	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 1 of 33
	BATCH MANUFACTURING RECORD		Product Code: A08 Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BMR. No.: BMR/T/107-01 Customer:	Batch No.: GF200501 Generic Health Care Pvt. Ltd.

BATCH MANUFACTURING RECORD COVER SHEET

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

RECOVERY ADDITION RECORD

BATCH NO	MFG	EXP	QUANTITY	REVISED BATCH SIZE
		ms		

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

This BMR contains 33 Pages + 11 Additional Pages

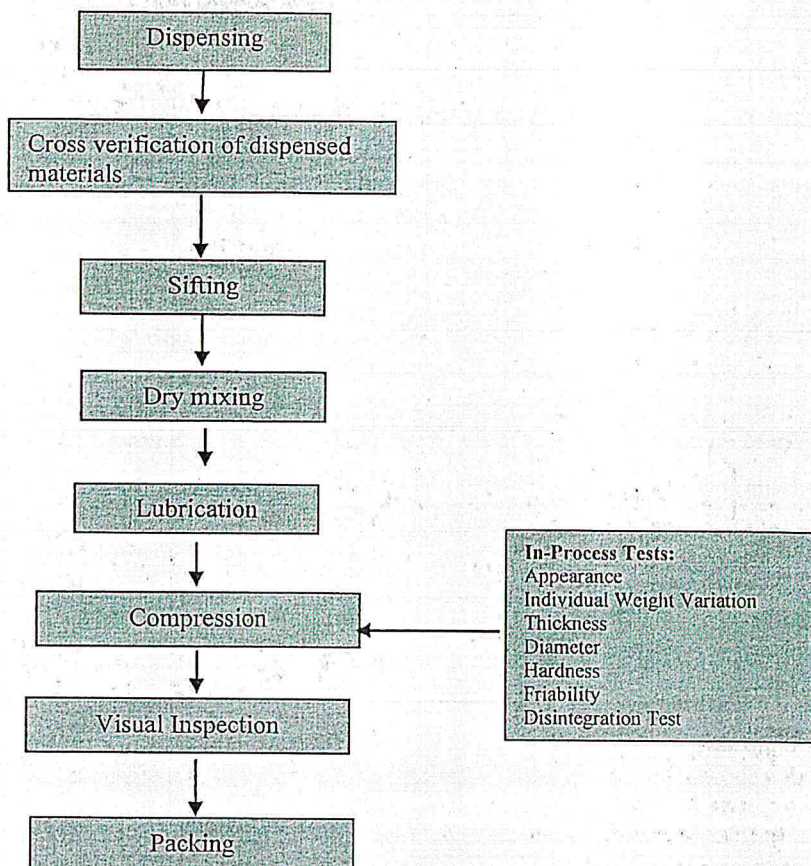
Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ke	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	21/05/2020	21/05/2020	22/05/2020	22/05/2020

UNCONTROLLED COPY

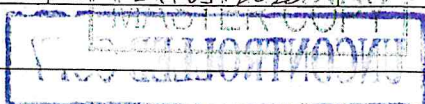
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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 3 of 33
	BATCH MANUFACTURING RECORD	Product Code: A08	Batch Size: 6,00,000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

2.0 PROCESS FLOW CHART



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



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

3.0 INDENT OF ACTIVE INGREDIENTS & EXCIPIENTS:

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

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

OA: Overages, PL: Process loss

Potency calculation:

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

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

Item losses 6% moisture.

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

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. Ka</i>	<i>S. S. S. S.</i>	<i>P. H. S.</i>	<i>S. S. S.</i>
Date	21/05/2020	21/05/2020	22/05/2020	21/5/20

