 SAI PRIMUS LIFE BIOTECH PVT 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 29
	BATCH PACKING RECORD	Product Code: G13	Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00	Batch No.: <u>G1F210301</u>
		Customer:	Generic Health Care Pvt. Ltd.


BATCH PACKAGING RECORD COVER SHEET

PRODUCT NAME	: GENSET
GENERIC NAME	: Cetirizine Tablets BP 10 mg Each film coated tablet contains:
LABEL CLAIM	: Cetirizine Hydrochloride BP10 mg Excipients q.s. Colour: Approved colour used
CODE NO.	: PON/DRUGS/19 13 4323
DOSAGE FORM	: Tablet
BPR No.	: BPR/T/195-00
REVISION No.	: 00
SUPERSEDE No	: NIL
EFFECTIVE BATCH. No. /DATE	: <u>G1F210101 / 04/01/2021</u>
MARKET	: Export
SHELF LIFE	: 36 Months
BATCH SIZE	: 30,00,000 Tablets
PACKING CONFIGURATION	: 3 x 10 Tablets Sales Pack (Blister Packing)
BPR ISSUED BY/DATE (QA)	: <u>[Signature] 25/03/2021</u>
BPR CHECKED & RECEIVED BY/DATE (PRODUCTION)	: <u>L.K. 25/03/2021</u>
MFG. DATE: <u>03/01/2021</u>	EXP. DATE: <u>02/2024</u>
ALLOTTED BY: QA SIGN/DATE: <u>[Signature] 25/03/2021</u>	COUNTER CHECKED BY: QA SIGN/DATE: <u>[Signature] 25/03/21</u>
QUANTITY RECEIVED FROM PRODUCTION	: 2907445
DATE OF COMMENCEMENT: <u>03/01/2021</u>	DATE OF COMPLETION: <u>11/05/2021</u>
QUANTITY	: 30700000
RELEASED QUANTITY OF PACKED TABLETS	: 2890800
RELEASE OF BATCH BY HEAD QA SIGN/DATE:	: <u>[Signature] 11/05/21</u>

This BPR contains 29 Pages + 02 Additional Pages

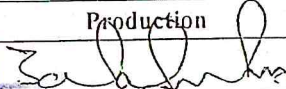
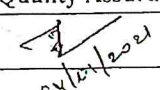
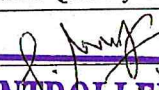
Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L.K.</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>03/01/2021</u>	<u>03/01/2021</u>	<u>04/01/2021</u>	<u>04/01/2021</u>

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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 29
	BATCH PACKING RECORD	Product Code: G13	Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00	Batch No.: G1F210301
		Customer:	Generic Health Care Pvt. Ltd.

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7	Verification of dispensed packing material	8
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Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.			
Date	03/01/2021	03/01/2021	04/01/2021	04/01/2021

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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 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product GENSET	BPR. No.: BPR/T/195-00		Batch No.: G1F210301
	Customer:		Generic Health Care Pvt. Ltd.

2. CHECKLIST FOR BATCH PACKING RECORD REVIEW:

Instruction:

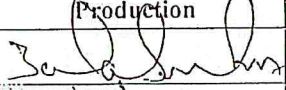
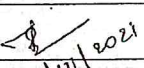
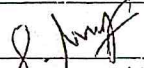
Check the following points before submitting the documents for final Review

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, show box 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	Yes
7.	Complete set of BPR Submitted	Yes


Checked By QA/Date: 11/05/21

*Mention total number of pages.

Remarks (If any) -ok-

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K.			
Date	03/01/2021	03/01/2021	04/01/2021	04/01/2021

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	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 4 of 29
	BATCH PACKING RECORD	Product Code: G13	Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00	Batch No.: G1F210301
		Customer:	Generic Health Care Pvt. Ltd.

3. PACKING MATERIAL SPECIFICATION AND INDENT:

Sr. No.	Material	Printed item material code	Specification	UOM	Standard Qty. for Batch Size 30.0 Lac.	% Over ages	Qty. Required 30.0 Lac with overages
1	144mm Genset double side printed foil 0.025	PPF/SP/G013	Width – 144 ± 1 mm Thickness – 0.025 mm Language – French Color – 2 Colors GHPL ITEM CODE – 13/0241	Kg	45.000 (To be established)	2	45.900 (To be established)
2	148 mm PVC Film Clear (60 GSM)	PBF/SP/P002	Width – 148 mm Clear PVC	Kg	150.000 (To be established)	2	153.000 (To be established)
3	3x10's Genset printed carton	PHC/SP/G001	Size – 130 x 60 x 25 mm (L x W x H) Board – 300 gsm ITC Cyber XL, UV varnished. Colour – 3 colour Language – English/French GHPL ITEM CODE – 15/0362	No	100000	2	102000
4	Genset Insert	PHL/SP/G001	Size – 140 x 180 mm (L x H) Specification – NLT 60 gsm Maplitho Paper. Colour – 2 colours Language – French/ English GHPL ITEM CODE – 16/0259	No	100000	2	102000
5	Shrink Sleeves (PVC)	PPS/SP/P001	Plain PVC Shrink Sleeves	No	5000	2	5100
6	5 PLY 390X390X260 MM C/BOXES	PUS/GH/C001	A 5 Ply flute vertical corrugated inner unprinted in nature. (24 B.F.) Outer Size – 390 x 390 x 430 mm (L x W x H) Bursting Strength – NLT 15.00 Kg/cm ²	No	209	-	209
7	3' GHPL Printed Bopp Tape	PPB/SP/B002	Clear Transparent Length of roll – 65m Width – 60 mm Printing – GHPL repeats in Blue	No	15	-	15
8	3' Plain BOPP Tape	PUB/SP/B001	Plain BOPP Tape	No.	3	-	3
9	Strapping role.	PPR/SP/S001	White or milky white colour. Width – 12 mm Thickness – 0.6 mm	Mtrs	500	-	500
10	Shipper Label	NA	Half A4 size Computer printed label	No	209	-	209

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. K.</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	03/01/2021	03/01/2021	04/01/2021	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 5 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: Generic Health Care Pvt. Ltd.

4. DISPENSING LINE CLEARANCE CHECKS

Date: 03/05/2021 Time: 14:19

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/LAR/001	NA	NA	ST/BAL/011	Port Stone
Previous Product	Voglow 0.3				
B. No.	Vom2102D				
Cleaned by Sign/Date	B. N. P. 03/05/2021				
Checked by Store Sign/Date	T. S. 03/05/2021				
Verified by IPQA Sign/Date	03/05/21				


ENVIRONMENTAL CONDITIONS: Date: 03/05/2021 Time: 14:15	Observation	Checked by Store Sign/Date	Verified by IPQA Sign/Date
(For Reference SOP No.: QAGN/011)			
Temperature (Limit: NMT 25°C)	23°C	03/05/2021	03/05/21

APPROVAL FOR DISPENSING BY IPQA: Sign: _____ Date: 03/05/21
Dispensing start Time: 14:30 End Time: 15:20

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	30/05/2021	04/05/2021	03/05/2021
Date	03/01/2021	03/01/2021		

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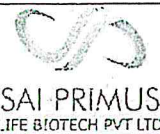
 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 6 of 29
	BATCH PACKING RECORD	Product Code: G13	Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00	Batch No.:
		Customer:	Generic Health Care Pvt. Ltd.

5. DISPENSING RECORD OF PACKING MATERIALS: Date: 03/05/2021 Shift: 01 Time: 14:10

Material Name	Item code	UOM	Req. Qty. for 30.0 Lac	Issued Qty.	A.R No.	No. of Roll/Box	Issued and Checked by Store	Verified by IPQA
144mm Genset double side printed foil 0.025	PPF/SP/G013	Kg	45.900 (To be established)	52.230	pmg/00804	05	<i>[Signature]</i> 03/05/2021	<i>[Signature]</i> 02/05/2021
148 mm PVC Film Clear (60 GSM)	PBF/SP/P002	Kg	153.000 (To be established)	60.280 155.92 + 39.000	pmg/00040	10	<i>[Signature]</i> 03/05/2021	<i>[Signature]</i> 02/05/2021
3x10's Genset printed carton	PHC/SP/G001	No	102000	102000	pmg/01106	01	<i>[Signature]</i> 03/05/2021	<i>[Signature]</i> 02/05/2021
Genset Insert	PHL/SP/G001	No	102000	102000	pmg/01107	01	<i>[Signature]</i> 03/05/2021	<i>[Signature]</i> 02/05/2021
Shrink Sleeves (PVC)	PPS/SP/P001	No	5100	5100	pmg/00193	01	<i>[Signature]</i> 03/05/2021	<i>[Signature]</i> 02/05/2021
5 PLY 390X390X260 MM C/BOXES	PUS/GH/C001	No	209	209	pmg/01095	21	<i>[Signature]</i> 03/05/2021	<i>[Signature]</i> 02/05/2021
3' GHPL Printed Bopp Tape	PPB/SP/B002	No	15	15	pmg/00126	01	<i>[Signature]</i> 03/05/2021	<i>[Signature]</i> 02/05/2021
3' Plain BOPP Tape	PUB/SP/B001	No	3	3	pmg/00935	01	<i>[Signature]</i> 03/05/2021	<i>[Signature]</i> 02/05/2021
Strapping role.	PPR/SP/S001	Mtrs	500	500	pmg/00032	01	<i>[Signature]</i> 03/05/2021	<i>[Signature]</i> 02/05/2021
Shipper Label	NA	No	209					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	03/01/2021	03/01/2021	04/01/2021	04/01/2021

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 7 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: G1F210301 Generic Health Care Pvt. Ltd.

6. LINE CLEARANCE CHECKS:

6.1 PRIMARY PACKING:

Date/ Shift 05/05/2021 G1 / NK

Previous Product: <u>Genet Veglow M-0.2</u>		Batch No.: <u>V012102D</u>		06/05/2021		
Sr. No.	Checks	Time	Observation			
			10.15 Packing	IPQA	9.30 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: Satisfactory 05/05/2021
 Checked by Packing (Sign./Date): [Signature]
 Cleaning satisfactory/Not-satisfactory: Satisfactory
 Verified by IPQA (Sign./Date): [Signature]

#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: <u>Veglow M-0.2</u>				Batch No.: <u>V012102D</u>			
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/APP/100	B	PDGN/006	Amba	D.D.	[Signature]
2.	Blister Packing Machine	PD/BLP/100	B	PDOP/021, PDCL/021 PDOP/022, PDCL/022	Amba	D.D.	[Signature]

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: 05/05/21 Time: 10:25			Date: 06/05/21 Time: 9:15		
	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	[Signature]	[Signature]	23°C	[Signature]	[Signature]
RH % Limit: NMT 60%	55%	[Signature]	[Signature]	55%	[Signature]	[Signature]
DP Limit: NLT 10 Pascal	11	[Signature]	[Signature]	11	[Signature]	[Signature]
Primary Packing Started Date/Time: 05/05/2021 16:15 Completed Date/Time: 06/05/2021 18:00						

APPROVAL FOR PRIMARY PACKING: IPQA Sign./Date: [Signature] 05/05/2021

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	[Signature]	[Signature]	[Signature]	[Signature]	
Date	05/05/2021	03/05/2021			

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 8 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: G1F210301 Generic Health Care Pvt. Ltd.

7. VERIFICATION OF DISPENSED PACKING MATERIALS: Date: 05/05/2021 Shift: G1 Time: 10:10

Material Name	Item code	UOM	AR No.	Number of Rolls/Packs	Checked by Packing	Verified by QA
144mm Genset double side printed foil 0.025	PPF/SP/G013	Kg	pmg/00804	05	05/05/21	
148 mm PVC Film Clear (60 GSM)	PBF/SP/P002	Kg	pmg/00040	08	05/05/21	
3x10's Genset printed carton	PHC/SP/G001	No	pmg/01106	01	05/05/21	
Genset Insert	PHL/SP/G001	No	pmg/01107	01	05/05/21	
Shrink Sleeves (PVC)	PPS/SP/P001	No	NA			
5 PLY 390X390X260 MM C/BOXES	PUS/GH/C001	No	pmg/01095	21	05/05/21	
3' GHPL Printed Bopp Tape	PPB/SP/B002	No	pmg/00036	01	05/05/21	
3' Plain BOPP Tape	PUB/SP/B001	No	pmg/00935	01	05/05/21	
Strapping role.	PPR/SP/S001	Mtrs	pmg/00092	01	05/05/21	
Shipper Label	NA	No	NA			

8. STEREO ISSUANCE AND SETTING RECORD

S. No.	Type of Stereos	No. of Stereos Issued	Issued By (QA) Sign. & Date	Received By (Packing) Sign. & Date	Stereos Setting Done By	Checked By (Packing) Sign. & Date	Verified By QA Sign. & Date
1.	Stereos	24	05/05/2021	05/05/2021	05/05/2021	05/05/2021	05/05/2021

9. RECEIPT OF PRODUCT AND MATERIALS: Date/Shift: 05/05/2021 Time: 10:35
(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	05/05/21	05/05/21
2.	Relative Humidity observed on display (Limit: NMT 60%)	53%	05/05/21	05/05/21
3.	Bulk product containers are of the required product/Batch number and is approved by QC	Yes	05/05/21	05/05/21
4.	Status label of machine/ line is for same product	Yes	05/05/21	05/05/21
5.	Printed foil/Base rolls are of the required product.	Yes	05/05/21	05/05/21
6.	All secondary packing materials are of the required product	Yes	05/05/21	05/05/21

10. DETAIL OF THE PRODUCT AS PER BMR:

Sr. No.	Description	Observations	Checked By (Packing)	Verified By (IPQA)
1.	Average Weight	120.05 Kg	05/05/21	05/05/21
2.	Colour of Tablet	White	05/05/21	05/05/21
3.	Quantity (Net Qty.in Kg)	319.04	05/05/21	05/05/21
4.	Number of Containers	10	05/05/21	05/05/21

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. R.	05/05/2021	05/05/2021	05/05/2021
Date	03/01/2021	02/01/2021	04/01/2021	05/05/2021

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 9 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product: GENSET	BPR. No.: BPR/T/195-00 Customer:		Batch No.: G13210301 Generic Health Care Pvt. Ltd.

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

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

1. Verify the semi-finished Tablets before starting the packing operation.
2. Verify the batch details on the labels affixed over the Containers against the respective BMR and record the details in below table.

Product Name	Batch No.	Mfg. Date	Exp. Date	Qty. recd. For packing	No. of Containers taken for packing
Genset	G13210301	03/2021	02/2024	349.04 Kg Equivalent to 290745 Nos.	From Container No. <u>01</u> To Container No. <u>10</u> Total No. of Containers taken <u>10</u>
Checked by Packing (Sign./Date): <u>[Signature]</u> 05/05/21				Verified By IPQA (Sign./Date): <u>[Signature]</u> 05/05/21	

12. 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	31.410	Ingur	P	16			
2	36.010	Ingur	P	17			
3	35.320	Ingur	P	18			
4	27.520	Ingur	P	19			
5	37.740	Ingur	P	20			
6	44.930	Ingur	P	21			
7	33.030	Ingur	P	22			
8	29.510	Ingur	P	23			
9	43.980	Ingur	P	24			
10	42.03	Ingur	P	25			
11				26			
12				27			
13				28			
14				29			
15				30			


13. CONTAINER CONSUMPTION DETAILS:

S. No	Time		Container No.	Consumed by	S. No	Time		Container No.	Consumed by
	From	To				From	To		
1	16:15	18:00	01	Suhv	16				
2	08:30	14:20	01	Suhv	17				
3	08:25	18:50	02	Suhv	18				
4	08:40	15:20	03	Suhv	19				
5	15:10	18:00	04	Suhv	20				
6	08:40	14:10	05	Suhv	21				
7	14:10	17:00	06	Suhv	22				
8	08:30	14:20	07	Rahv	23				
9	14:30	18:00	08	Rahv	24				
10	08:30	14:20	09	Rahv	25				
11	14:15	18:00	10	Rahv	26				
12					27				
13					28				
14					29				
15					30				

Checked By Packing (Sign./Date): [Signature] 05/05/21 Verified by IPQA (Sign./Date): [Signature] 05/05/21

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	
Date	03/01/2021	03/01/2021	04/01/2021	04/01/2021	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 10 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: G13210301 Generic Health Care Pvt. Ltd.

14. OVERPRINTING OF PRIMARY PACKAGING MATERIALS:

Initial checks of Overprinting Details

Overprinting Details	Overprinted Text	Printed AL. Foil (OK/ not OK)
Code No.: PON/DRUGS/19 13 4323	PON/DRUGS/19134323	OK
Batch No.:	G13210301	OK
Mfg. Date:	03/2021	OK
Exp. Date:	02/2024	OK
Item Code: 13/0241	13/0241	OK
Other instructions if any	NA	OK
Initiated by	Sugumar	OK
Checked by Packing (Sign. & Date)	S. N. S.	OK
Verified by IPQA (Sign. & Date)	S. N. S.	OK

15. SPECIMEN OF PRINTED FOIL:

S. No.	Date	Specimen No.	Done By Sign & Date	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01.	05/05/2021 G1	1	Sugumar 05/05/21	OK	OK
02.	06/05/2021 G1	1	Sugumar 06/05/21	OK	OK
03.	07/05/2021 G1	1	Sugumar 07/05/21	OK	OK
04.	08/05/2021 G1	1	Sugumar 08/05/21	OK	OK

16. PACKING INSTRUCTIONS:

- Verify the status of dispensed primary packaging materials and transfer to the Primary Packing Area.
- Issue the stereotypes to the concerned Technician and set as per SOP No. QAGN/030 and Record the details in respective table.
- Set and operate Blister Packing Machine as per SOP No. PDOP/021 & PDOP/022.
- Verify the status label of overprinted packaging materials and transfer to the packing line in secondary packing hall.
- Perform Leak Test as per SOP No. QAGN/045 and enter the observations in respective table.
- 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.
- Attach proof of printed foil from each roll dispensed as and when used on machine.
- 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.
- Affix first overprinted AL. foil, Carton, Shipper and shipper label duly checked by Packing and verified by IPQA.
- Pack 10 tablets 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.	05/05/2021 G1	16.15	18.00	16.30	18.00	OK
02.	06/05/2021 G1	9.40	19.00	9.30	18.00	OK
03.	07/05/2021 G1	9.40	18.00	9.30	18.00	OK
04.	08/05/2021 G1	9.40	17.00	9.30	18.00	OK
05.	10/05/2021 G1	9.50	18.00	9.30	18.00	OK
06.	11/05/2021 G1	18.15	19.45	9.30	17.30	OK


17. 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.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	S. N. S.	S. N. S.	S. N. S.
Date	03/01/2021	03/01/2021	03/01/2021	03/01/2021

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 11 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: G1F210301 Generic Health Care Pvt. Ltd.

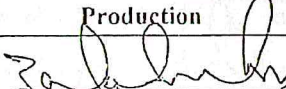
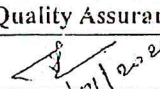
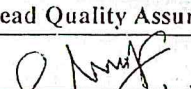
18. **BLISTER PACKING MACHINE PARAMETERS:** Date/Shift: 05/05/2021 Time: 1.15 PM

Parameters	Standard and Limits	Observation	Checked by Packing Sign. / Date	Checked by IPQA Sign. / Date
Change Parts Details	PPC 09 20/6 112.1	OK	DD 05/05/2021	Jes 05/05/2021
Sealing Temperature	(150-200°C) To be established	180°C	DD 05/05/2021	Jes 05/05/2021
Forming Temperature	(110-160°C) To be established	140°C	DD 05/05/2021	Jes 05/05/2021
Leak test to be performed on Blister	Nil (No Blister should fail in leak test)	YES	DD 05/05/2021	Jes 05/05/2021
Machine Speed	To be established	30	DD 05/05/2021	Jes 05/05/2021


19. **MACHINE IN-PROCESS CONTROL:**

Date/ Shift	05/05/2021 and 06/05/2021															
Machine Operator Name	Sugumar															
Time of inspection	16:15	16:30	17:15	17:40	18:15	18:40	19:15	19:40	20:15	20:40	21:15	21:40	22:15	22:40	23:15	23:40
Sealing Temperature (To be established)	163°C	163°C	163°C	163°C	163°C	163°C	163°C	163°C	163°C	163°C	163°C	163°C	163°C	163°C	163°C	163°C
Forming Temperature (To be established)	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C
Leak test on Blister* (Qty.: 35 06)	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/ 19 13 4323	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
B. No.: G1F210301	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Mfg. Date	03/2021	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Exp. Date	02/2024	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Machine Speed To be established	20	20	30	25	25	20	20	25	25	25	25	25	25	25	25	25
Checked by (Packing)	DD	NA	DD	DD	NA	DD	DD	NA	DD	DD	DD	DD	NA	DD	DD	NA
Checked by (IPQA)	NA	Jes	NA	NA	Jes	NA	NA	Jes	NA	Jes	NA	NA	Jes	NA	NA	Jes

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			
Date	03/01/2021	03/01/2021	04/01/2021	04/01/2021

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 12 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: G1F210301 Generic Health Care Pvt. Ltd.


19.1 MACHINE IN-PROCESS CONTROL:

Date/ Shift	07/05/2021														
Machine Operator Name	Sugumar														
Time of inspection	9.40	10.00	10.40	11.20	12.00	12.15	12.50	13.00	14.00	15.00	15.00	16.00	17.00	17.40	
Sealing Temperature (To be established)	170.3°C	170.3°C	170.3°C	170.3°C	170.3°C	170.3°C	170.3°C	170.3°C	170.3°C	170.3°C	169.3°C	169.3°C	169.3°C	169.3°C	
Forming Temperature (To be established)	170.4°C	170.4°C	170.4°C	170.4°C	170.3°C	170.3°C	170.3°C	170.4°C	170.4°C	170.4°C	169.6°C	169.6°C	170.4°C	169.4°C	
Leak test on Blister* (Qty.: 06)	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	
Pocket Formation	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	
Vertical cutting	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	
Code No.: PON/DRUGS/ 19 13 4323	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
B. No.: G1F210301	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Mfg. Date 03/2021	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Exp. Date 02/2024	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Machine Speed To be established	25	25	25	25	25	25	25	25	25	25	25	25	25	25	
Checked by (Packing)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
Checked by (IPQA)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	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.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L.K.</i>	<i>Sugumar</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	03/01/2021	03/01/2021	03/01/2021	03/01/2021

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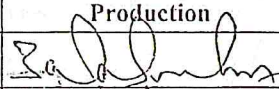
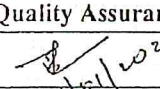

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 13 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product GENSET	BPR. No.: BPR/T/195-00 Customer:		Batch No.: <u>G13210301</u> Generic Health Care Pvt. Ltd.

19.2 MACHINE IN-PROCESS CONTROL:


Date/ Shift	08/05/2021 G												
Machine Operator Name	Sugumar												
Time of inspection	9.40	10.15	10.40	11.10	12.15	12.40	13.40	14.15	14.40	15.40	16.20	16.40	
Sealing Temperature (To be established)	170.4	170.3	170.6	170.8	170.3	170.8	170.3	170.3	170.4	170.8	170.3	170.8	
Forming Temperature (To be established)	165.4	169.2	166.4	168.2	168.4	166.4	166.4	169.2	166.4	166.4	169.2	166.4	
Leak test on Blister* (Qty.: <u>06</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/ 19 13 4323	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
B. No.: G13210301	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Mfg. Date: 03/2021	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Exp. Date: 02/2024	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Machine Speed To be established	22	25	25	25	25	22	22	25	22	22	25	22	
Checked by (Packing)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
Checked by (IPQA)	NA	NA	NA	NA	NA	NA	NA	NA	NA	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.

100.E.
200

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

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 14 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product GENSET	BPR. No.: BPR/T/195-00 Customer:		Batch No.: <u>G1F210301</u> Generic Health Care Pvt. Ltd.

19.3 MACHINE IN-PROCESS CONTROL:

Date/ Shift	10/05/2021 CH												
Machine Operator Name	Sugumar												
Time of inspection	9.50	10.00	10.50	11.50	12.00	13.05	14.05	14.00	15.05	16.00	16.05	17.10	
Sealing Temperature (To be established)	171.0°C	171.0°C	171.0°C	171.0°C	171.0°C	171°C	171°C	170.4°C	170.4°C	170.4°C	170.4°C	170.4°C	
Forming Temperature (To be established)	167.9°C	167.9°C	167.9°C	167.9°C	167.9°C	167.9°C	167.9°C	167.9°C	167.9°C	167.9°C	167.9°C	167.9°C	
Leak test on Blister* (Qty.: _____)	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/ 19 13 4323	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
B. No.: G1F210301	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Mfg. Date 03/2021	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Exp. Date 02/2024	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Machine Speed To be established	20	20	20	20	25	25	25	25	25	25	25	25	
Checked by (Packing)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
Checked by (IPQA)	NA	NA	NA	NA	NA	NA	NA	NA	NA	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.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K	[Signature]	[Signature]	[Signature]
Date	03/01/2021	03/01/2021	04/01/2021	

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

BATCH PACKING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

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

Batch No.: 61F210301




Customer:

Generic Health Care Pvt. Ltd.

19.4 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/ 19 13 4323										
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.

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

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

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

Page 16 of 29

BATCH PACKING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

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

Batch No.: G1F210301

Customer:

Generic Health Care Pvt. Ltd.

19.5 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)
10/05/2021	11:00	14:00	2.600 kg	selvi, devi, Ravi	10/05/2021	10/05/2021
Total Weight of De-foiled Tablets			2.600 kg	Checked By / Date (Packing): 10/05/2021		Verified By / Date (IPQA): 10/05/2021

19.6 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		
10/05/2021	14:05	14:30	selvi, Peri	2.540	21166	0.060	500	10/05/2021	10/05/2021
Total				2.540	21166	0.060	500		
Total Quantity of Rejected Tablets Destroyed				Checked By / Date (Packing): 10/05/2021			Verified By / Date (IPQA): 10/05/2021		
0.060 Kgs 500 Nos.									

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	1-K	3-1-2021	2-1-2021	2-1-2021
Date	10/05/2021	10/05/2021	10/05/2021	10/05/2021

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 17 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product GENSET	BPR. No.: BPR/T/195-00		Batch No.: G1F210301
	Customer:		Generic Health Care Pvt. Ltd.

20. 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.					
2	Check and ensure that waste bin is emptied out and cleaned					
3	Check the Pallets and crates area clean and free from any leftovers of previous product /Batch.					
4	Check and ensure the Correct status board is written.			NA		
5	Check and ensure the previous batch details are deleted from the inkjet machine.					
6	Check and ensure the rejected Cartons of previous product/batch are removed.					
7	Check and ensure the cleanliness of hatch for conveyor belt.					
8	Check and ensure the cleanliness of conveyer belt with collateral block.					
9	Check and ensure the dispensed secondary packing material.					
10	Check and ensure the Preventive maintenance records and log book.					

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

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

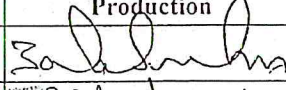
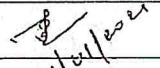
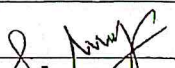
Cleaning Satisfactory / Not satisfactory#
(IPQA) Sign. /Date:

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.

20.1 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.:	NA		
Cleaned by:			
Checked by Packing:			
Verified by IPQA:			

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka			
Date	03/01/2021	03/01/2021	04/01/2021	04/01/2021

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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 18 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: GPF210301 Generic Health Care Pvt. Ltd.

20.2 OVERPRINTING DETAILS:

Overprinting Details	Overprinted Text	Carton (OK/ Not OK)
Batch No.:	GPF210301	OK
Mfg. Date:	03/2021	OK
Exp. Date:	02/2024	OK
Item Code: 15/0362	13/0241	OK
Code No.: PON/DRUGS/19 13 4323	PON/DRUGS/19/134323	OK
Other instructions if any	NA	OK
Initiated by Sign. & Date	Sugumar	OK
Checked by Packing Sign. & Date	Dr. O	OK
Verified by IPQA Sign. & Date	Jey 05/05/2021	Jey 05/05/2021

20.3 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		


20.4 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.	L. K.	Sugumar	Jey 04/01/2021	Jey 04/01/2021
Date	03/01/2021	03/01/2021		

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 19 of 29
	BATCH PACKING RECORD	Product Code: G13	Batch Size: 30,00,000 Tablets
	Product	GENSET	BPR. No.: BPR/T/195-00
		Customer:	Generic Health Care Pvt. Ltd.

21. LINE CLEARANCE CHECKS - SECONDARY PACKING

Date/ Shift ..05/05/2021...G1...and...06/05/2021...G1

Previous Product: <u>Voglow M.O.2</u>		Batch No.: <u>VD12102D</u>				
Sr. No.	Checks	Time	Observation			
			10.15		9.30	
			Packing	IPQA	Packing	IPQA
1	Check and ensure that the area is visually clean and free from previous product.		✓	✓	✓	✓
2	Check and ensure that waste bin is emptied out and cleaned		✓	✓	✓	✓
3	Check the Pallets area clean and free from any leftovers of previous product /Batch.		✓	✓	✓	✓
4	Check and ensure the Correct status board is written.		✓	✓	✓	✓
5	Check and ensure the stereo of the previous product/batch removed and cut into pieces.		✓	✓	✓	✓
6	Check and ensure the Blisters, rejected Carton, Shipper and shipper label of previous product/batch are removed.		✓	✓	✓	✓
7	Check and ensure the cleanliness of hatch for conveyor belt.		✓	✓	✓	✓
8	Check and ensure the cleanliness of conveyer belt with collateral block.		✓	✓	✓	✓
9	Check and ensure the dispensed secondary packing material.		✓	✓	✓	✓
10	Check and ensure the cleanliness of documentation table.		✓	✓	✓	✓
11	Check and ensure the Preventive maintenance records and log book.		✓	✓	✓	✓

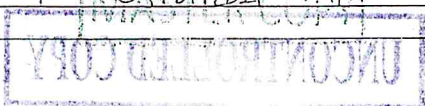
Note: Tick mark (✓) if Complies, (X) if does not comply and (NA) if not applicable.

Cleaning Satisfactory / Not satisfactory# 05/05/2021 (Packing) Sign. /Date: Jesj Cleaning Satisfactory / Not satisfactory# 05/05/2021 (IPQA) Sign. /Date: Jesj


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/BLP/001</u>	<u>PD/BAL/015</u>	<u>NA</u>	<u>M</u>	<u>PD/BAL/035</u>	Secondary Packing Hall
Previous Product:	<u>Voglow M.O.2</u>					
Batch No.:	<u>Voglow VD12102D</u>					
Cleaned by:	<u>Amra</u>					
Checked by Packing:	<u>05/05/2021</u>					
Verified by IPQA:	<u>Jesj</u>					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L.K</u>	<u>3a</u>	<u>24/01/2021</u>	<u>8.1</u>
Date	<u>03/01/2021</u>	<u>03/01/2021</u>		<u>03/01/2021</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 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product: GENSET	BPR. No.: BPR/T/195-00 Customer:		Batch No.: G1F210301 Generic Health Care Pvt. Ltd.

21.1 ENVIRONMENTAL CONDITIONS:

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

Shift:.....G1.....		Date/Time: 05/05/2021 16.15		Date/Time: 06/05/2021			
		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	23°C	D. Nayak 05/05/21	[Signature] 05/05/21	23°C	D. Nayak 06/05/21	[Signature] 06/05/21
Secondary Packing Started Date/Time: 05/05/2021 16.30		Completed Date/Time: 06/05/2021 17.20		* 11/05/2021 17.20			
APPROVAL FOR SECONDARY PACKING:		Approved by IPQA Sing/Date: [Signature] 06/05/21					

21.2 PACKING DETAILS:

10 Tablets in each Blister, over code the Blister with the batch details given below,
Place 3 x 10's Blister and one leaflet in each carton.
Place 20 filled carton in a Shrink Sleeve.
Place 24 Shrink sleeves in each 5 ply shipper.
Seal the shipper with BOPP tape with "H" type.

OVER PRINTING DETAILS:

Overprinting Details (Secondary & Tertiary PM)


Overprinting Details	Overprinted Text	Carton (OK/ Not OK)	5 Ply Shipper Label (OK/ Not OK)
Batch No.:	G1F210301	OK	OK
Mfg. Date:	03/2021	OK	OK
Exp. Date:	02/2024	OK	OK
Code No.: PON/DRUGS/19 13 4323	PON/DRUGS/19134323	OK	NA
Pack size:	NA	3 x 10's	24 x 20 x 3 x 10's
Other instructions if any	NA	NA	NA
Initiated by Sign. & Date	NA	NA	NA
Checked by Packing Sign. & Date	D. Nayak 05/05/21	D. Nayak 05/05/21	D. Nayak 05/05/21
Verified by IPQA Sign. & Date	[Signature] 05/05/21	[Signature] 05/05/21	[Signature] 05/05/21

24.1 Shipper Label Specimen:

S. No.	Date	Shipper Label Specimen No.	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01.	05/05/2021	01	D. Nayak 05/05/21	[Signature] 05/05/21

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	[Signature]	[Signature]	[Signature]
Date	10/3/01/2021	10/3/01/2021	10/3/01/2021	10/3/01/2021

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 21 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product GENSET	BPR. No.: BPR/T/195-00		Batch No.: 61F210301
Customer:			Generic Health Care Pvt. Ltd.

23. CARTON WEIGHT LIMIT SETTING: Date/Shift: 05/05/2021 Time: 16:30

Weight of ten individual empty cartons are given below:

1. 3.8	3. 3.8	5. 3.8	7. 2.7	9. 3.8
2. 3.9	4. 3.7	6. 3.8	8. 3.8	10. 3.8

Total weight of ten empty cartons = 37.9

Average weight of an empty carton (A) = Total weight of ten empty carton / 10 = 3.79

Weight of ten individual Blister are given below:

1. 2.3	3. 2.3	5. 2.4	7. 2.4	9. 2.4
2. 2.4	4. 2.4	6. 2.3	8. 2.4	10. 2.4

Total weight of ten Blister = 23.7

Avg. Weight of a Blister (B): total weight of ten Blister / 10 = 2.37

Weight of ten individual Leaflets are given below:

1. 1.5	3. 1.5	5. 1.5	7. 1.4	9. 1.4
2. 1.4	4. 1.5	6. 1.4	8. 1.5	10. 1.5

Total weight of ten Leaflets = 14.6

Avg. Weight of a Leaflet (C): total weight of ten Leaflets / 10 = 1.46

23.1 WEIGHT CHECKS ON CARTON:

Weight of ten empty Carton: 37.9	Average weight of one empty Carton (A): 3.79
Weight of ten filled Blister: 23.7	Average weight of one filled Blister (B): 2.37
Weight of ten Leaflets: 14.6	Average weight of one Leaflet (C): 1.46
Weight of one filled Carton D = (A+3B+C) 12.36	Limit: E = D ± 1 % = 12.23 - 12.48 (To be established)
Checked by Packing/Date: Anand 05/05/21	Verified by IPQA/Date: [Signature] 05/05/21

23.2 SAMPLE DRAWN RECORD:

Sr. No.	Stage of Sample collection	Qty. of Sample	Collected by (Sign. /Date)
1	Control Sample (Initial)	7 x 10 ⁵	Jesp 05/05/2021
2	Control Sample (Middle)	6 x 10 ⁵	Jesp 05/05/21
3	Control Sample (Final)	7 x 10 ⁵	Jesp 11/05/21
4	Stability Sample	100 x 10 ⁵	Jesp 11/05/21
5	Other Sample	NA	NA
6	Analytical sample	12 x 10 ⁵	Jesp 05/05/2021
Total Qty.		172 x 10 ⁵	Jesp 11/05/21

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	[Signature]	[Signature]	[Signature]
Date	03/01/2021	03/01/2021	04/01/2021	04/01/2021

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

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BATCH PACKING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

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

Batch No.: G1F210301

Customer:

Generic Health Care Pvt. Ltd.

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

Date/ Shift	05/05/2021	07 and 06/05/2021 07							05/05/2021 & 06/05/2021						
Parameters	Specification	observation													
		Packing							IPQA						
Time		17:30		19:30	18:30	11:30	12:30	13:30	14:30	11:35	13:35	15:35	14:35		
No. of Blister in a carton	3 Blister with 10 tabs each 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	20 packed cartons	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		
No. of shrink sleeves in a 5 ply shipper	24 shrinks	OK		OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Shipper strapping	Proper strapping	OK	N	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		
Sealing of the shipper with BOPP Tape	H type	OK		OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Checked by		AP		AP	AP	AP	AP	AP	AP	AP	AP	AP	AP		

*Temperature to be mentioned.

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

24.7		SECURITY PRINTING IN PROGRESS					07/05/2021				
Date/ Shift		observation									
Parameters	Specification	06/05/21					07/05/21				
		Packing					IPQA				
Time		14:30	15:30	16:30	17:30		14:30	15:30	16:30	17:30	
No. of Blister in a carton	3 Blister with 10 tabs each and one leaflet.	OK	OK	OK	OK		OK	OK	OK	OK	
Carton Overprinting	Legible and readable	OK	OK	OK	OK		OK	OK	OK	OK	
No. of cartons in a shrink sleeves	20 packed cartons	OK	OK	OK	OK		OK	OK	OK	OK	
Shrink wrapping temperature*		OK	OK	OK	OK		OK	OK	OK	OK	
No. of shrink sleeves in a 5 ply shipper	24 shrinks	OK	OK	OK	OK		OK	OK	OK	OK	
Shipper strapping	Proper strapping	OK	OK	OK	OK		OK	OK	OK	OK	
Label appearance and Shipper appearance	Legible and readable	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	
Checked by		OK	OK	OK	OK		OK	OK	OK	OK	

*Temperature to be mentioned.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L.K.</i>	<i>3a. Sathya</i>	<i>8. Sathya</i>	<i>8. Sathya</i>
Date	03/01/2021	03/01/2021	03/01/2021	03/01/2021

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

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BATCH PACKING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

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

Batch No.: 9P210301

Customer:

Generic Health Care Pvt. Ltd.

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

Date/ Shift		08/05/2021 G 7 09/05/2021 11/05/2021															
Parameters	Specification	Revised. observation															
		Packing								IPQA							
Time		16:30	17:32	09:50	10:45	11:37	12:40	13:25	14:15	15:55	17:10	18:10	19:10				
No. of Blister in a carton	3 Blister with 10 tabs each 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	20 packed cartons	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				
No. of shrink sleeves in a 5 ply shipper	24 shrinks	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		A	A	A	A	A	A	A	A	A	A	A	A				

*Temperature to be mentioned.

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

Date/ Shift		09/05/2021 G 7 10/05/2021															
Parameters	Specification	observation															
		Packing								IPQA							
Time		14:42	15:46	16:33	17:41	09:48	10:55	11:40									
No. of Blister in a carton	3 Blister with 10 tabs each and one leaflet.	ok	ok	ok	ok	ok	ok	ok									
Carton Overprinting	Legible and readable	ok	ok	ok	ok	ok	ok	ok									
No. of cartons in a shrink sleeves	20 packed cartons	ok	ok	ok	ok	ok	ok	ok									
Shrink wrapping temperature*		ok	ok	ok	ok	ok	ok	ok									
No. of shrink sleeves in a 5 ply shipper	24 shrinks	ok	ok	ok	ok	ok	ok	ok									
Shipper strapping	Proper strapping	ok	ok	ok	ok	ok	ok	ok									
Label appearance and Shipper appearance	Legible and readable	ok	ok	ok	ok	ok	ok	ok									
Sealing of the shipper with BOPP Tape	H type	ok	ok	ok	ok	ok	ok	ok									
Checked by		A	A	A	A	A	A	A									

*Temperature to be mentioned.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	10/05/2021	03/01/2021	06/01/2021	06/01/2021

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DEPARTMENT OF THE HISTORY OF ARTS AND ARCHITECTURE

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

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BATCH PACKING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

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

Batch No.: GF 210301

Customer:

Generic Health Care Pvt. Ltd.

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

Date/ Shift	10/05/2021		11/05/2021											
Parameters	Specification	observation												
		Packing				IPQA								
Time		12:38	13:39	14:42	15:46	16:44	17:39	18:52						
No. of Blister in a carton	3 Blister with 10 tabs each and one leaflet.	OK	OK	OK	OK	OK	OK	OK						
Carton Overprinting	Legible and readable	OK	OK	OK	OK	OK	OK	OK						
No. of cartons in a shrink sleeves	20 packed cartons	OK	OK	OK	OK	OK	OK	OK						
Shrink wrapping temperature*		OK	OK	OK	OK	OK	OK	OK						
No. of shrink sleeves in a 5 ply shipper	24 shrinks	OK	OK	OK	OK	OK	OK	OK						
Shipper strapping	Proper strapping	OK	OK	OK	OK	OK	OK	OK						
Label appearance and Shipper appearance	Legible and readable	OK	OK	OK	OK	OK	OK	OK						
Sealing of the shipper with BOPP Tape	H type	OK	OK	OK	OK	OK	OK	OK						
Checked by		OK	OK	OK	OK	OK	OK	OK						

*Temperature to be mentioned.

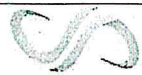
24.1 SECONDARY PACKING IN-PROCESS CHECKS: (Please keep ✓ mark if found "Ok")

Date/ Shift	11/05/2021												
Parameters	Specification	observation								IPQA			
		Packing											
Time		10:47	11:53	12:44	13:38	14:50	15:55	16:50					
No. of Blister in a carton	3 Blister with 10 tabs each and one leaflet.	OK	OK	OK	OK	OK	OK	OK					
Carton Overprinting	Legible and readable	OK	OK	OK	OK	OK	OK	OK					
No. of cartons in a shrink sleeves	20 packed cartons	OK	OK	OK	OK	OK	OK	OK					
Shrink wrapping temperature*		OK	OK	OK	OK	OK	OK	OK					
No. of shrink sleeves in a 5 ply shipper	24 shrinks	OK	OK	OK	OK	OK	OK	OK					
Shipper strapping	Proper strapping	OK	OK	OK	OK	OK	OK	OK					
Label appearance and Shipper appearance	Legible and readable	OK	OK	OK	OK	OK	OK	OK					
Sealing of the shipper with BOPP Tape	H type	OK	OK	OK	OK	OK	OK	OK					
Checked by		OK	OK	OK	OK	OK	OK	OK					

*Temperature to be mentioned.

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	
Date	11/05/2021	03/01/2021	01/01/2021	01/01/2021	

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SAI PRIMUS
LIFE BIOTECH PVT LTD

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

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BATCH PACKING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets.

Product

GENSET

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

Batch No.: 6F21030

Customer:

Generic Health Care Pvt. Ltd.

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

Date/ Shift	07/05/2021 G1												08/05/2021				
Parameters	Specification	Packing								observation							
										IPQA							
Time		11:15	12:15	13:15	14:15	15:25	16:16	17:15	18:25	19:25	20:30	21:45					
No. of Blister in a carton	3 Blister with 10 tabs each 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	20 packed cartons	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					
No. of shrink sleeves in a 5 ply shipper	24 shrinks	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					
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	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok					
Checked by		ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok					

*Temperature to be mentioned.

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

Date/ Shift		08/05/2021 G1								09/05/2021 10/05/2021							
Parameters	Specification	09:30 observation															
		Packing								IPQA							
Time		09:30	10:30	11:35	12:40	13:35	14:30	15:30	16:00	12:05	14:00	16:01	17:40				
No. of Blister in a carton	3 Blister with 10 tabs each 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	20 packed cartons	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				
No. of shrink sleeves in a 5 ply shipper	24 shrinks	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		one	one	one	one	one	one	one	fast	fast	fast	fast	fast				

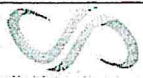
*Temperature to be mentioned.

W.F

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	08/05/2021	08/05/2021	08/05/2021	08/05/2021

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SAI PRIMUS
LIFE BIOTECH PVT LTDSAI 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: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

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

Batch No.: CTF210301

Customer:

Generic Health Care Pvt. Ltd.

25. SHIPPERS WEIGHING:

Date/Shift: 05/05/2021... Time: 17:30... Balance I.D. No. PD/BAL/1039

Weight of ten Shrinks:

3278.4

Average weight of one filled Shrink (H):

327.840

Weight of ten empty shippers:

7.60

Average weight of one empty shipper (I):

0.760

Weight of one filled shipper (J) = (24H+I):

7.317

Limit: K = J ± 1% =
(to be established)

7.243 - 7.390

Checked by Packing/Date:

P. S. / 05/05/2021

Verified by IPQA/Date:

J. S. / 05/05/2021

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	7.310	Prabha	56	7.085	Kaityan	111	7.050	Ansh	166	6.900	Ajanta
2	7.305	Prabha	57	7.080	Kaityan	112	7.135	Ansh	167	6.901	Ajanta
3	7.310	Prabha	58	7.085	Kaityan	113	7.085	Ansh	168	6.930	Ajanta
4	7.310	Prabha	59	6.975	Kaityan	114	7.100	Ansh	169	6.890	Ajanta
5	7.295	Prabha	60	7.110	Kaityan	115	7.075	Ansh	170	6.890	Ajanta
6	7.305	Prabha	61	6.955	Kaityan	116	7.115	Ansh	171	6.890	Ajanta
7	7.300	Prabha	62	6.900	Kaityan	117	7.075	Ansh	172	6.900	Ajanta
8	7.300	Prabha	63	7.090	Kaityan	118	7.075	Ansh	173	6.900	Ajanta
9	7.310	Prabha	64	7.065	Kaityan	119	7.150	Ansh	174	6.890	Ajanta
10	7.215	Prabha	65	7.105	Kaityan	120	7.090	Ansh	175	6.900	Ajanta
11	7.305	Prabha	66	6.900	Kaityan	121	7.080	Ansh	176	6.980	Ajanta
12	7.305	Prabha	67	6.950	Kaityan	122	7.110	Ansh	177	7.125	Ajanta
13	7.310	Prabha	68	6.950	Kaityan	123	7.150	Ansh	178	7.050	Ajanta
14	7.310	Prabha	69	7.060	Kaityan	124	7.125	Ansh	179	7.044	Ajanta
15	7.305	Prabha	70	7.010	Kaityan	125	7.095	Ansh	180	7.095	Ajanta
16	7.300	Prabha	71	7.035	Kaityan	126	7.040	Ansh	181	6.955	Ajanta
17	7.300	Prabha	72	7.080	Kaityan	127	7.020	Ansh	182	6.960	Ajanta
18	7.295	Prabha	73	6.995	Kaityan	128	6.985	Kaityan	183	6.915	Ajanta
19	7.295	Prabha	74	7.095	Kaityan	129	6.950	Kaityan	184	6.985	Ajanta
20	7.315	Prabha	75	7.155	Kaityan	130	6.940	Ansh	185	6.901	Ajanta
21	7.300	Prabha	76	6.895	Kaityan	131	7.230	Ansh	186	6.945	Ajanta
22	7.290	Prabha	77	7.280	Kaityan	132	6.900	Ansh	187	7.025	Ajanta
23	7.300	Prabha	78	6.930	Kaityan	133	7.115	Kaityan	188	7.040	Ajanta
24	7.290	Prabha	79	7.095	Kaityan	134	7.025	Ansh	189	7.020	Ajanta
25	7.305	Prabha	80	7.245	Kaityan	135	7.020	Ansh	190	7.060	Ajanta
26	7.300	Prabha	81	7.020	Kaityan	136	7.000	Ansh	191	7.085	Ajanta
27	7.300	Prabha	82	7.025	Kaityan	137	6.950	Kaityan	192	7.160	Ajanta
28	7.305	Prabha	83	7.035	Kaityan	138	7.010	Kaityan	193	7.280	Ajanta
29	7.305	Prabha	84	7.110	Kaityan	139	7.010	Kaityan	194	7.135	Ajanta
30	7.325	Prabha	85	7.095	Ansh	140	6.995	Kaityan	195	7.190	Ajanta
31	7.305	Prabha	86	7.110	Kaityan	141	7.015	Kaityan	196	7.315	Ajanta
32	7.305	Prabha	87	7.190	Kaityan	142	7.075	Kaityan	197	7.300	Ajanta
33	7.310	Prabha	88	7.205	Kaityan	143	7.020	Kaityan	198	7.375	Ajanta
34	7.320	Prabha	89	7.170	Kaityan	144	6.940	Kaityan	199	7.370	Ajanta
35	7.325	Prabha	90	7.145	Kaityan	145	7.255	Kaityan	200	7.365	Ajanta

Prepared by:

Checked by:

Approved By:

Dept.

Production

Production

Quality Assurance

Head Quality Assurance

Sign.

Date


03/01/2021

03/01/2021

03/01/2021

03/01/2021

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 25 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product GENSET	BPR. No.: BPR/T/195-00		Batch No.: 61F210301
		Customer:	Generic Health Care Pvt. Ltd.

36	7.325	Prabha	91	7.090	Ansara	146	6.960	Kaigai	201	5.725	Kay
37	7.325	Prabha	92	7.010	Ansara	147	7.020	Kaigai	202		
38	7.340	Prabha	93	6.965	Ansara	148	6.940	Kaigai	203		
39	7.315	Prabha	94	6.980	Ansara	149	7.000	Kaigai	204		
40	7.330	Prabha	95	6.950	Ansara	150	6.910	Kaigai	205		
41	7.320	Prabha	96	6.970	Ansara	151	6.955	Kaigai	206		
42	7.320	Prabha	97	7.060	Ansara	152	7.020	Kaigai	207		
43	7.325	Prabha	98	7.040	Ansara	153	7.000	Kaigai	208		
44	7.325	Prabha	99	7.055	Ansara	154	7.025	Kaigai	209		
45	6.990	Prabha	100	7.165	Ansara	155	7.105	Kaigai	210		
46	7.300	Prabha	101	7.115	Ansara	156	7.085	Kaigai	211		
47	7.180	Prabha	102	7.195	Ansara	157	7.030	Kaigai	212		
48	7.380	Prabha	103	7.130	Ansara	158	6.935	Kaigai	213		
49	7.250	Prabha	104	7.170	Ansara	159	6.940	Kaigai	214		
50	7.000	Prabha	105	7.115	Ansara	160	6.940	Kaigai	215		
51	7.005	Prabha	106	7.050	Ansara	161	6.936	Kaigai	216		
52	7.350	Prabha	107	7.125	Ansara	162	6.035	Kaigai	217		
53	7.015	Prabha	108	7.015	Ansara	163	7.030	Kaigai	218		
54	6.990	Prabha	109	7.040	Ansara	164	7.040	Kaigai	219		
55	7.060	Prabha	110	7.125	Ansara	165	7.045	Kaigai	220		
Total No. of shippers weighed:		De-foiled tablets packed in Shipper No:		Checked by Sign / Date:		Verified by Sign / Date:		Loose-pack details:			
201		201		Ar2		Jey 11/05/21		Shipper No: 201.....			
								Quantity...1.8...2.0...3...3			
								Weight....5...7.21			

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

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K	30/01/2021	30/01/2021	30/01/2021
Date	03/01/2021	03/01/2021		

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

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

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BATCH PACKING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

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

Batch No.: G1F210301

Customer:

Generic Health Care Pvt. Ltd.


26. MAN POWER ALLOCATION:

DATE: 05/05/2021 SHIFT: G1		DATE: 06/05/2021 SHIFT: G1	
ACTIVITIES	DONE BY	ACTIVITIES	DONE BY
Blister Checking	Amsaraka, Phushpa	Blister Checking	Phushpa, Revathi
Printing Checking in Blister	Meenachi, Dhana Lakshmi	Printing Checking in Blister	Amsaraka, Dhana Lakshmi
Insertion of Blister and leaflet into carton	Nakashvari, Vacteriya, Aarthi, Samshya, Sujitha	Insertion of Blister and leaflet into carton	Bakiya, Parkali, Vitoriya, Kanga, Shanthi, Komathi
Cartons weighing	Prabha	Cartons weighing	Prabha
Insertion of carton into shrink sleeve	Kangna, Prabha, Komathi	Insertion of carton into shrink sleeve	Kangna, Prabha, Komathi
Insertion of shrink wrapped carton into shipper	Sujitha, Bakiya	Insertion of shrink wrapped carton into shipper	Sujitha, Bakiya
Shipper Label Pasting	Nadhine	Shipper Label Pasting	Nadhine
Shipper Weighing	Nadhine	Shipper Weighing	Nadhine
Shipper Strapping	Kathavarayan	Shipper Strapping	Kathavarayan
Shipper packed	From 01 to 12	Shipper packed	From 13 to 59
Signature of Packing	C	Signature of Packing	C



DATE: 07/05/2021 SHIFT: G1		DATE: 08/05/2021 SHIFT: G1	
ACTIVITIES	DONE BY	ACTIVITIES	DONE BY
Blister Checking	Phushpa, Revathi	Blister Checking	Phushpa, Revathi
Printing Checking in Blister	Amsaraka, Dhana Lakshmi	Printing Checking in Blister	Amsaraka, Dhana Lakshmi
Insertion of Blister and leaflet into carton	Parkodi, Vitoriya, Kanga, Shanthi, Komathi	Insertion of Blister into carton	Parkodi, Vitoriya, Parkali, Kanga, Shanthi, Komathi
Cartons weighing	Bakiya	Cartons weighing	Prabha
Insertion of carton into shrink sleeve	Prabha, mapji	Insertion of carton into shrink sleeve	manjira, indra
Insertion of shrink wrapped carton into shipper	Sujitha, Bakiya	Insertion of shrink wrapped carton into shipper	Bakiya, Sujitha
Shipper Label Pasting	Nadhine	Shipper Label Pasting	Nadhine
Shipper Weighing	Nadhine	Shipper Weighing	Nadhine
Shipper Strapping	Kathavarayan	Shipper Strapping	Kathavarayan
Shipper packed	From 60 to 100	Shipper packed	From 101 to 140
Signature of Packing	C	Signature of Packing	C


Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K.	B. Lakshmi	outlet	J. Jeyaraj
Date	03/01/2021	03/01/2021		


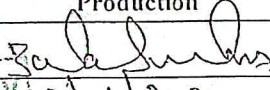
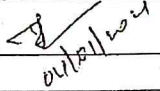
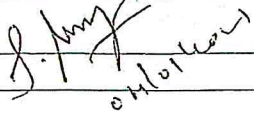
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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 26 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: G1F210301 Generic Health Care Pvt. Ltd.

26. MAN POWER ALLOCATION:

DATE: 09/05/2021..		DATE: 10/05/2021.	
SHIFT:G1.....		SHIFT:G1.....	
ACTIVITIES	DONE BY	ACTIVITIES	DONE BY
Blister Checking	Pushpa, Meenachi	Blister Checking	Pushpa, Meenachi
Printing Checking in Blister	Dhanalakshmi, Tamil	Printing Checking in Blister	Tamil, Dhanalakshmi
Insertion of Blister and leaflet into carton	Bakiya, Anbu, Porbedi, Shanthi, Velli	Insertion of Blister and leaflet into carton	Bakiya, Anbu, Shanthi, Velli
Cartons weighing	Mageshvari	Cartons weighing	Mageshvari
Insertion of carton into shrink sleeve	Leema, Kasthuri	Insertion of carton into shrink sleeve	Leema, Kasthuri
Insertion of shrink wrapped carton into shipper	Amsa	Insertion of shrink wrapped carton into shipper	Amsa
Shipper Label Pasting	Prabha	Shipper Label Pasting	Prabha
Shipper Weighing	Prabha	Shipper Weighing	Prabha
Shipper Strapping	Prabha	Shipper Strapping	Prabha
Shipper packed	From 141 to 170	Shipper packed	From 171 to 190
Signature of Packing		Signature of Packing	

DATE: 11/05/2021.		DATE:	
SHIFT:G1.....		SHIFT:	
ACTIVITIES	DONE BY	ACTIVITIES	DONE BY
Blister Checking	Pushpa, Tamil	Blister Checking	
Printing Checking in Blister	Meenachi, Bakiya	Printing Checking in Blister	
Insertion of Blister and leaflet into carton	Velli, Shanthi, Anbu, Dhanalakshmi	Insertion of Blister into carton	
Cartons weighing	Amsa	Cartons weighing	
Insertion of carton into shrink sleeve	Prabha, Leema	Insertion of carton into shrink sleeve	
Insertion of shrink wrapped carton into shipper	Prabha	Insertion of shrink wrapped carton into shipper	
Shipper Label Pasting	Prabha	Shipper Label Pasting	
Shipper Weighing	Prabha	Shipper Weighing	
Shipper Strapping	Prabha	Shipper Strapping	
Shipper packed	From 191 to 220	Shipper packed	From to
Signature of Packing		Signature of Packing	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	03/01/2021	03/01/2021		

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 27 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: G1F210301 Generic Health Care Pvt. Ltd.

27. 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	112.51	386.92	10200	10200	5100	209	500	15
B	Additional material received for the batch	NA	NA	NA	NA	NA	NA	NA	NA
C	Total material received (A+B)	112.51	386.92	10200	10200	5100	209	500	15
D	Quantity packed	89.35	360.19	9636	9636	4818	201	500	15
E	Quantity rejected (Online) & Destroyed	1.218	4.614	5598	5598	282	08	NA	NA
F	Quantity Returned	21.85	21.98	NA	NA	NA	NA	NA	NA
G	Sample affixed on BPR	0.050	NA	01	01	NA	NA	NA	NA
H	QC samples	0.010	0.040	NA	NA	NA	NA	NA	NA
I	Other samples (If any)	0.032	0.096	41	41	NA	NA	NA	NA
J	Total accountable Quantity (D+ E+F+G+H+I)	112.51	386.92	10200	10200	5100	209	500	15
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

28. EXCESS PACKING MATERIAL RETURN TO STORE: MRN NO. f/d

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	21.85	21.98						
Material returned by packing Sign./Date	31/05/2021	31/05/2021						
Verified By IPQA Sign./Date	31/05/2021	31/05/2021						
Material received by Store Sign./Date	31/05/2021	31/05/2021						


29. 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)
31/05/2021	24	1.218	4.614	5598	5598	282	08	NA	NA
Total Qty. Destroyed	24	1.218	4.614	5598	5598	282	08	NA	NA
Destroyed by (Packing)	31/05/2021								
Verified by (IPQA)	31/05/2021								

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L.R.	31/05/2021	31/05/2021	31/05/2021	
Date	31/05/2021	31/05/2021	31/05/2021	31/05/2021	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 28 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product: GENSET	BPR. No.: BPR/T/195-00 Customer:		Batch No.: G1F210301 Generic Health Care Pvt. Ltd.

30. BATCH RECONCILIATION:

A	Batch Size	30,00,000 Nos.
B	Quantity received for packing	2907455
C	Total quantity packed	2890800
D	Control samples	200
E	Analytical Samples	120
F	In process samples	5300
G	Others samples if any (Stability, Regulatory Samples, etc.)	2000
H	Packing Loss = B - (C + D + E + F + G)	10035
I	Total Loss = A - (C + D + E + F + G)	102580
J	Packing yield % (C + D + E + F + G) / B X 100 (Yield Limit %.....)*	99.65
K	Batch Yield % (C + D + E + F + G) / A X 100 (Yield Limit %.....)*	96.58

*To be established

Checked by Packing /Date: 11/05/2021

Verified by IPQA/Date: 11/05/21

31. 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
11/05/2021	0117	Sales	3x100	24x26x3x100	200	288000	Q	P	Q
				15x20x3x100	01	1080	Q	P	Q
Total Qty. Transferred						289080	Q	P	Q

32. 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:

33. BPR REVIEW DETAILS:

Reviewed by	Name	Sign. /Date
Packing Executive	J. Panivaraman	Q 11/05/2021
QA Executive	Jesintha	Q 11/05/21
Production Assistant Manager/ HOD	Siva Kumar	M 11/05/21
QA Manager/ HOD	Ram Kumar	CM 11/05/21

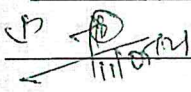
Prepared by:	Checked by:	Approved By:
Dept. Production	Production Quality Assurance	Head Quality Assurance
Sign. L.K.	Q 11/05/21	Q 11/05/21
Date 11/05/2021	03/01/2021	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 29 of 29
	BATCH PACKING RECORD	Product Code: G13	Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00	Batch No.: G1F210301
		Customer:	Generic Health Care Pvt. Ltd.

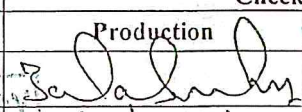
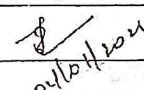
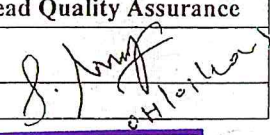
34. BATCH RELEASED FOR DESPATCH:

Total quantity released: 2570880 No's

Head QA sign/ Date: 

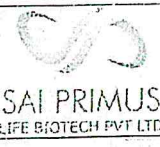
35. REVISION HISTORY:

S. No.	Document No.	Reason for Changes	Supersedes Doc. No.
1	BPR/T/195-00	New Document	Nil


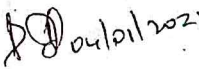
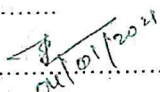


Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K.</u>	<u></u>	<u></u>	<u></u>
Date	<u>03/01/2021</u>	<u>03/01/2021</u>	<u>03/01/2021</u>	<u>03/01/2021</u>

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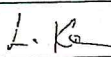
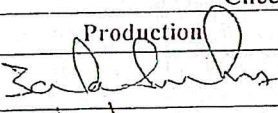
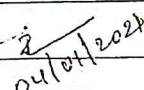
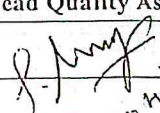
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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 1 of 29
	BATCH PACKING RECORD	Product Code: G13	Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00	Batch No.: GF210101
		Customer:	Generic Health Care Pvt. Ltd.


BATCH PACKAGING RECORD COVER SHEET

PRODUCT NAME	: GENSET
GENERIC NAME	: Cetirizine Tablets BP 10 mg
LABEL CLAIM	: Each film coated tablet contains: Cetirizine Hydrochloride BP10 mg Excipients q.s. Colour: Approved colour used
CODE NO.	: PON/DRUGS/19 13 4323
DOSAGE FORM	: Tablet
BPR No.	: BPR/T/195-00
REVISION No.	: 00
SUPERSEDE No	: NIL
EFFECTIVE BATCH. No. /DATE	: GF210101 / 04/01/2021
MARKET	: Export
SHELF LIFE	: 36 Months
BATCH SIZE	: 30,00,000 Tablets
PACKING CONFIGURATION	: 3 x 10 Tablets Sales Pack (Blister Packing)
BPR ISSUED BY/DATE (QA)	:  04/01/2021
BPR CHECKED & RECEIVED BY/DATE (PRODUCTION)	:  04/01/2021
MFG. DATE: 01/2021	EXP. DATE: 12/2023
ALLOTTED BY: QA SIGN/DATE:  04/01/2021	COUNTER CHECKED BY: QA SIGN/DATE:  04/01/21
QUANTITY RECEIVED FROM PRODUCTION	: 2973278
DATE OF COMMENCEMENT: <u>11/01/2021</u>	DATE OF COMPLETION: <u>21/01/2021</u>
QUANTITY	: 2882880 3,00,000
RELEASED QUANTITY OF PACKED TABLETS	: 2882880
RELEASE OF BATCH BY HEAD QA SIGN/DATE:	 03/01/21

This BPR contains 29 Pages + Additional Pages

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	 L.R.		 04/01/2021	
Date	03/01/2021	03/01/2021		04/01/2021

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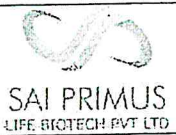
 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 2 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: <u>G1F210101</u> 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	Stereo Issuance and setting Record, Receipt of product and materials, Detail of the product as per BMR	8
9	Weight verification record of received semi-finished product	9
10	Container weight details, Container consumption details	9
11	Over printing of primary packing, Specimen of printed foil	10
12	Packing instruction, specimen of printed foil, time record for packing detail, Packing In-process checks for primary packing	10
13	Blister packing machine parameters	11
14	Challenge test for Non Filling Detection System	11
15	Machine In-Process control	12-14
16	Defoiling of Blister, Inspection of defoiled Tablets	15
17	Line Clearance for Batch Coding, Area and equipment clearance for coding, Overprinting Details, Time record for batch coding, Carton overprinting specimen	16-17
18	Line clearance for secondary packing, Environmental condition, Packing Details	18-19
19	Over printing details, Shipper Label specimen	19
20	Carton Weight Limit Setting, Weight Checks On Carton, Sample Drawn Record	20
21	Secondary Packing In process Checks	21-22
22	Shipper Weighing	23
23	Man power allocation	24
24	Product Counter Check Line Clearance	25-26
25	Packing material reconciliation	27
26	Excess packing material return to store	27
27	Destruction of rejected/unused printed packing materials and stereotypes	27
28	Batch reconciliation	28
29	Transfer of finished goods	28
30	Deviation Detail	28
31	BPR review details	28
32	Batch released for Despatch	29
33	Revision History	29

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ke</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	03/01/2021	03/01/2021	03/01/2021	03/01/2021

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 3 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product GENSET	BPR. No.: BPR/T/195-00		Batch No.: G F 210101
	Customer:		Generic Health Care Pvt. Ltd.

2. CHECKLIST FOR BATCH PACKING RECORD REVIEW:

Instruction:

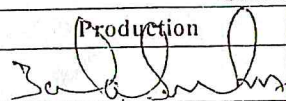
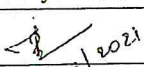
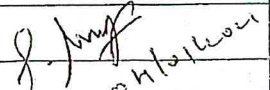
Check the following points before submitting the documents for final Review

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	-
b)	Approved specimen of printed foil, show box 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	Yes
7.	Complete set of BPR Submitted	Yes

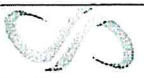
Checked By QA/Date: 25/01/21

*Mention total number of pages.

Remarks (If any)

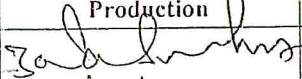
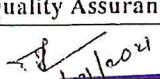
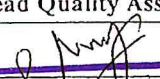
Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka			
Date	03/01/2021	03/01/2021	04/01/2021	04/01/2021

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 4 of 29
	BATCH PACKING RECORD	Product Code: G13	Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00	Batch No.: GF210101
		Customer:	Generic Health Care Pvt. Ltd.

3. PACKING MATERIAL SPECIFICATION AND INDENT:

Sr. No.	Material	Printed item material code	Specification	UOM	Standard Qty. for Batch Size 30.0 Lac.	% Over ages	Qty. Required 30.0 Lac with overages
1	144mm Genset double side printed foil 0.025	PPF/SP/G013	Width – 144 ± 1 mm Thickness – 0.025 mm Language – French Color – 2 Colors GHPL ITEM CODE – 13/0241	Kg	45.000 (To be established)	2	45.900 (To be established)
2	148 mm PVC Film Clear (60 GSM)	PBF/SP/P002	Width – 148 mm Clear PVC	Kg	150.000 (To be established)	2	153.000 (To be established)
3	3x10's Genset printed carton	PHC/SP/G001	Size – 130 x 60 x 25 mm (L x W x H) Board – 300 gsm ITC Cyber XL, UV varnished. Colour – 3 colour Language – English/French GHPL ITEM CODE – 15/0362 1510374	No	100000	2	102000
4	Genset Insert	PHL/SP/G001	Size – 140 x 180 mm (L x H) Specification – NLT 60 gsm Maplitho Paper. Colour – 2 colours Language – French/ English GHPL ITEM CODE – 16/0259	No	100000	2	102000
5	Shrink Sleeves (PVC)	PPS/SP/P001	Plain PVC Shrink Sleeves	No	5000	2	5100
6	5 PLY 390X390X260 MM C/BOXES	PUS/GH/C001	A 5 Ply flute vertical corrugated inner unprinted in nature. (24 B.F.) Outer Size – 390 x 390 x 430 mm (L x W x H) Bursting Strength – NLT 15.00 Kg/cm ²	No	209	-	209
7	3' GHPL Printed Bopp Tape	PPB/SP/B002	Clear Transparent Length of roll – 65m Width – 60 mm Printing – GHPL repeats in Blue	No	15	-	15
8	3' Plain BOPP Tape	PUB/SP/B001	Plain BOPP Tape	No.	3	-	3
9	Strapping role.	PPR/SP/S001	White or milky white colour. Width – 12 mm Thickness – 0.6 mm	Mtrs	500	-	500
10	Shipper Label	NA	Half A4 size Computer printed label	No	209	-	209

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

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	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 5 of 29
	BATCH PACKING RECORD	Product Code: G13	Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00	Batch No.: GF210101
		Customer:	Generic Health Care Pvt. Ltd.

4. DISPENSING LINE CLEARANCE CHECKS

Date: 04/01/2021 Time: 17:48

Sr. No.	CHECKS	Observation*	
		Store	IPQA
1	Check and ensure that empty SS containers, polythene bags, Tags, documents and scrap from waste bin of previous batch/product are removed from the area.	✓	✓
2	Check and ensure that display stand and weighing balance are clean.	✓	✓
3	Check and ensure that SS 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/LA/F1001	ST/B04011	na	na
Previous Product	P Pan - DSR			
B. No.	P0121010			
Cleaned by Sign/Date	K. Lapan / 04/01/2021			
Checked by Store Sign/Date	Key / 04/01/2021			
Verified by IPQA Sign/Date	[Signature] / 04/01/2021			

ENVIRONMENTAL CONDITIONS: Date: 04/01/2021 Time: 17:58	Observation	Checked by Store Sign/Date	Verified by IPQA Sign/Date
(For Reference SOP No.: QAGN/011)			
Temperature (Limit: NMT 25°C)	22°C	04/01/2021	04/01/2021

APPROVAL FOR DISPENSING BY IPQA: Sign: [Signature] Date: 04/01/2021
Dispensing start Time 18:00 End Time 18:40

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	[Signature]	[Signature]	[Signature]
Date	03/01/2021	03/01/2021	04/01/2021	04/01/2021

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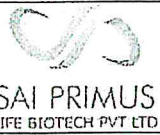
 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 6 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product: GENSET	BPR. No.: BPR/T/195-00		Batch No.: GF 210 101
		Customer:	Generic Health Care Pvt. Ltd.

5. DISPENSING RECORD OF PACKING MATERIALS: Date: 04/01/2021 Shift: Day Time: 18:00

Material Name	Item code	UOM	Req. Qty. for 30.0 Lac	Issued Qty.	A.R No.	No. of Roll/Box	Issued and Checked by Store	Verified by IPQA
144mm Genset double side printed foil 0.025	PPF/SP/G013	Kg	45.900 (To be established)	50.500	pmc1/00804	08	ky 04/01/2021	04/01/2021
148 mm PVC Film Clear (60 GSM)	PBF/SP/P002	Kg	153.000 (To be established)	153.40	pmc1/00714	09	ky 04/01/2021	04/01/2021
3x10's Genset printed carton	PHC/SP/G001	No	102000	102000	pmc1/00602	20	ky 04/01/2021	04/01/2021
Genset Insert	PHL/SP/G001	No	102000	102000	pmc1/00606	08	ky 04/01/2021	04/01/2021
Shrink Sleeves (PVC)	PPS/SP/P001	No	5100					04/01/2021
5 PLY 390X390X260 MM C/BOXES	PUS/GH/C001	No	209	209	pmc1/00756	21	ky 04/01/2021	04/01/2021
3' GHPL Printed Bopp Tape	PPB/SP/B002	No	15	15	pmc1/00036	04	ky 04/01/2021	04/01/2021
3' Plain BOPP Tape	PUB/SP/B001	No	3	03	pmc1/24119/02	01	ky 04/01/2021	04/01/2021
Strapping role.	PSP/SP/S001	Mtrs	500	500	pmc1/00032	01	ky 04/01/2021	04/01/2021
Shipper Label	NA	No	209					04/01/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. R.	30/01/2021	04/01/2021	04/01/2021
Date	03/01/2021	04/01/2021		

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 7 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product GENSET	BPR. No.: BPR/T/195-00 Customer:		Batch No.: GF210101 Generic Health Care Pvt. Ltd.

6. LINE CLEARANCE CHECKS:

6.1 PRIMARY PACKING:

Date/ Shift ...04/01/2021... G..... 05/01/2021... L.....

Previous Product: <u>Frndcal Mr</u>		Batch No.: <u>FR02005L</u>				
Sr. No.	Checks	Time	Observation			
			<u>17:00</u> Packing	IPQA	<u>10:00</u> 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

L. Ka
04/01/2021

Cleaning satisfactory/Not satisfactory

Verified by IPQA (Sign. /Date):

P. Sathish
04/01/2021

#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: <u>Frndcal Mr</u>				Batch No.: <u>FF02005L</u>			
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	<u>BLD/PFF/001</u>	<u>B</u>	<u>PDGN/006</u>	<u>Raghu</u> 04/01/2021	<u>L. Ka</u> 04/01/2021	<u>P. Sathish</u> 04/01/2021
2.	Blister Packing Machine	<u>PD/BLP/00</u>	<u>B</u>	<u>PDOP/021, PDCL/021</u> <u>PDOP/022, PDCL/022</u>	<u>Raghu</u> 04/01/2021	<u>L. Ka</u> 04/01/2021	<u>P. Sathish</u> 04/01/2021


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: <u>04/01/2021</u> Time: <u>17:05</u>			Date: <u>05/01/2021</u> Time: <u>10:00</u>		
	Observation	Packing Sign/Date	Verified by IPQA Sign/Date	Observation	Packing Sign/Date	Verified by IPQA Sign/Date
Temp °C Limit: NMT 25°C	<u>24.1°C</u>	<u>L. Ka</u>	<u>P. Sathish</u> 04/01/2021	<u>22.4°C</u>	<u>P. Sathish</u> 05/01/2021	<u>P. Sathish</u> 05/01/2021
RH % Limit: NMT 60%	<u>54.6°C</u>	<u>L. Ka</u>	<u>P. Sathish</u> 04/01/2021	<u>54.1°C</u>	<u>P. Sathish</u> 05/01/2021	<u>P. Sathish</u> 05/01/2021
DP Limit: NLT 10 Pascal	<u>10 Pascal</u>	<u>L. Ka</u>	<u>P. Sathish</u> 04/01/2021	<u>11 Pascal</u>	<u>P. Sathish</u> 05/01/2021	<u>P. Sathish</u> 05/01/2021
Primary Packing Started Date/Time: <u>04/01/2021</u> 17:05 Completed Date/Time: <u>05/01/2021</u> 10:00.....						
APPROVAL FOR PRIMARY PACKING: IPQA Sign. /Date: <u>P. Sathish</u> 04/01/2021						

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<u>L. Ka</u>	<u>P. Sathish</u>	<u>P. Sathish</u>	<u>P. Sathish</u>	
Date	<u>03/01/2021</u>	<u>03/01/2021</u>	<u>04/01/2021</u>	<u>04/01/2021</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 8 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: GF210101 Generic Health Care Pvt. Ltd.

7. VERIFICATION OF DISPENSED PACKING MATERIALS: Date: 04/01/2021 Shift: N Time: 17:00

Material Name	Item code	UOM	AR No.	Number of Rolls/Packs	Checked by Packing	Verified by QA
144mm Genset double side printed foil 0.025	PPF/SP/G013	Kg	PmG/00804	05	sh	sh
148 mm PVC Film Clear (60 GSM)	PBF/SP/P002	Kg	PmG/00714	09	sh	sh
3x10's Genset printed carton	PHC/SP/G001	No	PmG/00603	20	sh	sh
Genset Insert	PHL/SP/G001	No	PmG/00606	08	sh	sh
Shrink Sleeves (PVC)	PPS/SP/P001	No	NA			
5 PLY 390X390X260 MM C/BOXES	PUS/GH/C001	No	PmG/00756	21	sh	sh
3' GHPL Printed Bopp Tape	PPB/SP/B002	No	PmG/00036	04	sh	sh
3' Plain BOPP Tape	PUB/SP/B001	No	PmB/241019/02	01	sh	sh
Strapping role.	PPR/SP/S001	Mtrs	PmG/00032	01	sh	sh
Shipper Label	NA	No	NA			

8. STEREO ISSUANCE AND SETTING RECORD

S. No.	Type of Stereos	No. of Stereos Issued	Issued By (QA) Sign. & Date	Received By (Packing) Sign. & Date	Stereos Setting Done By	Checked By (Packing) Sign. & Date	Verified By QA Sign. & Date
1.	Stereos	24	sh	sh	sh	L. R	sh

9. RECEIPT OF PRODUCT AND MATERIALS: Date/Shift: 04/01/2021/ N Time: 17:02
(Check the following before start of packing activity and record the observation.)

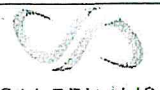
S. No.	Check Points	Observation	Done by (Packing)	Verified By (IPQA)
1.	Temperature observed on display (Limit: NMT 25°C)	24.1°C	sh	sh
2.	Relative Humidity observed on display (Limit: NMT 60%)	54.4%	sh	sh
3.	Bulk product containers are of the required product/Batch number and is approved by QC	yes	sh	sh
4.	Status label of machine/ line is for same product	yes	sh	sh
5.	Printed foil/Base rolls are of the required product.	yes	sh	sh
6.	All secondary packing materials are of the required product	yes	sh	sh

10. DETAIL OF THE PRODUCT AS PER BMR:

Sr. No.	Description	Observations	Checked By (Packing)	Verified By (IPQA)
1.	Average Weight	120.130 mg	sh	sh
2.	Colour of Tablet	white	sh	sh
3.	Quantity (Net Qty.in Kg)	357.180	sh	sh
4.	Number of Containers	13	sh	sh

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. R	sh	sh	sh
Date	03/01/2021	03/01/2021		

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 9 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: G1F210101 Generic Health Care Pvt. Ltd.

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

Balance I.D. No.: 01012017

1. Verify the semi-finished Tablets before starting the packing operation.
2. Verify the batch details on the labels affixed over the Containers against the respective BMR and record the details in below table.

Product Name	Batch No.	Mfg. Date	Exp. Date	Qty. recd. For packing	No. of Containers taken for packing
Gen set	01210101	01/10/2021	12/12/23	357.180 Kg Equivalent to 2973278 Nos.	From Container No. 01 To Container No. 13 Total No. of Containers taken 13
Checked by Packing (Sign. /Date): 01/10/2021				Verified By IPQA (Sign. /Date): 01/10/2021	

12. 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	24.400	hopi	✓	16			
2	28.210	hopi	✓	17			
3	32.800	hopi	✓	18			
4	23.700	hopi	✓	19			
5	26.210	hopi	✓	20			
6	27.390	hopi	✓	21			
7	31.220	hopi	✓	22			
8	24.900	hopi	✓	23			
9	31.370	hopi	✓	24			
10	26.200	hopi	✓	25			
11	27.120	hopi	✓	26			
12	26.820	hopi	✓	27			
13	25.440	hopi	✓	28			
14				29			
15				30			


13. CONTAINER CONSUMPTION DETAILS:

S. No	Time		Container No.	Consumed by	S. No	Time		Container No.	Consumed by
	From	To				From	To		
1	09:00	12:10	1	Urmal	16				
2	12:15	14:15	2	Ran	17				
3	14:15	17:55	3	Ran	18				
4	09:10	09:35	4	Ran	19				
5	09:35	12:00	5	Ran	20				
6	12:00	14:25	6	Ran	21				
7	14:25	16:10	7	Ran	22				
8	16:10	18:00	8	Ran	23				
9	09:30	12:00	9	Ran	24				
10	12:45	17:55	10	Ran	25				
11	09:40	11:10	10	Ran	26				
12	11:10	16:45	11	Ran	27				
13	10:00	11:10	12	Ran	28				
14	11:10	16:45	13	Ran	29				
15	10:00	17:00	13	Ran	30				

Checked By Packing (Sign. /Date): 01/10/2021 Verified by IPQA (Sign. /Date): 01/10/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	01/10/2021	01/10/2021	01/10/2021
Date	01/10/2021	01/10/2021	01/10/2021	01/10/2021

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 10 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: GF210101 Generic Health Care Pvt. Ltd.

14. OVERPRINTING OF PRIMARY PACKAGING MATERIALS:

Initial checks of Overprinting Details

Overprinting Details	Overprinted Text	Printed AL. Foil (OK/ not OK)
Code No.: PON/DRUGS/19 13 4323	PON/DRUGS/19134323	OK
Batch No.:	GF210101	OK
Mfg. Date:	01/2021	OK
Exp. Date:	12/2023	OK
Item Code: 13/0241	13/0241	OK
Other instructions if any	na	na
Initiated by	Ram	Ram
Checked by Packing (Sign. & Date)	17/05/2021	17/05/2021
Verified by IPQA (Sign. & Date)	17/05/2021	17/05/2021

15. SPECIMEN OF PRINTED FOIL:

S. No.	Date	Specimen No.	Done By Sign & Date	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01	05/01/2021	01	Ram	17/05/2021	17/05/2021
02	11/01/2021	01	Ram	17/05/2021	17/05/2021
03	12/01/2021	01	Ram	17/05/2021	17/05/2021
04	13/01/2021	01	Ram	17/05/2021	17/05/2021

16. PACKING INSTRUCTIONS:

- Verify the status of dispensed primary packaging materials and transfer to the Primary Packing Area.
- Issue the stereos to the concerned Technician and set as per SOP No. QAGN/030 and Record the details in respective table.
- Set and operate Blister Packing Machine as per SOP No. PDOP/021 & PDOP/022.
- Verify the status label of overprinted packaging materials and transfer to the packing line in secondary packing hall.
- Perform Leak Test as per SOP No. QAGN/045 and enter the observations in respective table.
- 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.
- Attach proof of printed foil from each roll dispensed as and when used on machine.
- 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.
- Affix first overprinted AL. foil, Carton, Shipper and shipper label duly checked by Packing and verified by IPQA.
- Pack 10 tablets 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	11/01/2021	09:00	19:00	09:10	18:00	17/05/2021
02	12/01/2021	09:00	18:05	09:15	19:00	17/05/2021
03	13/01/2021	09:10	19:00	09:15	19:10	17/05/2021
04	18/01/2021	10:00	18:00	09:30	18:15	17/05/2021
05	19/01/2021	10:05	18:10	09:40	18:10	17/05/2021
06	20/01/2021	10:00	15:05	10:00	18:00	17/05/2021


17. 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.

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka	[Signature]	[Signature]	[Signature]	
Date	03/01/2021	03/01/2021	03/01/2021	03/01/2021	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 10 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product GENSET	BPR. No.: BPR/T/195-00 Customer:		Batch No.: GF210101(A) Generic Health Care Pvt. Ltd.

14. OVERPRINTING OF PRIMARY PACKAGING MATERIALS:

Initial checks of Overprinting Details

Overprinting Details	Overprinted Text	Printed AL. Foil (OK/ not OK)
Code No.: PON/DRUGS/19 13 4323	PON/DRUGS/19134323	OK
Batch No.:	GF210101	OK
Mfg. Date:	01/2021	OK
Exp. Date:	12/2021	OK
Item Code: 13/0241	13/0241	OK
Other instructions if any	NA	NA
Initiated by	Ram V	Ram V
Checked by Packing (Sign. & Date)	GF 18/10/2021	GF 18/10/2021
Verified by IPQA (Sign. & Date)	GF 18/10/2021	GF 18/10/2021

15. SPECIMEN OF PRINTED FOIL:

S. No.	Date	Specimen No.	Done By Sign & Date	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
06	18/10/2021	01	Ram V 18/10/2021	GF 18/10/2021	GF 18/10/2021
07	19/10/2021	01	Ram V 19/10/2021	GF 19/10/2021	GF 19/10/2021
08	20/10/2021	01	Ram V 20/10/2021	GF 20/10/2021	GF 20/10/2021
			N/A		

16. PACKING INSTRUCTIONS:

- Verify the status of dispensed primary packaging materials and transfer to the Primary Packing Area.
- Issue the stereotypes to the concerned Technician and set as per SOP No. QAGN/030 and Record the details in respective table.
- Set and operate Blister Packing Machine as per SOP No. PDOP/021 & PDOP/022.
- Verify the status label of overprinted packaging materials and transfer to the packing line in secondary packing hall.
- Perform Leak Test as per SOP No. QAGN/045 and enter the observations in respective table.
- 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.
- Attach proof of printed foil from each roll dispensed as and when used on machine.
- 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.
- Affix first overprinted AL. foil, Carton, Shipper and shipper label duly checked by Packing and verified by IPQA.
- Pack 10 tablets 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	20/10/2021/1st	09:40	14:30	10:05	18:00	GF 20/10/2021
02	22/10/2021/1st	- NA -	- NA -	09:30	12:20	GF 22/10/2021


17. 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.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	Ram V	GF 20/10/2021	GF 20/10/2021
Date	03/01/2022	03/01/2022		

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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 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: GF210101 Generic Health Care Pvt. Ltd.

18. BLISTER PACKING MACHINE PARAMETERS:

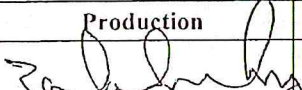
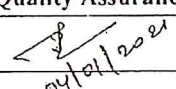
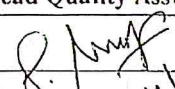
Date/Shift: 05/01/2021 Time: 12:00 PM

Parameters	Standard and Limits	Observation	Checked by Packing Sign. / Date	Checked by IPQA Sign. / Date
Change Parts Details	PFC 0920161121	PFC 0920161121	PFC 05/01/2021	PFC 05/01/2021
Sealing Temperature	(150-200°C) To be established	194°C	PFC 05/01/2021	PFC 05/01/2021
Forming Temperature	(110-160°C) To be established	160°C	PFC 05/01/2021	PFC 05/01/2021
Leak test to be performed on 6 Blister	Nil (No Blister should fail in leak test)	Pass	PFC 05/01/2021	PFC 05/01/2021
Machine Speed	To be established	40	PFC 05/01/2021	PFC 05/01/2021

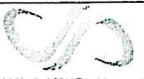
19. MACHINE IN-PROCESS CONTROL:

Date/ Shift	11/01/2021															
Machine Operator Name	Vineet															
Time of inspection	09:05	09:15	09:25	09:35	09:45	09:55	10:05	10:15	10:25	10:35	10:45	10:55	11:05	11:15	11:25	11:35
Sealing Temperature (To be established)	190°C	190°C	190°C	190°C	190°C	190°C	190°C	190°C	190°C	190°C	190°C	190°C	190°C	190°C	190°C	190°C
Forming Temperature (To be established)	164°C	165°C	165°C	165°C	165°C	165°C	165°C	165°C	165°C	165°C	165°C	165°C	165°C	165°C	165°C	165°C
Leak test on Blister* (Qty.: 06)	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/ 19 13 4323	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
B. No.: GF210101	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Mfg. Date 01/2021	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Exp. Date 12/2023	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Machine Speed To be established	35	35	30	30	35	30	30	35	35	30	35	30	35	30	35	35
Checked by (Packing)	PFC	WA	PFC	PFC	NA	PFC	PFC	NA	PFC	PFC	NA	PFC	PFC	NA	PFC	PFC
Checked by (IPQA)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	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.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K			
Date	03/01/2021	03/01/2021	04/01/2021	04/01/2021

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 12 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: <u>G1F210101</u> Generic Health Care Pvt. Ltd.


19.1 MACHINE IN-PROCESS CONTROL:

Date/ Shift	12/01/2021																
Machine Operator Name	vimal																
Time of inspection	07:15	07:30	08:20	09:20	09:35	10:15	11:15	11:20	12:10	13:05	13:50	14:10	15:10	15:50	16:10	17:15	
Sealing Temperature (To be established)	200°C	200°C	190°C	195°C	200°C	194°C	192°C	200°C	196°C	194°C	191°C	190°C	192°C	197°C	190°C	195°C	
Forming Temperature (To be established)	165°C	165°C	160°C	164°C	160°C	162°C	160°C	161°C	164°C	163°C	157°C	160°C	160°C	158°C	160°C	163°C	
Leak test on Blister* (Qty.: <u>06</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/ 19 13 4323	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
B. No.:	G1F210101	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Mfg. Date	01/2021	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Exp. Date	12/2023	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Machine Speed To be established	35	35	30	30	30	35	30	35	30	35	30	35	35	35	35	35	
Checked by (Packing)	sh	NA	sh	sh	NA	sh	sh	NA	sh	sh	NA	sh	sh	NA	sh	sh	
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.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. K.</i>	<i>S. S. S.</i>	<i>S. S. S.</i>	<i>S. S. S.</i>
Date	03/01/2021	03/01/2021	03/01/2021	03/01/2021

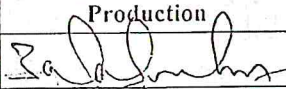
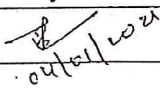
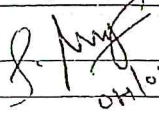
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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 13 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product GENSET	BPR. No.: BPR/T/195-00 Customer:		Batch No.: GF210101 Generic Health Care Pvt. Ltd.

19.2 MACHINE IN-PROCESS CONTROL:

Date/ Shift	12/01/2021 12/01/2021								13/01/2021							
Machine Operator Name	Viney								Viney							
Time of inspection	17:55	09:15	09:25	10:15	11:15	11:30	12:10	13:20	13:40	14:20	15:10	15:30	16:10	17:20	17:30	30
Sealing Temperature (To be established)	178°C	200°C	200°C	198°C	196°C	199°C	192°C	190°C	194°C	192°C	195°C	197°C	192°C	195°C	198°C	198°C
Forming Temperature (To be established)	160°C	157°C	154°C	154°C	155°C	156°C	157°C	154°C	153°C	158°C	155°C	153°C	158°C	157°C	157°C	157°C
Leak test on Blister* (Qty.: 06)	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/ 19 13 4323	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
B. No.:	GF210101	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Mfg. Date	01/2021	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Exp. Date	12/2023	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Machine Speed To be established	35	35	35	35	30	35	35	35	35	35	35	30	35	35	35	OK
Checked by (Packing)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Checked by (IPQA)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	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.

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

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

Page 14 of 29

BATCH PACKING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

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

Batch No.: GF 210101




Customer:

Generic Health Care Pvt. Ltd.


19.3 MACHINE IN-PROCESS CONTROL:

Date/ Shift		13/01/2024 18/01/2024										19/01/2024					
Machine Operator Name		Ramu										Ramu					
Time of inspection		18:10		10:05	10:15	11:10	12:10	13:20	14:10	15:10	15:20	16:00	17:15	17:20		09:10	09:20
Sealing Temperature (To be established)		194°C		194°C	195°C	192°C	190°C	192°C	194°C	190°C	194°C	194°C	190°C	190°C		191°C	192°C
Forming Temperature (To be established)		160°C		160°C	160°C	161°C	160°C	161°C	160°C	159°C	159°C	159°C	160°C	159°C		160°C	159°C
Leak test on Blister* (Qty.: 06)		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
Pocket Formation		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
Vertical cutting		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
Code No.:	PON/DRUGS/ 19 13 4323	OK		OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		OK	OK
B. No.:	GF210101	OK		OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		OK	OK
Mfg. Date	01/2021	OK		OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		OK	OK
Exp. Date	12/2023	OK		OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		OK	OK
Machine Speed To be established		35		40	40	40	35	34	35	35	35	35	35	35		35	35
Checked by (Packing)		SB		SB	SB	SB	SB	SB	SB	SB	SB	SB	SB	SB		SB	SB
Checked by (IPQA)		NA		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	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.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.			
Date	02/01/2021	03/01/2021	04/01/2021	

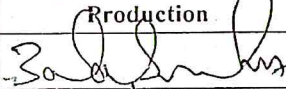
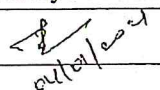
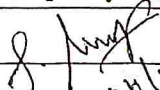
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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 15 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: G F 21 01 01 Generic Health Care Pvt. Ltd.


19.4 MACHINE IN-PROCESS CONTROL:

Date/ Shift	19/01/2021										20/01/2021/4									
Machine Operator Name	Ramu										Ramu									
Time of inspection	10:05	11:05	11:25	12:10	12:00	13:15	14:00	15:05	15:25	16:15	17:30	17:35	09:40	09:50	10:35	11:40				
Sealing Temperature (To be established)	190°C	190°C	191°C	191°C	191°C	191°C	192°C	190°C	191°C	190°C	192°C	190°C	194°C	195°C	190°C	194°C				
Forming Temperature (To be established)	160°C	164°C	166°C	160°C	160°C	160°C	160°C	159°C	161°C	159°C	160°C	160°C	160°C	158°C	160°C	160°C				
Leak test on Blister* (Qty.: _____)	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/ 19 13 4323	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
B. No.: G F 21 01 01	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Mfg. Date 01/2021	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Exp. Date 12/2023	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Machine Speed To be established	35	39	38	38	38	39	38	38	38	38	39	39	39	39	38	38				
Checked by (Packing)	RA	RA	RA	RA	RA	RA	RA	RA	RA	RA	RA	RA	RA	RA	RA	RA				
Checked by (IPQA)	RA	RA	RA	RA	RA	RA	RA	RA	RA	RA	RA	RA	RA	RA	RA	RA				

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.			
Date	03/01/2021	03/01/2021		04/01/2021

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 16 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: GF-210101 Generic Health Care Pvt. Ltd.

19.5 DEFOILING OF BLISTERS:

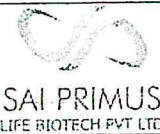
Date	De-foiling started at	De-foiling completed at	Weight of De-foiled tablets	De-foiling Done by	Checked by/ Date (Packing)	Verified by Date (QA)
20/01/2021	16:00	10:50	2.300	mudathy, putha	20/01/2021	
Total Weight of De-foiled Tablets			2.300	Checked By / Date (Packing): 20/01/2021		Verified By / Date (IPQA):

19.6 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		
20/01/2021	11:00	11:25	mudathy	2.170	18063	0.130	1082	20/01/2021	
Total				2.170	18063	0.130	1082		
Total Quantity of Rejected Tablets Destroyed				Checked By / Date (Packing):			Verified By / Date (IPQA):		
0.130 Kgs 1082 Nos.				20/01/2021			20/01/2021		

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	20/01/2021	20/01/2021	20/01/2021	

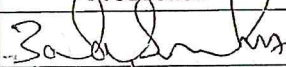
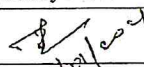
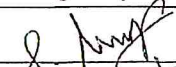
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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 15 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET		BPR. No.: BPR/T/195-00 Batch No.: GF 210101(B)
		Customer:	Generic Health Care Pvt. Ltd.


19.4 MACHINE IN-PROCESS CONTROL:

Date/ Shift	20/01/2021									
Machine Operator Name										
Time of inspection	11:00	12:30	13:30	14:15	14:30					
Sealing Temperature (To be established)	171°C	190°C	190°C	190°C	191°C					
Forming Temperature (To be established)	160°C	160°C	160°C	159°C	160°C					
Leak test on Blister* (Qty.: _____)	OK	OK	OK	OK	OK					
Knurling /Sealing	OK	OK	OK	OK	OK					
Pocket Formation	OK	OK	OK	OK	OK					
Horizontal cutting	OK	OK	OK	OK	OK					
Vertical cutting	OK	OK	OK	OK	OK					
Quality of Over printing	OK	OK	OK	OK	OK					
Code No.: PON/DRUGS/ 19 13 4323	OK	OK	OK	OK	OK					
B. No.: GF210101	OK	OK	OK	OK	OK					
Mfg. Date	01/2021	OK	OK	OK	OK					
Exp. Date	12/2023	OK	OK	OK	OK					
Machine Speed To be established	38	39	39	39	40					
Checked by (Packing)	MA	MA	MA	MA	MA					
Checked by (IPQA)	MA	MA	MA	MA	MA					

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.			
Date	03/01/2021	03/01/2021		

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 17 of 29
	BATCH PACKING RECORD		Product Code: G13... Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: <u>G1F910101</u> Generic Health Care Pvt. Ltd.

20. 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.					
2	Check and ensure that waste bin is emptied out and cleaned					
3	Check the Pallets and crates area clean and free from any leftovers of previous product /Batch.					
4	Check and ensure the Correct status board is written.					
5	Check and ensure the previous batch details are deleted from the inkjet machine.					
6	Check and ensure the rejected Cartons of previous product/batch are removed.					
7	Check and ensure the cleanliness of hatch for conveyor belt.					
8	Check and ensure the cleanliness of conveyer belt with collateral block.					
9	Check and ensure the dispensed secondary packing material.					
10	Check and ensure the Preventive maintenance records and log book.					

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.


20.1 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:			04/01/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>Salahuddin</u>	<u>out/01/2021</u>	<u>J. Anwar</u>
Date	03/01/2021	03/01/2021		04/01/2021

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 18 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: GF210101 Generic Health Care Pvt. Ltd.

20.2 OVERPRINTING DETAILS:

Overprinting Details	Overprinted Text	Carton (OK/Not OK)
Batch No.:	GF210101	OK
Mfg. Date:	01/01/21	OK
Exp. Date:	12/12/23	OK
Item Code: 15/0362	15/0362	OK
Code No.: PON/DRUGS/19 13 4323	PON/DRUGS/19 13 4323	OK
Other instructions if any	NA	NA
Initiated by Sign. & Date	NA	NA
Checked by Packing Sign. & Date	04/01/2021	04/01/2021
Verified by IPQA Sign. & Date	04/01/2021	04/01/2021

20.3 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		

20.4 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

04/01/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.			
Date	03/01/2021	03/01/2021	04/01/2021	

UNCONTROLLED COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 20 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product: GENSET	BPR. No.: BPR/T/195-00		Batch No.: G F 210101
		Customer:	Generic Health Care Pvt. Ltd.

21.1 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: 05/01/2021 / 9		Date/Time: 01/01/2021			
		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	24°C	CP	BP	24°C	CP	BP
Secondary Packing Started Date/Time: 11/01/2021 / 09:15 Completed Date/Time: 24/01/2021 / 12:30 ..							
APPROVAL FOR SECONDARY PACKING:				Approved by IPQA Sing/Date: [Signature] 01/01/2021			

21.2 PACKING DETAILS:

10 Tablets in each Blister, over code the Blister with the batch details given below,

Place 3 x 10's Blister and one leaflet in each carton.

Place 20 filled carton in a Shrink Sleeve.

Place 24 Shrink sleeves in each 5 ply shipper.

Seal the shipper with BOPP tape with "H" type.

22. OVER PRINTING DETAILS:

Overprinting Details (Secondary & Tertiary PM)


Overprinting Details	Overprinted Text	Carton (OK/ Not OK)	5 Ply Shipper Label (OK/ Not OK)
Batch No.:	G F 210101	OK	OK
Mfg. Date:	01/2021	OK	OK
Exp. Date:	12/2023	OK	OK
Code No.: PON/DRUGS/19 13 4323	PON/DRUGS/19/24323	OK	NA
Pack size:	NA	3 x 10's	24 x 20 x 3 x 10's 6167
Other instructions if any	NA	NA	NA
Initiated by Sign. & Date	NA	NA	NA
Checked by Packing Sign. & Date	CP 05/01/2021	CP 05/01/2021	CP 01/01/2021
Verified by IPQA Sign. & Date	[Signature] 01/01/2021	[Signature] 01/01/2021	[Signature] 01/01/2021

24.1 Shipper Label Specimen:

S. No.	Date	Shipper Label Specimen No.	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01	11/01/2021	01	CP 11/01/2021	[Signature] 11/01/2021
NA				

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K	[Signature]	[Signature]	[Signature]
Date	10/01/2021	03/01/2021	01/01/2021	01/01/2021

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 21 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: GF210101 Generic Health Care Pvt. Ltd.

23. CARTON WEIGHT LIMIT SETTING: Date/Shift: 11/01/2021 M... Time: 09:10.

Weight of ten individual empty cartons are given below:

1. 3.91	3. 3.94	5. 3.93	7. 3.96	9. 3.93
2. 3.95	4. 3.95	6. 3.89	8. 3.98	10. 3.96

Total weight of ten empty cartons = 39.4

Average weight of an empty carton (A) = Total weight of ten empty carton / 10 = 3.94

Weight of ten individual Blister are given below:

1. 2.01	3. 2.05	5. 2.07	7. 2.12	9. 2.13
2. 2.00	4. 2.05	6. 2.03	8. 2.13	10. 2.05

Total weight of ten Blister = 20.64

Avg. Weight of a Blister (B): total weight of ten Blister / 10 = 2.064

Weight of ten individual Leaflets are given below:

1. 1.46	3. 1.51	5. 1.52	7. 1.58	9. 1.53
2. 1.54	4. 1.53	6. 1.52	8. 1.53	10. 1.56

Total weight of ten Leaflets = 15.28

Avg. Weight of a Leaflet (C): total weight of ten Leaflets / 10 = 1.528

23.1 WEIGHT CHECKS ON CARTON:


Weight of ten empty Carton: 39.40	Average weight of one empty Carton (A): 3.940
Weight of ten filled Blister: 20.64	Average weight of one filled Blister (B): 2.064
Weight of ten Leaflets: 15.28	Average weight of one Leaflet (C): 1.528
Weight of one filled Carton D = (A+3B+C) 67.388 11.66	Limit: E = D ± 1 % = 66.744 to 68.061 (To be established) 11.543 to 11.776
Checked by Packing/Date: 11/01/2021	Verified by IPQA/Date: 11/01/2021

23.2 SAMPLE DRAWN RECORD:

Sr. No.	Stage of Sample collection	Qty. of Sample	Collected by (Sign. /Date)
1	Control Sample (Initial)	7x10's	11/01/2021
2	Control Sample (Middle)	6x10's	15/01/2021
3	Control Sample (Final)	7x10's	20/01/2021
4	Stability Sample	30x10's	20/01/2021
5	Other Sample	AS IS	
6	Analytical sample	12x10's	05/01/2021
Total Qty.		62x10's	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	3/1/2021	04/01/2021	04/01/2021
Date	03/01/2021	03/01/2021		

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 22 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: GF 210101 Generic Health Care Pvt. Ltd.

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

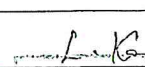
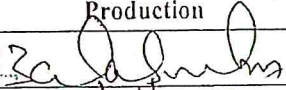
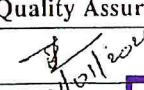
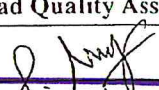
Date/ Shift	11/01/2021 / G	11/01/2021 / G													
Parameters	Specification	observation													
		Packing							IPQA						
Time		09:15	10:15	11:15	12:15	13:15	14:15	15:15	09:30	11:00	13:20	15:40	17:10		
No. of Blister in a carton	3 Blister with 10 tabs each and one leaflet.	OK	OK	OK	OK	OK	OK	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	20 packed cartons	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA		
Shrink wrapping temperature* cartons		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA		
No. of shrink sleeves in a 5 ply shipper	24 shrinks - 616 cartons	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		OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		

*Temperature to be mentioned.

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

Date/ Shift	11/01/2021	12/01/2021	12/01/2021 / 8													
Parameters	Specification	observation														
		Packing							IPQA							
Time		16:10	17:10	18:10	19:10	20:10	21:10	22:10	07:40	09:40	11:50	13:55	16:00	18:05	↑	
No. of Blister in a carton	3 Blister with 10 tabs each 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	20 packed cartons	NA	NA	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	NA	NA	
No. of shrink sleeves in a 5 ply shipper	24 shrinks - 616 cartons	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		OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	

*Temperature to be mentioned.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	11/01/2021	08/01/2021		

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SAI PRIMUS LIFE BIOTECH PVT LTD	BATCH PACKING RECORD	Product Code: G13	Batch Size: 30,00,000 Tablets
	GENSET	BPR. No.: BPR/T/195-00	Batch No.: GF 2101014
		Customer:	Generic Health Care Pvt. Ltd.

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

[illegible]

*Temperature to be mentioned.


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

[illegible]

*Temperature to be mentioned.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	03/01/2021	03/01/2021	03/01/2021	03/01/2021

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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 23 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: <u>G13210101</u> Generic Health Care Pvt. Ltd.

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

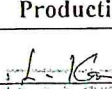
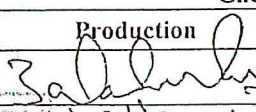
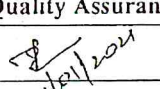
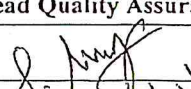
Date/ Shift									20/01/2021								
Parameters	Specification	19/01/2021/4 26/01/2021/4 observation															
		Packing								IPQA							
Time		12:10	15:10	16:10	17:05	09:20	10:45	11:30	09:40	11:35	13:10	15:50	17:30				
No. of Blister in a carton	3 Blister with 10 tabs each and one leaflet.	OK	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	20 packed cartons	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA				
Shrink wrapping temperature* ^{60°C}		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA				
No. of shrink sleeves in a 5 ply shipper	24 shrinks ⁶¹⁶ _{tabler}	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		PR	PR	PR	PR	PR	PR	PR	PR	PR	PR	PR	PR				

*Temperature to be mentioned.


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

Date/ Shift	20/01/2021 observation																21/01/2021 / 8				
Parameters	Specification	20/01/2021 Packing							IPQA												
		12:40	12:45	14:20	15:40	16:35	17:20		10:15	12:10											
Time																					
No. of Blister in a carton	3 Blister with 10 tabs each and one leaflet.	OK	OK	OK	OK	OK	OK		OK	OK											
Carton Overprinting	Legible and readable	OK	OK	OK	OK	OK	OK		OK	OK											
No. of cartons in a shrink sleeves	20 packed cartons	NA	NA	NA	NA	NA	NA		NA	NA											
Shrink wrapping temperature*		NA	NA	NA	NA	NA	NA		NA	NA											
No. of shrink sleeves in a 5 ply shipper	24 shrinks 616 extra	OK	OK	OK	OK	OK	OK		OK	OK											
Shipper strapping	Proper strapping	OK	OK	OK	OK	OK	OK		OK	OK											
Label appearance and Shipper appearance	Legible and readable	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											
Checked by		PR	PR	PR	PR	PR	PR		PR	PR											

*Temperature to be mentioned.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	19/01/2021	20/01/2021	20/01/2021	20/01/2021

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 23 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product GENSET	BPR. No.: BPR/T/195-00 Customer:		Batch No.: GF-210101 Generic Health Care Pvt. Ltd.

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

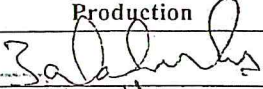
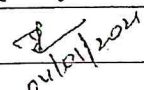
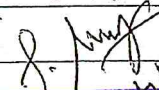
Date/ Shift	21/01/2021 (M)	observation											
Parameters	Specification	Packing						IPQA					
Time		10:10	11:15	12:10									
No. of Blister in a carton	3 Blister with 10 tabs each and one leaflet.	OK	OK	OK									
Carton Overprinting	Legible and readable	OK	OK	OK									
No. of cartons in a shrink sleeves	20 packed cartons	NA	NA	NA									
Shrink wrapping temperature*		NA	NA	NA									
No. of shrink sleeves in a 5 ply shipper	24 shrinks 616 cartons	OK	OK	OK									
Shipper strapping	Proper strapping	OK	OK	OK									
Label appearance and Shipper appearance	Legible and readable	OK	OK	OK									
Sealing of the shipper with BOPP Tape	H type	OK	OK	OK									
Checked by		GP	FP	GP									

* Temperature to be mentioned.

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

Date/ Shift		observation											
Parameters	Specification	Packing						IPQA					
Time													
No. of Blister in a carton	3 Blister with 10 tabs each and one leaflet.												
Carton Overprinting	Legible and readable												
No. of cartons in a shrink sleeves	20 packed cartons												
Shrink wrapping temperature*													
No. of shrink sleeves in a 5 ply shipper	24 shrinks												
Shipper strapping	Proper strapping												
Label appearance and Shipper appearance	Legible and readable												
Sealing of the shipper with BOPP Tape	H type												
Checked by													

* Temperature to be mentioned.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	23/01/2021	23/01/2021		23/01/2021

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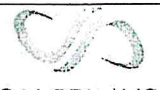
10/10/10

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

*Temperature to be mentioned.

Date/ Shift	13/01/2021														
Parameters	Specification	observation													
		Packing							IPQA						
Time		12:30	13:10	14:10	15:30	16:30	17:30	18:30							
No. of Blister in a carton	3 Blister with 10 tabs each and one leaflet.	OK	OK	OK	OK	OK	OK	OK							
Carton Overprinting	Legible and readable	OK	OK	OK	OK	OK	OK	OK							
No. of cartons in a shrink sleeves	20 packed cartons	N	N	N	N	N	N	N							
Shrink wrapping temperature*		N	N	N	N	N	N	N							
No. of shrink sleeves in a 5 ply shipper	24 shrinks 616 cartons	OK	OK	OK	OK	OK	OK	OK							
Shipper strapping	Proper strapping	OK	OK	OK	OK	OK	OK	OK							
Label appearance and Shipper appearance	Legible and readable	OK	OK	OK	OK	OK	OK	OK							
Sealing of the shipper with BOPP Tape	H type	OK	OK	OK	OK	OK	OK	OK							
Checked by		S/D	S/D	S/D	S/D	S/D	S/D	S/D							

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. G.</i>	<i>Zalaluri</i>	<i>[Signature]</i> 04/01/2021	<i>[Signature]</i> 04/01/2021
Date	03/01/2021	03/01/2021		

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 24 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product GENSET	BPR. No.: BPR/T/195-00 Customer:		Batch No.: GF 210 / 01 Generic Health Care Pvt. Ltd.


25. SHIPPERS WEIGHING:



 Date/Shift: **11/01/2021** Time: **11:30** Balance I.D. No.: **P.D. 1010101**

Weight of ten Shrinks: 115.20						Average weight of one filled Shrink (H): 11.520					
Weight of ten empty shippers: 103.350						Average weight of one empty shipper (I): 10.335					
Weight of one filled shipper (J) = (24H+I): * 8.331						Limit: K = J ± 1% = * 8.230 - 8.414					
Checked by Packing/Date: 8/11/01/2021						Verified by IPQA/Date: 8/11/01/2021					
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	8.340	Lakshmi	56	8.298	Lakshmi	111	8.210	Lakshmi	166		
2	8.350	Lakshmi	57	8.258	Lakshmi	112	8.260	Lakshmi	167		
3	8.350	Lakshmi	58	8.285	Lakshmi	113	8.247	Lakshmi	168		
4	8.360	Lakshmi	59	8.298	Lakshmi	114	8.283	Lakshmi	169		
5	8.340	Lakshmi	60	8.319	Lakshmi	115	8.286	Lakshmi	170		
6	8.300	Lakshmi	61	8.359	Lakshmi	116	8.286	Lakshmi	171		
7	8.290	Lakshmi	62	8.319	Lakshmi	117	8.275	Lakshmi	172		
8	8.280	Lakshmi	63	8.274	Lakshmi	118	8.280	Lakshmi	173		
9	8.270	Lakshmi	64	8.299	Lakshmi	119	8.286	Lakshmi	174		
10	8.320	Lakshmi	65	8.338	Lakshmi	120	8.251	Lakshmi	175		
11	8.280	Lakshmi	66	8.299	Lakshmi	121	8.355	Lakshmi	176		
12	8.270	Lakshmi	67	8.262	Lakshmi	122	8.285	Lakshmi	177		
13	8.290	Lakshmi	68	8.256	Lakshmi	123	8.319	Lakshmi	178		
14	8.300	Lakshmi	69	8.292	Lakshmi	124	8.288	Lakshmi	179		
15	8.260	Lakshmi	70	8.303	Lakshmi	125	8.248	Lakshmi	180		
16	8.250	Lakshmi	71	8.330	Lakshmi	126	8.222	Lakshmi	181		
17	8.300	Lakshmi	72	8.326	Lakshmi	127	8.238	Lakshmi	182		
18	8.280	Lakshmi	73	8.247	Lakshmi	128	8.274	Lakshmi	183		
19	8.260	Lakshmi	74	8.259	Lakshmi	129	8.263	Lakshmi	184		
20	8.300	Lakshmi	75	8.334	Lakshmi	130	8.251	Lakshmi	185		
21	8.300	Lakshmi	76	8.365	Lakshmi	131	8.253	Lakshmi	186		
22	8.270	Lakshmi	77	8.338	Lakshmi	132	8.341	Lakshmi	187		
23	8.320	Lakshmi	78	8.275	Lakshmi	133	8.305	Lakshmi	188		
24	8.270	Lakshmi	79	8.250	Lakshmi	134	8.270	Lakshmi	189		
25	8.320	Lakshmi	80	8.234	Lakshmi	135	8.267	Lakshmi	190		
26	8.320	Lakshmi	81	8.350	Lakshmi	136	8.256	Lakshmi	191		
27	8.310	Lakshmi	82	8.321	Lakshmi	137	8.260	Lakshmi	192		
28	8.320	Lakshmi	83	8.267	Lakshmi	138	8.220	Lakshmi	193		
29	8.370	Lakshmi	84	8.283	Lakshmi	139	8.215	Lakshmi	194		
30	8.390	Lakshmi	85	8.273	Lakshmi	140	8.244	Lakshmi	195		
31	8.340	Lakshmi	86	8.265	Lakshmi	141	8.210	Lakshmi	196		
32	8.050	Lakshmi	87	8.265	Lakshmi	142	8.253	Lakshmi	197		
33	8.270	Lakshmi	88	8.250	Lakshmi	143	8.280	Lakshmi	198		
34	8.320	Lakshmi	89	8.270	Lakshmi	144	8.324	Lakshmi	199		
35	8.290	Lakshmi	90	8.272	Lakshmi	145	8.260	Lakshmi	200		

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<i>L. Ka</i>	<i>3. Lakshmi</i>	<i>8. Lakshmi</i>	<i>8. Lakshmi</i>	
Date	03/01/2021	03/01/2021	03/01/2021	03/01/2021	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 25 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product GENSET	BPR. No.: BPR/T/195-00 Customer:		Batch No.: <u>G F 210101</u> Generic Health Care Pvt. Ltd.

36	8-300	Lakshmi	91	8-252	Lakshmi	146	8-250	Lakshmi	201		
37	8-250	Lakshmi	92	8-210	Lakshmi	147	8-266	Lakshmi	202		
38	8-250	Lakshmi	93	8-300	Lakshmi	148	8-200	Lakshmi	203		
39	8-230	Lakshmi	94	8-220	Lakshmi	149	8-260	Lakshmi	204		
40	8-270	Lakshmi	95	8-300	Lakshmi	150	8-274	Lakshmi	205		
41	8-390	Lakshmi	96	8-200	Lakshmi	151	8-254	Lakshmi	206		
42	8-360	Lakshmi	97	8-205	Lakshmi	152	8-274	Lakshmi	207		
43	8-390	Lakshmi	98	8-245	Lakshmi	153	8-276	Lakshmi	208		
44	8-350	Lakshmi	99	8-243	Lakshmi	154	8-270	Lakshmi	209		
45	8-380	Lakshmi	100	8-244	Lakshmi	155	8-266	Lakshmi	210		
46	8-380	Lakshmi	101	8-230	Lakshmi	156	8-274	Lakshmi	211		
47	8-355	Lakshmi	102	8-238	Lakshmi	157			212		
48	8-270	Lakshmi	103	8-242	Lakshmi	158			213		
49	8-330	Lakshmi	104	8-205	Lakshmi	159			214		
50	8-320	Lakshmi	105	8-277	Lakshmi	160			215		
51	8-328	Lakshmi	106	8-261	Lakshmi	161			216		
52	8-310	Lakshmi	107	8-243	Lakshmi	162			217		
53	8-259	Lakshmi	108	8-232	Lakshmi	163			218		
54	8-255	Lakshmi	109	8-234	Lakshmi	164			219		
55	8-285	Lakshmi	110	8-258	Lakshmi	165			220		
Total No. of shippers weighed:		De-foiled tablets packed in Shipper No:		Checked by Sign / Date:		Verified by Sign / Date:		Loose pack details:			
156		156		 21/01/2021		 21/01/2021		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.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K.</u>	<u>30/01/2021</u>	<u>30/01/2021</u>	<u>30/01/2021</u>
Date	<u>03/01/2021</u>	<u>03/01/2021</u>		

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 26 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product GENSET	BPR. No.: BPR/T/195-00 Customer:		Batch No.: GF210101 Generic Health Care Pvt. Ltd.

26. MAN POWER ALLOCATION: 022.3

DATE: 11/01/2021		DATE: 12/01/2021	
SHIFT: G1		SHIFT: G1	
ACTIVITIES	DONE BY	ACTIVITIES	DONE BY
Blister Checking	Pushpa, Nadhina	Blister Checking	Radha, Anchalachi
Printing Checking in Blister	Pushpa, Nadhina	Printing Checking in Blister	Radha, Anchalachi
Insertion of Blister and leaflet into carton	Rajakumari, umayal, Ashwini, Vishnu Pragas, Parvatha	Insertion of Blister and leaflet into carton	Radha, Anchalachi, Jayasudha, Sita Lakshmi
Cartons weighing	Lakshmi, Prabawathi	Cartons weighing	malathi, Parimala
Insertion of carton into shrink sleeve	Lakshmi	Insertion of carton into shrink sleeve	Parimala
Insertion of shrink wrapped carton into shipper	Lakshmi	Insertion of shrink wrapped carton into shipper	Parimala
Shipper Label Pasting	Lakshmi	Shipper Label Pasting	Parimala
Shipper Weighing	Lakshmi	Shipper Weighing	parimala
Shipper Strapping	Lakshmi	Shipper Strapping	Parimala
Shipper packed	From 01...to...12	Shipper packed	From 01...to...30
Signature of Packing	11/01/2021	Signature of Packing	12/01/2021

DATE: 12/01/2021		DATE: 13/01/2021	
SHIFT: G1		SHIFT: G1	
ACTIVITIES	DONE BY	ACTIVITIES	DONE BY
Blister Checking	Pushpa, Nadhina	Blister Checking	pushpa, nadhina
Printing Checking in Blister	pushpa, nadhina	Printing Checking in Blister	pushpa, nadhina
Insertion of Blister and leaflet into carton	Vishnu Pragas, umayal, Ashwini, Parvatha, Rajakumari	Insertion of Blister into carton	Rajakumari, umayal, Ashwini, Sathiyavani, Kanakchi
Cartons weighing	Prabawathi	Cartons weighing	Prabawathi
Insertion of carton into shrink sleeve	Lakshmi	Insertion of carton into shrink sleeve	Lakshmi
Insertion of shrink wrapped carton into shipper	Lakshmi	Insertion of shrink wrapped carton into shipper	Lakshmi
Shipper Label Pasting	Lakshmi	Shipper Label Pasting	Lakshmi
Shipper Weighing	Lakshmi	Shipper Weighing	Lakshmi
Shipper Strapping	Lakshmi	Shipper Strapping	Lakshmi
Shipper packed	From 31...to...42	Shipper packed	From 43...to...59
Signature of Packing	12/01/2021	Signature of Packing	13/01/2021

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

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SAI PRIMUS
LIFE BIOTECH PVT LTD

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

Page 26 of 29

BATCH PACKING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

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

Batch No.: GF-210101/13

Customer:

Generic Health Care Pvt. Ltd.

26. MAN POWER ALLOCATION:

DATE: 18/01/2021		DATE: 18/01/2021	
SHIFT: 5		SHIFT: 5	
ACTIVITIES	DONE BY	ACTIVITIES	DONE BY
Blister Checking	Vishnu Prziya, Lakshmi, Pushpa	Blister Checking	Pushpa, Lakshmi
Printing Checking in Blister	Lakshmi, Pushpa	Printing Checking in Blister	Nadhina, Ashwini
Insertion of Blister and leaflet into carton	Raja Kumari, umayal, Ashwini, Pawithra	Insertion of Blister and leaflet into carton	Saraswathi, Pawithra, Raja Kumari, umayal
Cartons weighing	Vishnu Prziya	Cartons weighing	Prabavathi, Vishnu Prziya
Insertion of carton into shrink sleeve	Lakshmi	Insertion of carton into shrink sleeve	Vishnu Prziya
Insertion of shrink wrapped carton into shipper	Lakshmi	Insertion of shrink wrapped carton into shipper	Vishnu Prziya
Shipper Label Pasting	Lakshmi	Shipper Label Pasting	Vishnu Prziya
Shipper Weighing	Lakshmi	Shipper Weighing	Vishnu Prziya
Shipper Strapping	Lakshmi	Shipper Strapping	Vishnu Prziya
Shipper packed	From 9.0 to 12.0	Shipper packed	From 12.0 to 13.0
Signature of Packing	P. 18/01/2021	Signature of Packing	P.

DATE: 19/01/2021		DATE: 21/01/2021	
SHIFT: 5		SHIFT: 5	
ACTIVITIES	DONE BY	ACTIVITIES	DONE BY
Blister Checking	Nadhina, Pushpa	Blister Checking	Lakshmi, Pushpa
Printing Checking in Blister	Nadhina, Pushpa	Printing Checking in Blister	Nadhina, Saraswathi
Insertion of Blister and leaflet into carton	Pawithra, Raja Kumari, umayal, Ashwini, Kamatchi	Insertion of Blister into carton	Pawithra, umayal, Pushpa, Raja Kumari, Kamatchi, Vithani, Sathiyaveni
Cartons weighing	Prabavathi, Lakshmi	Cartons weighing	Prabavathi
Insertion of carton into shrink sleeve	Prabavathi, Lakshmi	Insertion of carton into shrink sleeve	Vishnu Prziya
Insertion of shrink wrapped carton into shipper	Lakshmi	Insertion of shrink wrapped carton into shipper	Vishnu Prziya
Shipper Label Pasting	Lakshmi	Shipper Label Pasting	Vishnu Prziya
Shipper Weighing	Lakshmi	Shipper Weighing	Vishnu Prziya
Shipper Strapping	Lakshmi	Shipper Strapping	Vishnu Prziya
Shipper packed	From 12.0 to 12.9	Shipper packed	From 13.0 to 15.0
Signature of Packing	P. 19/01/2021	Signature of Packing	21/01/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	[Signature]	[Signature]	[Signature]
Date	03/01/2021	03/01/2021	03/01/2021	03/01/2021

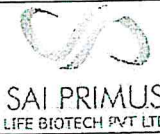
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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 27 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: G1F210101 Generic Health Care Pvt. Ltd.

27. 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	50.500	153.4	10200	10200	NA	209	500	15
B	Additional material received for the batch	30.00	165.00	NA	NA	NA	NA	NA	NA
C	Total material received (A+B)	80.500	318.4	10200	10200	NA	209	500	15
D	Quantity packed	72.072	311.350	9600	9600	NA	156	500	15
E	Quantity rejected (Online) & Destroyed	3.008	6.982	585	5	NA	3	NA	NA
F	Quantity Returned	5.40	NA	NA	5880	NA	50	NA	NA
G	Sample affixed on BPR	0.004	0.012	02	02	NA	NA	NA	NA
H	QC samples	0.003	0.013	NA	NA	NA	NA	NA	NA
I	Other samples (If any)	0.013	0.055	17	17	NA	NA	NA	NA
J	Total accountable Quantity (D+ E+F+G+H+I)	80.500	318.400	10200	10200	NA	209	500	15
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 %		NA	NA

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

NA

28. 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	5.40	NA	NA	5880	NA	50	NA	NA
Material returned by packing Sign./Date	30/01/2021	NA	NA	30/01/2021	NA	30/01/2021		
Verified By IPQA Sign./Date	30/01/2021	NA	NA	30/01/2021	NA	30/01/2021		
Material received by Store Sign./Date	30/01/2021	NA	NA	30/01/2021	NA	30/01/2021		

29. 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)
30/01/2021	24	3.008	6.982	5885	5	NA	3	NA	NA
Total Qty. Destroyed	24	3.008	6.982	5885	5	NA	3	NA	NA
Destroyed by (Packing)	[Signature]								
Verified by (IPQA)	[Signature]								

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L.K.	[Signature]	[Signature]	[Signature]	
Date	03/01/2021	03/01/2021	03/01/2021	03/01/2021	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 28 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: G F 210101 Generic Health Care Pvt. Ltd.

30. BATCH RECONCILIATION:

A	Batch Size	30,00,000 Nos.
B	Quantity received for packing	2973278
C	Total quantity packed	2882880
D	Control samples	200
E	Analytical Samples	120
F	In process samples	5100
G	Others samples if any (Stability, Regulatory Samples, etc.)	200
H	Packing Loss = B - (C + D + E + F + G)	84678
I	Total Loss = A - (C + D + E + F + G)	11400
J	Packing yield % (C + D + E + F + G) / B X 100 (Yield Limit %.....)*	97.14%
K	Batch Yield % (C + D + E + F + G) / A X 100 (Yield Limit %.....)*	96.28%

*To be established

Checked by Packing /Date: *[Signature]*

Verified by IPQA/Date: *[Signature]* 05/02/2024

31. 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
05/02/2024	1100	Sales	3x10 ⁵ S	61673710	156	288,288	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Total Qty. Transferred							<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>

32. 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		<i>[Signature]</i>		<i>[Signature]</i>

Checked by
Packing:

Verified by
Packing manager:


Approved by
Head QA:

33. BPR REVIEW DETAILS:

Reviewed by	Name	Sign. /Date
Packing Executive	J. Ravichandran	<i>[Signature]</i> 05/02/2024
QA Executive	Ramkumar	<i>[Signature]</i> 05/02/2024
Production Assistant Manager/ HOD	BRASUBRAMANIAN, B	<i>[Signature]</i> 07/02/2024
QA Manager/ HOD	Stephen R	<i>[Signature]</i> 08/02/2024


Prepared by:	Checked by:	Approved By:
Dept. Production	Production Quality Assurance	Head Quality Assurance
Sign. L. Ke	<i>[Signature]</i>	<i>[Signature]</i>
Date 03/01/2024	03/01/2024	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 29 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: GF210101 Generic Health Care Pvt. Ltd.


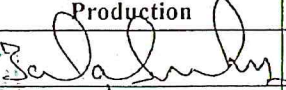
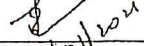
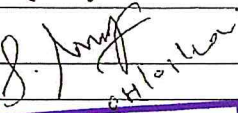
34. BATCH RELEASED FOR DESPATCH:

Total quantity released: 2882080 No's

Head QA sign/ Date:  03/01/21


35. REVISION HISTORY:

S. No.	Document No.	Reason for Changes	Supersedes Doc. No.
1	BPR/T/195-00	New Document	Nil






Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	11/03/2021	03/01/2021	04/01/2021	04/01/2021

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
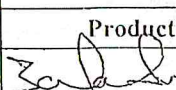
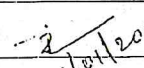
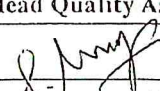
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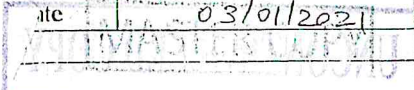
	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 1 of 29
	BATCH PACKING RECORD	Product Code: G13	Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00	Batch No.: GF210216
		Customer:	Generic Health Care Pvt. Ltd.

BATCH PACKAGING RECORD COVER SHEET


PRODUCT NAME	: GENSET
GENERIC NAME	: Cetirizine Tablets BP 10 mg
LABEL CLAIM	Each film coated tablet contains:
	Cetirizine Hydrochloride BP 10 mg
	Excipients q.s.
	Colour: Approved colour used
CODE NO.	: PON/DRUGS/19 13 4323
DOSAGE FORM	: Tablet
BPR No.	: BPR/T/195-00
REVISION No.	: 00
SUPERSEDE No	: NIL
EFFECTIVE BATCH. No. /DATE	: GF210101 / 04/01/2021
MARKET	: Export
SHELF LIFE	: 36 Months
BATCH SIZE	: 30,00,000 Tablets
PACKING CONFIGURATION	: 3 x 10 Tablets Sales Pack (Blister Packing)
BPR ISSUED BY/DATE (QA)	:  23/02/2021
BPR CHECKED & RECEIVED BY/DATE (PRODUCTION)	:  23/02/2021
MFG. DATE: 02/2021	EXP. DATE: 01/2024
ALLOTTED BY: QA SIGN/DATE:  23/02/2021	COUNTER CHECKED BY: QA SIGN/DATE:  23/02/21
QUANTITY RECEIVED FROM PRODUCTION	: 2978413 nos
DATE OF COMMENCEMENT: 01/03/2021	DATE OF COMPLETION: 09/03/2021
QUANTITY	: 30,00,000 nos
RELEASED QUANTITY OF PACKED TABLETS	: 2942820 nos
RELEASE OF BATCH BY HEAD QA SIGN/DATE:	:  10/03/21

This BPR contains 29 Pages + ... Additional Pages

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	03/01/2021	03/01/2021	04/01/2021	04/01/2021

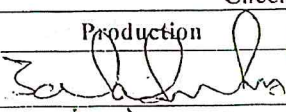
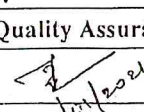
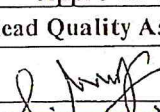


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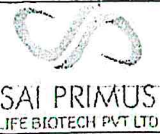
 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 2 of 29
	BATCH PACKING RECORD	Product Code: G13	Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00	Batch No.: GF 210216
		Customer:	Generic Health Care Pvt. Ltd.

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5	Dispensing record of packing materials	6
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Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ke			
Date	03/01/2021	03/01/2021	04/01/2021	

UNCONTROLLED COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 3 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: GF 210216 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	Yes
a)	Equipment clean tag and dispensing tag attached with batch record	Yes
b)	Packaging material is checked	Yes
5.	Packing	Yes
a)	Rinse water analysis report attached with BPR	NA
b)	Approved specimen of printed foil, show box 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	Yes
a)	Finished Goods Transfer Note	Yes
b)	Certificate of analysis of finished product is submitted	NA
c)	Stereo Impression Format	Yes
7.	Complete set of BPR Submitted	Yes

Checked By QA/Date:

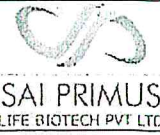
[Signature]
03/01/2021

*Mention total number of pages.

Remarks (If any) NA

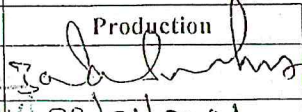
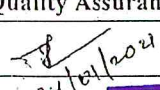
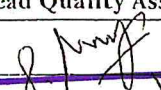
Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. Ka</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	03/01/2021	03/01/2021	04/01/2021	04/01/2021

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	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 4 of 29
	BATCH PACKING RECORD	Product Code: G13	Batch Size: 30,00,000 Tablets
	Product	GENSET	BPR. No.: BPR/T/195-00 Batch No.: GF210216 Customer: Generic Health Care Pvt. Ltd.

3. PACKING MATERIAL SPECIFICATION AND INDENT:

Sr. No.	Material	Printed item material code	Specification	UOM	Standard Qty. for Batch Size 30.0 Lac.	% Over ages	Qty. Required 30.0 Lac with overages
1	144mm Genset double side printed foil 0.025	PPF/SP/G013	Width – 144 ± 1 mm Thickness – 0.025 mm Language – French Color – 2 Colors GHPL ITEM CODE – 13/0241	Kg	45.000 (To be established)	2	45.900 (To be established)
2	148 mm PVC Film Clear (60 GSM)	PBF/SP/P002	Width – 148 mm Clear PVC	Kg	150.000 (To be established)	2	153.000 (To be established)
3	3x10's Genset printed carton	PHC/SP/G001	Size – 130 x 60 x 25 mm (L x W x H) Board – 300 gsm ITC Cyber XL, UV varnished. Colour – 3 colour Language – English/French GHPL ITEM CODE – 15/0362	No	100000	2	102000
4	Genset Insert	PHL/SP/G001	Size – 140 x 180 mm (L x H) Specification – NLT 60 gsm Maplitho Paper. Colour – 2 colours Language – French/ English GHPL ITEM CODE – 16/0259	No	100000	2	102000
5	Shrink Sleeves (PVC)	PPS/SP/P001	Plain PVC Shrink Sleeves	No	5000	2	5100
6	5 PLY 390X390X260 MM C/BOXES	PUS/GH/C001	A 5 Ply flute vertical corrugated inner unprinted in nature. (24 B.F.) Outer Size – 390 x 390 x 430 mm (L x W x H) Bursting Strength – NLT 15.00 Kg/cm ²	No	209	-	209
7	3' GH PL Printed Bopp Tape	PPB/SP/B002	Clear Transparent Length of roll – 65m Width – 60 mm Printing – GHPL repeats in Blue	No	15	-	15
8	3' Plain BOPP Tape	PUB/SP/B001	Plain BOPP Tape	No.	3	-	3
9	Strapping role.	PPR/SP/S001	White or milky white colour. Width – 12 mm Thickness – 0.6 mm	Mtrs	500	-	500
10	Shipper Label	NA	Half A4 size Computer printed label	No	209	-	209

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K.			
Date	03/01/2021	03/01/2021	04/01/2021	04/01/2021

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 5 of 29
	BATCH PACKING RECORD	Product Code: G13	Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00	Batch No.: G1F210216
		Customer:	Generic Health Care Pvt. Ltd.

4. DISPENSING LINE CLEARANCE CHECKS

Date: 26/02/2021 Time: 16:20

Sr. No.	CHECKS	Observation*	
		Store	IPQA
1	Check and ensure that empty SS containers, polythene bags, Tags, documents and scrap from waste bin of previous batch/product are removed from the area.	/	✓
2	Check and ensure that display stand and weighing balance are clean.	/	✓
3	Check and ensure that SS 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.	ST160P1001	ST160401	no	no	Foil store
Previous Product	Vitamin D3				
B. No.	052125				
Cleaned by Sign/Date	L. Ka / 26/02/2021				
Checked by Store Sign/Date	G. V / 26/02/2021				
Verified by IPQA Sign/Date	[Signature] / 26/02/2021				

ENVIRONMENTAL CONDITIONS: Date: 26/02/2021 Time: 16:30	Observation	Checked by Store Sign/Date	Verified by IPQA Sign/Date
(For Reference SOP No.: QAGN/011)			
Temperature (Limit: NMT 25°C)	23°C	[Signature]	[Signature]

APPROVAL FOR DISPENSING BY IPQA: Sign: [Signature]	Date: 26/02/2021
Dispensing start Time: 16:35	End Time: 17:20

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	[Signature]	[Signature]	[Signature]
Date	03/01/2021	03/01/2021	04/01/2021	04/01/2021

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 6 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: G1F 210216 Generic Health Care Pvt. Ltd.


5. DISPENSING RECORD OF PACKING MATERIALS: Date: 26/02/2021 Shift: 9 Time: 16:35

Material Name	Item code	UOM	Req. Qty. for 30.0 Lac	Issued Qty.	A.R No.	No. of Roll/Box	Issued and Checked by Store	Verified by IPQA
144mm Genset double side printed foil 0.025	PPF/SP/G013	Kg	* 100.00 45.900 (To be established)	62.60 53.20	Pm4/00804 Pm4/00808	06 05	my 26/02/2021	26/02/2021
148 mm PVC Film Clear (60 GSM)	PBF/SP/P002	Kg	* 300.00 153.000 (To be established)	306.10	Pm4/00907	15	my 26/02/2021	26/02/2021
3x10's Genset printed carton	PHC/SP/G001	No	102000	3000 99000	Pm4/00603 Pm4/00958	01 20	my 26/02/2021	26/02/2021
Genset Insert	PHL/SP/G001	No	102000	3000 99000	Pm4/00606 Pm4/00959	01 10	my 26/02/2021	26/02/2021
Shrink Sleeves (PVC)	PPS/SP/P001	No	5100			NA		26/02/2021
5 PLY 390X390X260 MM C/BOXES	PUS/GH/C001	No	209	209	Pm4/00906	21	my 26/02/2021	26/02/2021
3' GHPL Printed Bopp Tape	PPB/SP/B002	No	15	15	Pm4/00136	03	my 26/02/2021	26/02/2021
3' Plain BOPP Tape	PUB/SP/B001	No	3	03	Pm3/24419/02	01	my 26/02/2021	26/02/2021
Strapping role.	PPR/SP/S001	Mtrs	500	500	Pm4/00032	01	my 26/02/2021	26/02/2021
Shipper Label	NA NA NA	No	209					26/02/2021

0.02

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. R.	30/02/2021	26/02/2021	26/02/2021
Date.	03/01/2021	03/01/2021		

UNCONTROLLED COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 7 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: G1F210216 Generic Health Care Pvt. Ltd.

6. LINE CLEARANCE CHECKS:

6.1 PRIMARY PACKING:

Date/ Shift 01/03/2021 / 02/03/2021 / 15

Previous Product: B/met 500		Batch No.: 20121011				
Sr. No.	Checks	Time	Observation			
			12:05 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 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): P 01/03/2021			Cleaning satisfactory/Not satisfactory Verified by IPQA (Sign./Date): P 01/03/2021			
#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: B/met 500			Batch No.: 20121011				
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	01/03/2021	B	PDGN/006	Pam	P 01/03/2021	P 01/03/2021
2.	Blister Packing Machine	01/03/2021	B	PDOP/021, PDCL/021 PDOP/022, PDCL/022	Pm	P 01/03/2021	P 01/03/2021

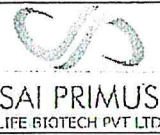
6.3 ENVIRONMENTAL CONDITIONS:

(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: 01/03/2021 Time: 12:05		Date: 02/03/2021 Time: 10:05			
	Observation	Packing Sign/Date	Verified by IPQA Sign/Date	Observation	Packing Sign/Date	Verified by IPQA Sign/Date
Temp °C Limit: NMT 25°C	24°C	P 01/03/2021	P 01/03/2021	24°C	P 02/03/2021	P 02/03/2021
RH % Limit: NMT 60%	56%	P 01/03/2021	P 01/03/2021	56%	P 02/03/2021	P 02/03/2021
DP Limit: NLT 10 Pascal	11 Pa	P 01/03/2021	P 01/03/2021	10 Pa	P 02/03/2021	P 02/03/2021
Primary Packing Started Date/Time: 01/03/2021 / 12:05 Completed Date/Time: 02/03/2021 / 10:05						
APPROVAL FOR PRIMARY PACKING: IPQA Sign./Date: P 01/03/2021						

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. B.	P. J.	P. J.	P. J.	
Date	03/01/2021	03/01/2021	03/01/2021	03/01/2021	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 8 of 29
	BATCH PACKING RECORD		Product Code: G13
	Product: GENSET		Batch Size: 30,00,000 Tablets
		BPR. No.: BPR/T/195-00	Batch No.: G1F210216
		Customer:	Generic Health Care Pvt. Ltd.

7. VERIFICATION OF DISPENSED PACKING MATERIALS: Date: 01/01/2021 Shift: 6 Time: 12:00 PM

Material Name	Item code	UOM	AR No.	Number of Rolls/Packs	Checked by Packing	Verified by QA
144mm Genset double side printed foil 0.025	PPF/SP/G013	Kg	pm4/00804 pm4/01008	01 10	CF	CF
148 mm PVC Film Clear (60 GSM)	PBF/SP/P002	Kg	pm4/00907	15	CF	CF
3x10's Genset printed carton	PHC/SP/G001	No	pm4/00603 pm4/00659	01 20	CF	CF
Genset Insert	PHL/SP/G001	No	pm4/00606 pm4/00659	01 10	CF	CF
Shrink Sleeves (PVC)	PPS/SP/P001	No				
5 PLY 390X390X260 MM C/BOXES	PUS/GH/C001	No	pm4/00906	21	CF	CF
3' GHPL Printed Bopp Tape	PPB/SP/B002	No	pm4/00131	03	CF	CF
3' Plain BOPP Tape	PUB/SP/B001	No	pm3/2419/02	01	CF	CF
Strapping role.	PPR/SP/S001	Mtrs	pm4/00032	01	CF	CF
Shipper Label	NA	No				

8. STEREO ISSUANCE AND SETTING RECORD

S. No.	Type of Stereos	No. of Stereos Issued	Issued By (QA) Sign. & Date	Received By (Packing) Sign. & Date	Stereos Setting Done By	Checked By (Packing) Sign. & Date	Verified By QA Sign. & Date
1.	Stereos	25	01/01/2021	01/01/2021	per	01/01/2021	01/01/2021

9. RECEIPT OF PRODUCT AND MATERIALS: Date/Shift: 01/01/2021/6 Time: 12:00 PM
(Check the following before start of packing activity and record the observation.)

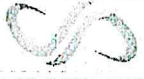
S. No.	Check Points	Observation	Done by (Packing)	Verified By (IPQA)
1.	Temperature observed on display (Limit: NMT 25°C)	25C	CF	CF
2.	Relative Humidity observed on display (Limit: NMT 60%)	56%	CF	CF
3.	Bulk product containers are of the required product/Batch number and is approved by QC	yes	CF	CF
4.	Status label of machine/ line is for same product	yes	CF	CF
5.	Printed foil/Base rolls are of the required product.	yes	CF	CF
6.	All secondary packing materials are of the required product	yes	CF	CF

10. DETAIL OF THE PRODUCT AS PER BMR:

Sr. No.	Description	Observations	Checked By (Packing)	Verified By (IPQA)
1.	Average Weight	119.93	CF	CF
2.	Colour of Tablet	white	CF	CF
3.	Quantity (Net Qty.in Kg)	357.350	CF	CF
4.	Number of Containers	12	CF	CF

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	01/01/2021	01/01/2021	01/01/2021
Date	03/01/2021	02/01/2021		

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 9 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: <u>G1F210216</u> Generic Health Care Pvt. Ltd.

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

Balance I.D. No.: PD/195/014

1. Verify the semi-finished Tablets before starting the packing operation.
2. Verify the batch details on the labels affixed over the Containers against the respective BMR and record the details in below table.

Product Name	Batch No.	Mfg. Date	Exp. Date	Qty. recd. For packing	No. of Containers taken for packing
GENSET	G1F210216	02/2021	01/2024	357.350 Kg Equivalent to 2978413 Nos.	From Container No. <u>01</u> To Container No. <u>12</u> Total No. of Containers taken <u>12</u>
Checked by Packing (Sign. /Date): <u>[Signature]</u>				Verified By IPQA (Sign. /Date): <u>[Signature]</u>	

12. 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	29.500	Ragu	[Signature]	16			
2	33.220	Ragu	[Signature]	17			
3	32.920	Ragu	[Signature]	18			
4	33.820	Ragu	[Signature]	19			
5	34.040	Ragu	[Signature]	20			
6	31.830	Ragu	[Signature]	21			
7	31.336	Ragu	[Signature]	22			
8	33.100	Ragu	[Signature]	23			
9	32.720	Ragu	[Signature]	24			
10	27.770	Ragu	[Signature]	25			
11	31.410	Ragu	[Signature]	26			
12	32.690	Ragu	[Signature]	27			
13				28			
14				29			
15				30			

13. CONTAINER CONSUMPTION DETAILS:

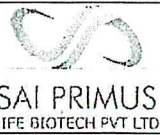
S. No	Time		Container No.	Consumed by	S. No	Time		Container No.	Consumed by
	From	To				From	To		
1	14:15	18:00	01	Ragu	16				
2	09:20	12:30	02	Ragu	17				
3	13:05	16:40	03	Ragu	18				
4	16:11	18:00	04	Ragu	19				
5	09:30	11:15	04	Ragu	20				
6	11:16	17:30	05	Ragu	21				
7	17:31	19:00	06	Ragu	22				
8	09:30	13:45	06	Ragu	23				
9	13:46	19:00	07	Ragu	24				
10	09:30	12:30	08	Ragu	25				
11	12:10	18:00	09	Ragu	26				
12	09:30	11:50	10	Ragu	27				
13	11:15	18:30	11	Ragu	28				
14	09:40	17:00	12	Ragu	29				
15			NA		30				

Checked By Packing (Sign. /Date): [Signature]

Verified by IPQA (Sign. /Date): [Signature]

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	
Date	<u>03/01/2021</u>	<u>03/01/2021</u>	<u>03/01/2021</u>	<u>03/01/2021</u>	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 10 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: G1F210216 Generic Health Care Pvt. Ltd.

14. OVERPRINTING OF PRIMARY PACKAGING MATERIALS:

Initial checks of Overprinting Details

Overprinting Details	Overprinted Text	Printed AL. Foil (OK/ not OK)
Code No.: PON/DRUGS/19 13 4323	PON/DRUGS/19 13 4323	OK
Batch No.:	G1F210216	OK
Mfg. Date:	02/02/21	OK
Exp. Date:	01/2024	OK
Item Code: 13/0241	13/0241	OK
Other instructions if any	NA	NA
Initiated by	Ram	Ram
Checked by Packing (Sign. & Date)	01/03/2021	01/03/2021
Verified by IPQA (Sign. & Date)	01/03/2021	01/03/2021

15. SPECIMEN OF PRINTED FOIL:

S. No.	Date	Specimen No.	Done By Sign & Date	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01	01/03/2021	01	Ram 01/03/2021	01/03/2021	01/03/2021
02	02/03/2021	01	Ram 02/03/2021	02/03/2021	02/03/2021
03	03/03/2021	01	Ram 03/03/2021	03/03/2021	03/03/2021
04	04/03/2021	01	Ram 04/03/2021	04/03/2021	04/03/2021

16. 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 tablets 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	01/03/2021	14:15	18:00	18:30	18:10	01/03/2021
02	02/03/2021	09:20	18:00	09:20	18:00	02/03/2021
03	03/03/2021	09:30	19:00	09:45	18:15	03/03/2021
04	04/03/2021	09:30	19:00	09:40	18:00	04/03/2021
05	05/03/2021	09:30	18:00	09:45	18:05	05/03/2021
06	06/03/2021	09:30	18:30	09:35	18:10	06/03/2021

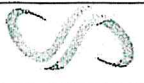
17. PACKING/IPQA IN-PROCESS CHECKS FOR PRIMARY PACKING:

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.

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

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 10 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets.
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: G1F210216A Generic Health Care Pvt. Ltd.

14. OVERPRINTING OF PRIMARY PACKAGING MATERIALS:

Initial checks of Overprinting Details

Overprinting Details	Overprinted Text	Printed AL. Foil (OK/ not OK)
Code No.: PON/DRUGS/19 13 4323	NA	
Batch No.:		
Mfg. Date:		
Exp. Date:		
Item Code: 13/0241		
Other instructions if any		
Initiated by		
Checked by Packing (Sign. & Date)		
Verified by IPQA (Sign. & Date)		

15. SPECIMEN OF PRINTED FOIL:

S. No.	Date	Specimen No.	Done By Sign & Date	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
05	05/03/2021 / 17	01	Paul Rajan	CP 05/03/2021	FFP
06	06/03/2021 / 17	01	Paul Rajan	CP 06/03/2021	FFP
			NA		

16. 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 tablets 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	
07	08/03/2021 / 17	09:40	17:00	09:45	18:00	CP 08/03/2021
08	09/03/2021 / 17	09:40	17:00	09:30	17:00	CP 09/03/2021
			NA			

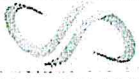
17. PACKING/IPQA IN-PROCESS CHECKS FOR PRIMARY PACKING:

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.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	Paul Rajan	CP 03/01/2021	CP 03/01/2021
Date	03/01/2021	03/01/2021	03/01/2021	03/01/2021

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 11 of 29
	BATCH PACKING RECORD		Product: Code: G13 Batch Size: 30,00,000 Tablets
	Product: GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: G1F210216 Generic Health Care Pvt. Ltd.

18. BLISTER PACKING MACHINE PARAMETERS:

Date/Shift: 01/03/2021 / N Time: 14:10

Parameters	Standard and Limits	Observation	Checked by Packing Sign. / Date	Checked by IPQA Sign. / Date
Change Parts Details	PPC 09 2016 1121 (150-200°C)	PPC 09 2016 1121	01/03/2021	01/03/2021
Sealing Temperature	To be established (110-160°C)	200°C	01/03/2021	01/03/2021
Forming Temperature	To be established	179°C	01/03/2021	01/03/2021
Leak test to be performed on Blister	Nil (No Blister should fail in leak test)	12-85	01/03/2021	01/03/2021
Machine Speed	To be established	30	01/03/2021	01/03/2021


19. MACHINE IN-PROCESS CONTROL:

Date/ Shift	01/03/2021 / N						01/03/2021 / B					
Machine Operator Name	Ravi						Raghu					
Time of inspection	14:15	14:30	15:15	16:30	16:40	17:20	17:30	17:40	18:30	18:40	19:20	19:30
Sealing Temperature (To be established)	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C
Forming Temperature (To be established)	179°C	179°C	179°C	179°C	179°C	179°C	179°C	179°C	179°C	179°C	179°C	179°C
Leak test on Blister* (Qty.: 15)	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/ 19 13 4323	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
B. No.: G1F210216	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Mfg. Date: 02/2021	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Exp. Date: 01/2024	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Machine Speed To be established	30	30	30	30	30	30	30	30	30	30	30	30
Checked by (Packing)	OK	NA	OK	OK	NA	OK	OK	NA	OK	OK	NA	OK
Checked by (IPQA)	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK

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.	[Signature]	[Signature]	[Signature]
Date	03/01/2021	03/01/2021	04/01/2021	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 12 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET		BPR. No.: BPR/T/195-00 Batch No.: GF210216
Customer:			Generic Health Care Pvt. Ltd.


19.1 MACHINE IN-PROCESS CONTROL:

Date/ Shift	02/03/2021 / B								03/03/2021							
Machine Operator Name	Ragu								Ragu							
Time of inspection	14:30	15:30	16:30	16:40	17:40	18:35	18:45		09:45	10:00	10:40	11:40	12:10	12:45	13:40	14:40
Sealing Temperature (To be established)	200°C	200°C	200°C	200°C	200°C	200°C	200°C		200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C
Forming Temperature (To be established)	176°C	174°C	175°C	176°C	176°C	176°C	176°C		174°C	176°C	176°C	176°C	176°C	176°C	176°C	176°C
Leak test on Blister* (Qty.: _____)	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
Pocket Formation	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
Vertical cutting	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
Code No.: PON/DRUGS/ 19 13 4323	OK	OK	OK	OK	OK	OK	OK		OK	OK	OK	OK	OK	OK	OK	OK
B. No.:	GF210216	OK	OK	OK	OK	OK	OK		OK	OK	OK	OK	OK	OK	OK	OK
Mfg. Date	02/2021	OK	OK	OK	OK	OK	OK		OK	OK	OK	OK	OK	OK	OK	OK
Exp. Date	01/2024	OK	OK	OK	OK	OK	OK		OK	OK	OK	OK	OK	OK	OK	OK
Machine Speed To be established	40	30	20	40	40	40	40		40	30	30	30	30	30	30	30
Checked by (Packing)	OK	OK	NA	OK	OK	NA	OK		OK	NA	OK	OK	NA	OK	OK	NA
Checked by (IPQA)			OK			OK				OK			OK			OK

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.	<i>L. K.</i>	<i>Santhosh</i>	<i>Santhosh</i>	<i>Santhosh</i>
Date	03/01/2021	03/01/2021	03/01/2021	03/01/2021

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 13 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: G1F210216 Generic Health Care Pvt. Ltd.

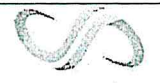
19.2 MACHINE IN-PROCESS CONTROL:

Date/ Shift		03/03/2021						04/03/2021											
Machine Operator Name		Ragu																	
Time of inspection		14:45	15:15	16:40	16:50	17:50	18:00		08:25	09:40	09:30	11:30	12:00	12:30	13:40	14:00	14:30		
Sealing Temperature (To be established)		200°C	200°C	200°C	200°C	200°C	200°C		200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C		
Forming Temperature (To be established)		150°C	150°C	150°C	150°C	150°C	150°C		150°C	150°C	150°C	150°C	150°C	150°C	150°C	150°C	150°C		
Leak test on Blister* (Qty.: 10)		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		
Pocket Formation		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		
Vertical cutting		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		
Code No.:	PON/DRUGS/ 19 13 4323	OK	OK	OK	OK	OK	OK		OK	OK	OK	OK	OK	OK	OK	OK	OK		
B. No.:	G1F210216	OK	OK	OK	OK	OK	OK		OK	OK	OK	OK	OK	OK	OK	OK	OK		
Mfg. Date	02/2021	OK	OK	OK	OK	OK	OK		OK	OK	OK	OK	OK	OK	OK	OK	OK		
Exp. Date	01/2024	OK	OK	OK	OK	OK	OK		OK	OK	OK	OK	OK	OK	OK	OK	OK		
Machine Speed To be established		40	40	30	40	40	40		30	30	30	30	30	30	30	30	30		
Checked by (Packing)		OK	OK	NA	OK	OK	OK		OK	NA	OK	OK	NA	OK	OK	NA	OK		
Checked by (IPQA)				OK					OK				OK			OK			

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.	Ragu	outail/2021	Ragu
Date	03/01/2021	03/01/2021		

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 14 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET		BPR. No.: BPR/T/195-00 Batch No.: G1F210216 Customer: Generic Health Care Pvt. Ltd.

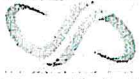
19.3 MACHINE IN-PROCESS CONTROL:

Date/ Shift		04/03/2021						05/03/2021									
Machine Operator Name		Ragu						Ravi.									
Time of inspection		15:40	16:40	16:45	17:45	18:30	18:40	09:30	10:00	10:25	11:30	12:00 12:40	12:40	13:20	13:25	14:05	14:30
Sealing Temperature (To be established)		200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C
Forming Temperature (To be established)		187°C	187°C	187°C	187°C	187°C	187°C	187°C	187°C	187°C	187°C	187°C	187°C	187°C	187°C	187°C	187°C
Leak test on Blister* (Qty.: _____)		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/ 19 13 4323	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
B. No.:	G1F210216	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Mfg. Date	02/2021	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Exp. Date	01/2024	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Machine Speed To be established		30	30	30	30	30	30	35	30	30	30	30	30	30	30	30	30
Checked by (Packing)		OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Checked by (IPQA)		OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK

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.	30/03/2021	04/03/2021	04/03/2021
Date	03/01/2021	03/01/2021	04/03/2021	04/03/2021

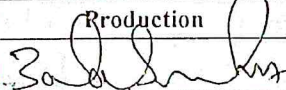
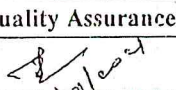
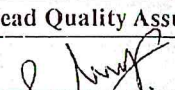
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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 15 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
	Product: GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: G1F210216 Generic Health Care Pvt. Ltd.

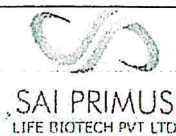
19.4 MACHINE IN-PROCESS CONTROL:

Date/ Shift	05/03/2021					06/03/2021				
Machine Operator Name	Rajni					Rajni				
Time of inspection	15:40	16:20	16:30	17:30	18:00	09:30	10:30	11:30	12:35	13:40
Sealing Temperature (To be established)	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C
Forming Temperature (To be established)	154°C	154°C	154°C	154°C	154°C	154°C	154°C	154°C	154°C	154°C
Leak test on Blister* (Qty.: _____)	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Knurling /Sealing	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Pocket Formation	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Horizontal cutting	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Vertical cutting	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Quality of Over printing	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Code No.: PON/DRUGS/ 19 13 4323	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
B. No.:	G1F210216	OK	OK	OK	OK	OK	OK	OK	OK	OK
Mfg. Date	02/2021	OK	OK	OK	OK	OK	OK	OK	OK	OK
Exp. Date	01/2024	OK	OK	OK	OK	OK	OK	OK	OK	OK
Machine Speed To be established	30	30	30	30	30	30	30	30	30	30
Checked by (Packing)		NA	Q	Q	NA	Q	NA	Q	Q	NA
Checked by (IPQA)		NA	Q	Q	NA	Q	NA	Q	Q	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.			
Date	03/01/2021	03/01/2021		





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
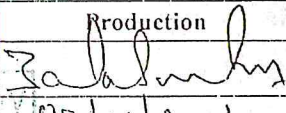
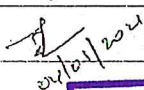
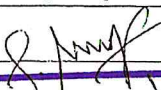
 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 16 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET		BPR. No.: BPR/T/195-00 Batch No.: GF 210216
Customer:			Generic Health Care Pvt. Ltd.

19.5 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)
06/01/2021	12:30	14:30	3.000	Durga Ram.		
				NA		
Total Weight of De-foiled Tablets			3.000	Checked By / Date (Packing): 		Verified By / Date (IPQA): 

19.6 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		
06/01/2021	14:31	15:00	Durga	2.900	24170	0.100	833		
						NA			
Total				2.900	2				
Total Quantity of Rejected Tablets Destroyed				Checked By / Date (Packing):			Verified By / Date (IPQA):		
0.100 Kgs ... 833 Nos.									

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	03/01/2021	03/01/2021	03/01/2021	03/01/2021

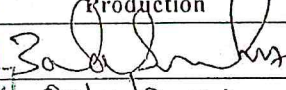
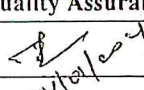
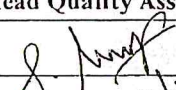
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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 15 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00	Batch No.: G1F 210216(A)
		Customer:	Generic Health Care Pvt. Ltd.

19.4 MACHINE IN-PROCESS CONTROL:


Date/ Shift	06/02/2021					08/02/2021									
Machine Operator Name	Ram					Ragu									
Time of inspection	14:30	15:20	16:20	16:30	17:30	09:30	10:30	10:30	11:30	11:30	12:30	12:30	13:30	14:30	15:30
Sealing Temperature (To be established)	200°C	200°C	200°C	199°C	199°C	199°C	197°C	199°C	199°C	199°C	199°C	199°C	199°C	199°C	199°C
Forming Temperature (To be established)	185°C	186°C	186°C	186°C	186°C	186°C	187°C	186°C	186°C	186°C	186°C	186°C	186°C	186°C	186°C
Leak test on Blister* (Qty.: 3)	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
Pocket Formation	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
Vertical cutting	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
Code No.: PON/DRUGS/ 19 13 4323	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
B. No.:	02/02/16	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Mfg. Date	02/02/21	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Exp. Date	01/02/24	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Machine Speed To be established	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30
Checked by (Packing)	OK	OK	NA	OK	OK	OK	NA	OK	OK	NA	OK	OK	NA	OK	OK
Checked by (IPQA)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	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.

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

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 15 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET		BPR. No.: BPR/T/195-00 Batch No.: GF210216(B) Customer: Generic Health Care Pvt. Ltd.

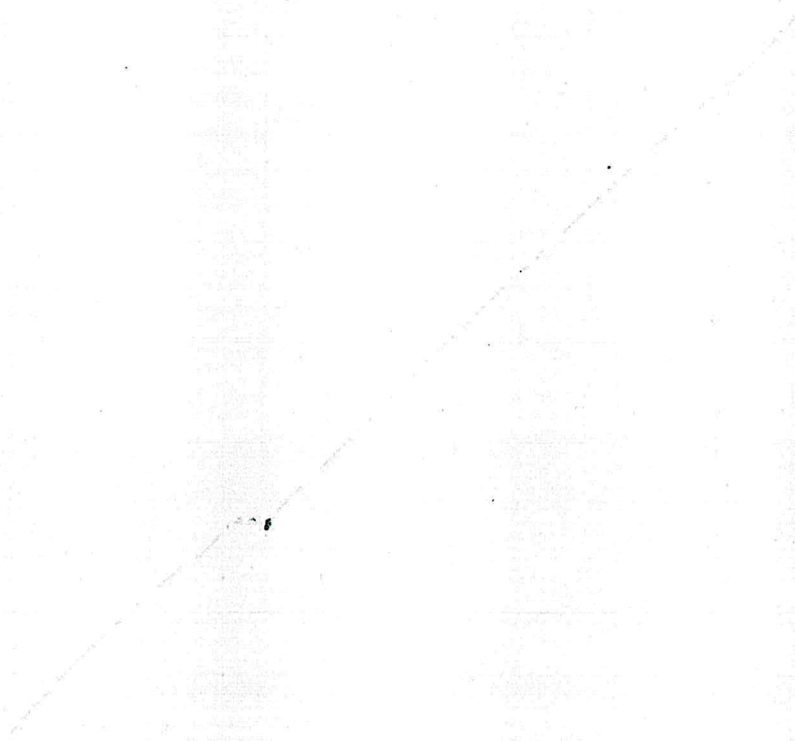
19.4 MACHINE IN-PROCESS CONTROL:

Date/ Shift	08/03/2021 / 1A														
Machine Operator Name	Ran														
Time of inspection	16:00	6:50													
Sealing Temperature (To be established)	200°C	199°C													
Forming Temperature (To be established)	180°C	180°C													
Leak test on Blister* (Qty.: _____)	OK	OK													
Knurling /Sealing	OK	OK													
Pocket Formation	OK	OK													
Horizontal cutting	OK	OK													
Vertical cutting	OK	OK													
Quality of Over printing	OK	OK													
Code No.:	PON/DRUGS/ 19 13 4323	OK	OK												
B. No.:	GF210216	OK	OK												
Mfg. Date	02/10/21	OK	OK												
Exp. Date	01/2024	OK	OK												
Machine Speed To be established	30	30													
Checked by (Packing)	NA	OK													
Checked by (IPQA)	OK														

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.	[Signature]	[Signature]	[Signature]
Date	03/01/2021	03/01/2021		

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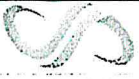
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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 17 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: GF 210216 Generic Health Care Pvt. Ltd.

20. 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.					
2	Check and ensure that waste bin is emptied out and cleaned					
3	Check the Pallets and crates area clean and free from any leftovers of previous product /Batch.					
4	Check and ensure the Correct status board is written.					
5	Check and ensure the previous batch details are deleted from the inkjet machine.					
6	Check and ensure the rejected Cartons of previous product/batch are removed.					
7	Check and ensure the cleanliness of hatch for conveyor belt.					
8	Check and ensure the cleanliness of conveyer belt with collateral block.					
9	Check and ensure the dispensed secondary packing material.					
10	Check and ensure the Preventive maintenance records and log book.					

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.


20.1 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.	L. R.	[Signature]	[Signature]	[Signature]
Date	03/01/2021	03/01/2021	03/01/2021	03/01/2021

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 18 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: G1F210216 Generic Health Care Pvt. Ltd.

20.2 OVERPRINTING DETAILS:

Overprinting Details	Overprinted Text	Carton (OK/ Not OK)
Batch No.:		
Mfg. Date:		
Exp. Date:		
Item Code: 15/0362		
Code No.: PON/DRUGS/19 13 4323		
Other instructions if any		
Initiated by Sign. & Date		
Checked by Packing Sign. & Date		
Verified by IPQA Sign. & Date		

20.3 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		

20.4 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

08/03/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. K.</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	03/01/2021	03/01/2021	04/01/2021	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 19 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: <u>GF 210216</u> Generic Health Care Pvt. Ltd.

21. LINE CLEARANCE CHECKS - SECONDARY PACKING:

Date/ Shift 01/03/2021 / 1 / 01/03/2021 / 1

Previous Product: B/mef 500		Batch No.: B012101B				
Sr. No.	Checks	Time	Observation			
			14:30 Packing	IPQA	09:30 Packing	IPQA
1	Check and ensure that the area is visually clean and free from previous product.		✓	✓	✓	✓
2	Check and ensure that waste bin is emptied out and cleaned		✓	✓	✓	✓
3	Check the Pallets area clean and free from any leftovers of previous product /Batch.		✓	✓	✓	✓
4	Check and ensure the Correct status board is written.		✓	✓	✓	✓
5	Check and ensure the stereo of the previous product/batch removed and cut into pieces.		✓	✓	✓	✓
6	Check and ensure the Blisters, rejected Carton, Shipper and shipper label of previous product/batch are removed.		✓	✓	✓	✓
7	Check and ensure the cleanliness of hatch for conveyor belt.		✓	✓	✓	✓
8	Check and ensure the cleanliness of conveyer belt with collateral block.		✓	✓	✓	✓
9	Check and ensure the dispensed secondary packing material.		✓	✓	✓	✓
10	Check and ensure the cleanliness of documentation table.		✓	✓	✓	✓
11	Check and ensure the Preventive maintenance records and log book.		✓	✓	✓	✓

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


Cleaning Satisfactory / Not-satisfactory# P Cleaning Satisfactory / Not-satisfactory# P
 (Packing) Sign. /Date: 01/03/2021 (IPQA) Sign. /Date: 01/03/2021

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/GOB/001</u>	<u>PD/BAY1016</u>	<u>NA</u>	<u>PD/STP/001</u>	<u>PD/BAY41023</u>	Secondary Packing Hall
Previous Product:	<u>B/mef 500</u>					
Batch No.:	<u>B012101B</u>					
Cleaned by:	<u>VISHW</u>					
Checked by Packing:	<u>P 01/03/2021</u>					
Verified by IPQA:	<u>P 01/03/2021</u>					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L.K.</u>	<u>Zalalunhu</u>	<u>outatou</u>	<u>P. Pankaj</u>
Date	<u>03/01/2021</u>	<u>03/01/2021</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 29
	BATCH PACKING RECORD		Product Code: G13
Product	GENSET	BPR. No.: BPR/T/195-00	Batch Size: 30,00,000 Tablets
		Customer:	Batch No.: G13 210216 Generic Health Care Pvt. Ltd.

21.1 ENVIRONMENTAL CONDITIONS:

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

Shift:..... 9	Date/Time: 01/03/2021			Date/Time: 02/03/2021		
	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	24°C	[Signature]	24°C	8	[Signature]
Secondary Packing Started Date/Time: 01/03/2021..... 14:30... Completed Date/Time: 02/03/2021..... 14:10.						
APPROVAL FOR SECONDARY PACKING: Approved by IPQA Sing/Date: 01/03/2021.....						

21.2 PACKING DETAILS:

10 Tablets in each Blister, over code the Blister with the batch details given below,

Place 3 x 10's Blister and one leaflet in each carton.

Place 20 filled carton in a Shrink Sleeve.

Place 24 Shrink sleeves in each 5 ply shipper.

Seal the shipper with BOPP tape with "H" type.

22. OVER PRINTING DETAILS:

Overprinting Details (Secondary & Tertiary PM)

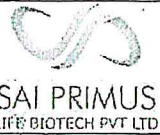
Overprinting Details	Overprinted Text	Carton (OK/ Not OK)	5 Ply Shipper Label (OK/ Not OK)
Batch No.:	G13 210216	OK	OK
Mfg. Date:	02/2021	OK	OK
Exp. Date:	01/2024	OK	OK
Code No.: PON/DRUGS/19 13 4323	PON/DRUGS/19 13 4323	OK	NA
Pack size:	NA	3 x 10's	24 x 20 x 3 x 10's
Other instructions if any	NA	NA	NA
Initiated by Sign. & Date	NA	NA	NA
Checked by Packing Sign. & Date	[Signature] 01/03/2021	[Signature] 01/03/2021	[Signature] 01/03/2021
Verified by IPQA Sign. & Date	[Signature] 01/03/2021	[Signature] 01/03/2021	[Signature] 01/03/2021

24.1 Shipper Label Specimen:

S. No.	Date	Shipper Label Specimen No.	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01	01/03/2021	01	[Signature] 01/03/2021	[Signature] 01/03/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	[Signature]	[Signature]	[Signature]
Date	03/01/2021	03/01/2021	03/01/2021	

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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 21 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
	Product: GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: GF 21 0216 Generic Health Care Pvt. Ltd.

23. CARTON WEIGHT LIMIT SETTING: Date/Shift: **08/03/2021** Time: **14:50**

Weight of ten individual empty cartons are given below:

1. 3.94	3. 3.930	5. 3.860	7. 3.860	9. 3.890
2. 3.865	4. 3.970	6. 3.910	8. 3.835	10. 3.925

Total weight of ten empty cartons = **38.985**

Average weight of an empty carton (A) = Total weight of ten empty carton / 10 = **3.898**

Weight of ten individual Blister are given below:

1. 2.130	3. 2.100	5. 2.160	7. 2.200	9. 2.120
2. 2.135	4. 2.110	6. 2.175	8. 2.170	10. 2.120

Total weight of ten Blister = **21.38**

Avg. Weight of a Blister (B): total weight of ten Blister / 10 = **2.138**

Weight of ten individual Leaflets are given below:

1. 1.560	3. 1.580	5. 1.535	7. 1.565	9. 1.560
2. 1.570	4. 1.535	6. 1.570	8. 1.565	10. 1.555

Total weight of ten Leaflets = **15.595**

Avg. Weight of a Leaflet (C): total weight of ten Leaflets / 10 = **1.559**

23.1 WEIGHT CHECKS ON CARTON:


Weight of ten empty Carton: 38.985	Average weight of one empty Carton (A): 3.898
Weight of ten filled Blister: 21.380	Average weight of one filled Blister (B): 2.138
Weight of ten Leaflets: 15.595	Average weight of one Leaflet (C): 1.559
Weight of one filled Carton D = (A+3B+C) 11.871	Limit: E = D ± 1% = 11.75 - 11.98 (To be established)
Checked by Packing/Date: 08/03/2021	Verified by IPQA/Date: 08/03/2021

23.2 SAMPLE DRAWN RECORD:

Sr. No.	Stage of Sample collection	Qty. of Sample	Collected by (Sign. /Date)
1	Control Sample (Initial)	7 x 10's	08/03/2021
2	Control Sample (Middle)	6 x 10's	08/03/2021
3	Control Sample (Final)	7 x 10's	08/03/2021
4	Stability Sample	30 x 10's	08/03/2021
5	Other Sample	NA	NA
6	Analytical sample	12 x 10's	08/03/2021
Total Qty.		62 x 10's	08/03/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	08/03/2021	08/03/2021	08/03/2021
Date	03/01/2021	03/01/2021	04/01/2021	08/03/2021

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 22 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: G1F210216 Generic Health Care Pvt. Ltd.

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

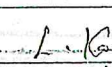
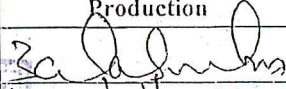
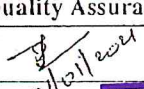
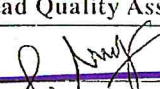
Date/ Shift	01/03/2021 14	03/03/2021 02/03/2021													
Parameters	Specification	observation													
		Packing							IPQA						
Time		14:35	15:20	16:40	17:45				18:00	18:00	18:00	18:05	19:40	11:10	19:45
No. of Blister in a carton	3 Blister with 10 tabs each and one leaflet.	OK	OK	OK	OK				OK	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	20 packed cartons	NA	NA	NA	NA				NA	NA	NA	OK	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	24 shrinks 616	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
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	OK	OK	OK	OK				OK	OK	OK	OK	OK	OK	OK
Checked by		OK	OK	OK	OK				OK	OK	OK	OK	OK	OK	OK

*Temperature to be mentioned.

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

Date/ Shift	01/03/2021 14	03/03/2021													
Parameters	Specification	observation													
		Packing							IPQA						
Time		09:40	10:35	11:40	12:35	13:40	14:35	15:30	16:00	16:05	16:30	17:05	18:10	19:20	19:45
No. of Blister in a carton	3 Blister with 10 tabs each 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	20 packed cartons	NA	NA	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	NA	NA
No. of shrink sleeves in a 5 ply shipper	24 shrinks 616	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		OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK

*Temperature to be mentioned.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	03/01/2021	03/01/2021	03/01/2021	03/01/2021

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

[illegible]

*Temperature to be mentioned.


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

Date/ Shift	03/03/2017	04/03/2017							05/03/2017						
Parameters	Specification	observation													
		Packing							IPQA						
Time		15:40	16:30	17:40	09:30	10:30	11:25	12:20	13:45	15:15	18:00				
No. of Blister in a carton	3 Blister with 10 tabs each and one leaflet.	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				
No. of cartons in a shrink sleeves	20 packed cartons	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA				
Shrink wrapping temperature*		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA				
No. of shrink sleeves in a 5 ply shipper	24 shrinks b/b	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Shipper strapping	Proper strapping	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				
Sealing of the shipper with BOPP Tape	H type	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Checked by		R	R	R	P	P	P	P	F	J	E				

*Temperature to be mentioned.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. K.</i>	<i>Zalal</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	03/11/2021	03/11/2021	04/11/2021	04/11/2021

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 24 of 29
	BATCH PACKING RECORD	Product Code: G13	Batch Size: 30,00,000 Tablets
	Product: GENSET	BPR. No.: BPR/T/195-00	Batch No.: GF210216
	Customer:	Generic Health Care Pvt. Ltd.	

25. SHIPPERS WEIGHING:


Date/Shift: 01/03/2021 Time: 11:15 AM Balance I.D. No.: 90/941032

Weight of ten Shrinkers: 118.7	Average weight of one filled Shrink (H): 11.87
Weight of ten empty shippers: 7.330	Average weight of one empty shipper (I): 0.733
Weight of one filled shipper (J) = (24H+I): 8.511	Limit: K = J ± 1% = 8.426 - 8.596 (to be established)
Checked by Packing/Date: [Signature]	Verified by IPQA/Date: [Signature] 01/03/2021

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	8.470	Devi	56	8.370	Priya	111	8.480	Devi	166		
2	8.500	Devi	57	8.415	Priya	112	8.390	Devi	167		
3	8.485	Devi	58	8.500	Priya	113	8.455	Priya	168		
4	8.460	Devi	59	8.425	Priya	114	8.395	Priya	169		
5	8.460	Devi	60	8.470	Priya	115	8.370	Priya	170		
6	8.455	Devi	61	8.470	Priya	116	8.430	Priya	171		
7	8.475	Devi	62	8.405	Priya	117	8.395	Priya	172		
8	8.500	Devi	63	8.475	Priya	118	8.440	Priya	173		
9	8.505	Devi	64	8.485	Priya	119	8.460	Priya	174		
10	8.505	Devi	65	8.460	Priya	120	8.430	Priya	175		
11	8.500	Sangeetha	66	8.480	Priya	121	8.395	Devi	176		
12	8.510	Sangeetha	67	8.440	Devi	122	8.455	Devi	177		
13	8.495	Sangeetha	68	8.470	Devi	123	8.460	Devi	178		
14	8.435	Sangeetha	69	8.475	Devi	124	8.390	Devi	179		
15	8.520	Sangeetha	70	8.415	Devi	125	8.430	Devi	180		
16	8.510	Sangeetha	71	8.420	Devi	126	8.390	Devi	181		
17	8.505	Sangeetha	72	8.405	Devi	127	8.365	Devi	182		
18	8.525	Sangeetha	73	8.420	Devi	128	8.380	Priya	183		
19	8.520	Sangeetha	74	8.430	Devi	129	8.380	Priya	184		
20	8.505	Sangeetha	75	8.420	Devi	130	8.515	Priya	185		
21	8.535	Devi	76	8.430	Devi	131	8.400	Priya	186		
22	8.535	Devi	77	8.465	Priya	132	8.470	Priya	187		
23	8.550	Devi	78	8.420	Priya	133	8.490	Priya	188		
24	8.570	Devi	79	8.420	Priya	134	8.505	Priya	189		
25	8.535	Devi	80	8.440	Priya	135	8.475	Priya	190		
26	8.510	Devi	81	8.420	Devi	136	8.525	Priya	191		
27	8.540	Devi	82	8.410	Devi	137	8.460	Priya	192		
28	8.465	Sangeetha	83	8.385	Devi	138	8.465	Priya	193		
29	8.560	Sangeetha	84	8.390	Devi	139	8.480	Priya	194		
30	8.550	Sangeetha	85	8.470	Devi	140	8.470	Priya	195		
31	8.515	Sangeetha	86	8.465	Devi	141	8.450	Priya	196		
32	8.510	Sangeetha	87	8.480	Devi	142	8.530	Priya	197		
33	8.525	Sangeetha	88	8.455	Devi	143	8.560	Priya	198		
34	8.500	Sangeetha	89	8.390	Devi	144	8.560	Priya	199		
35	8.510	Sangeetha	90	8.420	Devi	145	8.450	Priya	200		

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign:	[Signature]	[Signature]	[Signature]	[Signature]	
Date:	03/01/2021	03/01/2021			

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 23 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: GF210216(B) Generic Health Care Pvt. Ltd.

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


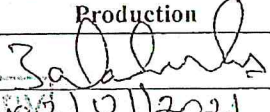
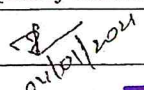
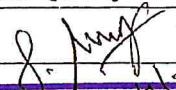
Date/ Shift		06/03/2021 / 4											
Parameters	Specification	observation											
		Packing								IPQA			
Time		09:00	10:30	11:30	12:40	13:00	14:30	15:40	07:15	11:56	14:02	16:05	
No. of Blister in a carton	3 Blister with 10 tabs each and one leaflet.	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Carton Overprinting	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
No. of cartons in a shrink sleeves	20 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	24-shrinks 616	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	
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	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Checked by		OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	

*Temperature to be mentioned.

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

Date/ Shift		08/03/2021 / 4											
Parameters	Specification	observation											
		Packing								IPQA			
Time		16:30	17:30	09:40	10:30	11:00	12:30	12:40	09:45	11:20	13:28		
No. of Blister in a carton	3 Blister with 10 tabs each and one leaflet.	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		
No. of cartons in a shrink sleeves	20 packed cartons	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA		
Shrink wrapping temperature*		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA		
No. of shrink sleeves in a 5 ply shipper	24-shrinks 616	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Shipper strapping	Proper strapping	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		
Sealing of the shipper with BOPP Tape	H type	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Checked by		OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		

*Temperature to be mentioned.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	08/03/2021	08/03/2021	08/03/2021	08/03/2021

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all available

admission to the school of the student

1. The student shall be admitted to the school of the student
2. The student shall be admitted to the school of the student
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all

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all

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 23 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: G1F210216(A) Generic Health Care Pvt. Ltd.

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

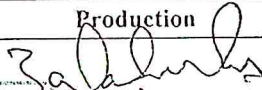
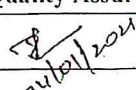
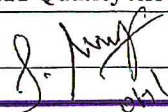
Date/ Shift	04/07/2021 / G	05/02/2021												
Parameters	Specification	observation												
		Packing						IPQA						
Time		13:20	14:30	15:40	16:30	17:40	18:50	19:50						
No. of Blister in a carton	3 Blister with 10 tabs each and one leaflet.	OK	OK	OK	OK	OK	OK	OK						
Carton Overprinting	Legible and readable	OK	OK	OK	OK	OK	OK	OK						
No. of cartons in a shrink sleeves	20 packed cartons	NA	NA	NA	NA	NA	NA	NA						
Shrink wrapping temperature*		NA	NA	NA	NA	NA	NA	NA						
No. of shrink sleeves in a 5 ply shipper	24-shrinks 6/6	OK	OK	OK	OK	OK	OK	OK						
Shipper strapping	Proper strapping	OK	OK	OK	OK	OK	OK	OK						
Label appearance and Shipper appearance	Legible and readable	OK	OK	OK	OK	OK	OK	OK						
Sealing of the shipper with BOPP Tape	H type	OK	OK	OK	OK	OK	OK	OK						
Checked by		Q	Q	Q	Q	Q	Q	Q						

*Temperature to be mentioned.

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

Date/ Shift	05/03/2021 / G												
Parameters	Specification	observation											
		Packing							IPQA				
Time		11:20	12:40	13:35	14:40	15:30	16:40	17:50					
No. of Blister in a carton	3 Blister with 10 tabs each and one leaflet.	OK	OK	OK	OK	OK	OK	OK					
Carton Overprinting	Legible and readable	OK	OK	OK	OK	OK	OK	OK					
No. of cartons in a shrink sleeves	20 packed cartons	NA	NA	NA	NA	NA	NA	NA					
Shrink wrapping temperature*		NA	NA	NA	NA	NA	NA	NA					
No. of shrink sleeves in a 5 ply shipper	24 shrinks 6/6	OK	OK	OK	OK	OK	OK	OK					
Shipper strapping	Proper strapping	OK	OK	OK	OK	OK	OK	OK					
Label appearance and Shipper appearance	Legible and readable	OK	OK	OK	OK	OK	OK	OK					
Sealing of the shipper with BOPP Tape	H type	OK	OK	OK	OK	OK	OK	OK					
Checked by		OK	OK	OK	OK	OK	OK	OK					


*Temperature to be mentioned.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	03/01/2021	03/01/2021	03/01/2021	03/01/2021



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1. The first part of the report
describes the general situation
of the country and the
main problems which
are facing it. It also
mentions the main
achievements of the
government in the
last few years.
The second part of the
report deals with the
economic situation and
the main problems which
are facing the economy.
It also mentions the
main achievements of the
government in the
last few years.

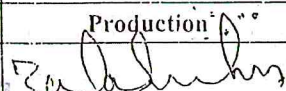
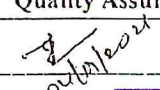
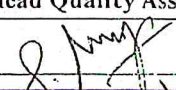
3. The third part of the
report deals with the
social situation and the
main problems which
are facing the society.
It also mentions the
main achievements of the
government in the
last few years.
The fourth part of the
report deals with the
cultural situation and the
main problems which
are facing the culture.
It also mentions the
main achievements of the
government in the
last few years.

 SAI PRIMUS LIFE BIOTECH PVT. LTD.		SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 25 of 29			
		BATCH PACKING RECORD		Product Code: G13		Batch Size: 30,00,000 Tablets	
Product		GENSET		BPR. No.: BPR/T/195-00		Batch No.: GF210216	
				Customer:		Generic Health Care Pvt. Ltd.	


36	8.545	Sangeetha	91	8.410	Devi	146	8.385	Priya	201		
37	8.500	Sangeetha	92	8.405	Devi	147	8.390	Priya	202		
38	8.565	Sangeetha	93	8.435	Devi	148	8.410	Priya	203		
39	8.525	Sangeetha	94	8.440	Devi	149	8.375	Priya	204		
40	8.435	Sangeetha	95	8.370	Devi	150	8.405	Priya	205		
41	8.470	Sangeetha	96	8.340	Devi	151	8.385	Priya	206		
42	8.510	Sangeetha	97	8.380	Devi	152	8.360	Priya	207		
43	8.545	Sangeetha	98	8.345	Devi	153	8.450	Priya	208		
44	8.490	Sangeetha	99	8.370	Devi	154	8.410	Priya	209		
45	8.540	Sangeetha	100	8.355	Devi	155	8.410	Priya	210		
46	8.500	Sangeetha	101	8.375	Devi	156	8.500	Priya	211		
47	8.445	Sangeetha	102	8.380	Devi	157	8.400	Priya	212		
48	8.540	Sangeetha	103	8.435	Devi	158	8.400	Priya	213		
49	8.500	Sangeetha	104	8.405	Devi	159	8.395	Priya	214		
50	8.425	Sangeetha	105	8.460	Priya	160	8.180	Priya	215		
51	8.470	Sangeetha	106	8.490	Priya	161			216		
52	8.420	Sangeetha	107	8.430	Priya	162			217		
53	8.400	Priya	108	8.380	Priya	163			218		
54	8.410	Priya	109	8.470	Priya	164			219		
55	8.365	Priya	110	8.480	Priya	165			220		

Total No. of shippers weighed: 160	De-billed tablets packed in Shipper No: 160	Checked by Sign / Date:  10/03/2021	Verified by Sign / Date: 	Loose pack details: Shipper No:160..... Quantity: 150 X 3 X 10's Weight: 3.180.....
--	---	---	--	---



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



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

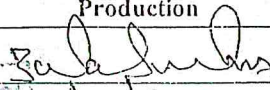
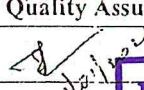
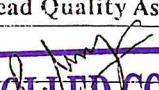
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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 26 of 29
	BATCH PACKING RECORD		Product Code: G13
Product	GENSET	BPR. No.: BPR/T/195-00	Batch Size: 30,00,000 Tablets
		Customer:	Batch No.: G1F210216 Generic Health Care Pvt. Ltd.

26. MAN POWER ALLOCATION:

DATE: 01/03/2021.....		DATE: 03/03/2021.....	
SHIFT: 4.....		SHIFT: 4.....	
ACTIVITIES	DONE BY	ACTIVITIES	DONE BY
Blister Checking	manju Anjaledevi	Blister Checking	manju Anjaledevi
Printing Checking in Blister	sumathi pushpa	Printing Checking in Blister	sumathi pushpa
Insertion of Blister and leaflet into carton	mangai, una, uma, bakkara, suganthi, prenu, savithri, sengara, swathi, priya	Insertion of Blister and leaflet into carton	mangai, una, uma, bakkara, suganthi, prenu, savithri, sengara, swathi, priya
Cartons weighing	meenakshi, Angawan	Cartons weighing	meenakshi, Angawan
Insertion of carton into shrink sleeve	N.A	Insertion of carton into shrink sleeve	N.A
Insertion of shrink wrapped carton into shipper	sangeetha, nalanidevi	Insertion of shrink wrapped carton into shipper	sangeetha, nalanidevi
Shipper Label Pasting	sangeetha	Shipper Label Pasting	sangeetha
Shipper Weighing	kathavarayan	Shipper Weighing	kathavarayan
Shipper Strapping	kathavarayan	Shipper Strapping	kathavarayan
Shipper packed	From 01 to 03	Shipper packed	From 01 to 03
Signature of Packing		Signature of Packing	

DATE: 02/03/2021.....		DATE: 04/03/2021.....	
SHIFT: 4.....		SHIFT: 4.....	
ACTIVITIES	DONE BY	ACTIVITIES	DONE BY
Blister Checking	manju Anjaledevi	Blister Checking	manju Anjaledevi
Printing Checking in Blister	sumathi, pushpa	Printing Checking in Blister	sumathi, pushpa
Insertion of Blister and leaflet into carton	mangai, una, uma, bakkara, suganthi, prenu, savithri, sengara, swathi, priya	Insertion of Blister into carton	mangai, una, uma, bakkara, suganthi, prenu, savithri, sengara, swathi, priya
Cartons weighing	meenakshi, Angawan	Cartons weighing	meenakshi, Angawan
Insertion of carton into shrink sleeve	N.A	Insertion of carton into shrink sleeve	N.A
Insertion of shrink wrapped carton into shipper	sangeetha, nalanidevi	Insertion of shrink wrapped carton into shipper	sangeetha, nalanidevi
Shipper Label Pasting	sangeetha	Shipper Label Pasting	sangeetha
Shipper Weighing	kathavarayan	Shipper Weighing	kathavarayan
Shipper Strapping	kathavarayan	Shipper Strapping	kathavarayan
Shipper packed	From 03 to 04	Shipper packed	From 03 to 04
Signature of Packing		Signature of Packing	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka			
Date	03/01/2021	03/01/2021	03/01/2021	03/01/2021

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

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BATCH PACKING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

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

Batch No.: GF 210216 (B)

Customer:

Generic Health Care Pvt. Ltd.

26. MAN POWER ALLOCATION:

DATE: 03/01/2021..

SHIFT: 01

ACTIVITIES	DONE BY
Blister Checking	manju, Anjaladevi
Printing Checking in Blister	Sumathi, Pushpa
Insertion of Blister and leaflet into carton	manjula, umma, Anasudhan, bulka, Suganya, Prema, Savithri, Anandha
Cartons weighing	meenashree, Anwaran
Insertion of carton into shrink sleeve	N. A
Insertion of shrink wrapped carton into shipper	Sangeetha, nalinidevi
Shipper Label Pasting	Sangeetha
Shipper Weighing	kathavarayan
Shipper Strapping	kathavarayan
Shipper packed	From 10.1 to 10.0
Signature of Packing	

DATE:

SHIFT:

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

DATE:

SHIFT:

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

DATE:

SHIFT:

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

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

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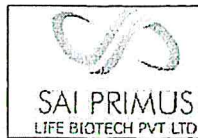
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SAI PRIMUS LIFE BIOTECH PVT LTD
Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate,
Villianur Commune, Puducherry-605009.

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BATCH PACKING RECORD		Product Code: G13	Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00	Batch No.: G1F210216
		Customer:	Generic Health Care Pvt. Ltd.

27. 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	115.800	306.100	102000	102000	NA	209	500	15
B	Additional material received for the batch	NA	NA	NA	NA	NA	NA	NA	NA
C	Total material received (A+B)	115.800	306.100	102000	102000	NA	209	500	15
D	Quantity packed	78.850	300.200	98094	98094	NA	160	500	15
E	Quantity rejected (Online) & Destroyed	1.530	3.232	3888	1788	NA	49	NA	NA
F	Quantity Returned	35.400	2.600	NA	2100	NA	NA	NA	NA
G	Sample affixed on BPR	0.004	NA	01	01	NA	NA	NA	NA
H	QC samples	0.003	0.013	NA	NA	NA	NA	NA	NA
I	Other samples (If any)	0.013	0.055	17	17	NA	NA	NA	NA
J	Total accountable Quantity (D+ E+F+G+H+I)	115.800	306.100	102000	102000	NA	209	500	15
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

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

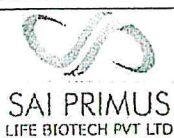
Material	Printed Alu. Foil (Kg)	Clear PVC (Kg)	Cartons (Nos)	Leaflets (Nos)	Shrink Sleeves (Nos)	5 Ply Shipper (Nos)	Strapping Role (Mtrs.)	BOPP Tape (GHPL Printed) (Nos)
Quantity Returned	35.400	306.100	NA	2100	NA	NA	NA	NA
Material returned by packing Sign./Date	<i>[Signature]</i>	<i>[Signature]</i>		<i>[Signature]</i>				
Verified By IPQA Sign./Date	<i>[Signature]</i>	<i>[Signature]</i>		<i>[Signature]</i>				
Material received by Store Sign./Date	<i>[Signature]</i>	<i>[Signature]</i>		<i>[Signature]</i>				

29. 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)
23/03/2021	25	1.530	3.232	3888	1788	NA	49	500 ^{NA}	NA
Total Qty. Destroyed	25	1.530	3.232	3888	1788	NA	49	500 ^{NA}	NA
Destroyed by (Packing)	<i>[Signature]</i>								
Verified by (IPQA)	<i>[Signature]</i>								

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<i>L. K.</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	
Date	23/03/2021	23/03/2021			

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

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BATCH PACKING RECORD

Product Code: G13

Batch Size: 30,00,000 Tablets

Product

GENSET

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

Batch No.: GF210216

Customer:

Generic Health Care Pvt. Ltd.

30. BATCH RECONCILIATION:

A	Batch Size	30,00,000 Nos.
B	Quantity received for packing	2978413
C	Total quantity packed	2942820
D	Control samples	200
E	Analytical Samples	120
F	In process samples	31150
G	Others samples if any (Stability, Regulatory Samples, etc.)	300
H	Packing Loss = B - (C + D + E + F + G)	3823
I	Total Loss = A - (C + D + E + F + G)	25410
J	Packing yield % (C + D + E + F + G) / B X 100 (Yield Limit %.....)*	99.87%
K	Batch Yield % (C + D + E + F + G) / A X 100 (Yield Limit %.....)*	99.15%

*To be established

Checked by Packing /Date:

10/03/2021

Verified by IPQA/Date:

10/03/2021

31. 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
10/03/2021	1210	30.01	3x10's	616x3x10's	159	293832	G	10/03/2021	10/03/2021
				150x3x10's	01	450	G	10/03/2021	10/03/2021
Total Qty. Transferred						294282	G	10/03/2021	10/03/2021

32. 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:

33. BPR REVIEW DETAILS:

Reviewed by	Name	Sign. /Date
Packing Executive	J. Ravivarmen	10/03/2021
QA Executive	N. Shanthy	10/03/2021
Production Assistant Manager/ HOD	BALASUBRAMANIAN.B	10/03/2021
QA Manager/ HOD	Stephen.R	10/03/2021

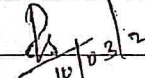
Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L.K.	10/03/2021	10/03/2021	10/03/2021	
Date	03/01/2021	03/01/2021	03/01/2021	03/01/2021	

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	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 29 of 29
	BATCH PACKING RECORD		Product Code: G13 Batch Size: 30,00,000 Tablets
Product	GENSET	BPR. No.: BPR/T/195-00 Customer:	Batch No.: GF210216 Generic Health Care Pvt. Ltd.

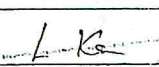
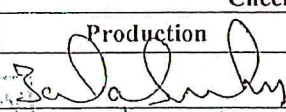
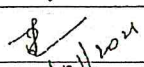
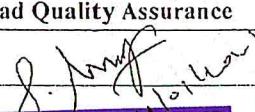
34. BATCH RELEASED FOR DESPATCH:

Total quantity released: 2942820 No's

Head QA sign/ Date:  10/03/21

35. REVISION HISTORY:

S. No.	Document No.	Reason for Changes	Supersedes Doc. No.
1	BPR/T/195-00	New Document	Nil

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	10/03/2021	03/01/2021	04/01/2021	04/01/2021

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