
 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 1 of 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00 Customer:	Batch No.: <u>G1822068</u> Generic Health Care Pvt. Ltd.

BATCH PACKAGING 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.
CODE NO.	: PON/DRUGS/21 14 4376
DOSAGE FORM	: Tablet
BPR No.	: BPR/T/305-00
REVISION No.	: 00
SUPERSEDE No	: NIL
EFFECTIVE BATCH. No. /DATE	: <u>G1822068 / 06/04/2022</u>
MARKET	: Export
SHELF LIFE	: 36 Months
BATCH SIZE	: 3,00,000 Tablets
PACKING CONFIGURATION	: 2 x 10's Tablets Pack (Blister Packing)
BPR ISSUED BY/DATE (QA)	: <u>[Signature] 06/04/2022</u>
BPR CHECKED & RECEIVED BY/DATE (PRODUCTION)	: <u>L. Ka 06/04/2022</u>
MFG. DATE: <u>04/2022</u>	EXP. DATE: <u>03/2025</u>
ALLOTTED BY: QA SIGN/DATE: <u>[Signature] 06/04/2022</u>	COUNTER CHECKED BY: QA SIGN/DATE: <u>[Signature] 06/04/22</u>
QUANTITY RECEIVED FROM PRODUCTION	: <u>292707 NOS</u>
DATE OF COMMENCEMENT: <u>11/04/2022</u>	DATE OF COMPLETION: <u>13/04/2022</u>
QUANTITY	: <u>300000 NOS</u>
RELEASED QUANTITY OF PACKED TABLETS	: <u>291960 NOS</u>
RELEASE OF BATCH BY HEAD QA SIGN/DATE:	: <u>[Signature] 12/04/22</u>
This BPR contains 21 Pages + .25.. Additional Pages	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>06/04/2022</u>	<u>06/04/2022</u>	<u>06/04/22</u>	<u>06/04/2022</u>

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

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Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. Ka</i>	<i>M</i>	<i>BB</i>	<i>V/A</i>
Date	06/04/2022	06/04/2022	06/04/2022	06/04/2022

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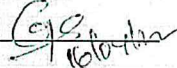
 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 3 of 21
	BATCH PACKING RECORD	Product Code: B05	Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00	Batch No.: <u>G1822068</u>
		Customer:	Generic Health Care Pvt. Ltd.

2. CHECKLIST FOR BATCH PACKING RECORD REVIEW:

Instruction:

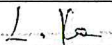
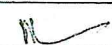
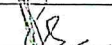
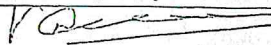
Check the following points before submitting the documents for final Review

Sr. No.	Checklist	Observation (Yes/No/NA/No.)*
1.	No. of pages of BPR+ Additional pages (If any) *	YES
2.	Line clearance and environmental record	YES
3.	Processing activity done by and checked by is signed	YES
4.	Dispensing	
a)	Equipment clean tag and dispensing tag attached with batch record	YES
b)	Packaging material is checked	YES
5.	Packing	
a)	Rinse water analysis report attached with BPR	YES
b)	Approved specimen of printed foil, carton and shipper label are attached	YES
c)	Control / Stability / Finished product analysis samples are withdrawn	YES
d)	Reconciliation of packing materials is done	YES
e)	Tablet reconciliation is done	YES
f)	In process checks parameters done at regular interval and recorded into BPR	YES
6.	Attachment	
a)	Finished Goods Transfer Note	YES
b)	Certificate of analysis of finished product is submitted	YES
c)	Stereo Impression Format	NA
7.	Complete set of BPR Submitted	YES

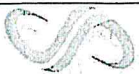
Checked By QA/Date: 

*Mention total number of pages.

Remarks (If any)NA.....

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u></u>	<u></u>	<u></u>	<u></u>
Date	06/04/2022	06/04/2022	06/04/22	06/04/2022

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	BATCH PACKING RECORD	Product Code: B05	Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00	Batch No.: <u>G18 22-068</u>
		Customer:	Generic Health Care Pvt. Ltd.

3. PACKING MATERIAL SPECIFICATION AND INDENT:

Sr. No.	Material	Item Code	Specification	UOM	Standard Qty. for Batch Size 3.0 Lac.
1	178mm Boncipro 500 Printed foil 0.025mm	PPF/SP/B009	Width – 178 ± 1 mm Thickness – 0.025 mm Language – French Color – 1 Color Item Code: 13/0442	Kg	14.100
2	182mm PVC Base Foil	PBF/SP/B037	Width – 182 ± 1 mm	Kg	64.500
3	2X10's Boncipro 500mg Pkt Carton	PPC/SP/B004	Size – 90 x 60 x 20 mm (L x W x H) Board – 300 gsm ITC cyber XL board Colour – 4 colours Item Code: 15/0724	No	15000
4	Boncipro Leaflet	PPL/SP/L015	Size – 210 x 230 mm (L x H) NLT 60 GSM Maplitho Paper Colour – 2 colour Item Code: 16/0437	No	15000
5	Shrink Sleeve	PPS/SP/P001	Plain PVC Shrink Sleeves	No	834
6	5 Ply 390X390X265 mm GHPL Printed Shipper	PUS/SP/G018	A 5 Ply flute vertical corrugated inner unprinted in nature. (24 B.F.) Outer Size – 390 x 390 x 265 mm (L x W x H) Bursting Strength – NLT 15.00 Kg/cm ²	No	53
7	3' GHPL Printed Bopp Tape	PPB/SP/B002	Clear Transparent Length of roll – 65m Width – 60 mm Printing – GHPL repeats in Blue	No	1
8	3' Plain BOPP Tape	PUB/SP/B001	Plain BOPP Tape	No.	1
9	Strapping role.	PPR/SP/S001	White or milky white colour. Width – 12 mm Thickness – 0.6 mm	Mtrs	500

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>M</u>	<u>JS</u>	<u>V. R.</u>
Date	06/04/2022	06/04/2022	06/04/2022	06/04/2022

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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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product BONCIPRO 500	BPR. No.: BPR/T/305-00		Batch No.: G1822068
	Customer:		Generic Health Care Pvt. Ltd.

4. DISPENSING LINE CLEARANCE CHECKS

Date: 09/04/2022 Time: 14:30

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 trolley are clean.	✓	✓
4	Check and ensure that area (floor, walls, ceiling, doors and windows) are clean.	✓	✓
5	Check and ensure that Magnelic gauges, tube light fixtures, supply grills, return riser grills and filters, electrical fixture are clean.	✓	✓
6	Check and ensure that all the sides of Mobile Laminar Air Flow is clean	✓	✓
7	Check all the gauges of Mobile Laminar Air flow 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	Mobile Laminar Air Flow	Weighing Balance		Area
ID No.	ST/LAF/001	ST/BA/011	- NA -	FOUR STORE
Previous Product	Litacold flu.			
B. No.	G1822071			
Cleaned by Sign/Date	Saran 09/04/2022			
Checked by Store Sign/Date	S4 09/04/2022			
Verified by IPQA Sign/Date	G 09/04/2022			

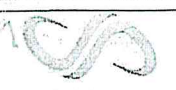
ENVIRONMENTAL CONDITIONS: Date: 09/04/2022 Time: 14:30	Observation	Checked by Store Sign/Date	Verified by IPQA Sign/Date
(For Reference SOP No.: QAGN/011)			
Temperature (Limit: NMT 25°C)	23°C	S4 09/04/2022	G 09/04/2022
Differential Pressure across the booth Limit: 5 to 20 mm Water	15mm	S4 09/04/2022	G 09/04/2022

APPROVAL FOR DISPENSING BY IPQA: Sign: G Date: 09/04/2022

Dispensing start Time: 14:40 End Time: 15:00

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K			
Date	06/04/2022	06/04/2022	06/04/2022	06/04/2022

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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 21
	BATCH PACKING RECORD	Product Code: B05	Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00	Batch No.: <u>G1822068</u>
		Customer:	Generic Health Care Pvt. Ltd.


5. DISPENSING RECORD OF PACKING MATERIALS: Date: 09/04/2022 Shift: G Time: 14:30

Material Name	Item code	UOM	Req. Qty. for 3.0 Lac	Issued Qty.	A.R No.	No. of Roll/Box	Issued and Checked by Store	Verified by IPQA
178mm Boncipro 500 Printed foil 0.025mm	PPF/SP/B009	Kg	14.100	<u>24.330</u>	<u>PmG/01541</u>	<u>02</u>	<u>[Signature]</u> 09/04/22	<u>[Signature]</u> 09/04/2022
182mm PVC Base Foil	PBF/SP/B037	Kg	64.500	<u>53.500</u> <u>18.530</u>	<u>PmG/00019</u> <u>PmG/00019</u>	<u>03</u> <u>01</u>	<u>[Signature]</u> 09/04/22	<u>[Signature]</u> 09/04/2022
2X10's Boncipro 500mg Pmt Carton	PPC/SP/B004	No	15000	<u>15000</u>	<u>PmG/01564</u>	<u>06</u>	<u>[Signature]</u> 09/04/22	<u>[Signature]</u> 09/04/2022
Boncipro Leaflet	PPL/SP/L015	No	15000	<u>15000</u>	<u>PmG/01566</u>	<u>03</u>	<u>[Signature]</u> 09/04/22	<u>[Signature]</u> 09/04/2022
Shrink Sleeve	PPS/SP/P001	No	834	<u>834</u>	<u>PmG/00095</u>	<u>01</u>	<u>[Signature]</u> 09/04/22	<u>[Signature]</u> 09/04/2022
5 Ply 390X390X265 mm GHPL Printed Shipper	PUS/SP/G018	No	<u>68</u> <u>55</u>	<u>68</u> <u>53</u>	<u>PmG/00012</u>	<u>06</u>	<u>[Signature]</u> 09/04/22	<u>[Signature]</u> 09/04/2022
3' GHPL Printed Bopp Tape	PPB/SP/B002	No	<u>1</u>	<u>01</u>	<u>PmG/00310</u>	<u>01</u>	<u>[Signature]</u> 09/04/22	<u>[Signature]</u> 09/04/2022
3' Plain BOPP Tape	PUB/SP/B001	No	<u>1</u>	<u>01</u>	<u>PmG/041019</u> <u>02</u>	<u>01</u>	<u>[Signature]</u> 09/04/22	<u>[Signature]</u> 09/04/2022
Strapping role.	PPR/SP/S001	Mtrs	<u>500</u>	<u>500</u>	<u>PmG/00095</u>	<u>01</u>	<u>[Signature]</u> 09/04/22	<u>[Signature]</u> 09/04/2022

N
09/04/22

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>06/04/2022</u>	<u>06/04/2022</u>	<u>06/04/2022</u>	<u>06/04/2022</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 7 of 21
	BATCH PACKING RECORD		Product Code: B05
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00	Batch Size: 3,00,000 Tablets
		Customer:	Batch No.: 51822068
			Generic Health Care Pvt. Ltd.

6. LINE CLEARANCE CHECKS:

6.1 PRIMARY PACKING:

Date/ Shift 11/04/2022 G1 16:45 / 12/04/2022 G1

Previous Product: Nubivolol GH 5		Batch No.: G1822061				
Sr. No.	Checks.	Time	Observation			
			16:46 Packing	IPQA	18:05 Packing	IPQA
1.	Area status board is updated for "CLEANED" status.		✓	✓	✓	✓
2.	Check and ensure that the area is visually clean and free from previous product		✓	✓	✓	✓
3.	Check and ensure the differential pressure of the area is within specified limit		✓	✓	✓	✓
4.	Check and ensure that waste bin is emptied out and cleaned		✓	✓	✓	✓
5.	Check the temperature and relative humidity of the area within specified limit		✓	✓	✓	✓
6.	Check the tablets of the previous product/ batch removed.		✓	✓	✓	✓
7.	Check the loose Blister cutting, rejected rolls, empty cores of foil of previous product /batch are removed.		✓	✓	✓	✓
8.	Check the surroundings of the machine and free from the previous products and batch		✓	✓	✓	✓
9.	Check the foil printing stereos, Labels of previous product/batch are removed.		✓	✓	✓	✓
10.	Check that the daily records (log book, balance, temp. & RH) are updated and signed.		✓	✓	✓	✓
11.	Check and ensure the Cleanliness following change part of Blister packing machine		✓	✓	✓	✓
12.	Check for the absence of previous batch/ product at machine conveyor belt.					
a)	Check Hopper from Top, bottom of machine, below the hopper, between bottom side of conveyor belt and collating unit.		✓	✓	✓	✓
b)	Check for cleaning of hopper, feeding channel, vibrator plate, in feed roller and sweep brush.		✓	✓	✓	✓
c)	Check tool box, thinner and ink box		✓	✓	✓	✓

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

Cleaning satisfactory/Not satisfactory: Not
 Checked by Packing (Sign./Date): 11/04/22
 Cleaning satisfactory/Not satisfactory: Not
 Verified by IPQA (Sign./Date): 6/5 11/04/2022

#In case the cleaning is not satisfactory / line is not certified then investigate the cause of the failure and take necessary action, recheck the area / line and record.

6.2 AREA AND EQUIPMENT CLEARANCE OF PRIMARY PACKING

Previous Product: Nebivolol GH 5				Batch No.: 51822061			
S. No.	Equipment / Area Name	Eq.ID. /Area. No.	Cleaning Type A/B	Operation and cleaning as per SOP number	Cleaned by Sign/Date	Checked by (Packing) Sign/Date	Verified by (IPQA) Sign/Date
1.	Blister Packing Area	SPL/AFF/BLP/001	B	PDGN/006	Sugumar	Not 11/04/22	6/5 11/04/2022
2.	Blister Packing Machine	PD/BLP/001	B	PDOP/021, PDCL/021 PDOP/022, PDCL/022	Sugumar	Not 11/04/22	6/5 11/04/2022


6.3 ENVIRONMENTAL CONDITIONS:

(Check the environmental conditions of primary packing area at the start of process and Record in the below in table)

Refer to SOP No.: SOP: QAGN/011	Date: 11/04/22 Time: 16:45			Date: 12/04/22 Time: 09:10		
	Observation	Packing Sign/Date	Verified by IPQA Sign/Date	Observation	Packing Sign/Date	Verified by IPQA Sign/Date
Temp °C Limit: NMT 25°C	22°C	<u>Not</u> 11/04/22	<u>6/5 11/04/2022</u>	23°C	<u>Not</u> 12/04/22	<u>6/5 12/04/2022</u>
RH % Limit: NMT 60%	58%	<u>Not</u> 11/04/22	<u>6/5 11/04/2022</u>	58%	<u>Not</u> 12/04/22	<u>6/5 12/04/2022</u>
DP Limit: NLT 10 Pascal	11 Pascal	<u>Not</u> 11/04/22	<u>6/5 11/04/2022</u>	11 Pascal	<u>Not</u> 12/04/22	<u>6/5 12/04/2022</u>
Primary Packing Started Date/Time: 11/04/22 17:00 Completed Date/Time: 12/04/2022 14:00						
APPROVAL FOR PRIMARY PACKING: IPQA Sign./Date: <u>6/5 11/04/2022</u>						

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L Ke</u>	<u>Not</u>	<u>Not</u>	<u>Not</u>
Date	06/04/2022	06/04/2022	06/04/22	06/04/2022

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

7. VERIFICATION OF DISPENSED PACKING MATERIALS: Date 11/04/2022 Shift C1 Time: 16:49

Material Name	Item code	UOM	AR No.	Number of Rolls/Packs	Checked by Packing	Verified by QA
178mm Boncipro 500 Printed foil 0.025mm	PPF/SP/B009	Kg	<u>pmc/01541</u>	<u>02</u>	<u>Nay</u>	<u>Gls</u>
182mm PVC Base Foil	PBF/SP/B037	Kg	<u>pmc/00019</u>	<u>01</u>	<u>Nay</u>	<u>Gls</u>
2X10's Boncipro 500mg Prt Carton	PPC/SP/B004	No	<u>pmc/01564</u>	<u>06</u>	<u>Nay</u>	<u>Gls</u>
Boncipro Leaflet	PPL/SP/L015	No	<u>pmc/01566</u>	<u>03</u>	<u>Nay</u>	<u>Gls</u>
Shrink Sleeve	PPS/SP/P001	No	<u>pmc/00895</u>	<u>01</u>	<u>Nay</u>	<u>Gls</u>
5 Ply 390X390X265 mm GHPL Printed Shipper	PUS/SP/G018	No	<u>pmc/00012</u>	<u>06</u>	<u>Nay</u>	<u>Gls</u>
3' GHPL Printed Bopp Tape	PPB/SP/B002	No	<u>pmc/00810</u>	<u>01</u>	<u>Nay</u>	<u>Gls</u>
3' Plain BOPP Tape	PUB/SP/B001	No	<u>pmc/041019/02</u>	<u>01</u>	<u>Nay</u>	<u>Gls</u>
Strapping role.	PPR/SP/S001	Mtrs	<u>pmc/00945</u>	<u>01</u>	<u>Nay</u>	<u>Gls</u>

8. RECEIPT OF PRODUCT AND MATERIALS: Date/Shift 11/04/2022 Shift C1 Time: 16:50
 (Check the following before start of packing activity and record the observation.)

S. No.	Check Points	Observation	Done by (Packing)	Verified By (IPQA)
1.	Temperature observed on display (Limit: NMT 25°C)	<u>23°C</u>	<u>Nay</u>	<u>Gls</u>
2.	Relative Humidity observed on display (Limit: NMT 60%)	<u>52%</u>	<u>Nay</u>	<u>Gls</u>
3.	Bulk product containers are of the required product/Batch number and is approved by QC	<u>YES</u>	<u>Nay</u>	<u>Gls</u>
4.	Status label of machine/ line is for same product	<u>YES</u>	<u>Nay</u>	<u>Gls</u>
5.	Printed foil/Base rolls are of the required product.	<u>YES</u>	<u>Nay</u>	<u>Gls</u>
6.	All secondary packing materials are of the required product	<u>YES</u>	<u>Nay</u>	<u>Gls</u>

9. DETAIL OF THE PRODUCT AS PER BMR:

Sr. No.	Description	Observations	Checked By (Packing)	Verified By (IPQA)
1.	Average Weight	<u>735 mg</u>	<u>Nay</u>	<u>Gls</u>
2.	Colour of Tablet	<u>Pink colour</u>	<u>Nay</u>	<u>Gls</u>
3.	Quantity (Net Qty.in Kg)	<u>213.140 kg</u>	<u>Nay</u>	<u>Gls</u>
4.	Number of Containers	<u>08</u>	<u>Nay</u>	<u>Gls</u>

10. WEIGHT VERIFICATION RECORD OF RECEIVED SEMI-FINISHED PRODUCT:

Balance I.D. No.: PD/BAL/014


1. Verify the semi-finished Tablets before starting the packing operation.

2. _____ as affixed over the Containers against the respective BMR

Product Name	Batch No.	Mfg. Date	Exp. Date	Qty. recd. For packing	No. of Containers taken for packing
BONCIPRO 500	<u>041</u> <u>G1822068</u>	<u>04/2022</u>	<u>03/2025</u>	<u>213.140 Kg</u> Equivalent to <u>292707 Nos.</u>	From Container No. <u>01</u> To Container No. <u>08</u> Total No. of Containers taken <u>08</u>
Checked by Packing (Sign./Date): <u>Nay</u> <u>11/04/22</u>				Verified By IPQA (Sign./Date): <u>Gls</u> <u>11/04/2022</u>	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K.</u>	<u>H.</u>	<u>RS</u>	<u>V. K.</u>
Date	<u>06/04/2022</u>	<u>06/04/2022</u>	<u>06/04/22</u>	<u>06/04/2022</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 9 of 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPRT/305-00 Customer:	Batch No.: 61822068 Generic Health Care Pvt. Ltd.

11. CONTAINER WEIGHT DETAILS:

Container No.	Gross Weight in Kg	Weighed By Packing	Checked By IPQA	Container No.	Gross Weight in Kg	Weighed By Packing	Checked By IPQA
1	28.810	Velu	Q15	4	28.270	Velu	Q15
2	30.010	Velu	Q15	5		NA	
3	31.290	Velu	Q15	6		NA	

12. CONTAINER CONSUMPTION DETAILS:

S. No	Time		Container No.	Consumed by	S. No	Time		Container No.	Consumed by
	From	To				From	To		
1	17:51	18:50	01	Sugumar	4	12:47	14:00	04	Sugumar
2	09:15	11:30	02	Sugumar	5			NA	
3	11:30	12:45	03	Sugumar	6			NA	

Checked By Packing (Sign./Date): May 10/04/2022 Verified by IPQA (Sign./Date): Q15 12/04/2022

13. OVERPRINTING OF PRIMARY PACKAGING MATERIALS (Embossing):

Initial checks of Overprinting Details

Overprinting Details	Overprinted Text	Printed AL. Foil (OK/ not OK)
Code No.: PON/DRUGS/21 14 4376	Preprinted	OK
Batch No.:	61822068	OK
Mfg. Date:	04/2022	OK
Exp. Date:	03/2025	OK
Item Code: 13/0442	Preprinted	OK
Initiated by	Sugumar	Sugumar
Checked by Packing (Sign. & Date)	May 11/04/2022	May 11/04/2022
Verified by IPQA (Sign. & Date)	Q15 11/04/2022	Q15 11/04/2022

13.1. SPECIMEN OF PRINTED FOIL:

S. No.	Date	Specimen No.	Done By Sign & Date	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01.	11/04/2022	02	Sugumar	May 11/04/2022	Q15 11/04/2022
02.	12/04/2022	02	Sugumar	May 12/04/2022	Q15 12/04/2022

14. PACKING INSTRUCTIONS:


1. Verify the status of dispensed primary packaging materials and transfer to the Primary Packing Area.
2. Issue the stereotypes to the concerned Technician and set as per SOP No. QAGN/030 and Record the details in respective table.
3. Set and operate Blister Packing Machine as per SOP No. PDOP/021 & PDOP/022.
4. Verify the status label of overprinted packaging materials and transfer to the packing line in secondary packing hall.
5. Perform Leak Test as per SOP No. QAGN/045 and enter the observations in respective table.
6. Perform Leak Test as per Table or during change of Printed foil rolls & plain film rolls and after every start of operation or when machine is stopped due to some break down.
7. Attach proof of printed foil from each roll dispensed as and when used on machine.
8. Overprinting Details on printed foil shall be checked by Packing and cross-checked by IPQA before starting the operation as per given in the respective Table.
9. Affix first overprinted Al. foil, Carton, Shipper and shipper label duly checked by Packing and verified by IPQA.
10. Pack 10 tablet per Blister.

Time record for packing detail

Sr. No.	Date/Shift	Primary packing		Secondary packing		Checked by (Packing) Sign. & Date
		Started at	Completed at	Started at	Completed at	
01.	11/04/2022 G1	17:51	18:50	18:00	18:55	May 11/04/2022
02.	12/04/2022 G1	09:15	14:00	09:30	18:00	May 12/04/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production.	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Kan</u>	<u>M</u>	<u>Pe</u>	<u>V. D.</u>
Date	06/04/2022	06/04/2022	06/04/2022	06/04/2022

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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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00 Customer:	Batch No.: 611822068 Generic Health Care Pvt. Ltd.

15. **PACKING/IPQA IN-PROCESS CHECKS FOR PRIMARY PACKING:**

In process checks frequency for packing and IPQA. (As per SOP No.: QAGN/024)

Stage	Packing	IPQA
Primary packing/Secondary Packing	At start of the batch, every one hour	At batch start, followed by every two-hour (random time) Minimum two In process checks by IPQA per batch.

16. **BLISTER PACKING MACHINE PARAMETERS:**

Date/Shift: 11/04/2022 Ct. Time: 17:00....

Parameters	Standard and Limits	Observation	Checked by Packing Sign. / Date	Checked by IPQA Sign. / Date
Change Parts Details	19023060	19023060	NA 11/04/22	GA 4/04/2022
Sealing Temperature	(150-200°C) To be established	196.2°C	NA 11/04/22	GA 11/04/2022
Forming Temperature	(110-160°C) To be established	156°C	NA 11/04/22	GA 11/04/2022
Leak test to be performed on 12 Blister	Nil (No Blister should fail in leak test)	YES	NA 11/04/2022	GA 4/04/2022
Machine Speed	To be established	40	NA 11/04/22	GA 11/04/2022


16.1 **MACHINE IN-PROCESS CONTROL:**

Date/ Shift		11/04/2022 Ct						12/04/2022 Ct									
Machine Operator Name		Sugumar						Sugumar									
Time of inspection		17:05	17:18	17:32	17:45	17:51	17:55	09:20	09:32	10:45	11:10	11:23	13:15				
Sealing Temperature (To be established)		176.5°C	190.15°C	195.1°C	175.3°C	196.2°C	195.0°C	196°C	195°C	199°C	199°C	196°C	199.2°C				
Forming Temperature (To be established)		120°C	156.6°C	118.3°C	117.3°C	156°C	154.6°C	156°C	155.1°C	158°C	158°C	157°C	158°C				
Leak test on Blister* (Qty.: <u>12=12</u>)		OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Knurling /Sealing		OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Pocket Formation		OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Horizontal cutting		OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Vertical cutting		OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Quality of Over printing		OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Code No.:	PON/DRUGS/ 21 14 4376	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
B. No.:	C11822068	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Mfg. Date	04/2022	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Exp. Date	03/2025	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Machine Speed To be established		25	50	25	50	40	40	40	40	40	40	40	40				
Checked by (Packing)		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA				
Checked by (IPQA)		GA	GA	GA	GA	NA	GA	NA	GA	NA	NA	GA	NA				

Note: * If leak test fails perform every 15 minutes for next one hour and all the shippers to be checked for leak test from the last successful leak test. All the shippers packed from the time of last successful leak test shall be segregated and random checked by IPQA and to be released after approval from QA.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	M	SC	V P
Date	06/04/2022	06/04/2022	06/04/22	06/04/2022

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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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00 Customer:	Batch No.: 518 22 068 Generic Health Care Pvt. Ltd.

16.2 MACHINE IN-PROCESS CONTROL:

Date/ Shift													
Machine Operator Name													
Time of inspection													
Sealing Temperature (To be established)													
Forming Temperature (To be established)													
Leak test on Blister* (Qty.: _____)													
Knurling /Sealing													
Pocket Formation													
Horizontal cutting													
Vertical cutting													
Quality of Over printing													
Code No.:	PON/DRUGS/ 21 14 4376												
B. No.:													
Mfg. Date													
Exp. Date													
Machine Speed To be established													
Checked by (Packing)													
Checked by (IPQA)													

Note: * If leak test fails perform every 15 minutes for next one hour and all the shippers to be checked for leak test from the last successful leak test. All the shippers packed from the time of last successful leak test shall be segregated and random checked by IPQA and to be released after approval from QA.

16.3 DEFOILING OF BLISTERS:


Date	De-foiling started at	De-foiling completed at	Weight of De-foiled tablets	De-foiling Done by	Checked by/ Date (Packing)	Verified by Date (QA)
12/04/22	12:20	12:50	0.820	Durga	Nand 12/04/22	GS 12/04/22
Total Weight of De-foiled Tablets			0.820	Checked By / Date (Packing):	Verified By / Date (IPQA):	
				Nand 12/04/22	GS 12/04/22	

16.4 INSPECTION OF DE-FOILED TABLETS:

Date	Inspection started at	Inspection completed at	Inspection Done by	Quantity of Good tablets		Qty. of Rejected Tablets		Checked by/ Date (Packing)	Verified by Date (QA)
				Kgs	Nos	Kgs	Nos		
12/04/22	12:52	13:10	Durga	0.230	313	0.590	803	Nand 12/04/22	GS 12/04/22
Total				0.230	313	0.590	803	Nand 12/04/22	GS 12/04/22
Total Quantity of Rejected Tablets Destroyed				Checked By / Date (Packing):		Verified By / Date (IPQA):			
..0.590. Kgs ..803.... Nos.				Nand 12/04/22		GS 12/04/22			

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka				
Date	06/04/2022	06/04/2022	06/04/22	06/04/2022	

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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 21
	BATCH PACKING RECORD		Product Code: B05
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00	Batch Size: 3,00,000 Tablets
		Customer:	Batch No.: 61822068
			Generic Health Care Pvt. Ltd.

17. LINE CLEARANCE CHECKS – BATCH CODING:

Date/ Shift 11/04/2022 61822069

Previous Product: Boncipro - 250		Batch No.: 61822069				
Sr. No.	Checks	Time	Observation			
			09:20 Packing			
1	Check and ensure that the area is visually clean and free from previous product. Check and ensure that waste bin is emptied out and cleaned		/	/		
2	Check the Pallets area clean and free from any leftovers of previous product /Batch.		/	/		
3	Check and ensure the rejected Carton of previous product/batch are removed.		/	/		
4	Check and ensure the environmental condition, formats, labels and log book.		/	/		
5	Check and ensure the previous batch details are deleted from the inkjet machine.		/	/		
6	Check and ensure that correct secondary packing material is dispensed		/	/		
7	Check and ensure the Correct status board is written.		/	/		

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

Cleaning Satisfactory / Not satisfactory#
(Packing) Sign. /Date: S. Manjiv 11/04/2022

Cleaning Satisfactory / Not satisfactory#
(IPQA) Sign. /Date: G. S. 11/04/2022

Remarks: # In case the cleaning is not satisfactory / line is not certified then investigate the cause of the failure and take necessary action, re check the area / line and record.

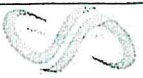
17.1 AREA AND EQUIPMENT CLEARANCE FOR CODING:

1. Check and ensure that the over printing area and machine is cleared from previous products.
2. Transfer uncoded printed Carton to Overprinting area.
3. Set and operate Overprinting Machine.
4. Overprinting shall be in indelible ink.
5. Overprinting Details shall be checked by Packing and cross-checked by QA before starting the operation.

Equipment	Inkjet Machine	Conveyor	Area
ID. No.:	pn/Imp/001		Batch Coding
Previous Product:	BONCIPRO - 250		
Batch No.:	61822069		
Cleaned by:	S. Manjiv 11/04/2022		
Checked by Packing:	S. Manjiv 11/04/2022		
Verified by IPQA:	G. S. 11/04/2022		

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.			
Date	06/04/2022	06/04/2022	06/04/2022	06/04/2022

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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 21
	BATCH PACKING RECORD	Product Code: B05	Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00	Batch No.: G1822068
		Customer:	Generic Health Care Pvt. Ltd.

17.2 OVERPRINTING DETAILS:

Overprinting Details	Overprinted Text	Carton (OK/ Not OK)
Batch No.:	61822068	OK
Mfg. Date:	04/04/22	OK
Exp. Date:	03/2025	OK
Item Code: 15/0724	15/0724	OK
Code No.: PON/DRUGS/21 14 4376	PON/DRUGS/21 14 4376	OK
Initiated by Sign. & Date	S. Manoj 11/04/2022	S. Manoj 11/04/2022
Checked by Packing Sign. & Date	S. Manoj 11/04/2022	S. Manoj 11/04/2022
Verified by IPQA Sign. & Date	S. Manoj 11/04/2022	S. Manoj 11/04/2022

17.3 TIME RECORD FOR BATCH CODING:

Sr. No.	Date/Shift	Batch Coding Done By	Batch Coding		Checked by (Packing) Sign. & Date	Verified by (IPQA) Sign. & Date
			Started at	Completed at		
01	11/04/2022	S. Manoj	9:10	18:00	S. Manoj 11/04/2022	S. Manoj 11/04/2022

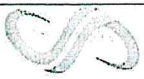
17.4 CARTON OVERPRINTING SPECIMEN:

S. No.	Date	Carton Specimen No.	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01	11/04/2022	01	S. Manoj 11/04/2022	S. Manoj 11/04/2022

Note – Attach specimen copy of over printed carton

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	S. Manoj	S. Manoj	S. Manoj	S. Manoj
Date	06/04/2022	06/04/2022	06/04/22	06/04/2022

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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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00 Customer:	Batch No.: <u>G 18 22068</u> Generic Health Care Pvt. Ltd.

18. LINE CLEARANCE CHECKS - SECONDARY PACKING:

Date/ Shift 11/04/2022 Q1 / 12/04/2022

Previous Product: <u>Nelivadol GH 5</u>		Batch No.: <u>G1822061</u>				
Sr. No.	Checks	Time	Observation			
			<u>11.05</u>		<u>09.10</u>	
			Packing	IPQA	Packing	IPQA
1	Check and ensure that the area is visually clean and free from previous product. Check and ensure that waste bin is emptied out and cleaned		<u>/</u>	<u>✓</u>	<u>/</u>	<u>✓</u>
2	Check the Pallets area clean and free from any leftovers of previous product /Batch.		<u>/</u>	<u>✓</u>	<u>/</u>	<u>✓</u>
3	Check and ensure the rejected blisters, rejected Carton, Shipper and shipper label of previous product/batch are removed.		<u>/</u>	<u>✓</u>	<u>/</u>	<u>✓</u>
4	Check and ensure the environmental condition, formats, labels and log book.		<u>/</u>	<u>✓</u>	<u>/</u>	<u>✓</u>
5	Check and ensure that correct secondary packing material is dispensed		<u>/</u>	<u>✓</u>	<u>/</u>	<u>✓</u>
6	Check and ensure the Correct status board is written.		<u>/</u>	<u>✓</u>	<u>/</u>	<u>✓</u>

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

Cleaning Satisfactory / Not satisfactory# <u>Day</u> (Packing) Sign./Date: <u>11/04/2022</u>	Cleaning Satisfactory / Not satisfactory# <u>Day</u> (IPQA) Sign./Date: <u>11/04/2022</u>
Remarks: # In case the cleaning is not satisfactory / line is not certified then investigate the cause of the failure and take necessary action, re check the area / line and record.	

Equipment	Packing Conveyor	Weighing Balance (Carton)	Shrink Sleeve	Strapping	Weighing Balance (shipper)	Area
ID. No.:	<u>PD/COB/002</u>	<u>PD/BAL/017</u>	<u>PD/SHN/002</u>	<u>PD/STM/001</u>	<u>PD/BAL/039</u>	Secondary Packing Hall
Previous Product:	<u>Nelivadol GH 5</u>					
Batch No.:	<u>G1822061</u>					
Cleaned by:	<u>Selvi</u>					
Checked by Packing:	<u>Day</u>					
Verified by IPQA:	<u>Gf 11/04/2022</u>					

18.1 ENVIRONMENTAL CONDITIONS:

(Check the environmental conditions of Secondary packing area at the start of process and Record in the below in table)							
Shift:..... <u>Q1</u>		Date/Time: <u>11/04/2022</u> <u>17:10</u>			Date/Time: <u>12/04/2022</u> <u>09:15</u>		
		Observation	Checked by Packing	Verified by IPQA	Observation	Checked by Packing	Verified by IPQA
Refer to SOP No.: SOP: QAGN/011	Temperature °C Limit: NMT 25°C	<u>23°C</u>	<u>Day</u>	<u>Gf</u>	<u>23°C</u>	<u>Day</u>	<u>Gf</u>
Secondary Packing Started Date/Time: <u>11/04/2022</u> <u>17:15</u> Completed Date/Time: <u>12/04/2022</u> <u>16:30</u>							
APPROVAL FOR SECONDARY PACKING:				Approved by IPQA Sign./Date: <u>Gf 11/04/2022</u>			

18.2 PACKING DETAILS:

10 Tablets in each Blister, over code the Blister with the batch details given below,
Place 2 x 10's Blister and one leaflet in each carton.
Place 18 filled carton in a Shrink Sleeve.
Place 16 Shrink sleeves in each 5 ply shipper. <u>12 shrink</u>
Seal the shipper with BOPP tape with "H" type. <u>12/04/2022</u>

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K</u>	<u>Day</u>	<u>Day</u>	<u>Day</u>
Date	<u>06/04/2022</u>	<u>06/04/2022</u>	<u>06/04/2022</u>	<u>06/04/2022</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 PACKING RECORD

Product Code: B05

Batch Size: 3,00,000 Tablets

Product BONCIPRO 500

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

Batch No.: 01822068

Customer:

Generic Health Care Pvt. Ltd.

19. OVER PRINTING DETAILS:

Overprinting Details (Secondary & Tertiary PM)

Overprinting Details	Overprinted Text	Carton (OK/ Not OK)	Insert	5 Ply Shipper Label (OK/ Not OK)
Batch No.:	01822068	ok	NA	ok
Mfg. Date:	04/2022	ok	NA	ok
Exp. Date:	03/2025	ok	NA	ok
Code No.: PON/DRUGS/21 14 4376	PON/DRUGS/21 14 4376	ok	NA	NA
Item Code : 16/0437 (Insert)	NA	NA	ok	NA
Item Code: 15/0724 (Carton)	NA	ok	NA	NA
Pack size:	NA	1 x 10's	NA	16 x 18 x 2 x 10's
Initiated by Sign. & Date	Manju	Manju	NA	Kalai
Checked by Packing Sign. & Date	Manju 11/04/2022	Manju 11/04/2022	Manju 11/04/2022	Manju 11/04/2022
Verified by IPQA Sign. & Date	Gys 11/04/2022	Gys 11/04/2022	Gys 11/04/2022	Gys 11/04/2022

19.1 Shipper Label Specimen:

S. No.	Date	Shipper Label Specimen No.	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01.	11/04/2022	01	Manju 11/04/2022	Gys 11/04/2022
		NA		

20. CARTON WEIGHT LIMIT SETTING: Date/Shift: 11/04/2022/Time: 17:12:0

Weight of ten individual empty cartons are given below:

1. 6.4	3. 6.4	5. 6.5	7. 6.4	9. 6.4
2. 6.4	4. 6.5	6. 6.4	8. 6.5	10. 6.5

Total weight of ten empty cartons = 64.4

Average weight of an empty carton (A) = Total weight of ten empty carton / 10 = 6.44

Weight of ten individual Blister are given below:

1. 9.0	3. 9.1	5. 9.0	7. 9.2	9. 9.1
2. 9.0	4. 9.0	6. 9.0	8. 9.0	10. 9.0

Total weight of ten Blister = 90.4

Avg. Weight of a Blister (B): total weight of ten Blister / 10 = 9.04

Weight of ten individual Leaflets are given below:

1. 3.0	3. 3.2	5. 3.0	7. 3.0	9. 3.2
2. 3.0	4. 3.0	6. 3.2	8. 3.0	10. 3.0

Total weight of ten Leaflets = 30.6


Avg. Weight of a Leaflet (C): total weight of ten Leaflets / 10 = 3.06

20.1 WEIGHT CHECKS ON CARTON:

Weight of ten empty Carton:	64.4	Average weight of one empty Carton (A):	6.44
Weight of ten filled Blister:	90.4	Average weight of one filled Blister (B):	9.04
Weight of ten Leaflets:	30.6	Average weight of one Leaflet (C):	3.06
Weight of one filled Carton D = (A + 2B + C)	27.58	Limit: E = D ± 1 % =	
		(To be established)	27.30 ± 27.8
Checked by Packing/Date:	Manju 11/04/2022	Verified by IPQA/Date:	Gys 11/04/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka			
Date	06/04/2022	06/04/2022	06/04/2022	06/04/2022

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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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product BONCIPRO 500	BPR. No.: BPR/T/305-00		Batch No.: 61822068
		Customer:	Generic Health Care Pvt. Ltd.

20.2 SAMPLE DRAWN RECORD:

Sr. No.	Stage of Sample collection	Qty. of Sample	Collected by (Sign. /Date)
1	Control Sample (Initial)	7 X 10 ¹ S	GS 11/04/2022
2	Control Sample (Middle)	7 X 10 ¹ S	GS 11/04/2022
3	Control Sample (Final)	6 X 10 ¹ S	GS 11/04/2022
4	Stability Sample	100 X 10 ¹ S	GS 11/04/2022
5	Other Sample	NA	NA
6	Analytical sample	12 X 10 ¹ S	GS 11/04/2022
Total Qty.		132 X 10 ¹ S	GS 11/04/2022

21. SECONDARY PACKING IN-PROCESS CHECKS: (Please keep ✓ mark if found "Ok")

Date/ Shift	Specification	observation													
Parameters	Specification	Packing							IPQA						
Time		17:20	09:30	10:47	11:12	12:48	13:30	14:10	17:23	09:39	11:19	13:29	15:18	17:35	
No. of Blister in a carton	2 Blister with 10 tabs and one leaflet.	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	
Carton Overprinting	Legible and readable	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	
No. of cartons in a shrink sleeves	18 packed cartons	NA	NA	NA	NA	NA	NA	NA	ok	ok	ok	ok	ok	ok	
Shrink wrapping temperature*		NA	NA	NA	NA	NA	NA	NA	ok	NA	NA	NA	NA	NA	
No. of shrink sleeves in a 5 ply shipper	16 shrink sleeves	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
Shipper strapping	Proper strapping	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
Label appearance and Shipper appearance	Legible and readable	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	
Sealing of the shipper with BOPP Tape	H type	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
Checked by		NA	NA	NA	NA	NA	NA	NA	GS	GS	GS	GS	GS	GS	


*Temperature to be mentioned.

21.1 SECONDARY PACKING IN-PROCESS CHECKS: (Please keep ✓ mark if found "Ok")

Date/ Shift	Specification	observation													
Parameters	Specification	Packing							IPQA						
Time		15:20	16:30	17:50											
No. of Blister in a carton	2 Blister with 10 tabs and one leaflet.	ok	ok	ok											
Carton Overprinting	Legible and readable	ok	ok	ok											
No. of cartons in a shrink sleeves	18 packed cartons	NA	NA	NA											
Shrink wrapping temperature*		NA	NA	NA											
No. of shrink sleeves in a 5 ply shipper	16 shrink sleeves	NA	NA	NA											
Shipper strapping	Proper strapping	NA	NA	NA											

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka				
Date	06/04/2022	06/04/2022			06/04/2022

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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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00 Customer:	Batch No.: <u>G18 22 068</u> Generic Health Care Pvt. Ltd.

Label appearance and Shipper appearance	Legible and readable	ok	ok	ok															
Sealing of the shipper with BOPP Tape	H type	NA	NA	NA															
Checked by		NA	NA	NA															

*Temperature to be mentioned.

21.2 SECONDARY PACKING IN-PROCESS CHECKS: (Please keep ✓ mark if found "Ok")

Date/ Shift	Receiving/	13/04/22							13/04/2022 /G							
Parameters	Specification	Packing								observation						
										IPQA						
Time		09:30	10:30	11:45	12:20	13:10	14:45	15:15	09:25	11:32	3:25	15:13	18:09			
No. of Blister in a carton	2 Blister with 10 tabs and one leaflet.	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok			
Carton Overprinting	Legible and readable	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok			
No. of cartons in a shrink sleeves	18 packed cartons	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok			
Shrink wrapping temperature*	160°C	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok			
No. of shrink sleeves in a 5 ply shipper	16 shrink sleeves	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok			
Shipper strapping	Proper strapping	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok			
Label appearance and Shipper appearance	Legible and readable	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok			
Sealing of the shipper with BOPP Tape	H type	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok			
Checked by		NA	NA	NA	NA	NA	NA	NA	G3	G3	G3	G3	G3			

*Temperature to be mentioned.


21.3 SECONDARY PACKING IN-PROCESS CHECKS: (Please keep ✓ mark if found "Ok")

SECONDARY PACKING IN-PROCESS CHECKS: (Please keep ✓ mark if found "OK")																
Date/ Shift	13/04/22															
Parameters	Specification	Packing						observation								
												IPQA				
Time		16:05	17:40													
No. of Blister in a carton	2 Blister with 10 tabs and one leaflet.	ok	ok													
Carton Overprinting	Legible and readable	ok	ok													
No. of cartons in a shrink sleeves	18 packed cartons	ok	ok													
Shrink wrapping temperature*	160°C	ok	ok													
No. of shrink sleeves in a 5 ply shipper	16 shrink sleeves	ok	ok													
Shipper strapping	Proper strapping	ok	ok													
Label appearance and Shipper appearance	Legible and readable	ok	ok													
Sealing of the shipper with BOPP Tape	H type	ok	ok													
Checked by		NS	NS													

*Temperature to be mentioned.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka			
Date	06/04/2022	06/04/2022	06/04/2022	06/04/2022

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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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product BONCIPRO 500	BPR. No.: BPR/T/305-00 Customer:		Batch No.: G1822068 Generic Health Care Pvt. Ltd.

22. SHIPPERS WEIGHING:

Date/Shift: **11/04/2022** Time: **17:40** Balance I.D. No: **PD/BAL/039**

Weight of ten Shrinks: 5059			Average weight of one filled Shrink (H): 505.9		
Weight of ten empty shippers: 10.45			Average weight of one empty shipper (I): 1.045		
Weight of one filled shipper (J) = (H/I): 7.115			Limit: $K = J \pm 1\% = 7.044 \pm 7.186$		
Checked by Packing/Date: Nay 11/04/2022			Verified by IPQA/Date: G18 11/04/2022		

Shipper No.	Gross weight (Kg)	Weighed By	Shipper No.	Gross weight (Kg)	Weighed By	Shipper No.	Gross weight (Kg)	Weighed By	Shipper No.	Gross weight (Kg)	Weighed By
1	7.110	Amsa	15	7.090	Amsa	29	7.105	Amsa	43	7.095	Amsa
2	7.100	Amsa	16	7.095	Amsa	30	7.105	Amsa	44	7.095	Amsa
3	7.125	Amsa	17	7.090	Amsa	31	7.130	Amsa	45	7.100	Amsa
4	7.070	Amsa	18	7.095	Amsa	32	7.100	Amsa	46	7.105	Amsa
5	7.110	Amsa	19	7.065	Amsa	33	7.095	Amsa	47	7.100	Amsa
6	7.130	Amsa	20	7.095	Amsa	34	7.085	Amsa	48	7.100	Amsa
7	7.105	Amsa	21	7.075	Amsa	35	7.125	Amsa	49	7.080	Amsa
8	7.100	Amsa	22	7.110	Amsa	36	7.105	Amsa	50	7.060	Amsa
9	7.075	Amsa	23	7.095	Amsa	37	7.100	Amsa	51	7.070	Amsa
10	7.100	Amsa	24	7.110	Amsa	38	7.105	Amsa	52	7.065	Amsa
11	7.110	Amsa	25	7.090	Amsa	39	7.100	Amsa	53	7.130	Amsa
12	7.105	Amsa	26	7.090	Amsa	40	7.105	Amsa	54	7.060	Amsa
13	7.105	Amsa	27	7.075	Amsa	41	7.080	Amsa	55	7.100	Amsa
14	7.095	Amsa	28	7.110	Amsa	42	7.095	Amsa	56	7.075	Amsa

Total No. of shippers weighed: NA	De-foiled tablets packed in Shipper No: NA	Checked by Sign / Date: Nay 11/04/2022	Verified by Sign / Date: G18 11/04/2022	Loose pack details: Shipper No: Quantity: Weight:
--	---	---	--	--


Note - If any shipper weight found out of limit, the same shall be checked physically by opening the shipper.

23. MAN POWER ALLOCATION:

DATE: 11/04/2022		DATE: 11/04/2022	
SHIFT: C1		SHIFT: C1	
ACTIVITIES	DONE BY	ACTIVITIES	DONE BY
Blister Checking	Selvi, Indhira	Blister Checking	Selvi, Indhira
Printing Checking in Blister	Pushpa, Janagi	Printing Checking in Blister	Pushpa, Janagi
Insertion of Blister and leaflet into carton	Kalpura, Tamil, Malathi	Insertion of Blister and leaflet into carton	Kalpura, Tamil, Malathi
Cartons weighing	Anbu	Cartons weighing	Anbu
Insertion of carton into shrink sleeve	NA	Insertion of carton into shrink sleeve	NA
Insertion of shrink wrapped carton into shipper	NA	Insertion of shrink wrapped carton into shipper	NA
Shipper Label Pasting	Amsa	Shipper Label Pasting	Amsa
Shipper Weighing	Amsa	Shipper Weighing	Amsa
Shipper Strapping	NA	Shipper Strapping	NA
Shipper packed	From 01 to 03	Shipper packed	From 04 to 02
Signature of Packing	Nay 11/04/2022	Signature of Packing	Nay 11/04/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	11	11	11
Date	06/04/2022	06/04/2022	06/04/2022	06/04/2022

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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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product BONCIPRO 500	BPR. No.: BPR/T/305-00 Customer:		Batch No.: G11822068(A) Generic Health Care Pvt. Ltd.

22. SHIPPERS WEIGHING: Date/Shift....12/04/22/9..Time...09:35 Balance I.D. No.: P.P./BAL/039

Weight of ten Shrinks: 5059			Average weight of one filled Shrink (H): 505.9		
Weight of ten empty shippers: 10.45			Average weight of one empty shipper (I): 1.045		
Weight of one filled shipper (J) = (16 H+I): 7.115			Limit: K = J ± 1% = 7.044 + 7.186		
Checked by Packing/Date: <i>Dany 12/04/2022</i>			Verified by IPQA/Date: <i>G. J. 12/04/2022</i>		
Shipper No.	Gross weight (Kg)	Weighed By	Shipper No.	Gross weight (Kg)	Weighed By
157	7.105	Amsa	29		
158	7.105	Amsa	30		
159	7.080	Amsa	31		
160	7.070	Amsa	32		
161	7.115	Amsa	33		
162	7.105	Amsa	34		
163	7.125	Amsa	35		
164	7.100	Amsa	36		
165	7.095	Amsa	37		
166	7.090	Amsa	38		
167	7.105	Amsa	39		
168	4.585	Amsa	40		
169			41		
170			42		
Total No. of shippers weighed: 68			De-foiled tablets packed in Shipper No: 68		
Checked by Sign / Date: <i>Dany 12/04/2022</i>			Verified by Sign / Date: <i>G. J. 12/04/2022</i>		
Loose pack details:			Shipper No: 68		
Quantity: 07. x 10. x 2 x 10 ¹⁵			Weight: 4.585		

Note – If any shipper weight found out of limit, the same shall be checked physically by opening the shipper.

23. MAN POWER ALLOCATION:

DATE: 12/04/22...		DATE:	
SHIFT: 01.....		SHIFT:	
ACTIVITIES	DONE BY	ACTIVITIES	DONE BY
Blister Checking	Kavi Prabhavathy	Blister Checking	
Printing Checking in Blister	Kow Salya, Jayarani	Printing Checking in Blister	
Insertion of Blister and leaflet into carton	Satya, Manirajalei	Insertion of Blister and leaflet into carton	
Cartons weighing	Shobana	Cartons weighing	
Insertion of carton into shrink sleeve	Prigamla, Sowdaniya	Insertion of carton into shrink sleeve	
Insertion of shrink wrapped carton into shipper	Nandhini, Jagataishini	Insertion of shrink wrapped carton into shipper	
Shipper Label Pasting	Keerthi	Shipper Label Pasting	
Shipper Weighing	Keerthi	Shipper Weighing	
Shipper Strapping	Kathavarayan	Shipper Strapping	
Shipper packed	From 01...to 68	Shipper packed	From.....to.....
Signature of Packing	<i>Dany 12/04/2022</i>	Signature of Packing	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. K.</i>	<i>H.</i>	<i>K.</i>	<i>P.</i>
Date	06/04/2022	06/04/2022	06/04/2022	06/04/2022

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1. The first part of the document is a list of names and addresses, which are arranged in a table-like format. The names are listed in the first column, and the addresses are listed in the second column. The names are: John Doe, Jane Smith, and Bob Johnson. The addresses are: 123 Main St, 456 Elm St, and 789 Oak St.

2. The second part of the document is a list of names and addresses, which are arranged in a table-like format. The names are listed in the first column, and the addresses are listed in the second column. The names are: John Doe, Jane Smith, and Bob Johnson. The addresses are: 123 Main St, 456 Elm St, and 789 Oak St.

3. The third part of the document is a list of names and addresses, which are arranged in a table-like format. The names are listed in the first column, and the addresses are listed in the second column. The names are: John Doe, Jane Smith, and Bob Johnson. The addresses are: 123 Main St, 456 Elm St, and 789 Oak St.

4. The fourth part of the document is a list of names and addresses, which are arranged in a table-like format. The names are listed in the first column, and the addresses are listed in the second column. The names are: John Doe, Jane Smith, and Bob Johnson. The addresses are: 123 Main St, 456 Elm St, and 789 Oak St.

5. The fifth part of the document is a list of names and addresses, which are arranged in a table-like format. The names are listed in the first column, and the addresses are listed in the second column. The names are: John Doe, Jane Smith, and Bob Johnson. The addresses are: 123 Main St, 456 Elm St, and 789 Oak St.

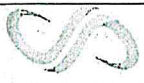
6. The sixth part of the document is a list of names and addresses, which are arranged in a table-like format. The names are listed in the first column, and the addresses are listed in the second column. The names are: John Doe, Jane Smith, and Bob Johnson. The addresses are: 123 Main St, 456 Elm St, and 789 Oak St.

7. The seventh part of the document is a list of names and addresses, which are arranged in a table-like format. The names are listed in the first column, and the addresses are listed in the second column. The names are: John Doe, Jane Smith, and Bob Johnson. The addresses are: 123 Main St, 456 Elm St, and 789 Oak St.

8. The eighth part of the document is a list of names and addresses, which are arranged in a table-like format. The names are listed in the first column, and the addresses are listed in the second column. The names are: John Doe, Jane Smith, and Bob Johnson. The addresses are: 123 Main St, 456 Elm St, and 789 Oak St.

9. The ninth part of the document is a list of names and addresses, which are arranged in a table-like format. The names are listed in the first column, and the addresses are listed in the second column. The names are: John Doe, Jane Smith, and Bob Johnson. The addresses are: 123 Main St, 456 Elm St, and 789 Oak St.

10. The tenth part of the document is a list of names and addresses, which are arranged in a table-like format. The names are listed in the first column, and the addresses are listed in the second column. The names are: John Doe, Jane Smith, and Bob Johnson. The addresses are: 123 Main St, 456 Elm St, and 789 Oak St.

 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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00 Customer:	Batch No.: 61822068 Generic Health Care Pvt. Ltd.

DATE:		DATE:	
SHIFT:		SHIFT:	
ACTIVITIES	DONE BY	ACTIVITIES	DONE BY
Blister Checking		Blister Checking	
Printing Checking in Blister		Printing Checking in Blister	
Insertion of Blister and leaflet into carton		Insertion of Blister and leaflet into carton	
Cartons weighing		Cartons weighing	
Insertion of carton into shrink sleeve		Insertion of carton into shrink sleeve	
Insertion of shrink wrapped carton into shipper		Insertion of shrink wrapped carton into shipper	
Shipper Label Pasting		Shipper Label Pasting	
Shipper Weighing		Shipper Weighing	
Shipper Strapping		Shipper Strapping	
Shipper packed	From.....to.....	Shipper packed	From.....to.....
Signature of Packing		Signature of Packing	

24. PACKING MATERIAL RECONCILIATION:

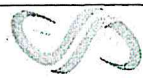
Sr. No.	Material	Printed Alu. Foil (Kg)	Clear PVC (Kg)	Cartons (Nos)	Leaflets (Nos)	Shrink Sleeves (Nos)	5 Ply Shipper (Nos)	Strapping Role (Mtrs.)	BOPP Tape (GHPL Printed) (Nos)
A	Quantity received for the batch	24.330	72.030	15000	15000	834	68	500	01
B	Additional material received for the batch	NA	NA	NA	NA	NA	NA	NA	NA
C	Total material received (A+B)	24.330	72.030	15000	15000	834	68	500	01
D	Quantity packed	11.150	58.900	14598	14598	811	68	500	01
E	Quantity rejected (Online) & Destroyed	0.740	1.276	339	191	23	NA	NA	NA
F	Quantity Returned	12.400	11.650	NA	150	NA	NA	NA	NA
G	Sample affixed on BPR	0.001	0.006	03	01	NA	NA	NA	NA
H	QC samples	0.003	0.018	NA	NA	NA	NA	NA	NA
I	Other samples (If any)	0.036	0.180	60	60	NA	NA	NA	NA
J	Total accountable Quantity (D+ E+F+G+H+I)	24.330	72.030	15000	15000	834	68	500	01
K	Variation (C - J)	NA	NA	NA	NA	NA	NA	NA	NA
L	%Variation (K x 100)/C	NA	NA	NA	NA	NA	NA	NA	NA
M	Acceptable limit	± 2 %	± 2 %	± 2 %	± 2 %	± 2 %			

If % Variation is out of the acceptable limit, investigate & specify the reason:

NA

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka			V. P.	
Date	06/04/2022	06/04/2022	06/04/2022	06/04/2022	

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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 PACKING RECORD

Product Code: B05

Batch Size: 3,00,000 Tablets

Product

BONCIPRO 500

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

Batch No.: 6118 22068

Customer:

Generic Health Care Pvt. Ltd.

25. EXCESS PACKING MATERIAL RETURN TO STORE: MRN NO. NA

Material	Printed Alu. Foil (Kg)	Clear PVC (Kg)	Cartons (Nos)	Leaflets (Nos)	Shrink Sleeves (Nos)	5 Ply Shipper (Nos)	Strapping Role (Mtrs.)	BOPP Tape (GHPL Printed) (Nos)
Quantity Returned	12.400	11.650	NA	150	NA	NA	NA	NA
Material returned by packing Sign./Date	S.K	S.K		S.K				
Verified By IPQA Sign./Date	(4)	(4)		(4)				
Material received by Store Sign./Date	\$y!-	\$y!-		\$y!-				

26. DESTRUCTION OF REJECTED/UNUSED PRINTED PACKING MATERIALS AND STEREOS:

Date	Stereos	Printed Alu. Foil (Kg)	Clear PVC (Kg)	Cartons (Nos)	Leaflets (Nos)	Shrink Sleeves (Nos)	5 Ply Shipper (Nos)	Strapping Role (Mtrs.)	BOPP Tape (GHPL Printed) (Nos)
12/04/2022	NA	0.740	1.276	339	191	23	NA	NA	NA
				NA					
Total Qty. Destroyed	NA	0.740	1.276	339	191	23	NA	NA	NA
Destroyed by (Packing)	Nay 12/04/2022			Verified by (IPQA)			(4) 12/04/2022		

27. BATCH RECONCILIATION:

A	Batch Size	3,00,000 Nos.
B	Quantity received for packing	292707
C	Total quantity packed	291960
D	Control samples	200
E	Analytical Samples	120
F	In process samples	1440
G	Others samples if any (Stability, Regulatory Samples, etc.)	1000
H	Packing Loss = B - (C + D + E + F + G)	2013
I	Total Loss = A - (C + D + E + F + G)	5280
J	Packing yield % (C + D + E + F + G) / B X 100 (Yield Limit %.....)*	100.68 %
K	Batch Yield % (C + D + E + F + G) / A X 100 (Yield Limit %.....)*	98.24 %

*To be established

Checked by Packing /Date: Nay 12/04/2022


Verified by IPQA/Date: (4) 12/04/2022

28. TRANSFER OF FINISHED GOODS:

Date	FGTN No.	Sales	Pack Size	No. of Units in a shipper	No. of Shippers	Transferred Quantity	FGTN Raised by Packing	FGTN Checked by IPQA	FGTN Received by Stores
16/04/22	00021	3.01	2x10's	12x18x2x10's	67	28944	Nay	(4)	R.m
				07x18x2x10's	01	252	Nay	(4)	R.m
Total Qty. Transferred						29196	Nay	(4)	R.m

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka			
Date	06/04/2022	06/04/2022	06/04/22	06/04/2022

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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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00 Customer:	Batch No.: G18 22 1768 Generic Health Care Pvt. Ltd.

29. DEVIATION/EXCEPTION DETAILS:

During process if there is any Deviation / Exception are observed then record in below table

Deviation / Exception details

Sr. No.	Stage	Deviation / Exception details	Action taken	Observed By
1				

Checked by
Packing:

Verified by
Packing manager:

Approved by
Head QA:

30. BPR REVIEW DETAILS:

Reviewed by	Name	Sign. /Date
Packing Executive	(4) SUCHANYA NANCY RANIL	Nancy 16/04/22
QA Executive	G. SENTHIL KUMARAN	G. Senthil Kumaran 16/04/2022
Production Assistant Manager/ HOD	S. SIVAKUMAR	S. Sivakumar 16/04/2022
QA Manager/ HOD	R. Stephen	R. Stephen 16/04/22

31. BATCH RELEASED FOR DESPATCH:

Total quantity released: 291960 No's

Head QA sign/ Date:

32. REVISION HISTORY:

S. No.	Document No.	Reason for Changes	Supersedes Doc. No.
1	BPR/T/305-00	New Document	Nil

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka			
Date	06/04/2022	06/04/2022	06/04/22	06/04/2022

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VALIDATION BATCH

STABILITY BATCH

SAI PRIMUS LIFE BIOTECH PVT LTD		Page 1 of 21	
Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.			
SAI PRIMUS LIFE BIOTECH PVT LTD	BATCH PACKING RECORD	Product Code: B05	Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00	Batch No.: <u>G18 22117</u>
		Customer:	Generic Health Care Pvt. Ltd.


BATCH PACKAGING 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.
CODE NO.	: PON/DRUGS/21 14 4376
DOSAGE FORM	: Tablet
BPR No.	: BPR/T/305-00
REVISION No.	: 00
SUPERSEDE No	: NIL
EFFECTIVE BATCH. No. /DATE	: <u>G18 22068 / 06/04/2022</u>
MARKET	: Export
SHELF LIFE	: 36 Months
BATCH SIZE	: 3,00,000 Tablets
PACKING CONFIGURATION	: 2 x 10's Tablets Pack (Blister Packing)
BPR ISSUED BY/DATE (QA)	: <u>85/05/09/2022</u>
BPR CHECKED & RECEIVED BY/DATE (PRODUCTION)	: <u>L.V. 15/09/2022</u>
MFG. DATE: <u>09/2022</u>	EXP. DATE: <u>08/2025</u>
ALLOTTED BY: QA SIGN/DATE: <u>85/05/09/2022</u>	COUNTER CHECKED BY: QA SIGN/DATE: <u>15/09/2022</u>
QUANTITY RECEIVED FROM PRODUCTION	: <u>292002 NOS</u>
DATE OF COMMENCEMENT: <u>16/09/2022</u>	DATE OF COMPLETION: <u>16/09/2022</u>
QUANTITY	: <u>292002 - 3,00,000 NOS</u>
RELEASED QUANTITY OF PACKED TABLETS	: <u>290520 NOS</u>
RELEASE OF BATCH BY HEAD QA SIGN/DATE:	: <u>C.F. 06/04/2022</u>

This BPR contains 21 Pages + .05. Additional Pages

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L.V.</u>	<u>M</u>	<u>85/05/09/2022</u>	<u>15/09/2022</u>
Date	<u>06/04/2022</u>	<u>06/04/2022</u>	<u>06/04/2022</u>	<u>06/04/2022</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 2 of 21
	BATCH PACKING RECORD	Product Code: B05	Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00	Batch No.: G18 22 117
		Customer:	Generic Health Care Pvt. Ltd.

1. INDEX

Sr. No.	Content	Page No.
	Batch Packaging cover sheet	1
1	Index	2
2	Check list for batch packing record review	3
3	Packing Material Specification and Indent	4
4	Dispensing line clearance	5
5	Dispensing record of packing materials	6
6	Line clearance for primary packing	7
7	Verification of dispensed packing material	8
8	Receipt of product and materials, Detail of the product as per BMR	8
9	Weight verification record of received semi-finished product	8
10	Container weight details, Container consumption details, Overprinting of Primary Packaging Material (Embossing), specimen of printed foil	9
11	Packing instruction, time record for packing detail, Packing In-process checks for primary packing	9-10
12	Blister packing machine parameters	10
13	Machine In-Process control, Defoiling of Blister, Inspection of defoiled Tablets	10-11
14	Line Clearance for Batch Coding, Area and equipment clearance for coding, Overprinting Details, Time record for batch coding, Carton overprinting specimen	12-13
15	Line clearance for secondary packing, Environmental condition, Packing Details	14
16	Over printing details, Shipper Label specimen, Carton Weight Limit Setting	15
17	Weight Checks On Carton, Sample Drawn Record	15-16
18	Secondary Packing In process Checks	16-17
19	Shipper Weighing	18
20	Man power allocation	18-19
21	Packing material reconciliation	19
22	Excess packing material return to store	20
23	Destruction of rejected/unused printed packing materials and stereotypes	20
24	Batch reconciliation	20
25	Transfer of finished goods	20
26	Deviation Detail	21
27	BPR review details	21
28	Batch released for Despatch	21
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Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	M	SR	V. A
Date	06/04/2022	06/04/2022	06/04/2022	06/04/2022

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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 3 of 21
	BATCH PACKING RECORD	Product Code: B05	Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00	Batch No.: G18 22117
		Customer:	Generic Health Care Pvt. Ltd.

2. CHECKLIST FOR BATCH PACKING RECORD REVIEW:

Instruction:

Check the following points before submitting the documents for final Review

Sr. No.	Checklist	Observation (Yes/No/NA/No.*)
1.	No. of pages of BPR+ Additional pages (If any) *	NA
2.	Line clearance and environmental record	YES
3.	Processing activity done by and checked by is signed	YES
4.	Dispensing	
a)	Equipment clean tag and dispensing tag attached with batch record	YES
b)	Packaging material is checked	YES
5.	Packing	
a)	Rinse water analysis report attached with BPR	YES
b)	Approved specimen of printed foil, carton and shipper label are attached	YES
c)	Control / Stability / Finished product analysis samples are withdrawn	YES
d)	Reconciliation of packing materials is done	YES
e)	Tablet reconciliation is done	YES
f)	In process checks parameters done at regular interval and recorded into BPR	YES
6.	Attachment	
a)	Finished Goods Transfer Note	YES
b)	Certificate of analysis of finished product is submitted	YES
c)	Stereo Impression Format	NA
7.	Complete set of BPR Submitted	YES


Checked By QA/Date: G18 21/04/2022

*Mention total number of pages.

Remarks (If any) NA

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	M	De	V. Ka
Date	06/04/2022	06/04/2022	06/04/2022	06/04/2022

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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 4 of 21
	BATCH PACKING RECORD	Product Code: B05	Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00	Batch No.: G1822117
		Customer:	Generic Health Care Pvt. Ltd.

3. PACKING MATERIAL SPECIFICATION AND INDENT:

Sr. No.	Material	Item Code	Specification	UOM	Standard Qty. for Batch Size 3.0 Lac.
1	178mm Boncipro 500 Printed foil 0.025mm	PPF/SP/B009	Width – 178 ± 1 mm Thickness – 0.025 mm Language – French Color – 1 Color Item Code: 13/0442	Kg	14.100
2	182mm PVC Base Foil	PBF/SP/B037	Width – 182 ± 1 mm	Kg	64.500
3	2X10's Boncipro 500mg Prt Carton	PPC/SP/B004	Size – 90 x 60 x 20 mm (L x W x H) Board – 300 gsm ITC cyber XL board Colour – 4 colours Item Code: 15/0724	No	15000
4	Boncipro Leaflet	PPL/SP/L015	Size – 210 x 230 mm (L x H) NLT 60 GSM Maplitho Paper Colour – 2 colour Item Code: 16/0437	No	15000
5	Shrink Sleeve	PPS/SP/P001	Plain PVC Shrink Sleeves	No	834
6	5 Ply 390X390X265 mm GHPL Printed Shipper	PUS/SP/G018	A 5 Ply flute vertical corrugated inner unprinted in nature. (24 B.F.) Outer Size – 390 x 390 x 265 mm (L x W x H) Bursting Strength – NLT 15.00 Kg/cm ²	No	53
7	3' GHPL Printed Bopp Tape	PPB/SP/B002	Clear Transparent Length of roll – 65m Width – 60 mm Printing – GHPL repeats in Blue	No	1
8	3' Plain BOPP Tape	PUB/SP/B001	Plain BOPP Tape	No.	1
9	Strapping role.	PPR/SP/S001	White or milky white colour. Width – 12 mm Thickness – 0.6 mm	Mtrs	500

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	M		
Date	06/04/2022	06/04/2022		

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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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00 Customer:	Batch No.: G18 22 117 Generic Health Care Pvt. Ltd.

4. DISPENSING LINE CLEARANCE CHECKS


Date: 15/09/2022 Time: 17:05




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 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 Mobile Laminar Air Flow is clean	✓	✓
7	Check all the gauges of Mobile Laminar Air flow 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	Mobile Laminar Air Flow	Weighing Balance		Area
ID No.	ST/LAF/001	ST/BAL/011	— NA —	FOIL STORE
Previous Product	G1ENSET			
B. No.	G1822112			
Cleaned by Sign/Date	Saran 15/09/2022			
Checked by Store Sign/Date	BY: 15/09/2022			
Verified by IPQA Sign/Date	Q15/09/2022			

ENVIRONMENTAL CONDITIONS: Date: 15/09/2022 Time: 17:10	Observation	Checked by Store Sign/Date	Verified by IPQA Sign/Date
(For Reference SOP No.: QAGN/011)			
Temperature (Limit: NMT 25°C)	23°C	BY: 15/09/22	Q15/09/22
Differential Pressure across the booth Limit: 5 to 20 mm Water	14mm	BY: 15/09/22	Q15/09/22

APPROVAL FOR DISPENSING BY IPQA: Sign:  Date: 15/09/2022
Dispensing start Time 17:15 End Time 17:35

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka			
Date	06/04/2022	06/04/2022	06/04/2022	06/04/2022

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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 21
	BATCH PACKING RECORD	Product Code: B05	Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00	Batch No.: G18 22 117
		Customer:	Generic Health Care Pvt. Ltd.

5. DISPENSING RECORD OF PACKING MATERIALS: Date: 15/09/2022 Shift: G Time: 17:15

Material Name	Item code	UOM	Req. Qty. for 3.0 Lac	Issued Qty.	A.R No.	No. of Roll/Box	Issued and Checked by Store	Verified by IPQA
178mm Boncipro 500 Printed foil 0.025mm	PPF/SP/B009	Kg	14.100	21.960	PmG/100550	02	By: 15/09/22	G 15/09/2022
182mm PVC Base Foil	PBF/SP/B037	Kg	64.500	6.500 73.950	PmG/100559 PmG/100599	01 03	By: 15/09/22	G 15/09/2022
2X10's Boncipro 500mg Prt Carton	PPC/SP/B004	No	15000	16000	PmG/100523	07	By: 15/09/22	G 15/09/2022
Boncipro Leaflet	PPL/SP/L015	No	15000	15000	PmG/100585	02	By: 15/09/22	G 15/09/2022
Shrink Sleeve	PPS/SP/P001	No	834	834	PmG/100895	01	By: 15/09/22	G 15/09/2022
5 Ply 390X390X265 mm GHPL Printed Shipper	PUS/SP/G018	No	53	53	PmG/101545	06	By: 15/09/22	G 15/09/2022
3' GHPL Printed Bopp Tape	PPB/SP/B002	No	1	03	PmG/100310	01	By: 15/09/22	G 15/09/2022
3' Plain BOPP Tape	PUB/SP/B001	No	1	01	PmG/100505	01	By: 15/09/22	G 15/09/2022
Strapping role.	PPR/SP/S001	Mtrs	500	01	PmG/100945	01	By: 15/09/22	G 15/09/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K			
Date	06/09/2022	06/09/2022	06/09/2022	06/09/2022

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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 7 of 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00 Customer:	Batch No.: G18 22117 Generic Health Care Pvt. Ltd.

6. LINE CLEARANCE CHECKS:

6.1 PRIMARY PACKING:

Date/ Shift ..16/09/22..G1.09.00.../.....NA

Previous Product: BONCIPRO 500		Batch No.: G1822116				
Sr. No.	Checks	Time	Observation			
			09.05 Packing	IPQA	Packing	IPQA
1.	Area status board is updated for "CLEANED" status.		✓	✓		
2.	Check and ensure that the area is visually clean and free from previous product		✓	✓		
3.	Check and ensure the differential pressure of the area is within specified limit		✓	✓		
4.	Check and ensure that waste bin is emptied out and cleaned		✓	✓		
5.	Check the temperature and relative humidity of the area within specified limit		✓	✓		
6.	Check the tablets of the previous product/ batch removed.		✓	✓		
7.	Check the loose Blister cutting, rejected rolls, empty cores of foil of previous product /batch are removed.		✓	✓		
8.	Check the surroundings of the machine and free from the previous products and batch		✓	✓		
9.	Check the foil printing stereotypes, Labels of previous product/batch are removed.		✓	✓		
10.	Check that the daily records (log book, balance, temp. & RH) are updated and signed.		✓	✓		
11.	Check and ensure the Cleanliness following change part of Blister packing machine		✓	✓		
12.	Check for the absence of previous batch/ product at machine conveyor belt.		✓			
a)	Check Hopper from Top, bottom of machine, below the hopper, between bottom side of conveyor belt and collating unit.		✓	✓		
b)	Check for cleaning of hopper, feeding channel, vibrator plate, in feed roller and sweep brush.		✓	✓		
c)	Check tool box, thinner and ink box		✓	✓		

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

Cleaning satisfactory/Not-satisfactory

Checked by Packing (Sign./Date): P. D. 16/09/22

Cleaning satisfactory/Not-satisfactory

Verified by IPQA (Sign./Date): G. S. 16/09/2022

#In case the cleaning is not satisfactory / line is not certified then investigate the cause of the failure and take necessary action, recheck the area / line and record.

6.2 AREA AND EQUIPMENT CLEARANCE OF PRIMARY PACKING

Previous Product: BONCIPRO 500				Batch No.: G1822116			
S. No.	Equipment / Area Name	Eq.ID. /Area. No.	Cleaning Type A/B	Operation and cleaning as per SOP number	Cleaned by Sign/Date	Checked by (Packing) Sign/Date	Verified by (IPQA) Sign/Date
1.	Blister Packing Area	SPL/AFB/BLP/001	B	PDGN/006	Velu	P. D.	G. S. 16/09/22
2.	Blister Packing Machine	PD/BLR/001	B	PDOP/021, PDCL/021 PDOP/022, PDCL/022	Velu	P. D.	G. S. 16/09/22


6.3 ENVIRONMENTAL CONDITIONS:

(Check the environmental conditions of primary packing area at the start of process and Record in the below in table)

Refer to SOP No.: SOP: QAGN/011		Date: 16/09/22... Time: 09.03.....		Date:..... Time:.....		
Observation	Packing Sign/Date	Verified by IPQA Sign/Date	Observation	Packing Sign/Date	Verified by IPQA Sign/Date	
Temp °C Limit: NMT 25°C	23°C	P. D. 16/09/22				
RH % Limit: NMT 60%	58%	P. D. 16/09/22				
DP Limit: NLT 10 Pascal	10 pascal	P. D. 16/09/22				
Primary Packing Started Date/Time: 16/09/22..12:30.. Completed Date/Time: 16/09/2022..13:50..						
APPROVAL FOR PRIMARY PACKING: IPQA Sign./Date: G. S. 16/09/22						

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. K.				
Date	06/04/2022	06/04/2022			

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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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00 Customer:	Batch No.: <u>G18 22 117</u> Generic Health Care Pvt. Ltd.

7. VERIFICATION OF DISPENSED PACKING MATERIALS: Date: 16/09/2022 Shift: G1 Time: 09:10

Material Name	Item code	UOM	AR No.	Number of Rolls/Packs	Checked by Packing	Verified by QA
178mm Boncipro 500 Printed foil 0.025mm	PPF/SP/B009	Kg	Pm 6100550	02	S. Vey	Gf
182mm PVC Base Foil	PBF/SP/B037	Kg	Pm 6100559 Pm 6100599	01 03	S. Vey	Gf
2X10's Boncipro 500mg Pkt Carton	PPC/SP/B004	No	Pm 6100583	07	S. Vey	Gf
Boncipro Leaflet	PPL/SP/L015	No	Pm 6100585	02	S. Vey	Gf
Shrink Sleeve	PPS/SP/P001	No	Pm 6100895	01	S. Vey	Gf
5 Ply 390X390X265 mm GHPL Printed Shipper	PUS/SP/G018	No	Pm 6101545	06	S. Vey	Gf
3' GHPL Printed Bopp Tape	PPB/SP/B002	No	Pm 6100310	01	S. Vey	Gf
3' Plain BOPP Tape	PUB/SP/B001	No	Pm 6100565	01	S. Vey	Gf
Strapping role.	PPR/SP/S001	Mtrs	Pm 6100945	01	S. Vey	Gf

8. RECEIPT OF PRODUCT AND MATERIALS: Date/Shift: 16/09/2022 Shift: G1 Time: 09:10

(Check the following before start of packing activity and record the observation.)

S. No.	Check Points	Observation	Done by (Packing)	Verified By (IPQA)
1.	Temperature observed on display (Limit: NMT 25°C)	23°C	S. Vey	Gf
2.	Relative Humidity observed on display (Limit: NMT 60%)	58%	S. Vey	Gf
3.	Bulk product containers are of the required product/Batch number and is approved by QC	Yes	S. Vey	Gf
4.	Status label of machine/ line is for same product	Yes	S. Vey	Gf
5.	Printed foil/Base rolls are of the required product.	Yes	S. Vey	Gf
6.	All secondary packing materials are of the required product	Yes	S. Vey	Gf

9. DETAIL OF THE PRODUCT AS PER BMR:

Sr. No.	Description	Observations	Checked By (Packing)	Verified By (IPQA)
1.	Average Weight	720 mg	S. Vey	Gf
2.	Colour of Tablet	Pink colour	S. Vey	Gf
3.	Quantity (Net Qty. in Kg)	214.330	S. Vey	Gf
4.	Number of Containers	06	S. Vey	Gf

10. WEIGHT VERIFICATION RECORD OF RECEIVED SEMI-FINISHED PRODUCT:

Balance I.D. No.: DD/BAL/014


1. Verify the semi-finished Tablets before starting the packing operation.

2. _____ s affixed over the Containers against the respective BMR

Product Name	Batch No.	Mfg. Date	Exp. Date	Qty. recd. For packing	No. of Containers taken for packing
BONCIPRO 500	G1822117	09/06/22	08/12/25	214.330 Kg Equivalent to 292002 Nos.	From Container No. <u>01</u> To Container No. <u>06</u> Total No. of Containers taken <u>06</u>
Checked by Packing (Sign. /Date): <u>S. Vey 16/09/22</u>				Verified By IPQA (Sign. /Date): <u>Gf 16/09/2022</u>	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>06/04/2022</u>	<u>06/04/2022</u>	<u>06/04/2022</u>	<u>06/04/2022</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 9 of 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00 Customer:	Batch No.: G1822117 Generic Health Care Pvt. Ltd.

11. CONTAINER WEIGHT DETAILS:

Container No.	Gross Weight in Kg	Weighed By Packing	Checked By IPQA	Container No.	Gross Weight in Kg	Weighed By Packing	Checked By IPQA
1	42.020	Mathan	Gfs	4	37.720	Mathan	Gfs
2	34.680	Mathan	Gfs	5	38.200	Mathan	Gfs
3	36.960	Mathan	Gfs	6	38.530	Mathan	Gfs

12. CONTAINER CONSUMPTION DETAILS:

S. No	Time		Container No.	Consumed by	S. No	Time		Container No.	Consumed by
	From	To				From	To		
1	10:30	11:10	01	Velu	4	14:16	15:30	Velu04	Velu
2	11:11	12:30	02	Velu	5	15:51	16:40	Velu05	Velu
3	12:05	14:15	03	Velu	6	16:41	18:50	Velu06	Velu

Checked By Packing (Sign. /Date): S. Velayutham 16/09/22 Verified by IPQA (Sign. /Date): G. S. 16/09/22

13. OVERPRINTING OF PRIMARY PACKAGING MATERIALS (Embossing):

Initial checks of Overprinting Details

Overprinting Details	Overprinted Text	Printed AL. Foil (OK/ not OK)
Code No.: PON/DRUGS/21 14 4376	Preprinted	ok
Batch No.:	G1822117	ok
Mfg. Date:	09/10/21	ok
Exp. Date:	08/20/25	ok
Item Code: 13/0442	Preprinted	ok
Initiated by	velumunagan	velumunagan
Checked by Packing (Sign. & Date)	G. S. 16/09/22	G. S. 16/09/22
Verified by IPQA (Sign. & Date)	G. S. 16/09/2022	G. S. 16/09/2022

13.1 SPECIMEN OF PRINTED FOIL:

S. No.	Date	Specimen No.	Done By Sign & Date	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01	16/09/2022	01	velu	G. S. 16/09/22	G. S. 16/09/22

14. PACKING INSTRUCTIONS:


1. Verify the status of dispensed primary packaging materials and transfer to the Primary Packing Area.
2. Issue the stereos to the concerned Technician and set as per SOP No. QAGN/030 and Record the details in respective table.
3. Set and operate Blister Packing Machine as per SOP No. PDOP/021 & PDOP/022.
4. Verify the status label of overprinted packaging materials and transfer to the packing line in secondary packing hall.
5. Perform Leak Test as per SOP No. QAGN/045 and enter the observations in respective table.
6. Perform Leak Test as per Table or during change of Printed foil rolls & plain film rolls and after every start of operation or when machine is stopped due to some break down.
7. Attach proof of printed foil from each roll dispensed as and when used on machine.
8. Overprinting Details on printed foil shall be checked by Packing and cross-checked by IPQA before starting the operation as per given in the respective Table.
9. Affix first overprinted Al. foil, Carton, Shipper and shipper label duly checked by Packing and verified by IPQA.
10. Pack 10 tablet per Blister.

Time record for packing detail

Sr. No.	Date/Shift	Primary packing		Secondary packing		Checked by (Packing) Sign. & Date
		Started at	Completed at	Started at	Completed at	
01	16/09/2022	10:30	18:50	10:42	19:00	G. S. 16/09/2022
			NA			

Prepared by:		Checked by:		Approved By:
Dept.	Production.	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Kan			
Date	06/04/2022	06/04/2022	06/04/2022	06/04/2022

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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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00 Customer:	Batch No.: <u>G18 22117</u> Generic Health Care Pvt. Ltd.

15. PACKING/IPQA IN-PROCESS CHECKS FOR PRIMARY PACKING:

In process checks frequency for packing and IPQA. (As per SOP No.: QAGN/024)

Stage	Packing	IPQA
Primary packing/Secondary Packing	At start of the batch, every one hour	At batch start, followed by every two-hour (random time) Minimum two In process checks by IPQA per batch.

16. BLISTER PACKING MACHINE PARAMETERS:

Date/Shift: 16/09/2022 Time: 10:32

Parameters	Standard and Limits	Observation	Checked by Packing Sign. / Date	Checked by IPQA Sign. / Date
Change Parts Details	19023060700	OK	<u>G</u> 16/09/22	<u>G</u> 16/09/2022
Sealing Temperature	(150-200°C) To be established	183°C	<u>G</u> 16/09/22	<u>G</u> 16/09/2022
Forming Temperature	(110-160°C) To be established	158°C	<u>G</u> 16/09/22	<u>G</u> 16/09/2022
Leak test to be performed on <u>12</u> Blister	Nil (No Blister should fail in leak test)	OK	<u>G</u> 16/09/22	<u>G</u> 16/09/2022
Machine Speed	To be established	36	<u>G</u> 16/09/22	<u>G</u> 16/09/2022

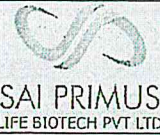
16.1 MACHINE IN-PROCESS CONTROL:

Date/ Shift	<u>16/09/2022</u>																
Machine Operator Name	<u>Velmurugan / Powerla</u>																
Time of inspection	10:33	10:41	10:48	10:54	11:05	11:27	12:16	13:25	13:35	14:32	15:38	15:47	16:45	17:52	17:55	18:45	
Sealing Temperature (To be established)	174°C	210°C	184°C	219°C	174°C	176°C	175°C	175°C	178°C	174°C	176°C	178°C	178°C	174°C	171°C	171°C	
Forming Temperature (To be established)	143°C	151°C	152°C	183°C	180°C	181°C	180°C	180°C	183°C	181°C	181°C	180°C	183°C	181°C	180°C	181°C	
Leak test on Blister* (Qty: <u>12</u>)	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Knurling / Sealing	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Pocket Formation	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Horizontal cutting	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Vertical cutting	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Quality of Over printing	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Code No.: PON/DRUGS/ 21 14 4376	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
B. No.: <u>G18 22117</u>	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Mfg. Date: <u>09/2022</u>	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Exp. Date: <u>08/2025</u>	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Machine Speed To be established	12	60	12	60	30	30	30	30	30	30	30	30	30	30	30	32	
Checked by (Packing)	NA	NA	NA	NA	<u>G</u>	NA	<u>G</u>	<u>G</u>	NA	<u>G</u>	<u>G</u>	NA	<u>G</u>	<u>G</u>	NA	<u>G</u>	
Checked by (IPQA)	<u>G</u>	<u>G</u>	<u>G</u>	<u>G</u>	NA	<u>G</u>	NA	NA	<u>G</u>	NA	NA	<u>G</u>	NA	NA	<u>G</u>	NA	

Note: * If leak test fails perform every 15 minutes for next one hour and all the shippers to be checked for leak test from the last successful leak test. All the shippers packed from the time of last successful leak test shall be segregated and random checked by IPQA and to be released after approval from QA.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>M</u>	<u>JS</u>	<u>V P</u>
Date	<u>06/04/2022</u>	<u>06/09/2022</u>	<u>06/09/2022</u>	<u>06/09/2022</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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product BONCIPRO 500	BPR. No.: BPR/T/305-00 Customer:		Batch No.: G1822117 Generic Health Care Pvt. Ltd.

16.2 MACHINE IN-PROCESS CONTROL:

Date/ Shift	
Machine Operator Name	
Time of inspection	
Sealing Temperature (To be established)	
Forming Temperature (To be established)	
Leak test on Blister* (Qty.:)	
Knurling /Sealing	
Pocket Formation	
Horizontal cutting	
Vertical cutting	
Quality of Over printing	
Code No.: PON/DRUGS/ 21 14 4376	
B. No.:	
Mfg. Date	
Exp. Date	
Machine Speed To be established	
Checked by (Packing)	
Checked by (IPQA)	

Note: * If leak test fails perform every 15 minutes for next one hour and all the shippers to be checked for leak test from the last successful leak test. All the shippers packed from the time of last successful leak test shall be segregated and random checked by IPQA and to be released after approval from QA.


16.3 DEFOILING OF BLISTERS:

Date	De-foiling started at	De-foiling completed at	Weight of De-foiled tablets	De-foiling Done by	Checked by/ Date (Packing)	Verified by Date (QA)
16/09/22	17:05	17:30	0.840	Deviya, Manju	S. Vey	G. S. 16/09/22
Total Weight of De-foiled Tablets			0.840	Checked By / Date (Packing): S. Vey	Verified By / Date (IPQA): G. S. 16/09/22	

16.4 INSPECTION OF DE-FOILED TABLETS:

Date	Inspection started at	Inspection completed at	Inspection Done by	Quantity of Good tablets		Qty. of Rejected Tablets		Checked by/ Date (Packing)	Verified by Date (QA)
				Kgs	Nos	Kgs	Nos		
16/09/22	17:31	18:05	Deviya	0.760	1056	0.080	111	S. Vey	G. S. 16/09/22
Total				0.760	1056	0.080	111	S. Vey	
Total Quantity of Rejected Tablets Destroyed				Checked By / Date (Packing): S. Vey		Verified By / Date (IPQA): G. S. 16/09/22			
0.080 Kgs .111..... Nos.									
Prepared by:			Checked by:			Approved By:			
Dept.	Production		Production		Quality Assurance		Head Quality Assurance		
Sign.	L. G								
Date	06/04/2022		06/04/2022						

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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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00 Customer:	Batch No.: G18 22 117 Generic Health Care Pvt. Ltd.

17. **LINE CLEARANCE CHECKS – BATCH CODING:**

Date/ Shift

Previous Product:		Batch No.:				
Sr. No.	Checks	Time	Observation			
			Packing	IPQA	Packing	IPQA
1	Check and ensure that the area is visually clean and free from previous product. Check and ensure that waste bin is emptied out and cleaned					
2	Check the Pallets area clean and free from any leftovers of previous product /Batch.					
3	Check and ensure the rejected Carton of previous product/batch are removed.					
4	Check and ensure the environmental condition, formats, labels and log book.					
5	Check and ensure the previous batch details are deleted from the inkjet machine.					
6	Check and ensure that correct secondary packing material is dispensed					
7	Check and ensure the Correct status board is written.					

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

Cleaning Satisfactory / Not satisfactory# (Packing) Sign. /Date:	Cleaning Satisfactory / Not satisfactory# (IPQA) Sign. /Date:
Remarks: # In case the cleaning is not satisfactory / line is not certified then investigate the cause of the failure and take necessary action, re check the area / line and record.	


17.1 AREA AND EQUIPMENT CLEARANCE FOR CODING:

1. Check and ensure that the over printing area and machine is cleared from previous products.
2. Transfer uncoded printed Carton to Overprinting area.
3. Set and operate Overprinting Machine.
4. Overprinting shall be in indelible ink.
5. Overprinting Details shall be checked by Packing and cross-checked by QA before starting the operation.

Equipment	Inkjet Machine	Conveyor	Area
ID. No.:			Batch Coding
Previous Product:			
Batch No.:			
Cleaned by:			
Checked by Packing:			
Verified by IPQA:			

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. Ka</i>	<i>M</i>	<i>SC</i>	<i>VP</i>
Date	06/04/2022	06/04/2022	06/04/2022	06/04/2022

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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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPRT/305-00 Customer:	Batch No.: <u>G18 22 117</u> Generic Health Care Pvt. Ltd.

17.2 OVERPRINTING DETAILS:

Overprinting Details	Overprinted Text	Carton (OK/ Not OK)
Batch No.:		
Mfg. Date:		
Exp. Date:		
Item Code: 15/0724		
Code No.: PON/DRUGS/21 144376		
Initiated by Sign. & Date		
Checked by Packing Sign. & Date		
Verified by IPQA Sign. & Date		

17.3 TIME RECORD FOR BATCH CODING:

Sr. No.	Date/Shift	Batch Coding Done By	Batch Coding		Checked by (Packing) Sign. & Date	Verified by (IPQA) Sign. & Date
			Started at	Completed at		


17.4 CARTON OVERPRINTING SPECIMEN:

S. No.	Date	Carton Specimen No.	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)

Note – Attach specimen copy of over printed carton

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>1. Ka</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>06/04/2022</u>	<u>06/04/2022</u>	<u>06/04/2022</u>	<u>06/04/2022</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 14 of 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00 Customer:	Batch No.: G18 22117 Generic Health Care Pvt. Ltd.

18. LINE CLEARANCE CHECKS - SECONDARY PACKING:

Date/ Shift: **16/09/2022 09:30** /

Previous Product: Bonchip 500		Batch No.: 418 22117				
Sr. No.	Checks	Time	Observation			
			08:30			
			Packing	IPQA	Packing	IPQA
1	Check and ensure that the area is visually clean and free from previous product. Check and ensure that waste bin is emptied out and cleaned		✓	✓		
2	Check the Pallets area clean and free from any leftovers of previous product /Batch.		✓	✓		
3	Check and ensure the rejected blisters, rejected Carton, Shipper and shipper label of previous product/batch are removed.		✓	✓		
4	Check and ensure the environmental condition, formats, labels and log book.		✓	✓		
5	Check and ensure that correct secondary packing material is dispensed		✓	✓		
6	Check and ensure the Correct status board is written.		✓	✓		

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

Cleaning Satisfactory / Not satisfactory# **16/09/2022** Cleaning Satisfactory / Not-satisfactory#
 (Packing) Sign. /Date: **16/09/2022** (IPQA) Sign. /Date: **16/09/2022**

Remarks: # In case the cleaning is not satisfactory / line is not certified then investigate the cause of the failure and take necessary action, re check the area / line and record.

Equipment	Packing Conveyor	Weighing Balance (Carton)	Shrink Sleeve	Strapping	Weighing Balance (shipper)	Area
ID. No.:	10/COB/002	10/BAC/0	10/KSM/001	10/STR/001	10/BAU/028	Secondary Packing Hall
Previous Product:	Boncipro 500					
Batch No.:	G18 22117					
Cleaned by:	Geetha					
Checked by Packing:	16/09/2022					
Verified by IPQA:	16/09/2022					

18.1 ENVIRONMENTAL CONDITIONS:

(Check the environmental conditions of Secondary packing area at the start of process and Record in the below in table)

Shift:..... G		Date/Time: 16/09/2022 09:32			Date/Time:		
		Observation	Checked by Packing	Verified by IPQA	Observation	Checked by Packing	Verified by IPQA
Refer to SOP No.:	Temperature °C	22°C	16/09/2022	16/09/2022		NA	
SOP: QAGN/011	Limit: NMT 25°C						

Secondary Packing Started Date/Time: **16/09/2022 12:42** Completed Date/Time: **16/09/2022 19:00**


APPROVAL FOR SECONDARY PACKING: Approved by IPQA Sing/Date: **16/09/2022**

18.2 PACKING DETAILS:

10 Tablets in each Blister, over code the Blister with the batch details given below,
Place 2 x 10's Blister and one leaflet in each carton.
Place 18 filled carton in a Shrink Sleeve.
Place 16 Shrink sleeves in each 5 ply shipper.
Seal the shipper with BOPP tape with "H" type.

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka	16/09/2022	16/09/2022	16/09/2022	
Date	06/04/2022	06/04/2022	06/04/2022	06/04/2022	

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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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00 Customer:	Batch No.: G1822117 Generic Health Care Pvt. Ltd.

19. OVER PRINTING DETAILS:

Overprinting Details (Secondary & Tertiary PM)

Overprinting Details	Overprinted Text	Carton (OK/ Not OK)	Insert	5 Ply Shipper Label (OK/ Not OK)
Batch No.:	G1822117	OK	NA	OK
Mfg. Date:	09/2022	OK	NA	OK
Exp. Date:	08/2025	OK	NA	OK
Code No.: PON/DRUGS/21 14 4376	PON/DRUGS/21144376	OK	NA	NA
Item Code : 16/0437 (Insert)	NA	NA	16/0437	NA
Item Code: 15/0724 (Carton)	NA	15/0724	NA	NA
Pack size:	NA	1 x 10's	NA	16 x 18 x 2 x 10's
Initiated by Sign. & Date	NA	NA	NA	Ravi
Checked by Packing Sign. & Date	S. Vengal 16/09/22	S. Vengal 16/09/22	S. Vengal 16/09/22	S. Vengal 16/09/22
Verified by IPQA Sign. & Date	G. S. 16/09/22	G. S. 16/09/22	G. S. 16/09/22	G. S. 16/09/22

19.1 Shipper Label Specimen:

S. No.	Date	Shipper Label Specimen No.	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01.	16/09/2022	01	S. Vengal 16/09/2022	G. S. 16/09/2022

20. CARTON WEIGHT LIMIT SETTING: Date/Shift: 16/09/2022 Time: 10:50.

Weight of ten individual empty cartons are given below:

1. 6.3	3. 6.2	5. 6.3	7. 6.3	9. 6.3
2. 6.3	4. 6.3	6. 6.2	8. 6.3	10. 6.2

Total weight of ten empty cartons = 62.7

Average weight of an empty carton (A) = Total weight of ten empty carton / 10 = 6.27

Weight of ten individual Blister are given below:

1. 8.9	3. 9.0	5. 9.0	7. 8.9	9. 9.0
2. 9.0	4. 8.9	6. 9.0	8. 9.0	10. 8.9

Total weight of ten Blister = 89.6

Avg. Weight of a Blister (B): total weight of ten Blister / 10 = 8.96

Weight of ten individual Leaflets are given below:

1. 2.8	3. 2.8	5. 2.8	7. 2.8	9. 2.7
2. 2.8	4. 2.7	6. 2.8	8. 2.8	10. 2.8

Total weight of ten Leaflets = 27.8

Avg. Weight of a Leaflet (C): total weight of ten Leaflets / 10 = 2.78

20.1 WEIGHT CHECKS ON CARTON:

Weight of ten empty Carton:	62.7	Average weight of one empty Carton (A):	6.27
Weight of ten filled Blister:	89.6	Average weight of one filled Blister (B):	8.96
Weight of ten Leaflets:	27.8	Average weight of one Leaflet (C):	2.78
Weight of one filled Carton D = (A + 2B + C)	26.9	Limit: E = D ± 1 % =	(To be established)
Checked by Packing/Date: S. Vengal 16/09/2022		Verified by IPQA/Date: G. S. 16/09/2022	26.7 - 27.1

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head. Quality Assurance
Sign.	L. K.			
Date	06/04/2022	06/04/2022		

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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 PACKING RECORD

Product Code: B05

Batch Size: 3,00,000 Tablets

Product

BONCIPRO 500

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

Batch No.: G18 22117

Customer:

Generic Health Care Pvt. Ltd.

20.2 SAMPLE DRAWN RECORD:

Sr. No.	Stage of Sample collection	Qty. of Sample	Collected by (Sign. /Date)
1	Control Sample (Initial)	7x10's	G/S 16/09/22
2	Control Sample (Middle)	7x10's	G/S 16/09/22
3	Control Sample (Final)	6x10's	G/S 16/09/22
4	Stability Sample	100x10's	G/S 16/09/22
5	Other Sample	- NA -	- NA -
6	Analytical sample	12x10's	G/S 16/09/22
Total Qty.		132x10's	G/S 16/09/22

21. SECONDARY PACKING IN-PROCESS CHECKS: (Please keep ✓ mark if found "Ok")

Date/ Shift		16/09/2022 G1							16/09/2022/G1						
Parameters	Specification	Packing							IPQA						
		observation													
Time		10:55	12:02	13:10	14:20	15:15	16:25	17:30	11:05	13:09	15:14	17:21			
No. of Blister in a carton	2 Blister with 10 tabs and one leaflet.	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK			
Carton Overprinting	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK			
No. of cartons in a shrink sleeves	18 packed cartons	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA			
Shrink wrapping temperature*		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA			
No. of shrink sleeves in a 5 ply shipper	16 shrink sleeves	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA			
Shipper strapping	Proper strapping	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA			
Label appearance and Shipper appearance	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK			
Sealing of the shipper with BOPP Tape	H type	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA			
Checked by		OK	OK	OK	OK	OK	OK	OK	G/S	G/S	G/S	G/S			

*Temperature to be mentioned.

21.1 SECONDARY PACKING IN-PROCESS CHECKS: (Please keep ✓ mark if found "Ok")

Date/ Shift	16/09/2022 G1					(Please keep ✓ mark in round OK)							
Parameters	Specification	observation											
		Packing						IPQA					
Time		18:42											
No. of Blister in a carton	2 Blister with 10 tabs and one leaflet.	ok											
Carton Overprinting	Legible and readable	ok											
No. of cartons in a shrink sleeves	18 packed cartons	NA											
Shrink wrapping temperature*		NA											
No. of shrink sleeves in a 5 ply shipper	16 shrink sleeves	NA											
Shipper strapping	Proper strapping	NA											

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ke				
Date	06/04/2022	06/04/2022	06/04/2022	06/04/2022	

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

Batch Size: 3,00,000 Tablets




Batch No.: G18 22117

Generic Health Care Pvt. Ltd.

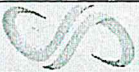
*Temperature to be mentioned.

*Temperature to be mentioned.

*Temperature to be mentioned.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka			
Date	06/04/2022	06/04/2022	06/04/2022	06/04/2022

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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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500		BPR. No.: BPR/T/305-00 Batch No.: 31822117
			Customer: Generic Health Care Pvt. Ltd.

22. SHIPPERS WEIGHING:

Date/Shift: 16/09/2022.....Time: 11:00... Balance I.D. No.: PD(BA)1/041

Weight of ten Shrinks: 4960						Average weight of one filled Shrink (H): 496.0					
Weight of ten empty shippers: 16.25						Average weight of one empty shipper (I): 1.625					
Weight of one filled shipper (J) = (16 H+I): 8.961						Limit: K = J ± 1% = 8.871 - 9.050					
Checked by Packing/Date: S. Vey 16/09/2022						Verified by IPQA/Date: G. 16/09/2022					

Shipper No.	Gross weight (Kg)	Weighed By	Shipper No.	Gross weight (Kg)	Weighed By	Shipper No.	Gross weight (Kg)	Weighed By	Shipper No.	Gross weight (Kg)	Weighed By
1	9.030	lakshmi	15	8.980	lakshmi	29	9.040	lakshmi	43	9.035	Seranya
2	9.020	lakshmi	16	8.955	lakshmi	30	9.040	lakshmi	44	9.040	Seranya
3	9.010	lakshmi	17	8.970	lakshmi	31	9.030	lakshmi	45	9.050	Seranya
4	9.050	lakshmi	18	9.020	lakshmi	32	9.020	lakshmi	46	9.035	Seranya
5	9.010	lakshmi	19	9.035	lakshmi	33	9.025	lakshmi	47	9.035	Seranya
6	9.005	lakshmi	20	9.025	lakshmi	34	9.025	lakshmi	48	9.040	Seranya
7	9.020	lakshmi	21	9.025	lakshmi	35	9.025	lakshmi	49	9.035	Seranya
8	9.020	lakshmi	22	9.035	lakshmi	36	9.030	lakshmi	50	9.040	Seranya
9	9.010	lakshmi	23	9.030	lakshmi	37	9.025	lakshmi	51	9.530	Seranya
10	9.000	lakshmi	24	9.020	lakshmi	38	9.025	lakshmi	52		
11	9.005	lakshmi	25	9.035	lakshmi	39	9.020	lakshmi	53		
12	9.010	lakshmi	26	9.010	lakshmi	40	9.035	lakshmi	54		
13	9.000	lakshmi	27	9.010	lakshmi	41	9.050	lakshmi	55		
14	9.005	lakshmi	28	9.035	lakshmi	42	9.035	Seranya	56		

Total No. of shippers weighed: 51	De-foiled tablets packed in Shipper No: 51	Checked by Sign / Date: S. Vey 21/09/22	Verified by Sign / Date: G. 21/09/2022	Loose pack details: Shipper No: 51..... Quantity: 9. x 7 x 18 x 2 x 10 s Weight: 4.530...
-----------------------------------	--	---	--	--

Note - If any shipper weight found out of limit, the same shall be checked physically by opening the shipper.


23. MAN POWER ALLOCATION:

DATE: 16/09/22....		DATE: 16/09/22	
SHIFT: G.....		SHIFT: G. (Recheck)	

ACTIVITIES	DONE BY	ACTIVITIES	DONE BY
Blister Checking	Indhana, Janagi	Blister Checking	barathi, Gowdya
Printing Checking in Blister	Komathi, Anagala, Pankaj	Printing Checking in Blister	JayaRani, Sathya
Insertion of Blister and leaflet into carton	Devi, valli, kalpana	Insertion of Blister and leaflet into carton	Praba
Cartons weighing	Seranya	Cartons weighing	Keerthana
Insertion of carton into shrink sleeve	Gunasundharan, Pankaj	Insertion of carton into shrink sleeve	Vinitha
Insertion of shrink wrapped carton into shipper	lakshmi	Insertion of shrink wrapped carton into shipper	vidhya
Shipper Label Pasting	lakshmi	Shipper Label Pasting	vidhya
Shipper Weighing	lakshmi	Shipper Weighing	vidhya
Shipper Strapping	lakshmi	Shipper Strapping	vidhya
Shipper packed	From 01...to 51..	Shipper packed	From 01...to 51
Signature of Packing	Vey 16/09/22	Signature of Packing	Vey 16/09/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.			
Date	06/04/2022	06/04/2022	06/04/2022	06/04/2022

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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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00 Customer:	Batch No.: G18 22117 Generic Health Care Pvt. Ltd.

DATE:		DATE:	
SHIFT:		SHIFT:	
ACTIVITIES	DONE BY	ACTIVITIES	DONE BY
Blister Checking		Blister Checking	
Printing Checking in Blister		Printing Checking in Blister	
Insertion of Blister and leaflet into carton		Insertion of Blister and leaflet into carton	
Cartons weighing		Cartons weighing	
Insertion of carton into shrink sleeve		Insertion of carton into shrink sleeve	
Insertion of shrink wrapped carton into shipper		Insertion of shrink wrapped carton into shipper	
Shipper Label Pasting		Shipper Label Pasting	
Shipper Weighing		Shipper Weighing	
Shipper Strapping		Shipper Strapping	
Shipper packed	From.....to.....	Shipper packed	From.....to.....
Signature of Packing		Signature of Packing	

24. PACKING MATERIAL RECONCILIATION:


Sr. No.	Material	Printed Alu. Foil (Kg)	Clear PVC (Kg)	Cartons (Nos)	Leaflets (Nos)	Shrink Sleeves (Nos)	5 Ply Shipper (Nos)	Strapping Role (Mtrs.)	BOPP Tape (GHPL Printed) (Nos)
A	Quantity received for the batch	21.960	80.450	16000	15000	834	53	01	01
B	Additional material received for the batch	NA	NA	NA	NA	NA	NA	NA	NA
C	Total material received (A+B)	21.960	80.450	16000	15000	834	53	01	01
D	Quantity packed	10.500	55.200	14526	14526	807	51	01	01
E	Quantity rejected (Online) & Destroyed	1.020	2.222	1413	413	27	02	NA	NA
F	Quantity Returned	10.400	22.800	NA	NA	NA	NA	NA	NA
G	Sample affixed on BPR	0.0001	0.004	01	01	NA	NA	NA	NA
H	QC samples	0.003	0.020	NA	NA	NA	NA	NA	NA
I	Other samples (If any)	0.036	0.204	60	60	NA	NA	NA	NA
J	Total accountable Quantity (D+ E+F+G+H+I)	21.960	80.450	16000	15000	834	53	01	01
K	Variation (C - J)	NA	NA	NA	NA	NA	NA	NA	NA
L	%Variation (K x 100)/C	NA	NA	NA	NA	NA	NA	NA	NA
M	Acceptable limit	± 2 %	± 2 %	± 2 %	± 2 %	± 2 %			

If % Variation is out of the acceptable limit, investigate & specify the reason:

NA

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka				
Date	06/04/2022	06/04/2022	06/04/2022	06/04/2022	

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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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500		BPR. No.: BPR/T/305-00 Batch No.: G1822117
	Customer:		Generic Health Care Pvt. Ltd.

25. EXCESS PACKING MATERIAL RETURN TO STORE: MRN NO. 00268

Material	Printed Alu. Foil (Kg)	Clear PVC (Kg)	Cartons (Nos)	Leaflets (Nos)	Shrink Sleeves (Nos)	5 Ply Shipper (Nos)	Strapping Role (Mtrs.)	BOPP Tape (GHPL Printed) (Nos)
Quantity Returned	10.400	22.800						
Material returned by packing Sign./Date	S. Vey 17/09/22	S. Vey 17/09/22						
Verified By IPQA Sign./Date	GJS 17/09/22	GJS 17/09/22						
Material received by Store Sign./Date	S. Vey 17/09/22	S. Vey 17/09/22						

26. DESTRUCTION OF REJECTED/UNUSED PRINTED PACKING MATERIALS AND STEREOS:

Date	Stereos	Printed Alu. Foil (Kg)	Clear PVC (Kg)	Cartons (Nos)	Leaflets (Nos)	Shrink Sleeves (Nos)	5 Ply Shipper (Nos)	Strapping Role (Mtrs.)	BOPP Tape (GHPL Printed) (Nos)
17/09/22	NA	1.020	2.222	1413	413	27	02	NA	NA
Total Qty. Destroyed	NA	1.020	2.222	1413	413	27	02	NA	NA
Destroyed by (Packing)	Dany				Verified by (IPQA)	GJS			

27. BATCH RECONCILIATION:

A	Batch Size	3,00,000 Nos.
B	Quantity received for packing	292000
C	Total quantity packed	290520
D	Control samples	200
E	Analytical Samples	120
F	In process samples	1920
G	Others samples if any (Stability, Regulatory Samples, etc.)	1000
H	Packing Loss = B - (C + D + E + F + G)	1758
I	Total Loss = A - (C + D + E + F + G)	6240
J	Packing yield % (C + D + E + F + G) / B X 100 (Yield Limit %.....)*	100.60%
K	Batch Yield % (C + D + E + F + G) / A X 100 (Yield Limit %.....)*	97.92%

*To be established

Checked by Packing /Date: Dany


Verified by IPQA/Date: GJS 17/09/22

28. TRANSFER OF FINISHED GOODS:

Date	FGTN No.	Sales	Pack Size	No. of Units in a shipper	No. of Shippers	Transferred Quantity	FGTN Raised by Packing	FGTN Checked by IPQA	FGTN Received by Stores
21/09/2022	00314	3-0L	2 x 10's	16 x 1200 x 10's	50	288000	S. Vey	GJS	Rm
				07 x 1200 x 10's	01	2520	S. Vey	GJS	Rm
Total Qty. Transferred						290520	S. Vey	GJS	Rm

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka			
Date	06/04/2022	06/04/2022	06/04/22	06/04/2022

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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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00 Customer:	Batch No.: <u>G118 22117</u> Generic Health Care Pvt. Ltd.

29. DEVIATION/ EXCEPTION DETAILS:

During process if there is any Deviation / Exception are observed then record in below table

Deviation / Exception details

Sr. No.	Stage	Deviation / Exception details	Action taken	Observed By

Checked by
Packing:

Verified by
Packing manager:

Approved by
Head QA:

30. BPR REVIEW DETAILS:

Reviewed by	Name	Sign. /Date
Packing Executive	<u>CH</u> SUCHANYA NANCY RANI. D	<u>Nancy</u> 21/04/2022
QA Executive	G. SENTHIL KUMARAN	<u>G. Senthil Kumaran</u> 21/04/2022
Production Assistant Manager/ HOD	S. SIVAKUMAR	<u>S. Sivakumar</u> 21/04/2022
QA Manager/ HOD	Ram Kumar	<u>CH</u> <u>Ram Kumar</u> 21/04/2022

31. BATCH RELEASED FOR DESPATCH:

Total quantity released: 290520 No's

Head QA sign/ Date: CH Ram Kumar 21/04/2022

32. REVISION HISTORY:

S. No.	Document No.	Reason for Changes	Supersedes Doc. No.
1	BPR/T/305-00	New Document	Nil

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ke</u>	<u>CH</u>	<u>CH</u>	<u>V. P.</u>
Date	<u>06/04/2022</u>	<u>06/04/2022</u>	<u>06/04/2022</u>	<u>06/04/2022</u>

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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 21
SAI PRIMUS LIFE BIOTECH PVT LTD	BATCH PACKING RECORD	Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00 Batch No.: <u>G18 22 116</u> Customer: Generic Health Care Pvt. Ltd.

BATCH PACKAGING 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.
CODE NO.	: PON/DRUGS/21 14 4376
DOSAGE FORM	: Tablet
BPR No.	: BPR/T/305-00
REVISION No.	: 00
SUPERSEDE No	: NIL
EFFECTIVE BATCH. No. /DATE	: <u>G18 22068 / 06/04/2022</u>
MARKET	: Export
SHELF LIFE	: 36 Months
BATCH SIZE	: 3,00,000 Tablets
PACKING CONFIGURATION	: 2 x 10's Tablets Pack (Blister Packing)
BPR ISSUED BY/DATE (QA)	: <u>05/09/2022</u>
BPR CHECKED & RECEIVED BY/DATE (PRODUCTION)	: <u>13/09/2022</u>
MFG. DATE: <u>09/2022</u>	EXP. DATE: <u>08/2025</u>
ALLOTTED BY: QA SIGN/DATE: <u>05/09/2022</u>	COUNTER CHECKED BY: QA SIGN/DATE: <u>03/09/2022</u>
QUANTITY RECEIVED FROM PRODUCTION	: <u>291989 Nos</u>
DATE OF COMMENCEMENT: <u>14/09/2022</u>	DATE OF COMPLETION: <u>15/09/2022</u>
QUANTITY	: <u>3,00,000 Nos</u>
RELEASED QUANTITY OF PACKED TABLETS	: <u>288000 Nos</u>
RELEASE OF BATCH BY HEAD QA SIGN/DATE:	: <u>21/09/22</u>
This BPR contains 21 Pages + <u>05</u> Additional Pages	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K.</u>	<u>M.</u>	<u>K.</u>	<u>V. P.</u>
Date	<u>06/04/2022</u>	<u>06/04/2022</u>	<u>06/04/2022</u>	<u>06/04/2022</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 2 of 21
	BATCH PACKING RECORD	Product Code: B05	Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00	Batch No.: G18 22116
		Customer:	Generic Health Care Pvt. Ltd.

1. INDEX

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3	Packing Material Specification and Indent	4
4	Dispensing line clearance	5
5	Dispensing record of packing materials	6
6	Line clearance for primary packing	7
7	Verification of dispensed packing material	8
8	Receipt of product and materials, Detail of the product as per BMR	8
9	Weight verification record of received semi-finished product	8
10	Container weight details, Container consumption details, Overprinting of Primary Packaging Material (Embossing), specimen of printed foil	9
11	Packing instruction, time record for packing detail, Packing In-process checks for primary packing	9-10
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14	Line Clearance for Batch Coding, Area and equipment clearance for coding, Overprinting Details, Time record for batch coding, Carton overprinting specimen	12-13
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23	Destruction of rejected/unused printed packing materials and stereotypes	20
24	Batch reconciliation	20
25	Transfer of finished goods	20
26	Deviation Detail	21
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Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	M	BB	V. A
Date	06/04/2022	06/04/2022	06/04/2022	06/04/2022

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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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product BONCIPRO 500	BPR. No.: BPR/T/305-00		Batch No.: <u>G18 22116</u>
	Customer:		Generic Health Care Pvt. Ltd.

2. CHECKLIST FOR BATCH PACKING RECORD REVIEW:

Instruction:

Check the following points before submitting the documents for final Review

Sr. No.	Checklist	Observation (Yes/No/NA/No.*)
1.	No. of pages of BPR+ Additional pages (If any) *	- NA -
2.	Line clearance and environmental record	YES
3.	Processing activity done by and checked by is signed	YES
4.	Dispensing	
a)	Equipment clean tag and dispensing tag attached with batch record	YES
b)	Packaging material is checked	YES
5.	Packing	
a)	Rinse water analysis report attached with BPR	YES
b)	Approved specimen of printed foil, carton and shipper label are attached	YES
c)	Control / Stability / Finished product analysis samples are withdrawn	YES
d)	Reconciliation of packing materials is done	YES
e)	Tablet reconciliation is done	YES
f)	In process checks parameters done at regular interval and recorded into BPR	YES
6.	Attachment	
a)	Finished Goods Transfer Note	YES
b)	Certificate of analysis of finished product is submitted	YES
c)	Stereo Impression Format	NA
7.	Complete set of BPR Submitted	YES


Checked By QA/Date: G/S 21/04/2022

*Mention total number of pages.

Remarks (If any) NA

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>N</u>	<u>JS</u>	<u>V</u>
Date	<u>06/04/2022</u>	<u>06/04/2022</u>	<u>06/04/22</u>	<u>06/04/2022</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 4 of 21
	BATCH PACKING RECORD	Product Code: B05
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00
		Customer:
		Batch Size: 3,00,000 Tablets
		Batch No.: G1822116
		Generic Health Care Pvt. Ltd.

3. PACKING MATERIAL SPECIFICATION AND INDENT:

Sr. No.	Material	Item Code	Specification	UOM	Standard Qty. for Batch Size 3.0 Lac.
1	178mm Boncipro 500 Printed foil 0.025mm	PPF/SP/B009	Width – 178 ± 1 mm Thickness – 0.025 mm Language – French Color – 1 Color Item Code: 13/0442	Kg	14.100
2	182mm PVC Base Foil	PBF/SP/B037	Width – 182 ± 1 mm	Kg	64.500
3	2X10's Boncipro 500mg Pkt Carton	PPC/SP/B004	Size – 90 x 60 x 20 mm (L x W x H) Board – 300 gsm ITC cyber XL board Colour – 4 colours Item Code: 15/0724	No	15000
4	Boncipro Leaflet	PPL/SP/L015	Size – 210 x 230 mm (L x H) NLT 60 GSM Maplitho Paper Colour – 2 colour Item Code: 16/0437	No	15000
5	Shrink Sleeve	PPS/SP/P001	Plain PVC Shrink Sleeves	No	834
6	5 Ply 390X390X265 mm GHPL Printed Shipper	PUS/SP/G018	A 5 Ply flute vertical corrugated inner unprinted in nature. (24 B.F.) Outer Size – 390 x 390 x 265 mm (L x W x H) Bursting Strength – NLT 15.00 Kg/cm ²	No	53
7	3' GHPL Printed Bopp Tape	PPB/SP/B002	Clear Transparent Length of roll – 65m Width – 60 mm Printing – GHPL repeats in Blue	No	1
8	3' Plain BOPP Tape	PUB/SP/B001	Plain BOPP Tape	No.	1
9	Strapping role.	PPR/SP/S001	White or milky white colour. Width – 12 mm Thickness – 0.6 mm	Mtrs	500

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	M	88	V P
Date	06/04/2022	06/04/2022	06/04/2022	06/04/2022

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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 21.
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00 Customer:	Batch No.: G118 22 116 Generic Health Care Pvt. Ltd.

4. DISPENSING LINE CLEARANCE CHECKS

Date: 13/09/2022 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 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 Mobile Laminar Air Flow is clean	✓	✓
7	Check all the gauges of Mobile Laminar Air flow 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	Mobile Laminar Air Flow	Weighing Balance		Area
ID No.	ST/LAF/001	ST/BAL/011	- NA -	- NA -
Previous Product	PRIFEN.			
B. No.	P112202.I.			
Cleaned by Sign/Date	Saran 13/09/2022			
Checked by Store Sign/Date	S41- 13/09/2022			
Verified by IPQA Sign/Date	G 13/09/2022			

ENVIRONMENTAL CONDITIONS: Date: 13/09/2022 Time: 15:05	Observation	Checked by Store Sign/Date	Verified by IPQA Sign/Date
(For Reference SOP No.: QAGN/011)			
Temperature (Limit: NMT 25°C)	23°C	S41 13/09/22	G 13/09/22
Differential Pressure across the booth Limit: 5 to 20 mm Water	14mm	S41 13/09/22	G 13/09/22

APPROVAL FOR DISPENSING BY IPQA: Sign: G Date: 13/09/2022	
Dispensing start Time 15:10 End Time 15:20	




Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K	H	V	V
Date	06/04/2022	06/04/2022	06/04/2022	06/04/2022

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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 21
	BATCH PACKING RECORD	Product Code: B05	Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00	Batch No.: G1822116
		Customer:	Generic Health Care Pvt. Ltd.

5. DISPENSING RECORD OF PACKING MATERIALS: Date: 13/09/2022 Shift: G Time: 15:10

Material Name	Item code	UOM	Req. Qty. for 3.0 Lac	Issued Qty.	A.R No.	No. of Roll/Box	Issued and Checked by Store	Verified by IPQA
178mm Boncipro 500 Printed foil 0.025mm	PPF/SP/B009	Kg	14.100	12.630 10.180	PmG/01541 PmG/00550	01 01	Py 13/09/22	G 13/09/2022
182mm PVC Base Foil	PBF/SP/B037	Kg	64.500	66.070	PmG/00559	03	Py 13/09/22	G 13/09/2022
2X10's Boncipro 500mg Prt Carton	PPC/SP/B004	No	15000	15886	PmG/00580	07	Py 13/09/22	G 13/09/2022
Boncipro Leaflet	PPL/SP/L015	No	15000	1100	PmG/01566	01	Py 13/09/22	G 13/09/2022
				13900	PmG/00585	02	Py 13/09/22	G 13/09/2022
Shrink Sleeve	PPS/SP/P001	No	834	834	PmG/00895	01	Py 13/09/22	G 13/09/2022
5 Ply 390X390X265 mm GHPL Printed Shipper	PUS/SP/G018	No	53	53	PmG/01545	06	Py 13/09/22	G 13/09/2022
3' GHPL Printed Bopp Tape	PPB/SP/B002	No	1	01	PmG/00310	01	Py 13/09/22	G 13/09/2022
3' Plain BOPP Tape	PUB/SP/B001	No	1	01	PmG/00505	01	Py 13/09/22	G 12/09/2022
Strapping role.	PPR/SP/S001	Mtrs	500	01	PmG/00945	01	Py 13/09/22	G 13/09/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka			
Date	06/04/2022	06/04/2022	05/04/22	06/04/2022

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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 7 of 21
	BATCH PACKING RECORD	Product Code: B05	Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00	Batch No.: G1822116
		Customer:	Generic Health Care Pvt. Ltd.

6. LINE CLEARANCE CHECKS:

6.1 PRIMARY PACKING:

Date/ Shift: 14/09/22 / G1 19:25 / 15/09/22 / M1

Previous Product: TAMVIR 45		Batch No.: T2622011				
Sr. No.	Checks	Time	Observation			
			19:30		09:15	
			Packing	IPQA	Packing	IPQA
1.	Area status board is updated for "CLEANED" status.		✓	✓	✓	✓
2.	Check and ensure that the area is visually clean and free from previous product		✓	✓	✓	✓
3.	Check and ensure the differential pressure of the area is within specified limit		✓	✓	✓	✓
4.	Check and ensure that waste bin is emptied out and cleaned		✓	✓	✓	✓
5.	Check the temperature and relative humidity of the area within specified limit		✓	✓	✓	✓
6.	Check the tablets of the previous product/ batch removed.		✓	✓	✓	✓
7.	Check the loose Blister cutting, rejected rolls, empty cores of foil of previous product /batch are removed.		✓	✓	✓	✓
8.	Check the surroundings of the machine and free from the previous products and batch		✓	✓	✓	✓
9.	Check the foil printing stereos, Labels of previous product/batch are removed.		✓	✓	✓	✓
10.	Check that the daily records (log book, balance, temp. & RH) are updated and signed.		✓	✓	✓	✓
11.	Check and ensure the Cleanliness following change part of Blister packing machine		✓	✓	✓	✓
12.	Check for the absence of previous batch/ product at machine conveyor belt.					
a)	Check Hopper from Top, bottom of machine, below the hopper, between bottom side of conveyor belt and collating unit.		✓	✓	✓	✓
b)	Check for cleaning of hopper, feeding channel, vibrator plate, in feed roller and sweep brush.		✓	✓	✓	✓
c)	Check tool box, thinner and ink box		✓	✓	✓	✓

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

Cleaning satisfactory/Not satisfactory

Checked by Packing (Sign./Date): S. J. 14/09/22

Cleaning satisfactory/Not satisfactory

Verified by IPQA (Sign./Date): G. 14/09/22

#In case the cleaning is not satisfactory / line is not certified then investigate the cause of the failure and take necessary action, recheck the area / line and record.

6.2 AREA AND EQUIPMENT CLEARANCE OF PRIMARY PACKING

Previous Product: TAMVIR 45				Batch No.: T262201T			
S. No.	Equipment / Area Name	Eq.ID. /Area. No.	Cleaning Type A/B	Operation and cleaning as per SOP number	Cleaned by Sign/Date	Checked by (Packing) Sign/Date	Verified by (IPQA) Sign/Date
1.	Blister Packing Area	SP2/AFB/BLP/001	B	PDGN/006	VEL	S. J. 14/09/22	G. 14/09/22
2.	Blister Packing Machine	PD/BLP/001	B	PDOP/021, PDCL/021 PDOP/022, PDCL/022	VEL	S. J. 14/09/22	G. 14/09/22


6.3 ENVIRONMENTAL CONDITIONS:

(Check the environmental conditions of primary packing area at the start of process and Record in the below in table)

Refer to SOP No.: SOP: QAGN/011	Date: 14/09/22... Time: 19:30			Date: 15/09/22... Time: 09:15		
	Observation	Packing Sign/Date	Verified by IPQA Sign/Date	Observation	Packing Sign/Date	Verified by IPQA Sign/Date
Temp °C Limit: NMT 25°C	23°C	S. J. 14/09/22	G. 14/09/22	23°C	S. J. 15/09/22	G. 15/09/22
RH % Limit: NMT 60%	58%	S. J. 14/09/22	G. 14/09/22	58%	S. J. 15/09/22	G. 15/09/22
DP Limit: NLT 10 Pascal	10 PASCAL	S. J. 14/09/22	G. 14/09/22	10 PASCALS	S. J. 15/09/22	G. 15/09/22
Primary Packing Started Date/Time: 14/09/22 20:05 Completed Date/Time: 15/09/22 18:15						
APPROVAL FOR PRIMARY PACKING: IPQA Sign./Date: S. J. 14/09/22						

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka	M	KS	VC	
Date	06/04/2022	06/04/2022	06/04/22	06/04/2022	

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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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500		BPR. No.: BPR/T/305-00 Batch No.: G1822116 Customer: Generic Health Care Pvt. Ltd.

7. VERIFICATION OF DISPENSED PACKING MATERIALS: Date: 14/09/22 Shift: G Time: 19:32

Material Name	Item code	UOM	AR No.	Number of Rolls/Packs	Checked by Packing	Verified by QA
178mm Boncipro 500 Printed foil 0.025mm	PPF/SP/B009	Kg	PmG101541 PmG100550	01 01	S. /	G18
182mm PVC Base Foil	PBF/SP/B037	Kg	PmG100559	03	S. /	G18
2X10's Boncipro 500mg Prt Carton	PPC/SP/B004	No	PmG100580	07	S. /	G18
Boncipro Leaflet	PPL/SP/L015	No	PmG101566 PmG100585	01 02	S. /	G18
Shrink Sleeve	PPS/SP/P001	No	PmG100895	01	S. /	G18
5 Ply 390X390X265 mm GHPL Printed Shipper	PUS/SP/G018	No	PmG101545	06	S. /	G18
3' GHPL Printed Bopp Tape	PPB/SP/B002	No	PmG100310	01	S. /	G18
3' Plain BOPP Tape	PUB/SP/B001	No	PmG100505	01	S. /	G18
Strapping role.	PPR/SP/S001	Mtrs	PmG100945	01	S. /	G18

8. RECEIPT OF PRODUCT AND MATERIALS: Date/Shift: 14/09/22 / G Time: 19:35

(Check the following before start of packing activity and record the observation.)

S. No.	Check Points	Observation	Done by (Packing)	Verified By (IPQA)
1.	Temperature observed on display (Limit: NMT 25°C)	23°C	S. /	G18
2.	Relative Humidity observed on display (Limit: NMT 60%)	58%	S. /	G18
3.	Bulk product containers are of the required product/Batch number and is approved by QC	YES	S. /	G18
4.	Status label of machine/ line is for same product	YES	S. /	G18
5.	Printed foil/Base rolls are of the required product.	YES	S. /	G18
6.	All secondary packing materials are of the required product	YES	S. /	G18

9. DETAIL OF THE PRODUCT AS PER BMR:

Sr. No.	Description	Observations	Checked By (Packing)	Verified By (IPQA)
1.	Average Weight	734.00	S. /	G18
2.	Colour of Tablet	PINK	S. /	G18
3.	Quantity (Net Qty.in Kg)	214.320	S. /	G18
4.	Number of Containers	07	S. /	G18

10. WEIGHT VERIFICATION RECORD OF RECEIVED SEMI-FINISHED PRODUCT:

Balance I.D. No.: PP/BAC/030


1. Verify the semi-finished Tablets before starting the packing operation.

2. _____ is affixed over the Containers against the respective BMR

Product Name	Batch No.	Mfg. Date	Exp. Date	Qty. recd. For packing	No. of Containers taken for packing
BONCIPRO-500	G1822116	09/2022	08/2025	214.320 Kg Equivalent to 291989 Nos.	From Container No. 01 To Container No. 07 Total No. of Containers taken 07
Checked by Packing (Sign. /Date): S. / 14/09/22				Verified By IPQA (Sign. /Date): G18 14/09/22	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. /			
Date	06/04/2022	06/04/2022	06/04/2022	06/04/2022

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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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPRT/305-00 Customer:	Batch No.: G1822116 Generic Health Care Pvt. Ltd.

11. CONTAINER WEIGHT DETAILS:

Container No.	Gross Weight in Kg	Weighed By Packing	Checked By IPQA	Container No.	Gross Weight in Kg	Weighed By Packing	Checked By IPQA
1	31.620	S. Vela	Velu	4	31.280	S. Vela	Velu
2	22.200	S. Vela	Velu	5	37.840	S. Vela	Velu
3	32.840	S. Vela	Velu	6,7	72.310	S. Vela	Velu

12. CONTAINER CONSUMPTION DETAILS:

S. No	Time		Container No.	Consumed by	S. No	Time		Container No.	Consumed by
	From	To				From	To		
1	20:15	20:40	01	Velu	4	11:56	14:10	04	Velu
2	09:30	10:52	02	Velu	5	14:11	15:20	05	Velu
3	10:53	11:55	03	Velu	6	15:21	18:50	06,07	Velu

Checked By Packing (Sign. /Date): S. Vela 15/09/22 Verified by IPQA (Sign. /Date): G18 15/09/2024

13. OVERPRINTING OF PRIMARY PACKAGING MATERIALS (Embossing):

Initial checks of Overprinting Details

Overprinting Details	Overprinted Text	Printed AL. Foil (OK/ not OK)
Code No.: PON/DRUGS/21 14 4376	Preprinted	OK
Batch No.:	G1822116	OK
Mfg. Date:	09/2022	OK
Exp. Date:	08/2025	OK
Item Code: 13/0442	Preprinted	OK
Initiated by	VFL	NA
Checked by Packing (Sign. & Date)	S. Vela 14/09/22	S. Vela 14/09/22
Verified by IPQA (Sign. & Date)	G18 14/09/22	G18 14/09/2024

13.1 SPECIMEN OF PRINTED FOIL:

S. No.	Date	Specimen No.	Done By Sign & Date	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01	14/09/22	01	VFL	S. Vela 14/09/22	G18 14/09/2024
02	15/09/22	01	Velu	S. Vela 15/09/22	G18 15/09/2024

14. PACKING INSTRUCTIONS:

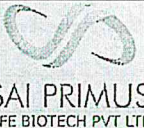
1. Verify the status of dispensed primary packaging materials and transfer to the Primary Packing Area.
2. Issue the stereos to the concerned Technician and set as per SOP No. QAGN/030 and Record the details in respective table.
3. Set and operate Blister Packing Machine as per SOP No. PDOP/021 & PDOP/022.
4. Verify the status label of overprinted packaging materials and transfer to the packing line in secondary packing hall.
5. Perform Leak Test as per SOP No. QAGN/045 and enter the observations in respective table.
6. Perform Leak Test as per Table or during change of Printed foil rolls & plain film rolls and after every start of operation or when machine is stopped due to some break down.
7. Attach proof of printed foil from each roll dispensed as and when used on machine.
8. Overprinting Details on printed foil shall be checked by Packing and cross-checked by IPQA before starting the operation as per given in the respective Table.
9. Affix first overprinted Al. foil, Carton, Shipper and shipper label duly checked by Packing and verified by IPQA.
10. Pack 10 tablet per Blister.

Time record for packing detail

Sr. No.	Date/Shift	Primary packing		Secondary packing		Checked by (Packing) Sign. & Date
		Started at	Completed at	Started at	Completed at	
01	14/09/22/G	20:15	20:40	NA	NA	S. Vela 14/09/2022
02	15/09/2022/G	09:30	10:50	09:35	10:00	S. Vela 15/09/2022
1			NA			

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Kan	H	S. Vela	V. D.
Date	06/04/2022	06/04/2022	06/04/2022	06/04/2022

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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 21
	BATCH PACKING RECORD	Product Code: B05	Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00	Batch No.: G1822116
		Customer:	Generic Health Care Pvt. Ltd.

15. PACKING/IPQA IN-PROCESS CHECKS FOR PRIMARY PACKING:

In process checks frequency for packing and IPQA. (As per SOP No.: QAGN/024)

Stage	Packing	IPQA
Primary packing/Secondary Packing	At start of the batch, every one hour	At batch start, followed by every two-hour (random time) Minimum two In process checks by IPQA per batch.

16. BLISTER PACKING MACHINE PARAMETERS:

Date/Shift: 14/09/22 / 15/09/22 Time: 9:10....

Parameters	Standard and Limits	Observation	Checked by Packing Sign. / Date	Checked by IPQA Sign. / Date
Change Parts Details	1902306	OK	S. / 14/09/22	G. / 14/09/22
Sealing Temperature	(150-200°C) To be established	183°C	S. / 14/09/22	G. / 14/09/22
Forming Temperature	(110-160°C) To be established	158°C	S. / 14/09/22	G. / 14/09/22
Leak test to be performed on 22 Blister	Nil (No Blister should fail in leak test)	YES	S. / 14/09/22	G. / 14/09/22
Machine Speed	To be established	30	S. / 14/09/22	G. / 14/09/22


16.1 MACHINE IN-PROCESS CONTROL:

Date/ Shift	14/09/22 / 15/09/2022															
Machine Operator Name	VEL															
Time of inspection	20:15	20:17	20:22	20:28	20:37	20:40	20:46	20:53	21:05	21:14	21:23	21:34	21:53	22:09	22:35	22:42
Sealing Temperature (To be established)	183°C	167°C	172°C	175°C	189°C	183°C	184°C	183°C	184°C	183°C	184°C	184°C	184°C	184°C	184°C	184°C
Forming Temperature (To be established)	158°C	155°C	158°C	176°C	200°C	158°C	155°C	158°C	155°C	157°C	155°C	155°C	166°C	155°C	158°C	157°C
Leak test on Blister* (Qty.: 22)	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Knurling /Sealing	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Pocket Formation	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Horizontal cutting	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Vertical cutting	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Quality of Over printing	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Code No.: PON/DRUGS/ 21 14 4376	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
B. No.: G1822116	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Mfg. Date 09/2022	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Exp. Date 08/2025	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Machine Speed To be established	30	10	33	10	32	30	30	30	30	30	30	30	30	30	30	30
Checked by (Packing)	S. /	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Checked by (IPQA)	NA	G.	G.	G.	G.	NA	G.	NA	NA	G.	NA	NA	G.	NA	NA	G.

Note: * If leak test fails perform every 15 minutes for next one hour and all the shippers to be checked for leak test from the last successful leak test. All the shippers packed from the time of last successful leak test shall be segregated and random checked by IPQA and to be released after approval from QA.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	M.	K.	V. P.
Date	06/04/2022	06/04/2022	06/04/22	06/04/2022

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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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00 Customer:	Batch No.: <u>G1822116</u> Generic Health Care Pvt. Ltd.

16.2 MACHINE IN-PROCESS CONTROL:

Date/ Shift	15/09/2022											
Machine Operator Name	Nalee											
Time of inspection	16:20	17:30	18:40									
Sealing Temperature (To be established)	184.2	185.1	184.2									
Forming Temperature (To be established)	153.0	156.2	154.2									
Leak test on Blister* (Qty.: <u>20</u>)	OK	OK	OK									
Knurling /Sealing	OK	OK	OK									
Pocket Formation	OK	OK	OK									
Horizontal cutting	OK	OK	OK									
Vertical cutting	OK	OK	OK									
Quality of Over printing	OK	OK	OK									
Code No.: PON/DRUGS/ 21 14 4376	OK	OK	OK									
E. No.: G1822116	OK	OK	OK									
Mfg. Date 09/2022	OK	OK	OK									
Exp. Date 08/2025	OK	OK	OK									
Machine Speed To be established	32	35	34									
Checked by (Packing)	NA	NA	NA									
Checked by (IPQA)	NA	NA	NA									

Note: * If leak test fails perform every 15 minutes for next one hour and all the shippers to be checked for leak test from the last successful leak test. All the shippers packed from the time of last successful leak test shall be segregated and random checked by IPQA and to be released after approval from QA.


16.3 DEFOILING OF BLISTERS:

Date	De-foiling started at	De-foiling completed at	Weight of De-foiled tablets	De-foiling Done by	Checked by/ Date (Packing)	Verified by Date (QA)
15/09/22	14:00	14:43	3.000	Devip, Saurin	S. Nay 15/09/22	G1822116
				NA		
Total Weight of De-foiled Tablets			3.000	Checked By / Date (Packing): S. Nay 15/09/22	Verified By / Date (IPQA): G1822116	

16.4 INSPECTION OF DE-FOILED TABLETS:

Date	Inspection started at	Inspection completed at	Inspection Done by	Quantity of Good tablets		Qty. of Rejected Tablets		Checked by/ Date (Packing).	Verified by Date (QA)
				Kgs	Nos	Kgs	Nos		
15/09/22	14:30	14:42	Devip	2.900	3950	0.100	136	S. Nay 15/09/22	G1822116
					nt				
Total				2.900	3950	0.100	136		
Total Quantity of Rejected Tablets Destroyed				Checked By / Date (Packing):			Verified By / Date (IPQA):		
0.100 Kgs 136 Nos.				S. Nay 15/09/22			G18 15/09/22		
Prepared by:			Checked by:				Approved By:		
Dept.	Production		Production		Quality Assurance		Head Quality Assurance		
Sign.	L. K		L		K		V Q		
Date	06/04/2022		06/04/2022		15/09/22		06/04/2022		

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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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00 Customer:	Batch No.: G18 22116 Generic Health Care Pvt. Ltd.

17. **LINE CLEARANCE CHECKS – BATCH CODING:**

Date/ Shift/...../.....

Previous Product:		Batch No.:				
Sr. No.	Checks	Time	Observation			
			Packing	IPQA	Packing	IPQA
1	Check and ensure that the area is visually clean and free from previous product. Check and ensure that waste bin is emptied out and cleaned					
2	Check the Pallets area clean and free from any leftovers of previous product /Batch.					
3	Check and ensure the rejected Carton of previous product/batch are removed.					
4	Check and ensure the environmental condition, formats, labels and log book.					
5	Check and ensure the previous batch details are deleted from the inkjet machine.					
6	Check and ensure that correct secondary packing material is dispensed					
7	Check and ensure the Correct status board is written.					

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

Cleaning Satisfactory / Not satisfactory# (Packing) Sign. /Date:	Cleaning Satisfactory / Not satisfactory# (IPQA) Sign. /Date:
---	--

Remarks: # In case the cleaning is not satisfactory / line is not certified then investigate the cause of the failure and take necessary action, re check the area / line and record.

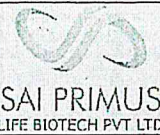
17.1 AREA AND EQUIPMENT CLEARANCE FOR CODING:

1. Check and ensure that the over printing area and machine is cleared from previous products.
2. Transfer uncoded printed Carton to Overprinting area.
3. Set and operate Overprinting Machine.
4. Overprinting shall be in indelible ink.
5. Overprinting Details shall be checked by Packing and cross-checked by QA before starting the operation.

Equipment	Inkjet Machine	Conveyor	Area
ID. No.:			Batch Coding
Previous Product:			
Batch No.:			
Cleaned by:			
Checked by Packing:			
Verified by IPQA:			

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. Ka</i>	<i>A</i>	<i>JS</i>	<i>VP</i>
Date	06/04/2022	06/04/2022	06/04/2022	06/04/2022

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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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00 Customer:	Batch No.: <u>G1822116</u> Generic Health Care Pvt. Ltd.

17.2 OVERPRINTING DETAILS:

Overprinting Details	Overprinted Text	Carton (OK/ Not OK)
Batch No.:		
Mfg. Date:		
Exp. Date:		
Item Code: 15/0724		
Code No.: PON/DRUGS/21 M 4376		
Initiated by Sign. & Date		
Checked by Packing Sign. & Date		
Verified by IPQA Sign. & Date		

17.3 TIME RECORD FOR BATCH CODING:

Sr. No.	Date/Shift	Batch Coding Done By	Batch Coding		Checked by (Packing) Sign. & Date	Verified by (IPQA) Sign. & Date
			Started at	Completed at		


17.4 CARTON OVERPRINTING SPECIMEN:

S. No.	Date	Carton Specimen No.	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)

Note – Attach specimen copy of over printed carton

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>1. Ka</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>06/04/2022</u>	<u>06/04/2022</u>	<u>06/04/2022</u>	<u>06/04/2022</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 14 of 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product BONCIPRO 500	BPR. No.: BPR/T/305-00 Customer:		Batch No.: <u>G1822116</u> Generic Health Care Pvt. Ltd.

18. LINE CLEARANCE CHECKS - SECONDARY PACKING:

Date/ Shift 15/09/2022/07...../.....

Previous Product: TAM VIR 45		Batch No.: T26 2201T				
Sr. No.	Checks	Time	Observation			
			09:30 Packing	IPQA	Packing	IPQA
1	Check and ensure that the area is visually clean and free from previous product. Check and ensure that waste bin is emptied out and cleaned		✓	✓	NA	
2	Check the Pallets area clean and free from any leftovers of previous product /Batch.		✓	✓		
3	Check and ensure the rejected blisters, rejected Carton, Shipper and shipper label of previous product/batch are removed.		✓	✓		
4	Check and ensure the environmental condition, formats, labels and log book.		✓	✓		
5	Check and ensure that correct secondary packing material is dispensed		✓	✓		
6	Check and ensure the Correct status board is written.		✓	✓		

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

Cleaning Satisfactory / Not satisfactory#
 (Packing) Sign. /Date: S. V. 15/09/22
 Cleaning Satisfactory / Not satisfactory#
 (IPQA) Sign. /Date: G/S 15/09/22

Remarks: # In case the cleaning is not satisfactory / line is not certified then investigate the cause of the failure and take necessary action, re check the area / line and record.

Equipment	Packing Conveyor	Weighing Balance (Carton)	Shrink Sleeve	Strapping	Weighing Balance (shipper)	Area
ID. No.:	<u>PD/COB/002</u>	<u>PD/BAL/017</u>	<u>PD/SWH/001</u>	<u>PD/STM/002</u>	<u>PD/BAL/038</u>	Secondary Packing Hall
Previous Product:	<u>TAM VIR 45</u>					
Batch No.:	<u>T262201T</u>					
Cleaned by:	<u>LAKSHMI</u>					
Checked by Packing:	<u>S. V. 15/09/22</u>					
Verified by IPQA:	<u>G/S 15/09/2022</u>					

18.1 ENVIRONMENTAL CONDITIONS:

(Check the environmental conditions of Secondary packing area at the start of process and Record in the below in table)


Shift: <u>07</u>		Date/Time: <u>15/09/22 09:21</u>		Date/Time:		
		Observation	Checked by Packing	Verified by IPQA	Observation	Checked by Packing
Refer to SOP No.: SOP: QAGN/011	Temperature °C Limit: NMT 25°C	<u>23°C</u>	<u>✓</u>	<u>G/S</u>	NA	NA
Secondary Packing Started Date/Time: <u>15/09/2022 09:25</u> Completed Date/Time: <u>15/09/2022 19:00</u>						
APPROVAL FOR SECONDARY PACKING: Approved by IPQA Sing/Date: <u>G/S 15/09/2022</u>						

18.2 PACKING DETAILS:

10 Tablets in each Blister, over code the Blister with the batch details given below,
Place 2 x 10's Blister and one leaflet in each carton.
Place 18 filled carton in a Shrink Sleeve.
Place 16 Shrink sleeves in each 5 ply shipper.
Seal the shipper with BOPP tape with "H" type.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K.</u>	<u>✓</u>	<u>✓</u>	<u>✓</u>
Date	<u>06/04/2022</u>	<u>06/04/2022</u>	<u>06/04/22</u>	<u>06/04/2022</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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product BONCIPRO 500	BPR. No.: BPR/T/305-00		Batch No.: <u>G1822116</u>
	Customer:		Generic Health Care Pvt. Ltd.

19. OVER PRINTING DETAILS:

Overprinting Details (Secondary & Tertiary PM)

Overprinting Details	Overprinted Text	Carton (OK/ Not OK)	Insert	5 Ply Shipper Label (OK/ Not OK)
Batch No.:	<u>G1822116</u>	OK	NA	OK
Mfg. Date:	<u>09/2022</u>	OK	NA	OK
Exp. Date:	<u>08/2025</u>	OK	NA	OK
Code No.: PON/DRUGS/21 14 4376	<u>PON/DRUGS/21 14 4376</u>	OK	NA	NA
Item Code : 16/0437 (Insert)	NA	NA	OK	NA
Item Code: 15/0724 (Carton)	NA	OK	NA	NA
Pack size:	NA	1 x 10's	NA	16 x 18 x 2 x 10's
Initiated by Sign. & Date	<u>NA</u>	<u>NA</u>	<u>NA</u>	<u>Siva Kumar</u>
Checked by Packing Sign. & Date	<u>S.V. 15/09/22</u>	<u>S.V. 15/09/22</u>	<u>S.V. 15/09/22</u>	<u>S.V. 15/09/22</u>
Verified by IPQA Sign. & Date	<u>G1822116</u>	<u>G1822116</u>	<u>G1822116</u>	<u>G1822116</u>

19.1 Shipper Label Specimen:

S. No.	Date	Shipper Label Specimen No.	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01.	<u>15/09/2022</u>	01	<u>S.V. 15/09/22</u>	<u>G1822116</u>

20. CARTON WEIGHT LIMIT SETTING: Date/Shift: 15/09/22...G1....Time: 09:140

Weight of ten individual empty cartons are given below:

1. <u>6.2</u>	3. <u>6.2</u>	5. <u>6.4</u>	7. <u>6.2</u>	9. <u>6.2</u>
2. <u>6.4</u>	4. <u>6.4</u>	6. <u>6.2</u>	8. <u>6.2</u>	10. <u>6.4</u>

Total weight of ten empty cartons = 62.8

Average weight of an empty carton (A) = Total weight of ten empty carton / 10 = 6.28

Weight of ten individual Blister are given below:

1. <u>9.1</u>	3. <u>9.0</u>	5. <u>9.1</u>	7. <u>9.1</u>	9. <u>9.0</u>
2. <u>9.0</u>	4. <u>9.1</u>	6. <u>9.0</u>	8. <u>9.0</u>	10. <u>9.1</u>

Total weight of ten Blister = 90.5

Avg. Weight of a Blister (B): total weight of ten Blister / 10 = 9.05

Weight of ten individual Leaflets are given below:

1. <u>2.8</u>	3. <u>2.7</u>	5. <u>2.8</u>	7. <u>2.7</u>	9. <u>2.7</u>
2. <u>2.7</u>	4. <u>2.8</u>	6. <u>2.7</u>	8. <u>2.8</u>	10. <u>2.8</u>

Total weight of ten Leaflets = 27.5

Avg. Weight of a Leaflet (C): total weight of ten Leaflets/10 = 2.75

20.1 WEIGHT CHECKS ON CARTON:

Weight of ten empty Carton: <u>62.8</u>	Average weight of one empty Carton (A): <u>6.28</u>
Weight of ten filled Blister: <u>90.5</u>	Average weight of one filled Blister (B): <u>9.05</u>
Weight of ten Leaflets: <u>27.5</u>	Average weight of one Leaflet (C): <u>2.75</u>
Weight of one filled Carton D = (A + 2B + C) <u>27.13</u>	Limit: E = D ± 1% = <u>26.85 - 27.40</u> (To be established)
Checked by Packing/Date: <u>S.V. 15/09/22</u>	Verified by IPQA/Date: <u>G1822116</u>

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head. Quality Assurance
Sign.	<u>L. K</u>	<u>L</u>	<u>RS</u>	<u>V. D</u>
Date	<u>06/04/2022</u>	<u>06/04/2022</u>	<u>06/04/22</u>	<u>06/04/2022</u>

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Product Code: B05

Batch Size: 3,00,000 Tablets

BONCIPRO 500

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

Batch No.: G1822116

Customer:

Generic Health Care Pvt. Ltd.

20.2 SAMPLE DRAWN RECORD:

Sr. No.	Stage of Sample collection	Qty. of Sample	Collected by (Sign. /Date)
1	Control Sample (Initial)	7×10^5	Gh 15/09/2022
2	Control Sample (Middle)	7×10^5	Gh 15/09/2022
3	Control Sample (Final)	6×10^5	Gh 15/09/2022
4	Stability Sample	100×10^5	Gh 15/09/2022
5	Other Sample	NA -	NA -
6	Analytical sample	12×10^5	Gh 15/09/2022
	Total Qty.	122×10^5	Gh 15/09/2022

21. SECONDARY PACKING IN-PROCESS CHECKS: (Please keep ☒ mark if found "Ok")

Date/ Shift	15/09/2022 / M							15/09/2022 / G							
Parameters	Specification	observation													
		Packing							IPQA						
Time		09:35	10:40	11:40	12:30	13:40	14:35	15:40	09:48	11:50	13:45	15:45	17:42		
No. of Blister in a carton	2 Blister with 10 tabs and one leaflet.	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Carton Overprinting	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
No. of cartons in a shrink sleeves	18 packed cartons	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA		
Shrink wrapping temperature*		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA		
No. of shrink sleeves in a 5 ply shipper	16 shrink sleeves	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA		
Shipper strapping	Proper strapping	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA		
Label appearance and Shipper appearance	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Sealing of the shippër with BOPP Tape	H type	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA		
Checked by		S. Viji	S. Viji	S. Viji	S. Viji	S. Viji	P. S. Prasad	P. S. Prasad	G. S. Suresh	G. S. Suresh	G. S. Suresh	G. S. Suresh	G. S. Suresh		


*Temperature to be mentioned.

21.1 SECONDARY PACKING IN-PROCESS CHECKS: (Please keep \checkmark mark if found "Ok")

[illegible]

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. Ka</i>	<i>A</i>	<i>JS</i>	<i>VP</i>
Date	06/04/2022	06/04/2022	06/04/2022	06/04/2022

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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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product BONCIPRO 500	BPR. No.: BPR/T/305-00 Customer:		Batch No.: <u>G1822116</u> Generic Health Care Pvt. Ltd.

Label appearance and Shipper appearance	Legible and readable	ok	ok	ok															
Sealing of the shipper with BOPP Tape	H type	NA	NA	NA															
Checked by		S. V. V.	S. V. V.	S. V. V.															

*Temperature to be mentioned.

21.2 SECONDARY PACKING IN-PROCESS CHECKS: (Please keep ✓ mark if found "Ok")

Date/ Shift	Specification	15/09/2022 G1 observation														15/09/2022 /G - Recheck			
Parameters	Specification	Packing							IPQA										
Time		10:40	11:50	13:00	14:10	15:18	16:30	17:42	18:41	19:43	20:44	21:45	22:46	23:47	24:48				
No. of Blister in a carton	2 Blister with 10 tabs and one leaflet.	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok				
Carton Overprinting	Legible and readable	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok				
No. of cartons in a shrink sleeves	18 packed cartons	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok				
Shrink wrapping temperature*		ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok				
No. of shrink sleeves in a 5 ply shipper	16 shrink sleeves	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok				
Shipper strapping	Proper strapping	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok				
Label appearance and Shipper appearance	Legible and readable	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok				
Sealing of the shipper with BOPP Tape	H type	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok				
Checked by		V. V. V.	V. V. V.	V. V. V.	V. V. V.	V. V. V.	V. V. V.	V. V. V.	G. S.	G. S.	G. S.	G. S.	G. S.	G. S.	G. S.				

*Temperature to be mentioned.


21.3 SECONDARY PACKING IN-PROCESS CHECKS: (Please keep ✓ mark if found "Ok")

Date/ Shift	Specification	15/09/2022 G1 observation																	
Parameters	Specification	Packing							IPQA										
Time		17:49	18:50																
No. of Blister in a carton	2 Blister with 10 tabs and one leaflet.	ok	ok																
Carton Overprinting	Legible and readable	ok	ok																
No. of cartons in a shrink sleeves	18 packed cartons	ok	ok																
Shrink wrapping temperature*		ok	ok																
No. of shrink sleeves in a 5 ply shipper	16 shrink sleeves	ok	ok																
Shipper strapping	Proper strapping	ok	ok																
Label appearance and Shipper appearance	Legible and readable	ok	ok																
Sealing of the shipper with BOPP Tape	H type	ok	ok																
Checked by		V. V. V.	V. V. V.																

*Temperature to be mentioned.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.			
Date	06/04/2022	06/04/2022	06/04/2022	06/04/2022

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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 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500		BPR. No.: BPR/T/305-00 Batch No.: <u>G1822116</u>
			Customer: Generic Health Care Pvt. Ltd.

22. SHIPPERS WEIGHING: Date/Shift: 15/09/22.....Time: 10:00..... Balance I.D. No: PD/BAL/1039

Weight of ten Shrinks: <u>5017</u>						Average weight of one filled Shrink (H): <u>5017</u>					
Weight of ten empty shippers: <u>10.4</u>						Average weight of one empty shipper (I): <u>1.040</u>					
Weight of one filled shipper (J) = (16 H+I): <u>9.067</u>						Limit: K = J ± 1% = <u>8.976 - 9.157</u>					
Checked by Packing/Date: <u>G1 15/09/22</u>						Verified by IPQA/Date: <u>G1 15/09/22</u>					
Shipper No.	Gross weight (Kg)	Weighed By	Shipper No.	Gross weight (Kg)	Weighed By	Shipper No.	Gross weight (Kg)	Weighed By	Shipper No.	Gross weight (Kg)	Weighed By
1	9.045	Jakshmi	15	9.055	Jakshmi	29	9.035	Jakshmi	43	9.025	Jakshmi
2	9.030	Jakshmi	16	9.020	Jakshmi	30	9.010	Jakshmi	44	9.055	Jakshmi
3	9.065	Jakshmi	17	9.050	Jakshmi	31	9.075	Jakshmi	45	9.025	Jakshmi
4	9.030	Jakshmi	18	9.010	Jakshmi	32	9.030	Jakshmi	46	9.055	Jakshmi
5	9.050	Jakshmi	19	9.045	Jakshmi	33	9.040	Jakshmi	47	9.065	Jakshmi
6	9.015	Jakshmi	20	9.035	Jakshmi	34	9.015	Jakshmi	48	9.050	Jakshmi
7	9.020	Jakshmi	21	9.025	Jakshmi	35	9.010	Jakshmi	49	9.065	Jakshmi
8	9.055	Jakshmi	22	9.025	Jakshmi	36	9.050	Jakshmi	50	9.055	Jakshmi
9	9.065	Jakshmi	23	9.030	Jakshmi	37	9.040	Jakshmi	51		
10	9.015	Jakshmi	24	9.055	Jakshmi	38	9.040	Jakshmi	52		
11	9.035	Jakshmi	25	9.035	Jakshmi	39	9.045	Jakshmi	53		
12	9.035	Jakshmi	26	9.015	Jakshmi	40	9.040	Jakshmi	54		
13	9.035	Jakshmi	27	9.015	Jakshmi	41	9.065	Jakshmi	55		
14	9.015	Jakshmi	28	9.035	Jakshmi	42	9.055	Jakshmi	56		
Total No. of shippers weighed: <u>50</u>		De-foiled tablets packed in Shipper No: <u>50</u>		Checked by Sign / Date: <u>Muy 15/09/22</u>		Verified by Sign / Date: <u>G1 15/09/22</u>		Loose pack details: Shipper No: <u>NA</u> Quantity: <u>NA</u> Weight: <u>NA</u>			


Note - If any shipper weight found out of limit, the same shall be checked physically by opening the shipper.

23. MAN POWER ALLOCATION:

DATE: <u>15/09/2022</u>		DATE: <u>15/09/2022</u>	
SHIFT: <u>G1</u>		SHIFT: <u>G1</u> <u>Recheck</u>	
ACTIVITIES	DONE BY	ACTIVITIES	DONE BY
Blister Checking	Indhira, Janagi	Blister Checking	Bhasathi, Sathy
Printing Checking in Blister	Gromathi, Parameshwari	Printing Checking in Blister	Sayerani, Karthika
Insertion of Blister and leaflet into carton	Kalpna, Drvi, Valli	Insertion of Blister and leaflet into carton	Ananya
Cartons weighing	Satanga	Cartons weighing	Vaanthini
Insertion of carton into shrink sleeve	Powma, Kuna, Sunthara	Insertion of carton into shrink sleeve	Keerthana
Insertion of shrink wrapped carton into shipper	Jakshmi	Insertion of shrink wrapped carton into shipper	Vinita
Shipper Label Pasting	Jakshmi	Shipper Label Pasting	Arsha
Shipper Weighing	Jakshmi	Shipper Weighing	Arsha
Shipper Strapping	Jakshmi	Shipper Strapping	Arsha
Shipper packed	From 01...to 50...	Shipper packed	From 01...to 50.
Signature of Packing	<u>Vey</u>	Signature of Packing	<u>Vey</u>

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>A</u>	<u>JK</u>	<u>V. Ka</u>
Date	<u>06/04/2022</u>	<u>06/04/2022</u>	<u>06/04/2022</u>	<u>06/04/2022</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 19 of 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00	Batch No.: <u>G1822116</u>
		Customer:	Generic Health Care Pvt. Ltd.

DATE:		DATE:	
SHIFT:		SHIFT:	
ACTIVITIES	DONE BY	ACTIVITIES	DONE BY
Blister Checking		Blister Checking	
Printing Checking in Blister		Printing Checking in Blister	
Insertion of Blister and leaflet into carton		Insertion of Blister and leaflet into carton	
Cartons weighing		Cartons weighing	
Insertion of carton into shrink sleeve		Insertion of carton into shrink sleeve	
Insertion of shrink wrapped carton into shipper		Insertion of shrink wrapped carton into shipper	
Shipper Label Pasting		Shipper Label Pasting	
Shipper Weighing		Shipper Weighing	
Shipper Strapping		Shipper Strapping	
Shipper packed	From.....to.....	Shipper packed	From.....to.....
Signature of Packing		Signature of Packing	

24. PACKING MATERIAL RECONCILIATION:


Sr. No.	Material	Printed Alu. Foil (Kg)	Clear PVC (Kg)	Cartons (Nos)	Leaflets (Nos)	Shrink Sleeves (Nos)	5 Ply Shipper (Nos)	Strapping Role (Mtrs.)	BOPP Tape (GHPL Printed) (Nos)
A	Quantity received for the batch	22.81	66.090	15886	15000	834	53	01	01
B	Additional material received for the batch	NA	NA	NA	NA	NA	NA	NA	NA
C	Total material received (A+B)	22.81	66.090	15886	15000	834	53	01	01
D	Quantity packed	11.520	56.840	14400	14400	800	50	01	01
E	Quantity rejected (Online) & Destroyed	1.235	7.500	1364	478	34	03	NA	NA
F	Quantity Returned	10.000	6.500	NA	NA	800	NA	NA	NA
G	Sample affixed on BPR	0.0002	0.005	02	02	NA	NA	NA	NA
H	QC samples	0.005	0.024	NA	NA	NA	NA	NA	NA
I	Other samples (If any)	0.012	0.216	120	120	NA	NA	NA	NA
J	Total accountable Quantity (D+ E+F+G+H+I)	22.810	66.090	15886	15000	834	53	01	01
K	Variation (C - J)	NA	NA	NA	NA	NA	NA	NA	NA
L	%Variation (K x 100)/C	NA	NA	NA	NA	NA	NA	NA	NA
M	Acceptable limit	± 2 %	± 2 %	± 2 %	± 2 %	± 2 %			

If % Variation is out of the acceptable limit, investigate & specify the reason:

NA

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K</u>	<u>M</u>	<u>RE</u>	<u>RE</u>
Date:	<u>06/04/2022</u>	<u>06/04/2022</u>	<u>06/04/2022</u>	<u>06/04/2022</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 20 of 21
	BATCH PACKING RECORD		Product Code: B05 Batch Size: 3,00,000 Tablets
Product BONCIPRO 500	BPR. No.: BPR/T/305-00 Customer:		Batch No.: G1822116 Generic Health Care Pvt. Ltd.

25. EXCESS PACKING MATERIAL RETURN TO STORE: MRN NO. _____

Material	Printed Alu. Foil (Kg)	Clear PVC (Kg)	Cartons (Nos)	Leaflets (Nos)	Shrink Sleeves (Nos)	5 Ply Shipper (Nos)	Strapping Role (Mtrs.)	BOPP Tape (GHPL Printed) (Nos)
Quantity Returned	10.000	6.500	1					
Material returned by packing Sign./Date	S. Vey 21/09/22	S. Vey 21/09/22			NA			
Verified By IPQA Sign./Date	S. Vey 21/09/22	S. Vey 21/09/22						
Material received by Store Sign./Date	S. Vey 21/09/22	S. Vey 21/09/22						

26. DESTRUCTION OF REJECTED/UNUSED PRINTED PACKING MATERIALS AND STEREOS:

Date	Stereos	Printed Alu. Foil (Kg)	Clear PVC (Kg)	Cartons (Nos)	Leaflets (Nos)	Shrink Sleeves (Nos)	5 Ply Shipper (Nos)	Strapping Role (Mtrs.)	BOPP Tape (GHPL Printed) (Nos)
15/09/22	NA	1.235	2.500	1364	478	34	03	NA	NA
Total Qty. Destroyed	NA	1.235	2.500	1364	478	34	03	NA	NA
Destroyed by (Packing)	S. Vey 15/09/22			Verified by (IPQA)		S. Vey 15/09/2022			

27. BATCH RECONCILIATION:

A	Batch Size	3,00,000 Nos.
B	Quantity received for packing	291989
C	Total quantity packed	288000
D	Control samples	200
E	Analytical Samples	120
F	In process samples	3300
G	Others samples if any (Stability, Regulatory Samples, etc.)	1000
H	Packing Loss = B - (C + D + E + F + G)	631
I	Total Loss = A - (C + D + E + F + G)	7380
J	Packing yield % (C + D + E + F + G) / B X 100 (Yield Limit %.....)*	100.21
K	Batch Yield % (C + D + E + F + G) / A X 100 (Yield Limit %.....)*	97.54%

*To be established

Checked by Packing /Date: S. Vey 21/09/22

Verified by IPQA/Date:


S. Vey 21/09/2022

28. TRANSFER OF FINISHED GOODS:

Date	FGTN No.	Sales	Pack Size	No. of Units in a shipper	No. of Shippers	Transferred Quantity	FGTN Raised by Packing	FGTN Checked by IPQA	FGTN Received by Stores
21/09/22	00313	20105	2x105	16x18x2x8	50	28800	S. Vey 21/09/22	Gls	R. M
Total Qty. Transferred						28800			

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka			
Date	06/04/2022	06/04/2022	06/04/22	06/04/2022

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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 21
	BATCH PACKING RECORD	Product Code: B05	Batch Size: 3,00,000 Tablets
Product	BONCIPRO 500	BPR. No.: BPR/T/305-00	Batch No.: G18 22116
		Customer:	Generic Health Care Pvt. Ltd.

29. DEVIATION/ EXCEPTION DETAILS:

During process if there is any Deviation / Exception are observed then record in below table

Deviation / Exception details

Sr. No.	Stage	Deviation / Exception details	Action taken	Observed By

Checked by
Packing:

Verified by
Packing manager:

Approved by
Head QA:

30. BPR REVIEW DETAILS:

Reviewed by	Name	Sign. /Date
Packing Executive	(G) SUGANYA NANCY RANI.D	Nay 21/09/2022
QA Executive	G. SENTHIL KUMARAN	G. Senthil Kumaran 21/09/2022
Production Assistant Manager/ HOD	S. SIVAKUMAR	21/09/2022
QA Manager/ HOD	Ramkumar	21/09/2022

31. BATCH RELEASED FOR DESPATCH:

Total quantity released: 288000 No's

Head QA sign/ Date: [Signature] 21/09/2022

32. REVISION HISTORY:

S. No.	Document No.	Reason for Changes	Supersedes Doc. No.
1	BPR/T/305-00	New Document	Nil

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	[Signature]	[Signature]	[Signature]
Date	06/04/2022	06/04/2022	06/04/2022	06/04/2022

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1944-1945

1946-1947

1948-1949

1950-1951

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