAMETERS: Date: 06/09/2022 Shift: GT Time: 19:21

Parameters	Instrument used	Equip ID No.	Observations of LHS		Observations of RHS		Limits				
			Min	Max	Min	Max					
Appearance	Visual	NA	OK		OK		White coloured caplet shaped uncoated tablet with breakline on one side and plain on other side.				
Group Weight	Electronic Balance	PD/BAL/007	14.397 g		14.419 g		14.400 g $\pm$ 3.0 % (13.968 g to 14.832 g)				
Average weight	Electronic Balance		719.85 mg		720.95 mg		720.000 mg $\pm$ 3.0 % (698.400 mg – 741.600 mg)				
Individual weight	Electronic Balance		713 mg	726 mg	711 mg	727 mg	720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)				
Uniformity of weight	Electronic Balance		0.96 %	0.84 %	1.36 %	0.83 %					
Thickness	Vernier Caliper	QANEC/004	5.32 mm		5.39 mm		5.20 mm $\pm$ 0.2 (5.00 mm – 5.40 mm) (To be Established)				
Hardness	Hardness Tester	QA/HRT/001	12.5	130	12.5	130	12.5	130	12.5	130	NLT 3.0 Kg (To be Established)
Friability	Friabilator	QA/FRT/002	0.08%		0.06%		NMT 1% w/w				
DT	DT Apparatus	QA/DTA/001	02 min 30 sec		02 min 22 sec		NMT 15 Minutes				

M/C set done by Operator Name: V. S. R. M/C set up Checked by Prod. Sign/Date: R. S. R. 06/09/2022
M/C Speed: 12 RPM

Initial Setting Tablets Destroyed by: Sign: R. S. R. Date: 06/09/2022 Quantity in Kg: 0.080 Quantity in No: 120

Approval for Batch Compression by IPQA: Sign: S. R. Date: 06/09/2022 Time: 19:35

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. R.	P. Accul	V. S. R.	V. S. R.
Date	30/08/2022	30/08/2022	30/08/2022	30/08/2022

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

BATCH MANUFACTURING RECORD

Product Code: B05

Batch Size: 3,00,000 Tablets

Product

BONCIPRO 500

BMR. No.: BMR/T/305-00

Batch No.: G18 22116

Customer:

Generic Health Care Pvt. Ltd.

[illegible]

Prepared by:

Checked by:

Approved By:

Dept.

Production

Production

Quality Assurance

Head Quality Assurance

Sign.

1	1
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P. Angel

✓

V P

Date _____

30/02/2022

30/03/2022

20/02/2020

24/02/2022

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

BATCH MANUFACTURING RECORD

Batch Size: 3,00,000 Tablets

BONCIPRO 500

Batch No.: G11822116

Generic Health Care Pvt. Ltd.

Date & Time	Appearance		Weight of 20 Tablets		Hardness				Thickness				Done by IPQA
	White coloured caplet shaped uncoated tablet with breakline on one side and plain on other side.		14.400 g $\pm$ 3.0 % (13.968 g to 14.832 g)		NLT 3.0 Kg (To be Established)				5.20 mm $\pm$ 0.2 (5.00 mm – 5.40 mm) (To be Established)				
	LHS	RHS	LHS	RHS	LHS	LHS	RHS	RHS	LHS	LHS	RHS	RHS	
19.12	OK	OK	14.405	14.409	13.0	12.5	12.0	13.0	5.37	5.36	5.28	5.36	GS
07/09/22	OK	High RPM	14.410	14.401	10.5	10.0	10.0	10.0	5.29	5.25	5.26	5.30	GS
09.11	OK	Low RPM	14.297	14.405	10.0	10.5	10.0	10.0	5.25	5.27	5.28	5.24	GS
10.00	OK	High Hardness	14.407	14.411	13.5	14.0	13.0	14.5	5.18	5.16	5.14	5.19	GS
10.09	OK	Low Hardness	14.408	14.395	8.5	9.5	9.0	9.0	5.35	5.37	5.35	5.32	GS
10.23	OK	Full Hopper	14.395	14.407	10.0	10.5	10.0	10.5	5.28	5.31	5.27	5.25	GS
12.21	OK	Mid Hopper	14.409	14.413	10.5	11.0	10.5	10.0	5.25	5.29	5.29	5.26	GS
14.28	OK	OK	14.296	14.391	10.0	10.5	10.0	10.5	5.27	5.28	5.25	5.24	GS
15.20	OK	END Hopper	14.407	14.403	10.5	10.0	10.5	10.0	5.28	5.29	5.26	5.29	GS
17.22	OK	Composite	14.401	14.409	12.0	11.0	10.5	10.0	5.30	5.26	5.27	5.32	GS

25/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 22 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500		BMR. No.: BMRT/305-00 Batch No.: G1822116 Customer: Generic Health Care Pvt. Ltd.

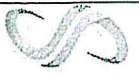
11.9 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION:

Date: 06/09/2022		Time: 19.38		Shift: G	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	720	8	718	15	722
2	718	9	721	16	721
3	722	10	719	17	722
4	719	11	722	18	721
5	724	12	719	19	725
6	717	13	722	20	721
7	723	14	718		
Balance ID No.: PD/BAL/015			M/C Speed: 12 RPM		
Group weight of 20 Tablets: 14.914 g. Avg. wt: 720.70 mg			Group weight of 20 Tablets: 14.925 g. Avg. wt: 721.25 mg		
Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)			Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)		
Min weight: 717 mg Max. weight: 725 mg			Min weight: 716 mg Max. weight: 724 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		LHS		RHS	
Disintegration Time (Limit - NMT 15 minutes)		0.07%		0.08%	
Equipment ID No.: QA/FRT/ 002		02 min 31 sec		02 min 35 sec	
Equipment ID No.: QA/DTA/ 001					
Done by: R. S. (Production)					
Date: 07/09/2022		Time: 09:40		Shift: A	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	718	8	722	15	721
2	720	9	719	16	719
3	717	10	722	17	722
4	715	11	721	18	723
5	717	12	719	19	717
6	716	13	720	20	719
7	715	14	719		
Balance ID No.: PD/BAL/015			M/C Speed: 12 RPM		
Group weight of 20 Tablets: 14.881 g. Avg. wt: 719.05 mg			Group weight of 20 Tablets: 14.890 g. Avg. wt: 719.50 mg		
Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)			Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)		
Min weight: 715 mg Max. weight: 723 mg			Min weight: 716 mg Max. weight: 724 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		LHS		RHS	
Disintegration Time (Limit - NMT 15 minutes)		0.05%		0.08%	
Equipment ID No.: QA/FRT/ 002		02 min 10 sec		02 min 15 sec	
Equipment ID No.: QA/DTA/ 001					
Done by: R. S. (Production)					

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. S.	P. Anand	V. S.	V. S.	
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 23 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:		Batch No.: 31822116 Generic Health Care Pvt. Ltd.

11.10 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION:

Date: 07/09/2022		Time: 11:45		Shift: A	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	721	8	722	15	722
2	723	9	724	16	724
3	719	10	721	17	717
4	721	11	719	18	720
5	719	12	720	19	721
6	720	13	719	20	720
7	718	14	721		
Balance ID No.: PD/BA1015			M/C Speed: 12 RPM		
Group weight of 20 Tablets: 14:41.3...g. Avg. wt.: 720.65mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 717...mg Max. weight: 724...mg			Group weight of 20 Tablets: 14:41.7...g. Avg. wt.: 720.85mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 716...mg Max. weight: 726...mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			LHS	RHS	Equipment ID No.: QA/FRT/ 002
Disintegration Time (Limit - NMT 15 minutes)			02 min 12 sec	02 min 25 sec	Equipment ID No.: QA/DTA/ 001
Done by: R. S. (Production)					
Date: 07/09/2022		Time: 13:49		Shift: A	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	720	8	719	15	724
2	719	9	721	16	721
3	718	10	718	17	720
4	719	11	725	18	719
5	720	12	721	19	720
6	719	13	718	20	718
7	721	14	720		
Balance ID No.: PD/BA1015			M/C Speed: 12 RPM		
Group weight of 20 Tablets: 14:40.0...g. Avg. wt.: 720.00mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 718...mg Max. weight: 725...mg			Group weight of 20 Tablets: 14:40.7...g. Avg. wt.: 720.35mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 718...mg Max. weight: 723...mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			LHS	RHS	Equipment ID No.: QA/FRT/ 002
Disintegration Time (Limit - NMT 15 minutes)			02 min 20 sec	02 min 25 sec	Equipment ID No.: QA/DTA/ 001
Done by: R. S. (Production)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	P. Arun	V. S.	R. S.
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 24 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:		Batch No.: <u>G18 22116</u> Generic Health Care Pvt. Ltd.

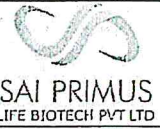
11.11 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION:

Date: <u>07/09/2022</u>		Time: <u>15:55</u>		Shift: <u>B</u>							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	721	8	715	15	720	1	719	8	719	15	724
2	724	9	720	16	718	2	721	9	722	16	724
3	718	10	719	17	721	3	722	10	721	17	720
4	716	11	721	18	719	4	723	11	719	18	719
5	722	12	718	19	724	5	725	12	720	19	721
6	722	13	720	20	724	6	721	13	721	20	718
7	721	14	721			7	717	14	723		
Balance ID No.: <u>PD/BM/1015</u>						M/C Speed: <u>12</u> RPM					
Group weight of 20 Tablets: <u>14404</u> g. Avg. wt: <u>720.20</u> mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: <u>715</u> mg Max. weight: <u>724</u> mg						Group weight of 20 Tablets: <u>14419</u> g. Avg. wt: <u>720.95</u> mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: <u>717</u> mg Max. weight: <u>725</u> mg					
						LHS		RHS			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						<u>0.06%</u>		<u>0.09%</u>		Equipment ID No.: QA/FRT/ <u>002</u>	
Disintegration Time (Limit - NMT 15 minutes)						<u>01 min 21 sec</u>		<u>01 min 12 sec</u>		Equipment ID No.: QA/DTA/ <u>001</u>	
Done by: <u>R. S. S.</u> (Production)											
Date:		Time:		Shift:		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: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: mg Max. weight: mg						Group weight of 20 Tablets: g. Avg. wt: mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 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.	<u>L. K.</u>	<u>P. Arund</u>	<u>[Signature]</u>	<u>[Signature]</u>	
Date	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 25 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: 1822116 Generic Health Care Pvt. Ltd.

11.12 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA:

Date: 06/09/2022		Time: 19.46		Shift: 'G'		(Full Hopper)	
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	721	8	720	15	726	1	720
2	718	9	722	16	721	2	720
3	715	10	725	17	720	3	724
4	724	11	723	18	724	4	718
5	720	12	722	19	715	5	714
6	722	13	717	20	718	6	719
7	721	14	719			7	725
Balance ID No.: QA/BAL/001				M/C Speed: 12 RPM			
Group weight of 20 Tablets: 14.905 g. Avg. wt: 720.40 mg				Group weight of 20 Tablets: 14.415 g. Avg. wt: 720.75 mg			
Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)				Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)			
Min weight: 715 mg Max. weight: 726 mg				Min weight: 714 mg Max. weight: 725 mg			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.06%		0.07%		Equipment ID No.: QA/FRT/001	
Disintegration Time (Limit - NMT 15 minutes)		02 min 40 sec		02 min 30 sec		Equipment ID No.: QA/DTA/001	
Done by: GS (IPQA)							
Date: 07/09/2022		Time: 09.45		Shift: A		High RPM	
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	719	8	718	15	715	1	718
2	717	9	722	16	716	2	719
3	715	10	716	17	719	3	715
4	721	11	722	18	714	4	716
5	720	12	715	19	723	5	720
6	718	13	720	20	722	6	719
7	719	14	721			7	721
Balance ID No.: QA/BAL/002				M/C Speed: 17 RPM			
Group weight of 20 Tablets: 14.377 g. Avg. wt: 718.85 mg				Group weight of 20 Tablets: 14.364 g. Avg. wt: 718.2 mg			
Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)				Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)			
Min weight: 715 mg Max. weight: 723 mg				Min weight: 715 mg Max. weight: 721 mg			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.09%		0.07%		Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)		02 min 31 sec		02 min 40 sec		Equipment ID No.: QA/DTA/001	
Done by: GS (IPQA)							

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. K.	P. Anand	V. S.	V. S.	
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 26 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500		BMR. No.: BMR/T/305-00 Batch No.: 318 22116 Customer: Generic Health Care Pvt. Ltd.

11.13 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA:

Date: 07/09/2022		Time: 09:55		Shift: A		Low RPM	
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	719	8	723	15	720	1	717
2	718	9	721	16	723	2	721
3	720	10	722	17	721	3	715
4	724	11	720	18	724	4	720
5	716	12	719	19	716	5	719
6	719	13	717	20	718	6	722
7	721	14	718			7	718
Balance ID No.: QA/BAL/002				M/C Speed: 10 RPM			
Group weight of 20 Tablets: 14.399.....g. Avg. wt: 719.95mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 716.....mg Max. weight: 724.....mg				Group weight of 20 Tablets: 14.326.....g. Avg. wt: 716.3mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 715.....mg Max. weight: 723.....mg			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				LHS		RHS	
Disintegration Time (Limit - NMT 15 minutes)				0.08/1		0.09/1	
Done by: 63.....(IPQA)				Equipment ID No.: QA/FRT/ 002		Equipment ID No.: QA/DTA/ 001	
Date: 07/09/2022				Time: 10:05		Shift: A	
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	715	8	719	15	722	1	719
2	719	9	717	16	724	2	721
3	721	10	717	17	720	3	723
4	720	11	720	18	715	4	722
5	717	12	724	19	724	5	720
6	719	13	723	20	717	6	718
7	723	14	720			7	719
Balance ID No.: QA/BAL/002				M/C Speed: 13 RPM			
Group weight of 20 Tablets: 14.394.....g. Avg. wt: 719.7mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 715.....mg Max. weight: 724.....mg				Group weight of 20 Tablets: 14.409.....g. Avg. wt: 720.45mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 715.....mg Max. weight: 725.....mg			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				LHS		RHS	
Disintegration Time (Limit - NMT 15 minutes)				0.07/1		0.08/1	
Done by: 63.....(IPQA)				Equipment ID No.: QA/FRT/ 002		Equipment ID No.: QA/DTA/ 001	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	P. Anand	[Signature]	[Signature]
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 27 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
	Product BONCIPRO 500	BMR. No.: BMRT/305-00 Customer:	Batch No.: <u>71822116</u> Generic Health Care Pvt. Ltd.

11.14 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA:

Date: <u>07/09/2022</u>		Time: <u>10.15</u>		Shift: <u>A</u>		Low Hardness	
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	721	8	719	15	723	1	717
2	720	9	717	16	720	2	715
3	723	10	722	17	719	3	720
4	719	11	720	18	717	4	723
5	717	12	716	19	721	5	724
6	721	13	720	20	716	6	721
7	720	14	719			7	720
Balance ID No.: <u>QA/RAL/002</u>				M/C Speed: <u>12</u> RPM			
Group weight of 20 Tablets: <u>14.389</u> ...g. Avg. wt.: <u>719.45</u> mg				Group weight of 20 Tablets: <u>14.401</u> ...g. Avg. wt.: <u>720.05</u> mg			
Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)				Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)			
Min weight: <u>716</u> ... mg Max. weight: <u>723</u> ...mg				Min weight: <u>715</u> ... mg Max. weight: <u>724</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)		02 mins 39 sec		02 mins 39 sec		Equipment ID No.: QA/DTA/ 001	
Done by: <u>G/S</u>(IPQA)							
Date: <u>07/09/2022</u>		Time: <u>10.25</u>		Shift: <u>A</u>		Full Hopper.	
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	719	8	718	15	717	1	720
2	720	9	716	16	718	2	719
3	725	10	722	17	721	3	720
4	720	11	721	18	715	4	718
5	715	12	724	19	723	5	717
6	721	13	722	20	725	6	715
7	723	14	719			7	719
Balance ID No.: <u>QA/RAL/002</u>				M/C Speed: <u>13</u> RPM			
Group weight of 20 Tablets: <u>14.405</u> ...g. Avg. wt.: <u>720.25</u> mg				Group weight of 20 Tablets: <u>14.385</u> ...g. Avg. wt.: <u>719.25</u> mg			
Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)				Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)			
Min weight: <u>715</u> ... mg Max. weight: <u>725</u> ...mg				Min weight: <u>715</u> ... mg Max. weight: <u>723</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)		02 mins 44 sec		02 mins 25 sec		Equipment ID No.: QA/DTA/ 001	
Done by: <u>A/S</u>(IPQA)							

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<u>L. Ka</u>	<u>P. Arun</u>	<u>[Signature]</u>	<u>[Signature]</u>	
Date	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 28 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: 61822116 Generic Health Care Pvt. Ltd.

11.15 WEIGHING RECORD OF COMPRESSED TABLETS:

S. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Weighed by	Checked by Production	Verified by IPQA
1	34.570	2.400	32.170	Ko80000	23	61
2	35.280	2.410	32.870	Ko80000	23	61
3	35.190	2.500	32.690	Ko80000	23	61
4	11.650	1.790	09.860	Ko80000	23	61
5	38.720	2.300	36.420	Ko80000	23	61
6	31.050	1.800	29.250	Ko80000	23	61
7	40.230	2.500	37.730	Ko80000	23	61
8						
9						
10						

11.16 RECONCILIATION (COMPRESSION STAGE):

Average weight of Uncoated Tablet: 7.20...mg

1.0	Standard Batch size	:	216.000 Kg.	3,00,000 No.
2.0	Actual weight of Lubricated granules	:	214.112 Kg.	297375 Nos.
3.0	Weight of compressed tablets	:	211.050 Kg.	293125 Nos.
4.0	Rejection during Compression @	:	0.080 Kg.	
5.0	In-process samples of all stages			
	A	IPQC Samples	: 0.200 Kg.	
	B	QC Samples	: 0.070 Kg.	
	C	Validation Samples	: 0.120 Kg.	
6.0	Total in process samples: (A + B + C)	:	0.450 Kg.	
7.0	Total: (3.0 + 6.0)	:	211.500 Kg.	293750 Nos.
8.0	Yield {7.0 / 1.0 x 100}*	:		97.92 %

* Actually yield will be calculated after 3 validation batches

@Total rejects destroyed: 2.530 Kg. (Rejected materials shall be destroyed as per SOP No.: QAGN/048)

Done by Production Sign/Date: 07/09/2022 Checked by IPQA Sign/Date: 07/09/2022

Test request form raised by Prod Sign/Date: 07/09/2022

Test request form received by IPQA Sign/Date: 07/09/2022

12.0 RELEASED FOR COATING:

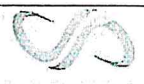
Reconciliation checked and compressed tablets released for coating:

IPQA Sign: [Signature] Date: 07/09/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. [Signature]	P. [Signature]	[Signature]	[Signature]
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 27 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: 41822116 (H) Generic Health Care Pvt. Ltd.

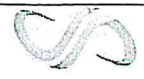
11.14 UNIFORMITY OF WEIGHT IN PROCESS CHECKS FOR IPQA:

Date: 07/09/2022		Time: 12.25		Shift: 12.25 'A'		MID Hopper	
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	725	8	725	15	716	1	720
2	720	9	721	16	718	2	724
3	723	10	720	17	715	3	721
4	718	11	723	18	721	4	720
5	719	12	720	19	720	5	719
6	722	13	722	20	719	6	715
7	720	14	725			7	717
Balance ID No.: QA/PAI/002				M/C Speed: 12 RPM			
Group weight of 20 Tablets: 14.412 g. Avg. wt.: 720.6 mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 715 mg Max. weight: 725 mg				Group weight of 20 Tablets: 14.402 g. Avg. wt.: 720.10 mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 715 mg Max. weight: 724 mg			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.06%		0.07%		Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)		02 min 29 sec		02 min 25 sec		Equipment ID No.: QA/DTA/001	
Done by: G.S. (IPQA)							
Date: 07/09/2022		Time: 15.29		Shift: 'B'		FND Hopper	
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	721	8	721	15	720	1	721
2	722	9	719	16	722	2	720
3	720	10	722	17	721	3	731
4	720	11	722	18	718	4	725
5	724	12	718	19	729	5	729
6	721	13	717	20	721	6	721
7	718	14	724			7	718
Balance ID No.: QA/PAI/002				M/C Speed: 13 RPM			
Group weight of 20 Tablets: 14.418 g. Avg. wt.: 720.9 mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 717 mg Max. weight: 724 mg				Group weight of 20 Tablets: 14.408 g. Avg. wt.: 720.40 mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 715 mg Max. weight: 731 mg			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.07%		0.07%		Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)		02 min 31 sec		02 min 27 sec		Equipment ID No.: QA/DTA/001	
Done by: G.S. (IPQA)							

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka	P. Arun	Veel	P. Arun	
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 27 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: 61822116 (B) Generic Health Care Pvt. Ltd.

11.14 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA:

Date: 07/09/2022		Time: 17.25		Shift: 'P'		Composite	
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	720	8	720	15	722	1	721
2	722	9	719	16	723	2	717
3	721	10	718	17	720	3	719
4	723	11	724	18	721	4	722
5	722	12	720	19	723	5	721
6	721	13	721	20	718	6	723
7	724	14	725			7	720
Balance ID No.: 20/001/002				M/C Speed: 13 RPM			
Group weight of 20 Tablets: 13.702 g. Avg. wt: 685.13 mg				Group weight of 20 Tablets: 14.415 g. Avg. wt: 720.65 mg			
Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)				Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)			
Min weight: 716 mg Max. weight: 725 mg				Min weight: 717 mg Max. weight: 725 mg			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		LHS		RHS		Equipment ID No.: QA/FRT/ 002	
Disintegration Time (Limit - NMT 15 minutes)		0.06 min		0.05 min		Equipment ID No.: QA/DTA/ 001	
Done by: [Signature] (IPQA)							
Date:		Time:		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1		8		15		1	
2		9		16		2	
3		10		17		3	
4		11		18		4	
5		12		19		5	
6		13		20		6	
7		14				7	
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: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)				Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 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. R.	P. Arundh	[Signature]	[Signature]	
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022	

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	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 29 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: 418 22116 Generic Health Care Pvt. Ltd.

13.0 LINE CLEARANCE FOR COATING SOLUTION PREPARATION:

Date/Shift/Time: 08/09/2022 / A / 01:03 /

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

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

Equipment	Solution preparation vessel and stirrer	Colloidal Mill	Area
Equipment ID No.	NA	PD/CLM/001	N2O coating
Previous product	Glivical-CMZ		
Batch No.	FGD32201H		
Cleaned by	Subu		
Checked by Production Sign/Date:	R-sh 08/09/2022		
Verified by IPQA Sign/Date:	R-sh 08/09/22		

ENVIRONMENTAL CONDITIONS:		Date: 08/09/2022	Time: 01:10	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	R-sh	X		
Relative Humidity % Limit: NMT 60%	52%	R-sh	X		

APPROVAL FOR COATING SOLUTION PREPARATION:

Production Sign/Date: R-sh 08/09/2022
 Line Clearance IPQA Sign. / Date: R-sh 08/09/22

Start Time/Date: 01:33 / 08/09/2022

End Time/Date: 01:44 / 08/09/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	P. Arun	Shu	R-sh
Date	30/03/2022	30/03/2022	30/03/2022	20/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 30 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: G1822116 Generic Health Care Pvt. Ltd.

14.0 Coating Procedure:

14.1 General Instructions:

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

14.2 TABLETS RECEIPT RECORD OF UNCOATED TABLETS FOR COATING:

Balance ID. No.: PD/BAL/015

Date/Shift/Time: 08/09/2022/A/01:13

Sr. No.	Description	Observations	Checked By (Production)	Verified By (IPQA)
1.	Total Quantity (Net Qty.in Kg)	211.650	R. Sll	R
2.	Number of Containers	07	R. Sll	R

14.3 COATING SOLUTION PREPARATION

Sr. No.	General Instructions	Balance ID.: <u>PD/BAL/015</u>
1.	Check the cleanliness of the Solution Preparation area and operation as per current version of SOP.	
2.	Use hand gloves while handling the materials	
3.	Transfer the verified coating materials to Coating solution preparation area.	

Step No.	Name of Ingredient & Operation	Time		Done by	Checked by Prod.	Verified by IPQA
		Start	Finish			
1	Take Purified water in a SS Vessel. Slowly disperse HPMC 6 cps, Titanium dioxide, Ponceau 4R Lake, Purified Talc and Polyethylene Glycol 6000 and stir well to disperse completely.	01:33	01:38	Subu	R. Sll	R
2	If required mill the solution through colloidal mill.	01:39	01:44	Subu	R. Sll	R

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>P. Anand</u>	<u>Subu</u>	<u>V. R</u>
Date	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 31 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: <u>G1822116</u> Generic Health Care Pvt. Ltd.

15.0 COATING AREA:

LINE CLEARANCE CHECKS:

Date/Shift/Time: 08/09/2022 / A / 01:17

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

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

Equipment		Coating Machine			Area				
Equipment ID No.		<u>PD/NEC/001</u>			Coating area				
Previous product		<u>Glivical - CMZ</u>							
Batch No.		<u>FG1032201H</u>							
Cleaned by		<u>Subu</u>							
Checked by Production Sign/Date:		<u>R. Sll</u> <u>08/09/2022</u>							
Verified by IPQA Sign/Date:		<u>R. Sll</u> <u>08/09/22</u>							
ENVIRONMENTAL CONDITIONS:		Date: <u>08/09/2022</u> Time: <u>01:22</u>		Date: _____ Time: _____		Date: _____ Time: _____			
			Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation
(Refer to SOP No.: QAGN/011)	Temperature °C Limit: NMT 25 °C	<u>23°C</u>	<u>R. Sll</u>	<u>R</u>					
	Relative Humidity % Limit: NMT 60%	<u>52%</u>	<u>R. Sll</u>	<u>R</u>					
	Differential Pressure (NLT 10 Pascal)	<u>11 pascal</u>	<u>R. Sll</u>	<u>R</u>					

APPROVAL FOR COATING:

Production Sign/Date: R. Sll 08/09/2022

Line Clearance IPQA Sign. / Date: R. Sll 08/09/22

Start Time/Date: 01:50 / 08/09/2022

End Time/Date: 05:03 / 08/09/2022

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<u>L. Ka</u>	<u>P. Asut</u>	<u>R. Sll</u>	<u>V. R</u>	
Date	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	

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SAI PRIMUS
LIFE BIOTECH PVT LTD

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

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BATCH MANUFACTURING RECORD

Product Code: B05

Batch Size: 3,00,000 Tablets

Product

BONCIPRO 500

BMR. No.: BMR/T/305-00

Batch No.: 61822116

Customer:

Generic Health Care Pvt. Ltd.

15.1 COATING PROCESS:

Process Steps

Step No.	Name of Ingredient & Operation	Time		Done by	Ckd by Prod.	Vfd by IPQA
		Start	Finish			
1	Transfer the compressed tablets in to the coating Area	01:50	01:55	Subu	R.ell	R
2	Pre-warm the tablet with inlet temp. 45°C to 55°C.	01:56	02:01	Subu	R.ell	R
3	Arrange the spray gun in such a way that the spray droplets just touch the tablet bed on upper rim. The spray should not fall on the wall of the pan. Weight gain obtained: 2.01 % (2.0 - 3.0%)	02:02	04:51	Subu	R.ell	R
4	When the spraying is complete, dry the tablets perfectly, in the pan by keeping inlet temp. 55°C-75 °C with intermittently flipping the tablets, until no more solvent odour is observed. Caution: Ensure the tablet bed temperature does not rise excessively.	04:52	04:57	Subu	R.ell	R
5	Monitor DT: Limit: NMT 30 minutes. Found Disintegration Time: 03 min 18 sec	04:58	05:03	Subu	R.ell	R
6	Unload the film coated tablets in a HDPE container lined with double polybag.			Subu	R.ell	R

15.2 INITIAL CHECKS OF COATING PARAMETERS:

S. No	Parameter	Set	Observed
1	Inlet air Temp.	55°C to 75°C (To be established)	60°C
2	Exhaust air Temp.	50 ± 5 °C (To be established)	50°C
3	Tablet Bed temp.	50°C-60 °C (To be established)	40°C
4	Atomization air pressure	1.0 - 4.0 Kg/cm ² (To be established)	3.0 kg/cm ²
5	Pan speed	1.0 - 10.0 RPM (To be established)	3.0 rpm
6	Spray rate	30 to 70 ml/min (To be established)	70 ml/min
Checked by Production/ Date			R. ell 03/09/2022
Verified by IPQA/ Date			R. ell 03/09/2022

15.3 INDIVIDUAL WEIGHT CHECKING OF PRE-WARMED TABLETS:

Sr. No.	Weight (mg)	Sr. No.	Weight (mg)
1	718	11	716
2	720	12	715
3	717	13	719
4	716	14	720
5	715	15	718
6	719	16	719
7	721	17	721
8	718	18	718
9	719	19	717
10	720	20	720
Total		14.366	
Avg. Weight		718.30	

15.4 FINAL COATING PARAMETERS CHECKS: (PRODUCTION)

Parameters	Limits	Observed
Description	Pink coloured caplet shaped film coated tablet with breakline on one side and plain on other side	OK
Theoretical weight per tablet	736.000 mg ± 3 % (713.920 mg - 758.080 mg)	736.82 (mg)
Weight of 20 tablets	14.720 g ± 3 % (14.278 g - 15.162 g)	14.736 g
Uniformity of weight	736.000 mg ± 5 % (699.200 mg - 772.800 mg)	-2.62% / 3.93%
Thickness	5.50 mm ± 0.2 mm (5.30 mm to 5.70 mm)	5.30 - 5.51 (mm)
Disintegration test	NMT 30 min	03 min 18 sec
Checked by Production/ Date		R. ell 03/09/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	P. Arul	V. S.	V. S.
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 33 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: 51822116 Generic Health Care Pvt. Ltd.

15.5 FINAL COATING PARAMETERS CHECKS: (IPQA)

Parameters	Limits	Observed
Description	Pink coloured caplet shaped film coated tablet with breakline on one side and plain on other side	OK
Theoretical weight per tablet	736.000 mg $\pm$ 3 % (713.920 mg – 758.080 mg)	736.80 (mg)
Weight of 20 tablets	14.720 g $\pm$ 3 % (14.278 g – 15.162 g)	14.7638 g
Uniformity of weight	736.000 mg $\pm$ 5 % (699.200 mg – 772.800 mg)	-1.99 % / 0.43 %
Thickness	5.50 mm $\pm$ 0.2 mm (5.30 mm to 5.70 mm)	5.30 to 5.44 mm
Disintegration test	NMT 30 min	03 min 45 sec
Checked by IPQA/ Date		Gps 08/04/2022

15.6 FILM COATING WEIGHT GAIN PARAMETER CHECKS:

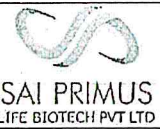
S. No.	Start time	End time	Inlet temp.	Outlet temp.	Bed temp.	Pan RPM	Atomizing air pressure	Initial weight gain (A)	Final weight gain (B)	Difference C = B - A	Percentage weight gain	Ckd by	Verified by
01	02:02	04:51	60°C	50°C	40°C	3.0	2.5 kg/cm ²	14.400	14.707	-0.307	2.08%	R. S. S.	Gps

15.7 WEIGHT CHECK FOR 20 TABLETS:

S. NO.	INITIAL WEIGHT	FINAL WEIGHT	S. NO.	INITIAL WEIGHT	FINAL WEIGHT
1	720	735	1	723	732
2	716	738	2	717	722
3	719	725	3	721	727
4	722	735	4	727	743
5	720	747	5	728	733
6	717	730	6	722	739
7	714	736	7	726	738
8	719	727	8	718	731
9	721	718	9	715	725
10	723	734	10	716	722
11	726	739	11	722	729
12	722	737	12	713	731
13	720	729	13	720	733
14	717	733	14	717	725
15	721	767	15	714	729
16	718	734	16	719	736
17	722	730	17	723	727
18	724	729	18	728	742
19	721	746	19	725	740
20	718	738	20	718	743
TOTAL	14,400	14,707	TOTAL	14,726	14,647
Checked by Production: R. S. S.		Checked by IPQA: Gps			

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka	P. Anand	Heel	V. P. S.	
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 34 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:		Batch No.: 41822116 Generic Health Care Pvt. Ltd.

15.8 PERCENTAGE OF COATING WEIGHT BUILDS UP:

$$\% \text{ of Weight buildup} = \frac{\text{Avg. wt. of coated tablets} - \text{Avg. wt. of core tablet (Pre-warmed)}}{\text{Avg. wt. of core tablets (Pre-warmed)}} \times 100$$

$$= 2.57\%$$

15.9 ACTUAL AVERAGE WEIGHT OF COATED TABLETS:

$$\frac{\text{Weight of 100 coated tablet}}{100} = 734 \text{ mg}$$

15.10 WEIGHT OF FILM COATED TABLETS:

Container No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Weighed by	Checked by Production	Verified by IPQA
1	31.150	1.950	29.200	Muthu	B2	G3
2	31.120	1.790	29.330	Muthu	B2	G3
3	33.440	2.500	30.940	Muthu	B2	G3
4	26.340	1.950	24.390	Muthu	B2	G3
5	32.660	2.500	30.160	Muthu	B2	G3
6	32.680	2.000	30.680	Muthu	B2	G3
7	37.840	1.800	36.040	Muthu	B2	G3
8						
9						
10						
TOTAL			214.700			

15.11 RECONCILIATION (COATING STAGE):

Average weight of coated Tablet: 734.00 mg

1.0	Batch size	:	220.800 Kg.	3,00,000 Nos.
2.0	Weight of coated tablets	:	214.700 Kg.	292506 Nos.
3.0	Coating loss@	:	0.040 Kg.	
4.0	In-process samples of all stages			
	A	IPQC Samples	: 0.050 Kg.	
	B	QC Samples	: 0.090 Kg.	
	C	Validation Samples	: NA Kg.	
5.0	Total in process samples: (A + B + C)	:	0.140 Kg.	
6.0	Total: (2.0 + 5.0)	:	214.840 Kg.	292697 Nos.
7.0	Yield {(6.0 x 100 / 1.0)*}	:		97.57 %

* Actually yield will be calculated after 3 validation batches

@Total rejects destroyed: ...0.040 Kg. (Rejected materials shall be destroyed as per SOP No.: QAGN/048)

Done by Production Sign/Date: ...02/03/2022 Checked by IPQA Sign/Date: ...02/03/2022

Test request form raised by Prod Sign/Date: ...02/03/2022

Test request form received by IPQA Sign/Date: ...02/03/2022

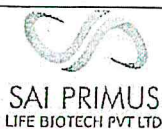
15.12 RELEASE FOR INSPECTION:

Reconciliation checked and Coated tablets released for inspection

IPQA Sign: ...02/03/2022 Date: ...02/03/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	P. Arun	V. Arun	V. Arun
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022





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

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BATCH MANUFACTURING RECORD

Product Code: B05

Batch Size: 3,00,000 Tablets

Product

BONCIPRO 500

BMR. No.: BMR/T/305-00

Batch No.: G11822116

Customer:

Generic Health Care Pvt. Ltd.

16.0 INSPECTION LINE CLEARANCE:

Date/Shift/Time: 09/09/2022 / G1

10/09/2022 / G1

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 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	✓	✓	MA	MS
11	Equipment status is updated for Cleaned, Qualification and Preventive maintenance.	✓	✓	✓	✓

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

Equipment	Inspection Belt	Metal Detector	Area
Equipment ID No.	PD/INB/002	PD/MED/002	Inspection - II
Previous product	G1PVCed - CMZ		
Batch No.	FG1032261H		
Cleaned by	victoria 19 Aug		
Checked by Production Sign/Date:	09/09/2022		
Verified by IPQA Sign/Date:	G1 09/09/2022		

ENVIRONMENTAL CONDITIONS:		Date: 09/09/2022 Time: 10:20		Date: 10/09/2022 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	MA 09/09/2022	24 °C	MA 09/09/2022
	Relative Humidity % Limit: NMT 60%	52%	MA 09/09/2022	53%	MA 09/09/2022

APPROVAL FOR INSPECTION:

Production Sign/Date: MA 09/09/2022

Line Clearance IPQA Sign. / Date: G1 09/09/2022

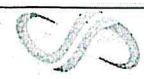
Start Time/Date: 10:30 / 09/09/2022

End Time/Date: 12:30 / 10/09/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. / 30	P. Arun	MA	MA
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 36 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: 61822116 Generic Health Care Pvt. Ltd.

17.0 INSPECTION PROCESS

17.1 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.

17.2 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/002 & PD/MED/..NA..					Checked by Production	Verified By IPQA
		Ferrous (0.3 mm)	Stainless steel (0.5 mm)	Non-Ferrous (0.4 mm)	Non-metallic	Result		
09/09/2022 16:35	1	✓	✓	✓	X	Pass	M. Kavya	Q3
	2	✓	✓	✓	X	Pass	M. Kavya	Q3
	3	✓	✓	✓	X	Pass	M. Kavya	Q3
09/09/2022 16:50	1	✓	✓	✓	X	Pass	M. Kavya	Q3
	2	✓	✓	✓	X	Pass	M. Kavya	Q3
	3	✓	✓	✓	X	Pass	M. Kavya	Q3
10/09/2022 10:30	1	✓	✓	✓	X	Pass	M. Kavya	Q3
	2	✓	✓	✓	X	Pass	M. Kavya	Q3
	3	✓	✓	✓	X	Pass	M. Kavya	Q3

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

17.3 TABLETS VISUAL INSPECTION RECORD:

Date	Container No		Time		Total Quantity Rejected	Tablet Inspection Done by/Date	Checked by/Date
	From	To	Started	Completed			
09/09/2022	01	04	10:30	17:50	0.200	Victory 09/09/2022	M. Kavya 09/09/2022
10/09/2022	05	07	09:37	12:30	0.180	Shrey 10/09/2022	M. Kavya 10/09/2022

17.4 WEIGHING RECORD OF INSPECTED TABLETS:

Container No	Gross weight Kg	Tare weight Kg	Net. weight Kg	Container No	Gross weight Kg	Tare weight Kg	Net. weight Kg
1	31.620	2.500	29.120	6	31.780	1.850	29.930
2	22.200	1.780	20.420	7	40.530	2.500	38.030
3	32.840	1.240	31.600	8			
4	31.280	1.900	29.380	9			
5	35.840	2.000	33.840	10			
Total			146.360 Kg	Total			67.960 Kg
				Grand Total			214.320 Kg

Weighing Done By: M. Kavya. Checked By Prod./ Date: M. Kavya. Verified by IPQA Sign./Date: Q3.

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka	P. Arun	M. Kavya	V. R.	
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 37 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMRT/305-00 Customer:	Batch No.: 1822116 Generic Health Care Pvt. Ltd.

17.5 RECONCILIATION: (INSPECTION OF TABLETS)

1.0	Theoretical weight of Tablets	:	220.800 kg	3,00,000 No's
2.0	Tablets transferred for Inspection	:	214.700 kg	292506 No's
3.0	Total weight of good Tablets	:	214.320 kg	291989 No's
4.0	Rejected Tablets	:	0.380 kg	517 No's
5.0	*Yield = $\frac{3.0}{1.0} \times 100$	:		99.32 %

*Actually yield will be calculated after 3 validation batches.

Total rejects destroyed:0.380.....Kg.

Rejected materials should be destroyed in the presence of QA.

Done by Production sign/Date: 19.09/10/09/2022

Checked by IPQA sign/Date: 10/09/2022

17.6 RELEASE FOR PACKING:

BMR reviewed by IPQA Sign/Date : 10/09/2022

BMR Released for packing by QA Head Sign/Date: 10/09/2022

18.0 BMR REVIEW DETAILS:

Reviewed by	Name	Sign./Date
Production Executive	K. Vi Swanth	<u>10/09/2022</u>
QA Executive	G. SENTHIL KUMARAN	<u>10/09/2022</u>
Production Assistant Manager/ HOD	M. Narmadha	<u>10/09/2022</u>
QA Manager/ HOD	Ram Kumar	<u>10/09/2022</u>

19.0 REVISION HISTORY:

Sr. No.	Document No.	Reason for Revision	Supersedes No.
1	BMRT/305-00	New Document	Nil

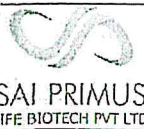
Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. R.</u>	<u>P. Anand</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>

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	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: 418 22 117 Generic Health Care Pvt. Ltd.

BATCH MANUFACTURING RECORD COVER SHEET

PRODUCT NAME : BONCIPRO 500
GENERIC NAME : Ciprofloxacin Tablets BP 500 mg
LABEL CLAIM : Each film coated tablet contains:
 Ciprofloxacin Hydrochloride BP
 Equivalent to 'Ciprofloxacin' 500 mg
 Colour: Approved Colour used.
MFR No. / Reference Document No. : MFR/T/177-00
BMR No. : BMR/T/305-00
REVISION No. : 00
SUPERSEDES No. : NIL
BMR EFFECTIVE BATCH NUMBER/DATE : 41822068 / 01/04/2022
MFG.LIC No. : PON/DRUGS/21 14 4376
STORAGE : Store in cool and dry place. Protect from light and moisture.
BMR ISSUED BY/DATE (QA) : S.S. 05/09/2022
BMR CHECKED & RECEIVED BY/DATE (PRODUCTION) : P. Anand 05/09/2022
SHELF LIFE : 36 Months
BATCH SIZE : 3,00,000 Tablets (220.800 Kg)
MFG. DATE: 09/2022 **EXP. DATE:** 08/2025

RECOVERY ADDITION RECORD

BATCH NO	MFG	EXP	QUANTITY	REVISED BATCH SIZE

ALLOTTED BY: S.S. 05/09/2022
QA SIGN/DATE: S.S. 05/09/2022
COUNTER CHECKED BY: P. Anand 05/09/2022
QA SIGN/DATE: P. Anand 05/09/2022
DATE OF COMMENCEMENT: 05/09/2022
DATE OF COMPLETION: 12/09/2022
RELEASED QUANTITY OF TABLETS FOR PACKING : 292002 Nos
RELEASE FOR PACKING STAGE
HEAD OF QA SIGN/DATE: P. Anand 12/09/2022

This BMR contains 37 Pages + Nil Additional Pages

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	P. Anand	P. Anand	P. Anand
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Pudukcherry-605009.		Page 2 of 37
	BATCH MANUFACTURING RECORD	Product Code: B05	Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMRT/305-00	Batch No.: 318 22 117
		Customer:	Generic Health Care Pvt. Ltd.

1.0 INDEX

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4.0	Calculation	5
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6.0	Line clearance for Sifting and granulation.	9
7.0	Granulation instruction, sieve integrity checks, sifting instruction, wet granulation, drying record, sifting and milling record.	10-13
8.0	Blending Line clearance, Blending and Lubrication process, Lubrication material sifting record, Blending and Lubrication records, Weight record, Reconciliation, Release for Compression	14-15
9.0	Compression Line Clearance	16
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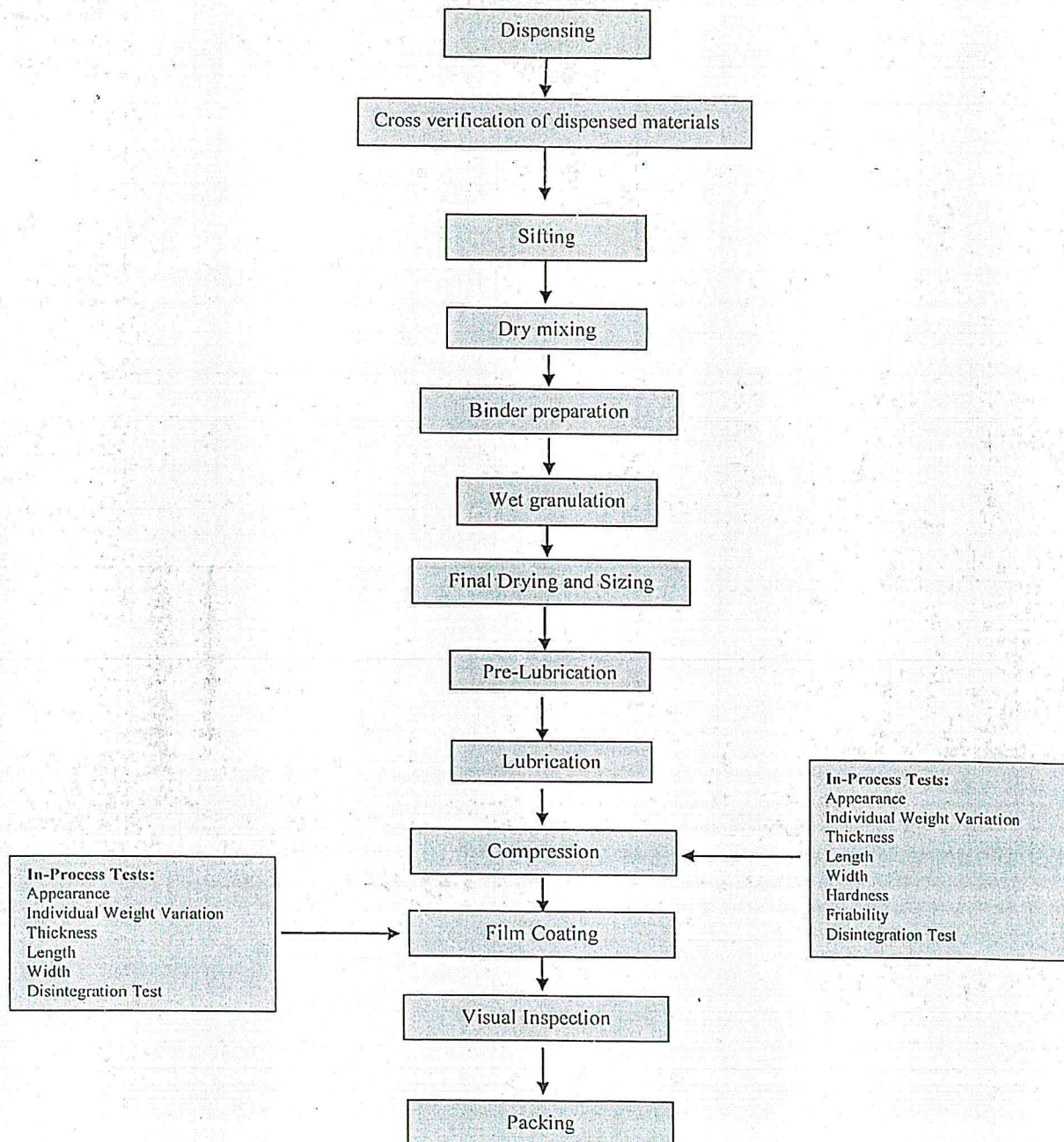
Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. G	P. Anand	[Signature]	[Signature]
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 3 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: G18 22117 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	P. Anna	V. S.	V. S.
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 4 of 37
	BATCH MANUFACTURING RECORD	Product Code: B05	Batch Size: 3,00,000 Tablets
	Product: BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: <u>G1822117</u> Generic Health Care Pvt. Ltd.

3.0 INDENT OF ACTIVE PHARMACEUTICAL INGREDIENTS & EXCIPIENTS:

Sr. No.	Name of the Ingredient	Spec.	Item Code	Quantity/ Tablets (mg)	Std. quantity per 3,00,000 tablets (kg)	OA/ PL (%)	Req. quantity per 3,00,000 tablets (kg)
Dry mixing material:							
1	Ciprofloxacin Hydrochloride*	BP	RAI/SP/C015	582.200	174.660	-	174.660
2	Microcrystalline cellulose PH102 **	BP	REX/SP/M010	108.050	32.415	-	32.415
Binder Material:							
3	Purified Water	BP	NA	q.s.	83.000	-	83.000
Theoretical Weight of Dried Granules				690.250	207.075	-	207.075
Lubrication Material:							
4	Sodium Stach Glycollate	BP	REX/SP/S004	21.000	6.300	-	6.300
5	Colloidal Silicon Dioxide	BP	REX/SP/C022	1.750	0.525	-	0.525
6	Magnesium Stearate	BP	REX/SP/M011	7.000	2.100	-	2.100
Theoretical Weight of the Lubricated granules				720.000	216.000	-	216.000
Theoretical weight of Compressed tablet				720.000	216.000	-	216.000
Coating Material:							
7	Hydroxy Propyl Methyl Cellulose (6 cps)	BP	REX/SP/H016	10.800	3.240	25	4.050
8	Titanium Dioxide	BP	REX/SP/T002	1.200	0.360	25	0.450
9	Ponceau 4R Lake	IHS	REX/SP/P006	0.600	0.180	25	0.225
10	Purified Talc	BP	REX/SP/P017	1.000	0.300	25	0.375
11	Polyethylene Glycol 6000	BP	REX/SP/P003	2.400	0.720	25	0.900
12	Purified Water	BP	NA	q.s.	42.500	-	42.500
Theoretical weight of Coated tablet ^s				736.000	220.800	-	220.800

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

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

\$ Average weight rounded off.

OA: Overages, PL: Process loss

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>P. Anand</u>	<u>Veel</u>	<u>V. Chandra</u>
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 5 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: G1822117 Generic Health Care Pvt. Ltd.

4.0 ASSAY AND LOD CALCULATIONS FOR CIPROFLOXACIN HYDROCHLORIDE:

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

Standard quantity of Ciprofloxacin Hydrochloride (A): 174.660 Kg

Standard quantity of Microcrystalline Cellulose PH 102 (B): 32.415 Kg

Calculation for Ciprofloxacin Hydrochloride:

- 1) Calculation for Single A. R. No. Rmcy 100046, Assay on dried basis: 100.50 w/w, LOD: 5.855 w/w
 Exp. Date: 10.12.22

$$\text{Actual Quantity (Kg) (C)} = \frac{\text{Standard qty. required} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{174.660 \times 100 \times 100}{100 \times (100 - 5.855)} = 186.522 \text{ Kg/2}$$

LOT I: 92.761 Kg, LOT II: 92.761 Kg

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

Actual Quantity (Kg) (D) = Standard quantity of Microcrystalline Cellulose PH 102 - Excess Calculated quantity of Ciprofloxacin Hydrochloride

$$= 32.415 \text{ Kg} - 10.862 \text{ Kg} = 21.553 \text{ Kg/2. LOT I: } 10.776 \text{ Kg, LOT II: } 10.776 \text{ Kg}$$

- 3) Calculation for Ciprofloxacin Hydrochloride Multiple A. R. No.:

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

Calculation for Remaining Quantity Required (G):

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

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

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

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

LOT I: _____ Kg, LOT II: _____ Kg

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

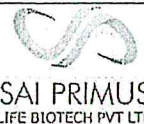
Actual Quantity (Kg) (D) = Standard quantity of Microcrystalline Cellulose PH 102 - Excess Calculated quantity of Ciprofloxacin Hydrochloride

$$= 32.415 \text{ Kg} - \text{_____ Kg} = \text{_____ Kg/2. LOT I: } \text{_____ Kg, LOT II: } \text{_____ Kg}$$

Done By/On (QA): [Signature] 28/09/2022 Checked By/On (Production): P. Anand 28/09/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>[Signature]</u>	<u>P. Anand</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 6 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: 51822117 Generic Health Care Pvt. Ltd.

5.0 DISPENSING LINE CLEARANCE CHECKS

Date: 05/09/2022 Time: 16:15

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.	ST08B1001	ST08B004	ST08B005	ST08B006	Dispensing Booth I
Previous Product	Bonicipro 500				
B. No.	91822116				
Cleaned by Sign/Date	Renmial / 05/09/2022				
Checked by Store Sign/Date	Raj / 05/09/2022				
Verified by IPQA Sign/Date	Raj / 05/09/2022				

ENVIRONMENTAL CONDITIONS: Date: 05/09/2022 Time: 16:25		Observation	Checked by Store Sign/Date	Verified by IPQA Sign/Date
(For Reference SOP No.: QAGN/011)				
Temperature (Limit: NMT 25°C)		23°C	ble 05/09/2022	ble 05/09/2022
Relative Humidity % (Limit: NMT 60%)		55%	ble 05/09/2022	ble 05/09/2022
Differential Pressure (NLT 10 Pascal)		11 Pascal	ble 05/09/2022	ble 05/09/2022
Differential Pressure across the booth Limit: 5 to 20 mm Water		11 mm	ble 05/09/2022	ble 05/09/2022

APPROVAL FOR DISPENSING BY IPQA: Sign: [Signature] Date: 05/09/2022

Dispensing start Time: 16:30 End Time: 17:30

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	[Signature]	[Signature]	[Signature]	[Signature]
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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SAI PRIMUS
LIFE BIOTECH PVT LTD

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

SAI PRIMUS LIFE BIOTECH PVT LTD

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Product

BATCH MANUFACTURING RECORD

Product Code: B05

Batch Size: 3,00,000 Tablets

BONCIPRO 500

BMR. No.: BMR/T/305-00

Batch No.: G18 22117

Customer:

Generic Health Care Pvt. Ltd.

5.1 Dispensing Weighing Sheet:

Balance ID: S11304004 28/12/2021 Shift: 16:30
Date: 30/03/2022 Time: 16:30

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

LOT - I

Dry mixing material:

1	Ciprofloxacin Hydrochloride	BP	RAI/SP/C015	Kg	87.330	92.761	Rm/100046	30.100 30.100 30.100	30.100 30.100 30.100	05/09/22	05/09/22	05/09/22	05/09/22
2	Microcrystalline cellulose PH102	BP	REX/SP/M010	Kg	16.208	10.776	Rm/101177	10.176 10.176 10.176	10.176 10.176 10.176	05/09/22	05/09/22	05/09/22	05/09/22

Binder Material:

3	Purified Water	BP	NA	Kg	41.500	41.500	Pur/2210627	41.500 41.500 41.500	41.500 41.500 41.500	05/09/22	05/09/22	05/09/22	05/09/22
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LOT - II

Dry mixing material:

4	Ciprofloxacin Hydrochloride	BP	RAI/SP/C015	Kg	87.330	92.761	Rm/100046	30.100 30.100 30.100	30.100 30.100 30.100	05/09/22	05/09/22	05/09/22	05/09/22
5	Microcrystalline cellulose PH102	BP	REX/SP/M010	Kg	16.208	10.776	Rm/101177	10.176 10.176 10.176	10.176 10.176 10.176	05/09/22	05/09/22	05/09/22	05/09/22

Binder Material:

6	Purified Water	BP	NA	Kg	41.500	41.500	Pur/2210627	41.500 41.500 41.500	41.500 41.500 41.500	05/09/22	05/09/22	05/09/22	05/09/22
---	----------------	----	----	----	--------	--------	-------------	----------------------------	----------------------------	----------	----------	----------	----------

Lubrication Material:

7	Sodium Stach Glycolate	BP	REX/SP/S004	Kg	6.300	6.300	Rm/101244	6.300 6.300 6.300	6.300 6.300 6.300	05/09/22	05/09/22	05/09/22	05/09/22
8	Colloidal Silicon Dioxide	BP	REX/SP/C022	Kg	0.525	0.525	Rm/100020	0.525 0.525 0.525	0.525 0.525 0.525	05/09/22	05/09/22	05/09/22	05/09/22
9	Magnesium Stearate	BP	REX/SP/M011	Kg	2.100	2.100	Rm/100020	2.100 2.100 2.100	2.100 2.100 2.100	05/09/22	05/09/22	05/09/22	05/09/22

Prepared by:

Production

Sign. L. K.

Date 30/03/2022

Checked by:

Quality Assurance

Sign. V. K.

Date 30/03/2022

Approved By:

Head Quality Assurance

Sign. V. K.

Date 30/03/2022

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SAI PRIMUS
LIFE BIOTECH PVT LTD

Product

SAI PRIMUS LIFE BIOTECH PVT LTD

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

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BATCH MANUFACTURING RECORD

Product Code: B05

Batch Size: 3,00,000 Tablets

BONCIPRO 500

BMR. No.: BMR/T/305-00

Batch No.: 6182217

Customer: Generic Health Care Pvt. Ltd.

Sr. No.	Ingredients	Spec.	Item code	UOM	Std. Qty.	Req. Qty.	A.R. No.	Issued Qty.		Weighed By Store (Sign & Date)	Checked By (IPQA) (Sign & Date)	Cross Checked by	
								Gross Wt.	Net Wt.			Checked by Production (Sign & Date)	Verified by IPQA (Sign & Date)
Coating Material:													
10	Hydroxy Propyl Methyl Cellulose (6 cps)	BP	REX/SP/H016	Kg	4.050	4.050	24/01/2022	4.120	0.080	05/08/2022	05/08/2022	05/08/2022	05/08/2022
11	Titanium Dioxide	BP	REX/SP/T002	Kg	0.450	0.450	24/01/2022	490.05	40.05	05/08/2022	05/08/2022	05/08/2022	05/08/2022
12	Ponceau 4R Lake	IHS	REX/SP/P006	Kg	0.225	0.225	24/01/2022	265.05	20.05	05/08/2022	05/08/2022	05/08/2022	05/08/2022
13	Purified Talc	BP	REX/SP/P017	Kg	0.375	0.375	24/01/2022	418.05	40.05	05/08/2022	05/08/2022	05/08/2022	05/08/2022
14	Polyethylene Glycol 6000	BP	REX/SP/P003	Kg	0.900	0.900	24/01/2022	940.05	700.05	05/08/2022	05/08/2022	05/08/2022	05/08/2022
15	Purified Water	BP	NA	Kg	42.500	42.500	24/01/2022	45.50	3.00	05/08/2022	05/08/2022	05/08/2022	05/08/2022

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Va	P. Aravind			
Date	30/03/2022	30/03/2022	30/03/2022		

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 9 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:		Batch No.: G18 22117 Generic Health Care Pvt. Ltd.

6.0 GRANULATION LINE CLEARANCE CHECKS: Date/Shift: **06/09/22 / 1 107/09/22 / E1**

Sr. No.	Checks	Time:	*Observations					
			13:25		06:35			
			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)		MA	NA	MA	NA		
12	Equipment status is updated for Cleaned and Preventive maintenance.		✓	✓	✓	✓		

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

Equipment	Sifter	Multimill	RMG/Mass Mixer	FBD/Tray Drier	Area
EQP. ID No.	Polvbs/002	Polmum1002	Polrmu/100	Polfbd/001	Granulation - II
Previous Product	Boncipro - 500				
Batch No.	G18 22116				
Cleaned by	Refn				
Checked by	M				
Verified by	G.P.				

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 06/09/22 Time: 15:27			Date: 07/09/22 Time: 06:40			Date: Time:		
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	28°C	M	G.P.	22°C	M	G.P.			
RH % (NMT 60%)	52%	M	G.P.	50%	M	G.P.			
DP (NLT 10 Pascal)	10	M	G.P.	11	M	G.P.			

APPROVAL FOR SIFTING AND GRANULATION:

Production Sign/Date:	M 06/09/22	M 07/09/22	
IPQA Sign/Date:	G.P. 06/09/22	G.P. 07/09/22	
Start and End Time:	15:30 19:30	07:00 08:51	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	P. Arund	V. S. S.	R. S. S.
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 10 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500		BMR. No.: BMRT/305-00 Batch No.: 61822117 Customer: Generic Health Care Pvt. Ltd.

7.0 LOT - I: GRANULATION SIFTING INSTRUCTIONS AND SIFTING RECORD: Date: 06/09/22 Shift: ..Ls.....

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	Vfd by
						From	To				
Dry mixing:											
1	Ciprofloxacin Hydrochloride	92.261	40#	P030-SE-4009	OK/ Not OK	15:30	15:52	OK/ Not OK	Rajan	my	hy
2	Microcrystalline cellulose PH102	10.776	40#	P030-SE-4009		15:53	15:58		Rajan	my	hy
Binder Material:											
3	Purified Water	41.500	NA	_____	NA	_____	_____	NA	_____	_____	_____

7.1 MANUFACTURING PROCESS:

Step No.	Process Instructions	Date: 06/09/22		Done by	Checked by	Verified by
		Time				
		Started	Completed			
1	Dry mixing: Transfer the sifted material from step 7.0 (1-2) into the RMG/Mass Mixer. Mix for 10 minute with impeller at slow speed and chopper 'off'. Impeller Speed: <u>45</u> RPM	16:00	16:10	Rajin	my	hy
2	Wet Granulation: Binder Addition: Add Purified water into the contents of RMG take 2 - 5 min for water addition with impeller slow speed and Chopper OFF. Impeller Speed: <u>45</u> RPM, Chopper: <u>NA</u> RPM	16:11	16:16	Rajin	my	hy
3	After Water addition allow mixing to form a coherent mass. If required allow mixing for 1 min or till required consistency of granules obtained with impeller at slow speed and chopper at slow speed. Impeller Speed: <u>55</u> RPM, Chopper Speed: <u>1800</u> RPM Additional quantity of Purified Water <u>NA</u> Kg	16:17	16:18	Rajin	my	hy
4	Note the Ampere at granulation end point ... <u>33</u> AMP.		no		my	hy
5	Discharge the wet mass to FBD bowl or Tray drier operating slow speed of Impeller and slow speed of Chopper. Impeller Speed: <u>55</u> RPM, Chopper Speed... <u>1800</u> RPM	16:19	16:23	Rajin	my	hy

7.2 DRYING:

Step No	Process Instructions	Date : 06/09/22		Done by	Checked by	Verified by
		Time				
		Started	Completed			
1	Load the wet mass into the FBD bowl and air dry the wet mass.					
2	Load the wet mass into the cleaned FBD bowl Dry at inlet temperature 60-65°C till the LOD reached up to 1.5 – 3.0% w/w.	16:25	18:28	Rajin	dmr	hy
3	LOD checking temperature at 105°C (Auto mode). LOD should be 1.5% - 3.0% w/w.	Observed LOD in %		Rajin	dmr	hy
		1.67				

7.3 FBD Finger bag Integrity checks:

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

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	I. K.	P. Arun	Nav	V. R.	
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 11 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500		BMR. No.: BMRT/305-00 Batch No.: G18 22 117 Customer: Generic Health Care Pvt. Ltd.

7.4 SET PARAMETERS:

Sr. No.	Operation	Started at	Inlet Temp. (60-65°C)	Outlet Temp.	Product Temp.	Completed at	Total Time (mins)	LOD Observed	Done by	Checked By
1.	Air-Drying-I	16:25	—	—	—	16:35	10	NA	Rajin	dm
2.	Raking-I	16:36	NA	NA	NA	16:40	04	NA	Rajin	dm
3.	Drying-I	16:41	65°C	40°C	39°C	17:11	30	6.91	Rajin	dm
4.	Raking-II	17:12	NA	NA	NA	17:16	04	NA	Rajin	dm
5.	Drying-II	17:17	65°C	40°C	37°C	17:47	30	3.69	Rajin	dm
6.	Raking-III	17:48	NA	NA	NA	17:52	04	NA	Rajin	dm
7.	Drying-III	17:53	65°C	42°C	40°C	18:28	35	1.67	Rajin	dm

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

Total Drying time:

LOD Verified By IPQA: *hy*

7.5 SIFTING AND MILLING:

S. No	Process Instructions	Date: 06/09/22	Time	Done by	Checked by	Verified by
		Started	Completed			
1.	Sift the dried granules through 20 # sieve. Record the observation.	18:31	18:43	Rajin	dm	hy
2.	Mill the oversized granules through 2.0 mm multi mill screen fitted with (knives forward medium speed) followed by sifting through 20# sieve on vibrating sifter and collect the sifted granules in double polythene lined cleaned HDPE containers, record the weights.	18:34	18:48	Rajin	dm	hy
3.	Unload the granules in to cleaned HDPE containers in double polythene bag.	18:49	18:56	Rajin	dm	hy

7.6 SIZING RECORD:

Mesh and screen size	Sieve ID No	Integrity checked before use	Date: 06/09/22	Time	Integrity checked After use	Done by	Checked by	Verified by
			Started	Completed				
20#	PD/30-SE-20/06	OK/ Not OK	18:31	18:43	OK/ Not OK	Rajin	dm	hy
2.0 mm	PD/mm-SE-2.0/02	OK/ Not OK	18:34	18:48	OK/ Not OK	Rajin	dm	hy

8.0 LOT - II: GRANULATION SIFTING INSTRUCTIONS AND SIFTING RECORD: Date: 06/09/22 Shift: ...L2.....

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	Vfd by
						From	To			
Dry mixing:										
1	Ciprofloxacin Hydrochloride	92.761	40#	PD/30-SE-40/09	OK/ Not OK	16:31	16:53	OK/ Not OK	Rajin	dm
2	Microcrystalline cellulose PH102	10.776	40#	PD/30-SE-40/09	OK/ Not OK	16:54	16:59	OK/ Not OK	Rajin	dm
Binder Material:										
3	Purified Water	41.300	NA	—	NA	—	—	NA	—	—
Lubrication Material:										
4	Sodium Stach Glycollate	6.300	60#	PD/30-SE-60/06	OK/ Not OK	09:24	09:28	OK/ Not OK	Rajin	dm
5	Colloidal Silicon Dioxide	0.525	60#	PD/30-SE-60/06	OK/ Not OK	09:29	09:33	OK/ Not OK	Rajin	dm
6	Magnesium Stearate	9.100	60#	PD/30-SE-60/06	OK/ Not OK	09:34	09:37	OK/ Not OK	Rajin	dm
Prepared by:										
Dept.	Production	Production	Quality Assurance	Head Quality Assurance						
Sign.	L. K.	P. Arun	V. S.	V. S.						
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022						

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 12 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: 218 22117 Generic Health Care Pvt. Ltd.

8.1 MANUFACTURING PROCESS:

Step No.	Process Instructions	Date: 06/09/22		Done by	Checked by	Verified by
		Time				
		Started	Completed			
1	Dry mixing: Transfer the sifted material from step 8.0 (1-2) into the RMG/Mass Mixer. Mix for 10 minute with impeller at slow speed and chopper 'off'. Impeller Speed: <u>45</u> RPM	17:01	17:11	Rajin	dm	ng
2	Wet Granulation: Binder Addition: Add Purified water into the contents of RMG take 2 - 5 min for water addition with impeller slow speed and Chopper OFF. Impeller Speed: <u>45</u> RPM, Chopper: <u>NA</u> RPM	17:12	17:17	Rajin	dm	ng
3	After Water addition allow mixing to form a coherent mass. If required allow mixing for 1 min or till required consistency of granules obtained with impeller at slow speed and chopper at slow speed. Impeller Speed: <u>55</u> RPM, Chopper Speed: <u>1800</u> RPM Additional quantity of Purified Water <u>NA</u> Kg	17:18	17:19	Rajin	dm	ng
4	Note the Ampere at granulation end point ... <u>32</u> AMP.		<u>NA</u>		dm	ng
5	Discharge the wet mass to FBD bowl or Tray drier operating slow speed of Impeller and slow speed of Chopper. Impeller Speed: ... <u>55</u> RPM, Chopper Speed... <u>1800</u> RPM	17:20	17:24	Rajin	dm	ng

8.2 DRYING:

Step No	Process Instructions	Date : 06/09/22		Done by	Checked by	Verified by
		Time				
		Started	Completed			
1	Load the wet mass into the FBD bowl and air dry the wet mass.					
2	Load the wet mass into the cleaned FBD bowl Dry at inlet temperature 60-65°C till the LOD reached up to 1.5 – 3.0% w/w.	18:36	19:27	Rajin	ng	ng
3	LOD checking temperature at 105°C (Auto mode). LOD should be 1.5% - 3.0% w/w.	Observed LOD in %		Rajin	ng	ng
		1.68 %				

8.3 FBD Finger bag Integrity checks:

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

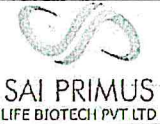
8.4 SET PARAMETERS:

Sr. No.	Operation	Started at	Inlet Temp. (60-65°C)	Outlet Temp.	Product Temp.	Completed at	Total Time (mins)	LOD Observed	Done by	Checked By
1.	Air-Drying-I	18:36		NA		18:46	10	NA	Rajin	dm
2.	Raking-I	18:47	NA	NA	NA	18:51	04	NA	Rajin	dm
3.	Drying-I	18:52	65°C	37°C	36°C	19:27	35	6.29	Rajin	dm
4.	Raking-II	19:28	NA	NA	NA	19:30	02	NA	Rajin	dm
5.	Drying-II	07:40	65°C	42°C	40°C	07:40	40	5.39	Rajin	ng
6.	Raking-III	07:41	NA	NA	NA	07:45	04	NA	Rajin	ng
7.	Drying-III	07:46	65°C	40°C	37°C	08:15	29	1.68	Rajin	ng
Total Drying Time (Exclude Raking & Air-Drying time): 104 min							LOD Verified By IPQA: g.r			
Total Drying time: 124 min										

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka	P. Anub	ng	g.r	
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 13 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00	Batch Size: 3,00,000 Tablets
		Customer:	Batch No.: G18 22 117
			Generic Health Care Pvt. Ltd.

8.5 SIFTING AND MILLING:

S. No	Process Instructions	Date : 07/09/22		Done by	Checked by	Verified by
		Time				
		Started	Completed			
1.	Sift the dried granules through 20 # sieve. Record the observation.	08:20	08:35	Rajin	My	G.P.
2.	Mill the oversized granules through 2.0 mm multi mill screen fitted with (knives forward medium speed) followed by sifting through 20# sieve on vibrating sifter and collect the sifted granules in double polythene lined cleaned HDPE containers, record the weights.	08:36	08:46	Rajin	My	G.P.
3.	Unload the granules in to cleaned HDPE containers in double polythene bag.	08:47	08:51	Rajin	My	G.P.

8.6 SIZING RECORD:

Mesh and screen size	Sieve ID No	Integrity checked before use	Date: 07/09/22		Integrity checked After use	Done by	Checked by	Verified by
			Time					
			Started	Completed				
20#	P0130-SE-20/06	OK/ Not OK	08:19	08:36	OK/ Not OK	Rajin	my	G.P.
2.0 mm	P0101-SE-2.0/02	OK/ Not OK	08:36	08:47	OK/ Not OK	Rajin	my	G.P.

8.7 WEIGHING OF DRIED GRANULES:

S. No.	Tare Weight (Kg)	Gross Weight (Kg)	Net Weight (Kg)	Weighed By	Checked By
1	2.100	32.820	30.720	Rajin	Alk
2	2.500	30.960	28.460	Rajin	Alk
3	2.450	37.220	34.770	Rajin	Alk
4	2.200	36.740	34.540	Rajin	Alk
5	2.690	48.680	40.990	Rajin	Alk
6	3.200	40.220	37.020	Rajin	Alk
7					
8			NA		
9					
10					
Total			206.500		

Theoretical Weight: 207.075 Kg

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

Actual Yield (Weight): 206.500 Kg % Yield: 99.72 %

Date: 07/09/2022

Production Executive Sign. /Date: 07/09/2022

Verified By IPQA: G.P. 07/09/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	P. Arul	V. S.	
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 14 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: 21822117 Generic Health Care Pvt. Ltd.

9.0 BLENDING LINE CLEARANCE CHECKS: Date/Shift: 08/09/2022 / 1

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)		NA	NA				
12	Equipment status is updated for Cleaned and Preventive maintenance.		/	/				

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

Equipment	Blender	Area
EQP. ID No.	PD 10CB1002	Blender - D
Previous Product	Boncipro 500	
Batch No.	21822117	
Cleaned by	S. S. S. S.	
Checked by	A. K.	
Verified by	G. P.	

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 08/09/22 Time: 09:13			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	A. K.	G. P.						
RH % (NMT 60%)	52%	A. K.	G. P.						
DP (NLT 10 Pascal)	10	A. K.	G. P.						

APPROVAL FOR SIFTING AND BLENDING:

Production Sign/Date:	A. K. 08/09/2022		
IPQA Sign/Date:	G. P. 08/09/2022		
Start and End Time:	09:24	10:50	

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. K.	P. Arund	V. S.	V. S.	
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 15 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:		Batch No.: 61822117 Generic Health Care Pvt. Ltd.

9.1 BLENDING AND LUBRICATION PROCESS:

Date: 02/09/22 Shift: 2

Step No.	Process Instructions	Time		Done by	Checked by Prod.	Verified by IPQA
		Started	Completed			
1	Use hand gloves and goggles while handling the materials.					
2	Operate the Octagonal Blender as per the current version of the SOP No. PDOP/009.					
Pre-lubrication:						
1	Load the dried and sifted granules from step 8.7, sifted Material from step 8.0 (4,5) in to the blender and mix at 10 RPM for 10 minutes.	10:01	10:11	Rajan	Ab	G.P
Lubrication:						
2	Load the Sifted Magnesium Stearate into the above Pre-lubricated blend and mix for further at 10 RPM for 3 minutes.	10:14	10:15			
3	Unload the lubricated blend in HDPE container having double lined	10:19	10:20	Rajan	Ab	G.P
		10:26	10:27			
3	Unload the lubricated blend in HDPE container having double lined	10:30	10:39	Rajan	Ab	G.P

9.2 WEIGHING OF FINAL BLEND: Balance I.D. No. BBA1005

Date: 02/09/22 Shift: 2 Time: 10:50

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	11.520	2.180	9.340	Ab	Rk	6	51.270	3.000	48.270	Ab	Rk
2	43.680	2.400	41.280	Ab	Rk	7	9.880	2.390	7.490	Ab	Rk
3	33.420	2.000	31.420	Ab	Rk	8					
4	40.560	2.400	38.160	Ab	Rk	9					
5	43.440	2.400	41.040	Ab	Rk	10					
Theoretical weight of Blend:						216.000 Kg					
Actual weight of Blend:						214.000 Kg					
Verified by IPQA						G.P					

9.3 RECONCILIATION:

1.0	Theoretical weight of blend	:	216.000 Kg
2.0	Actual Weight of blend	:	214.000 Kg
3.0	Manufacturing Loss (Blending stage) @	:	1.798 Kg
4.0	In-process samples		
	A IPQA Samples	:	0.030 Kg.
	B QC Samples	:	0.150 Kg.
	C Validation Samples	:	0.022 Kg.
5.0	Total samples: (A + B + C)	:	0.202 Kg
6.0	Total: (2.0 + 5.0)	:	214.202 Kg
7.0	Yield {6.0 / 1.0 x 100}*	:	99.16 %

* Actually yield will be calculated after 3 validation batches.

@Total rejects destroyed: 1.798 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: 02/09/22 Checked By IPQA sign/Date: G.P 02/09/22

Test request form raised by Prod Sign/Date: 02/09/22

Test request form received by IPQA Sign/Date: G.P 02/09/22

9.4 RELEASED FOR COMPRESSION:

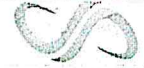
Reconciliation checked and blend is released for compression

IPQA Sign: G.P Date: 02/09/22

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	P. Asw		
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 16 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: 71822117 Generic Health Care Pvt. Ltd.

10.0 COMPRESSION LINE CLEARANCE CHECKS:

Date: 08/09/2022 / 09/09/2022

Sr. No.	Checks	Time:	*Observations					
			10:40	06:17	10:40	06:17	10:40	06:17
1	Check and ensure that empty SS containers/ containers polythene bags, Tags, and documents of previous batch/product are removed.		✓	✓	✓	✓		
2	Check and ensure that absence of tablets of previous batch/product from area below machine and inside machine by opening the guard of machine.		✓	✓	✓	✓		
3	Check and ensure that the machine body and machine parts like hoppers, feed frame, dust collection chute, hosepipe and ejection chute and control panel are clean.		✓	✓	✓	✓		
4	Check and ensure that absence of tablet of previous batch/product below the weighing balance, check the cleanliness of area and equipment.		✓	✓	✓	✓		
5	Check and ensure that working desk, analytical balance and other accessories are clean.		✓	✓	✓	✓		
6	Check and ensure that Deduster and hosepipe are clean.		✓	✓	✓	✓		
7	Check and ensure that Tube light fixture, supply grills, riser grills and filters and electrical fixtures are clean.		✓	✓	✓	✓		
8	Check and ensure that instruments to be used are within calibration due date, and Punch inspection record		✓	✓	✓	✓		
9	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.		✓	✓	✓	✓		
10	Check and ensure that environmental conditions are recorded in the BMR.		✓	✓	✓	✓		
11	Area, equipment and preventive maintenance status board is updated.		✓	✓	✓	✓		
12	Check and ensure that rinse water is released from QC and attached the test request from (TRF) in BMR		NA	NA	NA	NA		
13	Equipment status is updated for Cleaned and Preventive Maintenance label.		✓	✓	✓	✓		

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

Equipment	Compression Machine	Deduster	Area
EQP ID No.	PD1 COM1001	PD1DED1001, PD1DED1002	Comp-01
Previous Product	Boncipro 500		
Batch No.	71822116		
Cleaned by	V. S. S.		
Checked by	S. S.		
Verified by	S. S.		

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 08/09/22 Time: 10:43			Date: 09/09/22 Time: 06:30			Date: Time:		
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	23°C	S. S.	G. S.	22°C	S. S.	G. S.			
RH % (NMT 60%)	52%	S. S.	G. S.	52%	S. S.	G. S.			
DP (NLT 10 Pascal)	11 Pascal	S. S.	G. S.	11 Pascal	S. S.	G. S.			

APPROVAL FOR COMPRESSION:

Production Sign/Date:	S. S. 08/09/2022	S. S. 09/09/2022	
IPQA Sign/Date:	G. S. 08/09/2022	G. S. 09/09/2022	
Start and End Time:	12:20 21:49	06:45 07:54	

Prepared by:	Checked by:	Approved By:
Dept. Production	Production Quality Assurance	Head Quality Assurance
Sign. L. S.	P. Aravind	V. S. S.
Date 30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 17 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:		Batch No.: 61822117 Generic Health Care Pvt. Ltd.

11.0 COMPRESSION

11.1 PROCESS INSTRUCTIONS:

Sr. No.	Process Instructions
1	Check the cleanliness of area and equipment.
2	Ensure that the correct punch set are issued as per the Punch issue record.
3	Set the Double Rotary Compression Machine with a. Upper punches: 17.20 x 7.50 mm Caplet shaped with breakline on punches. b. Lower punches: 17.20 x 7.50 mm Caplet shaped plain punches. c. Dies: 17.20 x 7.50 mm suitable for above punches. d. Type of tooling - D.
	Punch Issued by: sign./Date: <u>08/09/2022</u> Checked and Received by Sign./Date: <u>08/09/2022</u> Verified by Sign./Date: <u>08/09/2022</u>
4	Transfer the blend to compression cubicle. Load the blend into hopper manually.
5	Operate the Double Rotary Compression machine as per the current version of SOP: PDOP/010 and reject tablets of the first three round which shall be destroyed as per SOP: QAGN/048.
6	Collect the tablets of one complete rotation and carry out In-process checks for thickness, weight and appearance, record the observations in the BMR. Verify the tablets for uniformity of weight and hardness and record in the BMR.
7	Collect the compressed tablets in double polythene bag lined and labelled cleaned HDPE containers/SS container.
8	Check and record the weight of the compressed tablets.

11.2 GRANULES RECEIPT RECORD:

Balance ID. No.: PD1840105 Date: 08/09/2022 Shift: B Time: 11:02

Sr. No.	Gross Weight in Kg	Issued By Production	Checked by Production
1	11.520	AK	21
2	43.680	AK	23
3	30.420	AK	25
4	40.560	AK	27
5	42.640	AK	29
6	51.270	AK	31
7	09.880	AK	33
8			
9			
10			

11.3 COMPRESSION SPECIFICATION / PARAMETERS:

Sr. No.	Parameter	Limits	No. of tablets to be checked from each side	Frequency	
				Production	IPQA
1.	Appearance	White coloured caplet shaped uncoated tablet with breakline on one side and plain on other side.	20	Every 30 min.	Every 2 Hr.
2.	Average weight (mg)	720.000 mg $\pm$ 3.0 % (698.400 mg – 741.600 mg)	20		
3.	Group Weight	14.400 g $\pm$ 3.0 % (13.968 g to 14.832 g)	20	Every 30 min.	Every 2 Hr.
4.	Uniformity of weight Tablets	720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)	20	Every 2 Hr.	Every 4 Hr.
5.	Hardness	NLT 3.0 Kg (To be Established)	4	Every 30 min.	Every 2 Hr.
6.	Thickness (mm)	5.20 mm $\pm$ 0.2 (5.00 mm – 5.40 mm) (To be Established)	4	Every 30 min.	Every 2 Hr.
7.	Friability	NMT 1% w/w	6 g	Every 2 Hr.	Every 4 Hr.
8.	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.	<u>L. K.</u>	<u>P. Anand</u>	<u>Heel</u>	<u>Heel</u>
Date	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 18 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500		BMR. No.: BMR/T/305-00 Batch No.: 1822117 Customer: Generic Health Care Pvt. Ltd.

11.4 COMPRESSION MACHINE RUNNING STATUS:

Date	Shift	Start Time	End Time	Total Hour	M/C Speed	Tablets Output	Done By	Checked By
08/09/2022	A	12:20	21:49	09:00	10	289933	Vetru	23
09/09/2022	A	06:45	07:54	01:30	10	3400	Vetru	23
						na		

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

Balance I.D. No.: PDRA1007

Date: 08/09/2022 Shift: A Time: 11:15

LHS						RHS					
Sr. No.	Appearance*	Weight (in mg)	Thickness (in mm)	Length (in mm)	Width (in mm)	Sr. No.	Appearance*	Weight (in mg)	Thickness (in mm)	Length (in mm)	Width (in mm)
1	OK	706	5.24	17.29	7.56	1	OK	732	5.21	17.24	7.59
2	OK	718	5.21	17.24	7.59	2	OK	734	5.26	17.28	7.54
3	OK	713	5.27	17.26	7.54	3	OK	728	5.22	17.30	7.58
4	OK	717	5.23	17.28	7.57	4	OK	728	5.19	17.25	7.53
5	OK	712	5.20	17.30	7.52	5	OK	727	5.23	17.29	7.56
6	OK	709	5.26	17.24	7.55	6	OK	729	5.26	17.26	7.59
7	OK	720	5.28	17.27	7.53	7	OK	739	5.22	17.22	7.54
8	OK	710	5.23	17.22	7.54	8	OK	738	5.20	17.26	7.51
9	OK	713	5.25	17.26	7.57	9	OK	729	5.24	17.28	7.55
10	OK	718	5.29	17.24	7.50	10	OK	733	5.27	17.25	7.58
11	OK	703	5.23	17.28	7.58	11	OK	722	5.23	17.30	7.53
12	OK	717	5.27	17.24	7.54	12	OK	737	5.28	17.29	7.55
13	OK	713	5.24	17.21	7.52	13	OK	728	5.24	17.26	7.57
14	OK	711	5.29	17.26	7.55	14	OK	729	5.22	17.22	7.52
15	OK	712	5.24	17.22	7.58	15	OK	729	5.20	17.25	7.56
16	OK	713	5.28	17.28	7.53	16	OK	731	5.25	17.28	7.53
17	OK	713	5.23	17.30	7.59	17	OK	727	5.19	17.25	7.59
18	OK	703	5.29	17.26	7.55	18	OK	730	5.21	17.22	7.55
19	OK	706	5.26	17.24	7.52	19	OK	731	5.20	17.27	7.59
20	OK	714	5.24	17.29	7.56	20	OK	729	5.24	17.29	7.54
21	OK	712	5.29	17.31	7.58	21	OK	730	5.20	17.26	7.51
22	OK	706	5.22	17.24	7.54	22	OK	732	5.25	17.30	7.55
23	OK	715	5.26	17.29	7.51	23	OK	729	5.21	17.24	7.58
24	OK	718	5.28	17.26	7.56	24	OK	729	5.24	17.28	7.56
25	OK	704	5.22	17.30	7.58	25	OK	732	5.20	17.25	7.59
26	OK	707	5.27	17.24	7.53	26	OK	740	5.26	17.22	7.53
27	OK	711	5.24	17.27	7.59	27	OK	724	5.23	17.27	7.57
28	OK	703	5.26	17.29	7.55	28	OK	726	5.27	17.24	7.52
29	OK	710	5.23	17.25	7.52	29	OK	730	5.22	17.21	7.58
30	OK	702	5.21	17.21	7.54	30	OK	730	5.26	17.26	7.58

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

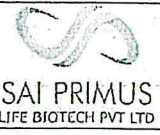
Done by Production Sign/Date..... 23/09/2022

Checked by IPQA Sign/Date..... 08/09/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	P. Asant	V. Asant	V. Asant
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 19 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: 61822117 Generic Health Care Pvt. Ltd.

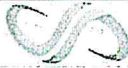
11.6 COMPRESSION SPECIFICATION AND PARAMETERS: Date: 08/09/22 Shift: A Time: 11:40

Parameters	Instrument used	Equip ID No.	Observations of LHS		Observations of RHS		Limits						
			Min	Max	Min	Max							
Appearance	Visual	NA	OK		OK		White coloured caplet shaped uncoated tablet with breakline on one side and plain on other side.						
Group Weight	Electronic Balance	PD/BAL/001	14.241 g		14.610 g		14.400 g $\pm$ 3.0 % (13.968 g to 14.832 g)						
Average weight	Electronic Balance		712.05 mg		730.50 mg		720.000 mg $\pm$ 3.0 % (698.400 mg – 741.600 mg)						
Individual weight	Electronic Balance		702 mg	720 mg	722 mg	740 mg	720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)						
Uniformity of weight	Electronic Balance		-1.42 %	1.10 %	-1.17 %	1.28 %							
Thickness	Vernier Caliper	0147601	5.20 mm	5.29 mm	5.19 mm	5.28 mm	5.20 mm $\pm$ 0.2 (5.00 mm – 5.40 mm) (To be Established)						
Hardness	Hardness Tester	0147601	10.0	10.5	10.0	10.5	10.0	10.5	10.0	10.5	10.0	10.5	NLT 3.0 Kg (To be Established)
Friability	Friabilator	QA/FRT/001	0.08%		0.10%		NMT 1% w/w						
DT	DT Apparatus	QA/DTA/001	01 min 20 sec		01 min 18 sec		NMT 15 Minutes						
M/C set done by Operator Name: V. V. M/C set up Checked by Prod. Sign/Date: 08/09/22 M/C Speed: 12 RPM													
Initial Setting Tablets Destroyed by: Sign: B. Date: 08/09/22 Quantity in Kg. 0.100 Quantity in No. 138													
Approval for Batch Compression by IPQA: Sign: G. S. Date: 08/09/22 Time: 11:22													

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	T. Anand	V. V.	V. V.
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 20 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500		Batch No.: G1822117 Customer: Generic Health Care Pvt. Ltd.

11.7 IN-PROCESS CHECKS: (For Production)

Date & Time	Appearance		Weight of 20 Tablets		Hardness				Thickness				Done by Production
	White coloured caplet shaped uncoated tablet with breakline on one side and plain on other side.		14.400 g $\pm$ 3.0 % (13.968 g to 14.832 g)		NLT 3.0 Kg (To be Established)				5.20 mm $\pm$ 0.2 (5.00 mm – 5.40 mm) (To be Established)				
	LHS	RHS	LHS	RHS	LHS	LHS	RHS	RHS	LHS	LHS	RHS	RHS	
12:20	OK	OK	14.413	14.384	10.0	10.0	10.5	10.0	5.24	5.27	5.22	5.28	22
13:15	OK	OK	14.401	14.397	10.5	10.0	10.5	10.0	5.26	5.27	5.23	5.27	R-11
13:47	OK	OK	14.397	14.391	10.0	10.5	10.0	10.5	5.27	5.26	5.27	5.26	R-11
14:19	OK	OK	14.401	14.410	10.5	10.0	10.5	10.0	5.26	5.27	5.26	5.25	R-11
14:50	OK	OK	14.371	14.399	10.0	10.5	10.0	10.5	5.27	5.29	5.27	5.27	R-11
15:20	OK	OK	14.399	14.402	10.5	10.0	10.5	11.0	5.27	5.26	5.26	5.27	R-11
15:50	OK	OK	14.401	14.405	10.0	10.5	11.0	10.5	5.29	5.27	5.25	5.26	R-11
16:23	OK	OK	14.388	14.401	11.0	10.5	11.0	10.5	5.27	5.23	5.27	5.27	R-11
16:53	OK	OK	14.391	14.405	10.5	10.5	10.0	10.5	5.27	5.26	5.28	5.26	R-11
17:25	OK	OK	14.401	14.379	10.5	10.0	10.5	10.0	5.26	5.25	5.24	5.27	R-11
17:55	OK	OK	14.381	14.404	10.0	11.0	10.5	10.5	5.27	5.26	5.27	5.26	R-11
18:25	OK	OK	14.391	14.400	11.0	10.5	10.0	10.5	5.23	5.27	5.26	5.25	R-11
19:00	OK	OK	14.389	14.400	10.5	10.0	10.5	10.0	5.27	5.26	5.25	5.27	R-11
19:30	OK	OK	14.410	14.398	11.0	11.0	10.5	10.5	5.26	5.25	5.24	5.26	R-11
20:02	OK	OK	14.399	14.397	11.0	10.5	11.0	10.5	5.27	5.26	5.27	5.25	R-11
20:31	OK	OK	14.403	14.401	10.5	11.0	10.5	10.5	5.27	5.23	5.29	5.26	R-11
21:09	OK	OK	14.397	14.407	11.0	10.5	10.0	10.0	5.26	5.25	5.26	5.25	R-11
21:39	OK	OK	14.408	14.400	10.5	10.5	10.5	10.0	5.27	5.26	5.25	5.27	R-11
06:45	OK	OK	14.389	14.396	10.5	11.0	10.5	10.5	5.28	5.24	5.27	5.29	22
07:06	OK	OK	14.402	14.407	11.0	10.5	11.0	11.0	5.28	5.28	5.29	5.30	22
07:54	OK	OK	14.392	14.402	10.5	10.0	11.0	10.5	5.27	5.24	5.26	5.25	22
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Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	P. Aravind	V. Aravind	V. Aravind
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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Batch Size: 3,00,000 Tablets

Batch No.: G18 22117

Generic Health Care Pvt. Ltd.

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 22 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500		BMR. No.: BMR/T/305-00 Batch No.: G18 22117 Customer: Generic Health Care Pvt. Ltd.

11.9 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION:

Date: 08/09/2022		Time: 13:25		Shift: A							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	719	8	714	15	714	1	718	8	716	15	720
2	721	9	721	16	721	2	722	9	715	16	719
3	718	10	722	17	726	3	729	10	717	17	726
4	720	11	724	18	724	4	720	11	719	18	725
5	718	12	716	19	721	5	719	12	720	19	720
6	720	13	720	20	719	6	720	13	719	20	721
7	718	14	716			7	717	14	721		
Balance ID No.: PD BAL 007				M/C Speed: 10 RPM							
Group weight of 20 Tablets: 14:39.2...g. Avg. wt: 119.60mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 714.....mg Max. weight: 724.....mg				Group weight of 20 Tablets: 14:40.1...g. Avg. wt: 120.005mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 715.....mg Max. weight: 727.....mg							
				LHS	RHS						
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				0.07%	0.06%	Equipment ID No.: QA/FRT/ 002					
Disintegration Time (Limit - NMT 15 minutes)				01 min 11 sec	01 min 20 sec	Equipment ID No.: QA/DTA/ 001					
Done by: R.ell (Production)											
Date: 08/09/2022		Time: 15:30		Shift: B							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	721	8	720	15	721	1	719	8	721	15	719
2	718	9	716	16	719	2	722	9	722	16	721
3	720	10	721	17	720	3	724	10	724	17	720
4	717	11	717	18	718	4	726	11	718	18	724
5	721	12	720	19	717	5	721	12	719	19	721
6	725	13	718	20	725	6	720	13	721	20	719
7	715	14	719			7	719	14	722		
Balance ID No.: PD BAL 007				M/C Speed: 10 RPM							
Group weight of 20 Tablets: 14:38.8...g. Avg. wt: 119.40mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 715.....mg Max. weight: 725.....mg				Group weight of 20 Tablets: 14:42.2...g. Avg. wt: 121.10mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 718.....mg Max. weight: 726.....mg							
				LHS	RHS						
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				0.05%	0.07%	Equipment ID No.: QA/FRT/ 002					
Disintegration Time (Limit - NMT 15 minutes)				01 min 10 sec	01 min 15 sec	Equipment ID No.: QA/DTA/ 001					
Done by: R.ell (Production)											

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	P. Arcub	V. Sree	V. Sree
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 23 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMRT/305-00 Customer:	Batch No.: 41822117 Generic Health Care Pvt. Ltd.

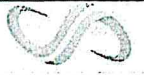
11.10 UNIFORMITY OF WEIGHT IN PROCESS CHECKS FOR PRODUCTION:

Date: 08/09/2022		Time: 17:35		Shift: B							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	716	8	724	15	721	1	722	8	720	15	725
2	720	9	716	16	724	2	721	9	716	16	724
3	719	10	718	17	718	3	724	10	722	17	723
4	720	11	721	18	720	4	725	11	725	18	721
5	718	12	720	19	721	5	716	12	720	19	720
6	721	13	720	20	719	6	715	13	724	20	718
7	719	14	719			7	721	14	719		
Balance ID No.: PD/BA/007						M/C Speed: 10 RPM					
Group weight of 20 Tablets: 14.394...g. Avg. wt.: 719.70mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 716...mg Max. weight: 724...mg						Group weight of 20 Tablets: 14.411...g. Avg. wt.: 720.55mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 715...mg Max. weight: 725...mg					
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						0.08%		0.05%		Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)						01 min 10 sec		01 min 15 sec		Equipment ID No.: QA/DTA/001	
Done by: R. S. (Production)											
Date: 08/09/2022		Time: 19:50		Shift: B							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	719	8	720	15	724	1	721	8	725	15	717
2	721	9	719	16	721	2	718	9	721	16	715
3	720	10	720	17	723	3	721	10	719	17	716
4	717	11	718	18	721	4	724	11	720	18	715
5	721	12	724	19	725	5	721	12	721	19	719
6	720	13	724	20	720	6	718	13	718	20	720
7	718	14	721			7	715	14	716		
Balance ID No.: PD/BA/007						M/C Speed: 10 RPM					
Group weight of 20 Tablets: 14.413...g. Avg. wt.: 720.65mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 718...mg Max. weight: 725...mg						Group weight of 20 Tablets: 14.380...g. Avg. wt.: 719.00mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 715...mg Max. weight: 725...mg					
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						0.07%		0.06%		Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)						01 min 12 sec		01 min 15 sec		Equipment ID No.: QA/DTA/001	
Done by: R. S. (Production)											

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	P. Arun	Ver	R. S.
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 24 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
	Product BONCIPRO 500	BMR No.: BMR/T/305-00 Customer:	Batch No.: 618 22 117 Generic Health Care Pvt. Ltd.

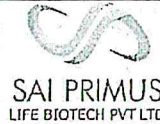
11.11 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION:

Date: 09/09/2022		Time: 07:11		Shift: A							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	719	8	722	15	720	1	718	8	721	15	716
2	722	9	717	16	716	2	714	9	717	16	719
3	720	10	722	17	719	3	719	10	714	17	714
4	716	11	718	18	721	4	722	11	720	18	719
5	724	12	720	19	723	5	720	12	716	19	721
6	719	13	724	20	719	6	716	13	719	20	720
7	717	14	717			7	719	14	722		
Balance ID No.: PD/RAC/007						M/C Speed: 10 RPM					
Group weight of 20 Tablets: 149.395 g. Avg. wt: 74.75 mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 716 mg Max. weight: 724 mg						Group weight of 20 Tablets: 149.366 g. Avg. wt: 74.683 mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 714 mg Max. weight: 722 mg					
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						LHS: 0.11%		RHS: 0.09%		Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)						01 min 20 sec		01 min 17 sec		Equipment ID No.: QA/DTA/001	
Done by: (Signature) (Production)											
Date:		Time:		Shift:		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: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: mg Max. weight: mg						Group weight of 20 Tablets: g. Avg. wt: mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: mg Max. weight: mg					
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						LHS:		RHS:		Equipment ID No.: QA/FRT/	
Disintegration Time (Limit - NMT 15 minutes)										Equipment ID No.: QA/DTA/	
Done by: (Production)											

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. K.	P. Arundh	(Signature)	(Signature)	
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 25 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: <u>G118 22 117</u> Generic Health Care Pvt. Ltd.

11.12 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA:

Date: <u>08/09/2022</u>		Time: <u>12:36</u>		Shift: <u>G</u>		Low RPM	
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	723	8	716	15	718	1	721
2	725	9	724	16	718	2	714
3	724	10	722	17	722	3	730
4	719	11	730	18	717	4	723
5	721	12	724	19	724	5	725
6	720	13	715	20	732	6	719
7	717	14	722			7	715
Balance ID No.: <u>QA/FRT/002</u>				M/C Speed: <u>10</u> RPM			
Group weight of 20 Tablets: <u>14.428</u> g. Avg. wt.: <u>721.4</u> mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: <u>715</u> mg Max. weight: <u>732</u> mg				Group weight of 20 Tablets: <u>14.409</u> g. Avg. wt.: <u>720.45</u> mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: <u>714</u> mg Max. weight: <u>737</u> mg			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.04%		0.06%		Equipment ID No.: QA/FRT/ 002	
Disintegration Time (Limit - NMT 15 minutes)		01 min 19 sec		01 min 40 sec		Equipment ID No.: QA/DTA/ 001	
Done by: <u>GS</u> (IPQA)							
Date: <u>08/09/2022</u>		Time: <u>12:43</u>		Shift: <u>G</u>		High RPM	
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	700	8	721	15	725	1	720
2	722	9	715	16	726	2	721
3	719	10	719	17	720	3	724
4	718	11	724	18	721	4	720
5	724	12	721	19	721	5	723
6	730	13	720	20	725	6	718
7	727	14	722			7	717
Balance ID No.: <u>QA/FRT/002</u>				M/C Speed: <u>17</u> RPM			
Group weight of 20 Tablets: <u>14.409</u> g. Avg. wt.: <u>720.45</u> mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: <u>715</u> mg Max. weight: <u>730</u> mg				Group weight of 20 Tablets: <u>14.422</u> g. Avg. wt.: <u>721.1</u> mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: <u>715</u> mg Max. weight: <u>726</u> mg			
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 19 sec		01 min 40 sec		Equipment ID No.: QA/DTA/ 001	
Done by: <u>GS</u> (IPQA)							

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<u>L. Ka</u>	<u>P. Anant</u>	<u>Veel</u>	<u>V. Anant</u>	
Date	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 26 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:		Batch No.: G1822117 Generic Health Care Pvt. Ltd.

11.13 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA:

Date: 08/09/2022		Time: 12:48		Shift: G1		Low Hardness	
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	723	8	723	15	715	1	721
2	720	9	725	16	719	2	718
3	718	10	720	17	720	3	717
4	714	11	721	18	718	4	719
5	719	12	722	19	720	5	720
6	721	13	718	20	720	6	721
7	720	14	717			7	721
Balance ID No.: QA/BAL/002				M/C Speed: 12 RPM			
Group weight of 20 Tablets: 14399 g. Avg. wt: 719.95 mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 714 mg Max. weight: 726 mg				Group weight of 20 Tablets: 14400 g. Avg. wt: 720.00 mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 715 mg Max. weight: 725 mg			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				0.07%		0.05%	
Disintegration Time (Limit - NMT 15 minutes)				01 min 12 sec		01 min 15 sec	
Equipment ID No.: QA/FRT/ 002							
Equipment ID No.: QA/DTA/ 001							
Done by: [Signature] (IPQA)							
Date: 08/09/2022		Time: 12:57		Shift: G1		High Hardness	
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	721	8	724	15	720	1	718
2	720	9	728	16	723	2	724
3	718	10	725	17	719	3	720
4	723	11	721	18	723	4	721
5	720	12	718	19	720	5	720
6	718	13	721	20	715	6	721
7	716	14	713			7	720
Balance ID No.: QA/BAL/001				M/C Speed: 13 RPM			
Group weight of 20 Tablets: 14606 g. Avg. wt: 730.30 mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 713 mg Max. weight: 728 mg				Group weight of 20 Tablets: 14418 g. Avg. wt: 720.90 mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 715 mg Max. weight: 730 mg			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				0.05%		0.07%	
Disintegration Time (Limit - NMT 15 minutes)				01 min 12 sec		01 min 15 sec	
Equipment ID No.: QA/FRT/ 002							
Equipment ID No.: QA/DTA/ 001							
Done by: [Signature] (IPQA)							

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. K.	P. Arun	[Signature]	[Signature]	
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Pudukcherry-605009.		Page 27 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product BONCIPRO 500	BMR. No.: BMRT/305-00 Customer:		Batch No.: G1822117 Generic Health Care Pvt. Ltd.

11.14 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA:

Date: 08/09/2022		Time: 13:14		Shift: G1		Full Hopper	
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	723	8	725	15	721	8	725
2	720	9	720	16	724	9	720
3	723	10	721	17	729	10	723
4	720	11	716	18	726	11	721
5	726	12	718	19	715	12	718
6	718	13	723	20	714	13	719
7	719	14	720			14	724
Balance ID No.: QA/BAL/002				M/C Speed: 13 RPM			
Group weight of 20 Tablets: 14.418 g. Avg. wt: 720.90 mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 714 mg Max. weight: 726 mg				Group weight of 20 Tablets: 14.468 g. Avg. wt: 723.40 mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 715 mg Max. weight: 727 mg			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.05%		RHS		0.07%	
Disintegration Time (Limit - NMT 15 minutes)		01 min		RHS		01 min	
Done by: G3 (IPQA)				Equipment ID No.: QA/FRT/ 002			
Date: 08/09/2022				Time: 17:18			
Date: 08/09/2022		Time: 17:18		Shift: G1		MID Hopper	
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	721	8	727	15	718	8	721
2	718	9	720	16	727	9	721
3	715	10	721	17	720	10	726
4	723	11	720	18	718	11	729
5	720	12	723	19	717	12	714
6	718	13	720	20	726	13	723
7	721	14	714			14	720
Balance ID No.: QA/BAL/002				M/C Speed: 13 RPM			
Group weight of 20 Tablets: 14.408 g. Avg. wt: 720.40 mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 714 mg Max. weight: 727 mg				Group weight of 20 Tablets: 14.402 g. Avg. wt: 720.10 mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight: 714 mg Max. weight: 729 mg			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.08%		RHS		0.07%	
Disintegration Time (Limit - NMT 15 minutes)		01 min		RHS		01 min	
Done by: (IPQA)				Equipment ID No.: QA/FRT/ 002			
Date: 30/03/2022				Time: 20/03/2022			
Date: 30/03/2022		Time: 20/03/2022		Shift: G1		MID Hopper	

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. B.	P. Aravind	[Signature]	[Signature]	
Date	30/03/2022	30/03/2022	20/03/2022	20/03/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 27 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:		Batch No.: <u>G18 221178</u> Generic Health Care Pvt. Ltd.

11.14 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA:

Date: <u>08/09/2022</u>		Time: _____		Shift: <u>21:30</u>							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	722	8	721	15	720	1	719	8	721	15	716
2	723	9	719	16	718	2	723	9	719	16	717
3	719	10	721	17	725	3	722	10	728	17	716
4	713	11	716	18	720	4	724	11	723	18	719
5	716	12	714	19	721	5	715	12	716	19	715
6	715	13	719	20	719	6	719	13	726	20	717
7	719	14	722			7	717	14	721		
Balance ID No.: <u>GA/BH/1002</u>				M/C Speed: <u>13</u> RPM							
Group weight of 20 Tablets: <u>14:32.4</u>g. Avg. wt: <u>719.20</u>mg				Group weight of 20 Tablets: <u>14:40.3</u>g. Avg. wt: <u>720.15</u>mg							
Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)				Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)							
Min weight: <u>713</u> mg Max. weight: <u>725</u>mg				Min weight: <u>715</u> mg Max. weight: <u>728</u> mg							
		LHS		RHS							
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.04%		0.05%							
Disintegration Time (Limit - NMT 15 minutes)		01 min 40 sec		01 min 30 sec							
Equipment ID No.: QA/FRT/002		Equipment ID No.: QA/DTA/001									
Done by: <u>mg</u>(IPQA)											
Date: <u>09/09/2022</u>		Time: <u>07:10</u>		Shift: <u>A</u>							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	721	8	723	15	723	1	723	8	725	15	719
2	720	9	715	16	720	2	720	9	726	16	715
3	723	10	724	17	721	3	722	10	725	17	723
4	717	11	718	18	722	4	713	11	726	18	725
5	712	12	716	19	724	5	723	12	724	19	724
6	718	13	719	20	723	6	718	13	720	20	719
7	719	14	719			7	719	14	719		
Balance ID No.: <u>GA/BH/1002</u>				M/C Speed: <u>12</u> RPM							
Group weight of 20 Tablets: <u>14:31.7</u>g. Avg. wt: <u>711.9</u>mg				Group weight of 20 Tablets: <u>14:42.7</u>g. Avg. wt: <u>721.35</u>mg							
Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)				Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg)							
Min weight: <u>712</u> mg Max. weight: <u>724</u>mg				Min weight: <u>713</u> mg Max. weight: <u>728</u> mg							
		LHS		RHS							
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.03%		0.05%							
Disintegration Time (Limit - NMT 15 minutes)		01 min 30 sec		01 min 40 sec							
Equipment ID No.: QA/FRT/002		Equipment ID No.: QA/DTA/001									
Done by: <u>g.e</u>(IPQA)											

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>P. Arun</u>	<u>Shel</u>	<u>V. Ramesh</u>
Date	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>20/03/2022</u>	<u>30/03/2022</u>

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	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 27 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500		BMR. No.: BMRT/305-00 Batch No.: <u>G18 22117</u> Customer: Generic Health Care Pvt. Ltd.

11.14 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA:

Composite

Date: <u>09/09/2022</u>		Time: <u>08.07</u>		Shift: <u>A</u>							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	718	8	724	15	725	1	717	8	713	15	720
2	721	9	720	16	721	2	722	9	719	16	720
3	720	10	721	17	726	3	720	10	727	17	714
4	723	11	724	18	726	4	722	11	720	18	718
5	720	12	716	19	723	5	721	12	724	19	725
6	714	13	717	20	715	6	720	13	721	20	728
7	719	14	726			7	718	14	723		
Balance ID No.: <u>QA/BAL/002</u>						M/C Speed: <u>13</u> RPM					
Group weight of 20 Tablets: <u>14399</u>g. Avg. wt.: <u>719.95</u> ...mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight.: <u>714</u>mg Max. weight.: <u>725</u>mg						Group weight of 20 Tablets: <u>14413</u>g. Avg. wt.: <u>720.65</u> ...mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight.: <u>713</u>mg Max. weight.: <u>724</u>mg					
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						LHS: <u>0.04%</u> RHS: <u>0.07%</u> Equipment ID No.: QA/FRT/ <u>002</u>					
Disintegration Time (Limit - NMT 15 minutes)						LHS: <u>01 min 19 sec</u> RHS: <u>01 min 15 sec</u> Equipment ID No.: QA/DTA/ <u>001</u>					
Done by: <u>G13</u>(IPQA)											
Date:		Time:		Shift:		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: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 mg) Min weight.:.....mg Max. weight.:.....mg						Group weight of 20 Tablets:.....g. Avg. wt.:.....mg Limit: 720.000 mg $\pm$ 5.0 % (684.000 mg – 756.000 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)						LHS: RHS: Equipment ID No.: QA/DTA/					
Done by:(IPQA)											

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<u>L. Ka</u>	<u>P. Aswathi</u>	<u>[Signature]</u>	<u>[Signature]</u>	
Date	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 28 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: <u>61822117</u> Generic Health Care Pvt. Ltd.

11.15 WEIGHING RECORD OF COMPRESSED TABLETS:

S. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Weighed by	Checked by Production	Verified by IPQA
1	31.350	1.910	29.440	Vatru	BT	GB
2	32.450	1.950	30.500	Vatru	BT	GB
3	37.290	2.100	35.190	Vatru	BT	GB
4	31.810	2.100	29.710	Vatru	BT	GB
5	35.850	2.400	33.450	Vatru	BT	GB
6	30.820	1.900	28.920	Vatru	BT	GB
7	26.290	2.300	23.990	Vatru	BT	GB
8						
9						
10						

11.16 RECONCILIATION (COMPRESSION STAGE):

Average weight of Uncoated Tablet: 72.0...mg

1.0	Standard Batch size	:	216.000 Kg.	3,00,000 No.
2.0	Actual weight of Lubricated granules	:	214.800 Kg.	297222 Nos.
3.0	Weight of compressed tablets	:	211.200 Kg.	293333 Nos.
4.0	Rejection during Compression @	:	0.100 Kg.	
5.0	In-process samples of all stages			
	A	IPQC Samples	: 0.080 Kg.	
	B	QC Samples	: 0.070 Kg.	
	C	Validation Samples	: 0.180 Kg.	
6.0	Total in process samples: (A + B + C)	:	0.330 Kg.	
7.0	Total: (3.0 + 6.0)	:	211.530 Kg.	293791 Nos.
8.0	Yield {7.0 / 1.0 x 100}*	:		97.93 %

* Actually yield will be calculated after 3 validation batches

@Total rejects destroyed: 2.370 Kg. (Rejected materials shall be destroyed as per SOP No.: QAGN/048)

Done by Production Sign/Date: 29/03/2022 Checked by IPQA Sign/Date: 29/03/2022

Test request form raised by Prod Sign/Date: 29/03/2022

Test request form received by IPQA Sign/Date: 29/03/2022

12.0 RELEASED FOR COATING:

Reconciliation checked and compressed tablets released for coating:

IPQA Sign: 29/03/2022 Date: 29/03/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>P. Asw</u>	<u>29/03/2022</u>	<u>29/03/2022</u>
Date	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 29 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: G1822117 Generic Health Care Pvt. Ltd.

13.0 LINE CLEARANCE FOR COATING SOLUTION PREPARATION:

Date/Shift/Time: 09/09/2022 / A /

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	Solution preparation vessel and stirrer	Colloidal Mill	Area
Equipment ID No.	NA	PD/CLM 601	NEC/601
Previous product	BONCIPRO 500		
Batch No.	G1822116		
Cleaned by	Sulim		
Checked by Production Sign/Date:	G.P. 09/09/2022		
Verified by IPQA Sign/Date:	G.P. 09/09/2022		

ENVIRONMENTAL CONDITIONS:

		Date: 09/09/22 Time: 06:11			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	22	G.P.			
	Relative Humidity % Limit: NMT 60%	52%	22	G.P.			

APPROVAL FOR COATING SOLUTION PREPARATION:

Production Sign/Date: 22 09/09/2022	
Line Clearance IPQA Sign. / Date: G.P. 09/09/2022	
Start Time/Date: 06:20 09/09/2022	End Time/Date: 06:55 09/09/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	P. Anand	V. S. S.	P. S. S.
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 30 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: <u>61822117</u> Generic Health Care Pvt. Ltd.

14.0 Coating Procedure:

14.1 General Instructions:

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

14.2 TABLETS RECEIPT RECORD OF UNCOATED TABLETS FOR COATING:

Balance ID. No.: PD/BAC015

Date/Shift/Time: 09/09/2022 / A / 06:30

Sr. No.	Description	Observations	Checked By (Production)	Verified By (IPQA)
1.	Total Quantity (Net Qty.in Kg)	211,200	<u>[Signature]</u>	<u>G.P</u>
2.	Number of Containers	08	<u>[Signature]</u>	<u>G.P</u>

14.3 COATING SOLUTION PREPARATION

Sr. No.	General Instructions	Balance ID.: PD/BAC015				
1.	Check the cleanliness of the Solution Preparation area and operation as per current version of SOP.					
2.	Use hand gloves while handling the materials					
3.	Transfer the verified coating materials to Coating solution preparation area.					
Step No.	Name of Ingredient & Operation	Time		Done by	Checked by Prod.	Verified by IPQA
		Start	Finish			
1	Take Purified water in a SS Vessel. Slowly disperse HPMC 6 cps, Titanium dioxide, Ponceau 4R Lake, Purified Talc and Polyethylene Glycol 6000 and stir well to disperse completely.	06:30	06:35	Sulav	SB	G.P
2	If required mill the solution through colloidal mill.	06:36	06:40	Sulav	SB	G.P

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>P. Anand</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 31 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: <u>G1822117</u> Generic Health Care Pvt. Ltd.

15.0 COATING AREA:

LINE CLEARANCE CHECKS:

Date/Shift/Time: 09/09/2022/4/16:12

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

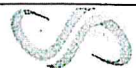
Note: *Tick mark (✓) if Complies and (X) if does not comply.

Equipment		Coating Machine			Area				
Equipment ID No.		PD1NEC001			Coating area -01				
Previous product		BONCIPRO-500							
Batch No.		G1822117							
Cleaned by		Sulim							
Checked by Production		234							
Sign/Date:		09/09/2022							
Verified by IPQA Sign/Date:		G.P. 09/09/2022							
ENVIRONMENTAL CONDITIONS:		Date: <u>09/09/2022</u>		Time: <u>16:13</u>		Date:		Time:	
		Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by
(Refer to SOP No.: QAGN/011)	Temperature °C Limit: NMT 25 °C	23°C	NA	G.P.					
	Relative Humidity % Limit: NMT 60%	52%	NA	G.P.					
	Differential Pressure (NLT 10 Pascal)	11 Pascal	NA	G.P.					
APPROVAL FOR COATING:									
Production Sign/Date: <u>23 09/09/2022</u>									
Line Clearance IPQA Sign. / Date: <u>G.P. 09/09/2022</u>									
Start Time/Date: <u>08:52 h/09/09/2022</u>					End Time/Date: <u>12:32/09/09/2022</u>				

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>P. A. A. A.</u>	<u>W. A. A.</u>	<u>V. A. A.</u>
Date	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>	<u>30/03/2022</u>

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

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

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BATCH MANUFACTURING RECORD

Product Code: B05

Batch Size: 3,00,000 Tablets

Product

BONCIPRO 500

BMR. No.: BMR/T/305-00

Batch No.: G1822117

Customer:

Generic Health Care Pvt. Ltd.

15.1 COATING PROCESS:

Process Steps

Step No.	Name of Ingredient & Operation	Time		Done by	Ckd by Prod.	Vfd by IPQA
		Start	Finish			
1	Transfer the compressed tablets in to the coating Area	08:52	08:57	Subu	AS	G.P
2	Pre-warm the tablet with inlet temp. 45°C to 55°C.	08:58	09:08	Subu	AS	G.P
3	Arrange the spray gun in such a way that the spray droplets just touch the tablet bed on upper rim. The spray should not fall on the wall of the pan. Weight gain obtained: 2.01 % (2.0 – 3.0%)	09:09	12:20	Subu	AS	G.P
4	When the spraying is complete, dry the tablets perfectly, in the pan by keeping inlet temp. 55°C-75 °C with intermittently flipping the tablets, until no more solvent odour is observed. Caution: Ensure the tablet bed temperature does not rise excessively.	12:21	12:26	Subu	AS	G.P
5	Monitor DT: Limit: NMT 30 minutes. Found Disintegration Time: 03 min 10 sec	12:27	12:32	Subu	AS	G.P
6	Unload the film coated tablets in a HDPE container lined with double polybag.			Subu	AS	G.P

15.2 INITIAL CHECKS OF COATING PARAMETERS:

S. No	Parameter	Set	Observed
1	Inlet air Temp.	55°C to 75°C (To be established)	59°C
2	Exhaust air Temp.	50 ± 5 °C (To be established)	52°C
3	Tablet Bed temp.	50°C-60 °C (To be established)	43°C
4	Atomization air pressure	1.0 - 4.0 Kg/cm ² (To be established)	2.5 Kg/cm ²
5	Pan speed	1.0 - 10.0 RPM (To be established)	8.0 rpm
6	Spray rate	30 to 70 ml/min (To be established)	70 ml/min
Checked by Production/ Date			AS 09/09/2022
Verified by IPQA/ Date			G.P 09/09/2022

15.3 INDIVIDUAL WEIGHT CHECKING OF PRE-WARMED TABLETS:

Sr. No.	Weight (mg)	Sr. No.	Weight (mg)
1	716	11	721
2	720	12	717
3	718	13	720
4	722	14	719
5	719	15	716
6	717	16	723
7	714	17	724
8	719	18	720
9	721	19	719
10	720	20	720
Total		14,385 @	
Avg. Weight		719.25 @	

15.4 FINAL COATING PARAMETERS CHECKS: (PRODUCTION)

Parameters	Limits	Observed
Description	Pink coloured caplet shaped film coated tablet with breakline on one side and plain on other side	OK
Theoretical weight per tablet	736.000 mg ± 3 % (713.920 mg – 758.080 mg)	734.120
Weight of 20 tablets	14.720 g ± 3 % (14.278 g – 15.162 g)	14.68.24
Uniformity of weight	736.000 mg ± 5 % (699.200 mg – 772.800 mg)	-1.11% / +0.92%
Thickness	5.50 mm ± 0.2 mm (5.30 mm to 5.70 mm)	5.35 – 5.45 mm
Disintegration test	NMT 30 min	03 min 10 sec
Checked by Production/ Date		R.ell 09/09/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	T. Anand	V. S.	V. S.
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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Product Code: B05

Batch Size: 3,00,000 Tablets

BONCIPRO 500

BMR. No.: BMR/T/305-00

Batch No.: G1822117

Customer:

Generic Health Care Pvt. Ltd.

Parameters	Limits	Observed
Description	Pink coloured caplet shaped film coated tablet with breakline on one side and plain on other side	ok
Theoretical weight per tablet	736.000 mg $\pm$ 3 % (713.920 mg – 758.080 mg)	733.142
Weight of 20 tablets	14.720 g $\pm$ 3 % (14.278 g – 15.162 g)	14.627
Uniformity of weight	736.000 mg $\pm$ 5 % (699.200 mg – 772.800 mg)	-0.821/ 0.544.
Thickness	5.50 mm $\pm$ 0.2 mm (5.30 mm to 5.70 mm)	5.39
Disintegration test	NMT 30 min	23 min 21 sec
Checked by IPQA/ Date		09/09/2022

Checked by IPOA/ Date

[illegible]

S. NO.	INITIAL WEIGHT	FINAL WEIGHT	S. NO.	INITIAL WEIGHT	FINAL WEIGHT
1	721	738	1	719	729
2	720	729	2	724	734
3	718	730	3	720	736
4	721	727	4	721	735
5	717	725	5	720	729
6	720	736	6	719	729
7	719	739	7	717	731
8	721	741	8	723	737
9	723	729	9	722	730
10	719	732	10	718	735
11	721	727	11	719	729
12	720	729	12	720	734
13	724	731	13	721	736
14	720	728	14	724	732
15	719	736	15	720	729
16	720	735	16	719	731
17	718	740	17	718	728
18	721	735	18	723	729
19	720	728	19	720	732
20	719	726	20	722	734
TOTAL	14401	14638	TOTAL	14407	14645
Checked by Production: R. <u>09/09/2022</u>			Checked by IPQA: R. <u>09/09/2022</u>		

Checked by Production:

Checked by IPQA:

Prepared by:

Checked by:

Approved By:

Dept.

Production

Production

Quality Assurance

Head Quality Assurance

Sign.

$$\frac{1}{K_a}$$

P. Acunt

Date _____

30/07/2022

3rd 10/10/22

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20/07/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 34 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: 61822117 Generic Health Care Pvt. Ltd.

15.8 PERCENTAGE OF COATING WEIGHT BUILDS UP:

$$\% \text{ of Weight buildup} = \frac{\text{Avg. wt. of coated tablets} - \text{Avg. wt. of core tablet (Pre-warmed)}}{\text{Avg. wt. of core tablets (Pre-warmed)}} \times 100$$

$$= 2.06\%$$

15.9 ACTUAL AVERAGE WEIGHT OF COATED TABLETS:

$$\frac{\text{Weight of 100 coated tablet}}{100} = 784.01 \text{ mg}$$

15.10 WEIGHT OF FILM COATED TABLETS:

Container No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Weighed by	Checked by Production	Verified by IPQA
1	34.480	2.340	32.140	Karthi	21	R
2	37.050	2.330	34.720	Karthi	21	R
3	42.850	2.700	40.150	Karthi	21	R
4	38.460	2.300	36.160	Karthi	21	R
5	37.850	2.550	35.300	Karthi	21	R
6	38.620	2.390	36.230	Karthi	21	R
7						
8						
9						
10						
TOTAL			214.700			

15.11 RECONCILIATION (COATING STAGE):

Average weight of coated Tablet: 784.01 mg

1.0	Batch size	:	220.800 Kg.	3,00,000 Nos.
2.0	Weight of coated tablets	:	214.700 Kg.	292502 Nos.
3.0	Coating loss@	:	0.030 Kg.	
4.0	In-process samples of all stages			
	A	IPQC Samples	: 0.040 Kg.	
	B	QC Samples	: 0.090 Kg.	
	C	Validation Samples	: N/A Kg.	
5.0	Total in process samples: (A + B + C)	:	0.130 Kg.	
6.0	Total: (2.0 + 5.0)	:	214.830 Kg.	292679 Nos.
7.0	Yield {6.0 x 100 / 1.0}*	:		97.56 %

* Actually yield will be calculated after 3 validation batches

@Total rejects destroyed: 0.030 Kg. (Rejected materials shall be destroyed as per SOP No.: QAGN/048)

Done by Production Sign/Date: ... 30/03/2022 ... Checked by IPQA Sign/Date: ... 30/03/2022 ...

Test request form raised by Prod Sign/Date: ... 30/03/2022 ...

Test request form received by IPQA Sign/Date: ... 30/03/2022 ...

15.12 RELEASE FOR INSPECTION:

Reconciliation checked and Coated tablets released for inspection

IPQA Sign: ... 30/03/2022 ... Date: ... 30/03/2022 ...

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	P. Arum	V. K.	V. K.
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 35 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMRT/305-00 Customer:	Batch No.: G1822117 Generic Health Care Pvt. Ltd.

16.0 INSPECTION LINE CLEARANCE: Date/Shift/Time: 10/09/2022 / G1/15:50/ 12/09/2022 / G1

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 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	na	na
11	Equipment status is updated for Cleaned, Qualification and Preventive maintenance.	✓	✓	✓	✓

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

Equipment	Inspection Belt	Metal Detector	Area
Equipment ID No.	PD/ENB/002	PD/MED/003	Inspection - II
Previous product	Boncipro 500		
Batch No.	G1822116		
Cleaned by	Sewarajani		
Checked by Production Sign/Date:	M. Jay 10/09/2022		
Verified by IPQA Sign/Date:	G18 10/09/2022		

ENVIRONMENTAL CONDITIONS:

(Refer to SOP No.: QAGN/011)	Temperature °C Limit: NMT 25 °C Relative Humidity % Limit: NMT 60%	Date: 10/09/2022 Time: 15:52			Date: 12/09/2022 Time:		
		Observation	Prod. Sign.	Verified by IPQA	Observation	Prod. Sign.	Verified by IPQA
		23°C	M. Jay	G18	23°C	M. Jay	G18
		52%	M. Jay	G18	52%	M. Jay	G18

APPROVAL FOR INSPECTION:

Production Sign/Date: M. Jay 10/09/2022

Line Clearance IPQA Sign. / Date: G18 10/09/2022

Start Time/Date: 16:05 10/09/2022

End Time/Date: 17:39 12/09/2022

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	I. Jay	P. Anand			
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 36 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: G1822117 Generic Health Care Pvt. Ltd.

17.0 INSPECTION PROCESS

17.1 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.

17.2 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/002 & PD/MED/NA...				Result	Checked by Production	Verified By IPQA
		Ferrous (0.3 mm)	Stainless steel (0.5 mm)	Non-Ferrous (0.4 mm)	Non-metallic			
10/09/2022 17:10	1	✓	✓	✓	X	pass	M.Kay	GB
	2	✓	✓	✓	X	pass	M.Kay	GB
	3	✓	✓	✓	X	pass	M.Kay	GB
12/09/2022 10:40	1	✓	✓	✓	X	pass	M.Kay	GB
	2	✓	✓	✓	X	pass	M.Kay	GB
	3	✓	✓	✓	X	pass	M.Kay	GB
12/09/2022 16:40	1	✓	✓	✓	X	pass	M.Kay	GB
	2	✓	✓	✓	X	pass	M.Kay	GB
	3	✓	✓	✓	X	pass	M.Kay	GB

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 / N

17.3 TABLETS VISUAL INSPECTION RECORD:

Date	Container No		Time		Total Quantity Rejected	Tablet Inspection Done by/Date	Checked by/Date
	From	To	Started	Completed			
10/09/2022	01	03	16:05	18:07	0.170	Devaraj 10/09/2022	M.Kay 10/09/2022
12/09/2022	03	06	10:35	17:39	0.200	Durga 12/09/2022	M.Kay 12/09/2022

17.4 WEIGHING RECORD OF INSPECTED TABLETS:

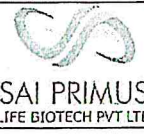
Container No	Gross weight Kg	Tare weight Kg	Net. weight Kg	Container No	Gross weight Kg	Tare weight Kg	Net. weight Kg
1	42.020	1.910	40.110	6	38.550	2.130	36.420
2	34.680	2.690	31.990	7			
3	36.960	2.350	34.610	8			
4	37.720	2.330	35.390	9			
5	38.200	2.390	35.810	10			
Total			177.910 Kg	Total			36.420 Kg
				Grand Total			214.330 Kg

Weighing Done By: Durga... Checked By Prod./ Date: M.Kay... 12/09/2022 Verified by IPQA Sign./Date: G.S. 12/09/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	P. Arun	Devi	V. Ramesh
Date	30/03/2022	30/03/2022	30/03/2022	30/03/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 37 of 37
	BATCH MANUFACTURING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BMR. No.: BMR/T/305-00 Customer:	Batch No.: G-18 22 117 Generic Health Care Pvt. Ltd.

17.5 RECONCILIATION: (INSPECTION OF TABLETS)

1.0	Theoretical weight of Tablets	:	220.800 kg	3,00,000 No's
2.0	Tablets transferred for Inspection	:	214.700 kg	292502 No's
3.0	Total weight of good Tablets	:	214.330 kg	292002 No's
4.0	Rejected Tablets	:	0.370 kg	504 No's
5.0	*Yield = $\frac{3.0}{1.0} \times 100$	:		97.33 %

*Actually yield will be calculated after 3 validation batches.

Total rejects destroyed:0.370.....Kg.

Rejected materials should be destroyed in the presence of QA.

Done by Production sign/Date: L. Ya 12/09/2022

Checked by IPQA sign/Date: G. Senthil Kumar 12/09/2022

17.6 RELEASE FOR PACKING:

BMR reviewed by IPQA Sign/Date : G. Senthil Kumar 12/09/2022

BMR Released for packing by QA Head Sign/Date: P. Anand 12/09/2022

18.0 BMR REVIEW DETAILS:

Reviewed by	Name	Sign./Date
Production Executive	<u>Vignesh</u>	<u>L</u> 12/09/2022
QA Executive	<u>G. Senthil Kumar</u>	<u>G. Senthil Kumar</u> 12/09/2022
Production Assistant Manager/ HOD	<u>M. Noor Mohamed</u>	<u>M</u> 12/09/2022
QA Manager/ HOD	<u>Ram Kumar</u>	<u>IP</u> 12/09/2022

19.0 REVISION HISTORY:

Sr. No.	Document No.	Reason for Revision	Supersedes No.
1	BMR/T/305-00	New Document	Nil

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ya</u>	<u>P. Anand</u>	<u>Vignesh</u>	<u>Vignesh</u>
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