

 SAI PRIMUS LIFE BIOTECH PVT 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 13
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PROCESS VALIDATION PROTOCOL			Batch Size: 600000
Generic name	AMLOPERIN 5MG/5MG	Effective Date	22/05/2020
Protocol No.	PVP-A08	Ref. SOP No.	QACN/017

PROCESS VALIDATION PROTOCOL

Generic Name	AMLODIPINE BESYLATE 5 MG AND PERINDOPRIL ERBUMINE 5MG TABLETS
Label claim	Each uncoated tablet contains: Amlodipine Besylate BP Equivalent to Amlodipine.....5 mg Perindopril Erbumine5 mg Excipients.....q.s
Dosage Form	Tablets
Reference BMR No	BMR/T/107-01
Batch Size	600000
Shelf Life	36 Months
MFG. LIC. NO.	PON/DRUGS/19 13 4323

PROTOCOL APPROVAL

	Department	Name	Designation	Sign & date
Prepared by	Quality Assurance	Ram Kumar	Executive	 22/05/2020
	Production	BALASUBRAMANIAN B	MANAGER	 22/05/2020
Reviewed by	Quality Control	A VALLARAJAN	MANAGER	 22/05/2020
	Quality Assurance	K.J. BALAMURUGAN	MANAGER	 22/05/2020
Approved by	President	SIVAPRAKASH - T.	PRESIDENT	 22/05/2020

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Generic name	AMLOPERIN 5MG/5MG	Effective Date	22/05/2020
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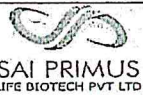
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Revision No: 01

PROCESS VALIDATION PROTOCOL

Batch Size: 600000

Generic name AMLOPERIN 5MG/5MG

Effective Date 22/05/2020

Protocol No. PVP-A08

Ref. SOP No. 0164/017

2.0 OBJECTIVE

To monitor the process for establishing documented evidence to ensure that the process variables including the critical process parameters are under control and to demonstrate that the process consistently produces a product meeting its predetermined specification and quality attributes.

3.0 SCOPE

The validation activity shall be carried out to ensure that this product, meets predetermined specification and quality attributes when manufactured in stages from Dispensing, Granulation, Compression and Packing.

4.0 RESPONSIBILITY

Department	Responsibilities
Quality Assurance	To prepare, review, approved and authorized the protocol. Execution these protocol samplings during validation as per sampling plan.
Production	To review and approve the protocol and to co-ordinate and support for process validation.
Quality Control	To review and approve the protocol and responsible to analysis of collected samples.

5.0 IDENTIFICATION OF VALIDATION TEAM AND TRAINING

Personnel shall be identified from QA, QC, PD department and trained for executing this validation activity.

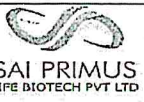
S. No.	Name	Department	Designation	Sign/Date
1.	P. Sathish Kumar	Prod. M.	For. Exe.	P. Sathish Kumar
2.	Jaganathan	Prod. M.	For. Exe.	Jaganathan
3.	Prabakaran	QA	Chemist	Prabakaran
4.	Gudha	QA	Chemist	Gudha

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Training details

Name of the trainer:

Duration:

Training details shall be attached in training attendance sheet.

6.0 ABBREVIATIONS

Acronym	Definition	Acronym	Definition
P	Protocol	NMT	Not more than
QA	Quality Assurance	°C	Degree Celsius
QC	Quality Control	%	Percentage
PV	Process validation	mg.	Milligram
BMR	Batch manufacturing record	RPM	Rotation per minute
TABS	Tablets	RSD	Relative standard deviation
IP	Indian pharmacopeia	OOS	Out of Specification
BP	British pharmacopeia	g.	Gram
USP	United states pharmacopeia	Kg.	Kilogram
ICH	International conference on harmonization	lt.	Litre
cGMP	Current Good Manufacturing practices	mm.	Millimetre
IH	In house	ml.	Millilitre
API	Active pharmaceutical ingredient	NLT	Not less than
PD	Production	FG	Finished goods
ID	Identification	RH	Relative humidity
S.	Serial	R-LAF	Reverse laminar Air flow
No.	Number	LOD	Loss on drying
CPP	Critical process parameter	DT	Disintegration time
CQA	Critical quality attributes	Qty.	Quantity
CPC	Critical process control	IPC	In process container
UV	Ultra violet	NA	Not applicable
HPLC	High performance liquid chromatography	MLT	Microbial limit test
Max.	Maximum	HMI	Human Machine Interface
Min.	Minimum		

7.0 TYPE OF VALIDATION

Prospective validation	-
Concurrent validation	√
Re-validation	-

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8.0 REASON FOR VALIDATION

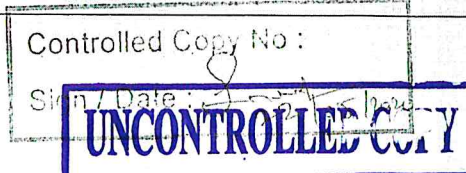
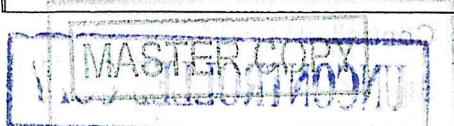
Reasons	Tick in the appropriate row	Reasons	Tick in the appropriate row
New formulation	-	Significant changes in process	-
Change in formulation	-	Change/modification in equipment	-
Change in location	√	Any other reasons (specify)	Concurrent validation
Critical change in some of materials	-		

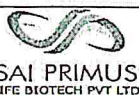
9.0 PRE REQUISITES OF PROCESS VALIDATION

1. The batches will be manufactured as per the respective batch manufacturing record.
2. The equipments utilized for manufacturing as per list of equipments and BMR.
3. The raw material used for manufacturing will be from approved manufacturer and shall be released by quality control.
4. The critical process parameters of the process will be evaluated with respect to quality attributes of the products
5. Sampling of in-process samples will be carried as per established sampling procedure and plan.
6. Critical in-process will be evaluated with respect to the laid down specification.
7. Finished drug product of these batches will be analysed as per laid down test procedures and comply with respect to the specifications.

10.0 PRODUCT DETAILS

Product Name	AMLOPERIN 5MG/5MG		
Dosage Form	Oral Tablet		
Label Claim	Each uncoated tablet contains: Amlodipine Besylate BP Equivalent to Amlodipine.....5 mg Perindopril Erbumine5 mg Excipients.....q.s		
Average weight of Uncoated tablet	140.00 mg		
Batch number	1	2	3
	61F 200405	61F 200501	61F 200502
Batch size	600000	600000	600000
Manufacturing date	04/2020	05/2020	05/2020
Expiry date	03/2023	04/2023	04/2023
Started on	18/04/2020	22/05/2020	22/05/2020
Completed on	29/04/2020	23/05/2020	23/05/2020



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11.0 BILL OF MATERIALS

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

12.0 RAW MATERIALS MANUFACTURER - API

1. Amlodipine Besylate:

Manufacturer Name: Codila Pharmaceuticals

A.R. No	Batch No	Mfg. date	Exp. date	Qty.
RHG/00011	20A DL 001	12/2019	11/2024	50.000kg
RHG/00001	20ADL 009	08/2020	07/2025	100.00kg
				✓

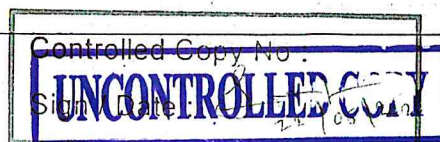
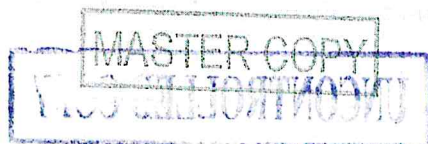
1. Perindopril Erbumine:

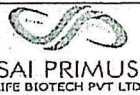
Manufacturer Name: Aarti Industries Limited

A.R. No	Batch No	Mfg. date	Exp. date	Qty.
RHG/00012	PE/1911/11/05/880	11/2019	10/2024	8.000kg
RHG/00007	PE/2002/02/059	02/2020	01/2025	32.000kg

13.0 RAW MATERIAL ANALYTICAL REPORT NUMBERS USED FOR BATCHES

All raw material analytical report numbers refer BMR.





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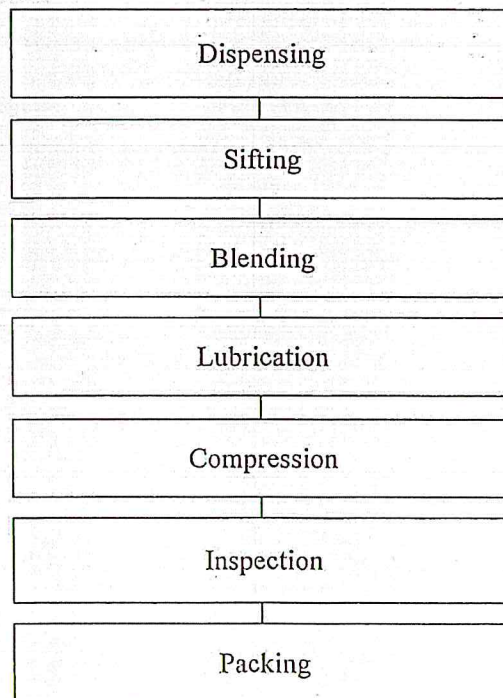
Protocol No. PVP-A08

Ref. SOP No. QA/GR/017

14.0 PROCESS EQUIPMENT DESCRIPTION

S. No.	Equipment name	Equipment ID No	Calibration/qualification status
			Next calibration due
1.	Dispensing Booth	ST / DPB / 001	Qualified
2.	Vibratory sifter	PDV / VBC / 001	Qualified
3.	Octagonal blender	PO / OCB / 001	Qualified
4.	Compression machine	PO / COM / 002	Qualified
5.	Packing machine (Alu Alu Packing)	PO / ALU / 001	Qualified
6.	Weighing balance (IPQA)	QA / BAL / 002	Calibrated
7.	Vernier caliper	QA / VEC / 001	Calibrated
8.	Friability apparatus	QA / FRF / 001	Calibrated
9.	Hardness tester	QA / HRT / 001	Calibrated
10.	Disintegration tester	QA / DTA / 002	Calibrated
11.	Dissolution test apparatus	QA / DTS / 001	Calibrated
12.	Sieve Shaker	QC / SSH / 001	Calibrated
13.	HPLC	QC / HPL / 001	Calibrated
14.	UV	QC / UV / 001	Calibrated
15.	Bulk Density/Tap Density	-	Calibrated

15.0 PROCESS FLOWCHART



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16.0 CRITICAL PROCESS PARAMETERS AND CRITICAL PROCESS ATTRIBUTES

S. No	Process stage	CPP	CQA	CPC	Rational for selection	Process verification
1.	Dispensing	Weighing balance	Weight variation	Manual	Critical process leads to affect product quality	Monthly calibration status and daily verification status will be verified before the use.
2.	Vibratory sifter	Sieve size	Size reduction	Manual	Size of the partial may leads to product quality	Sieve size selection done based on BMR. Sieve integrity shall be verified before and after use.
3.	Blending	RPM & Time	Assay and blend uniformity.	Manual	RPM and mixing time will affect the affect product quality.	- Set RPM & time intervals samples shall be collected. - Sampling locations shall be identified based on the occupancy of blender. - Blending/ lubrication time shall be concluded after execution of batches.
4.	Compression	Turret RPM Compression pressure Hopper level	Physical, chemical properties of tablets.	Manual	Turret speed, pressure, granule level in hopper will affect product quality.	- Sample shall be collect at thickness, various speed, hopper near empty level. - Turret RPM & pressure shall be verified.
5.	Packing	Machine speed	Description of tablets, leak test.	Manual	- Forming and sealing quality - Speed of the machine	Check the forming temperature, sealing temperature and machine speed, Leak test.

17.0 STAGE WISE SAMPLING LOCATION AND SAMPLE QUANTITY

Stage	Sample Location	Sample size	Test
At Lubrication (withdraw sample at 3, 4 and 5Mins)	10 Location Sample	Unit dose 1x to 3x, where x = 140 mg (140 mg to 420 mg).	Blend uniformity
Lubricated Blend	Composite sample	75 gm	Complete analysis as per in-process lubricated granules specification

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Compression	Hardness Challenge	LHS	100 tablets	Description, average weight, Uniformity of weight, thickness, hardness, friability, disintegration time and Dissolution.
		RHS		
Compression	Speed challenge (RPM)	LHS	100 tablets	Description, average weight, Uniformity of weight, thickness, hardness, friability, disintegration time and Assay
		RHS		
Compression	Hopper level challenge	LHS	100 tablets	Description, average weight, Uniformity of weight, thickness, hardness, friability, disintegration time and Content Uniformity.
		RHS		
Compression	Composite sample	100 tablets		Complete analysis as per in-process compressed tablets specification
		25 g		Microbial tests as per finished product specification
Packing (withdraw sample at High Temp & Low RPM)	temperature challenge	10 Alu blisters or entire sealing Plate Strips.		Appearance and Leak test
	Speed challenge.			

18.0 ACCEPTANCE CRITERIA FOR ALL STAGES

18.1 In process specification for Lubricated blend

S. No.	Test	Specification
1.	Appearance	white colour granular powder
2.	Blend uniformity (Amlodipine Besylate and Perindopril Erbumine)	NLT 90% and NMT 110.0%
3.	%RSD	NMT 5 %
4.	Bulk density	For information only
5.	Tap density	For information only
6.	Particle size	For information only
7.	Assay (Amlodipine Besylate and Perindopril Erbumine)	NLT 90% and NMT 110.0%

18.2 In process product specification (Compressed Tablets Specification)

S. No.	Test	Specification
1.	Appearance	White to off white coloured, circular shaped, biconvex, uncoated tablet with breakline on one side and plain on other side
2.	Average weight(mg)	140.000 mg $\pm$ 3.0 % (135.800 mg – 144.200 mg)
3.	Group Weight	2.800 g $\pm$ 3.0 % (2.716 gm to 2.884 gm)
4.	Uniformity of weight Tablets	140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)



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5.	Hardness (N)	NLT 4.0 Kg (To be established)
6.	Thickness (mm)	3.30 mm $\pm$ 0.2 (3.10 mm – 3.50 mm) (To be established)
7.	Friability	NMT 1% w/w
8.	Disintegration Time	NMT 15 Minutes

18.3 Finished Product Specification

S. No.	Test	Specification
1.	Description	white coloured, circular shaped, biconvex, uncoated tablet with Breakline on one side and plain on other side
2.	Identification • Amlodipine Besylate BP	The retention time of Amlodipine peaks in the chromatogram of sample preparation should correspond to that in chromatogram of the standard preparation as obtained in the assay.
	• Perindopril Erbumine BP	The retention time of Perindopril Erbumine peaks in the chromatogram of sample preparation should correspond to that in chromatogram of the standard preparation as obtained in the assay.
3.	Average Weight of Tablets	2.800 g $\pm$ 3.0 % (2.716 gm to 2.884 gm)
4.	Uniformity of weight Tablets	Not More Than 2 of the Individual weights deviate from the average by more than $\pm$ 7.5% and more deviate by more than $\pm$ 15.0%
5.	Diameter	6.80 mm $\pm$ 0.2mm
6.	Hardness	NLT 4.0 Kg
7.	Thickness (mm)	3.00 mm $\pm$ 0.2 (2.80 mm – 3.20 mm) (To be established)
8.	Friability	NMT 1 % w/w (Action Limit: NMT 0.5%)
9.	Disintegration Time	NMT 15 Minutes
10.	Assay Each Uncoated Tablet Contains: Amlodipine Besylate BP to Amlodipine 5mg	NLT 90.0% NMT 110.0%
	Perindopril Erbumine BP 5mg	NLT 90.0% NMT 110.0%
11.	Content Uniformity Amlodipine Besylate BP eq. to Amlodipine ...5mg	NLT 85.0% and NMT 115.0%
	Perindopril Erbumine BP 5mg	NLT 85.0% and NMT 115.0%
12.	Dissolution: Amlodipine Besylate BP eq. to Amlodipine ...5mg	NLT 80.0%
	Perindopril Erbumine BP 5mg	NLT 80.0%
13.	Related Substance Amlodipine Impurity A	NMT 1.00%
	Perindopril Impurity B	NMT 1.50%
	Perindopril Impurity C	NMT 0.60%
	Perindopril Impurity E	NMT 0.40%
	Perindopril Impurity F	NMT 1.50%

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Batch Size: 600000

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	Single Maximum unknown Impurity	NMT 0.5%
	Total Unknown Impurities	NMT 1.0%
	Total Impurities	NMT 5.0%
14.	Microbiological Limits	
	Total Aerobic Microbial counts	NMT 1000 cfu/g
	Total Yeasts and Mould Counts	NMT 100 cfu/g
	E.coli	Should Be absent
	Salmonella	Should Be absent
	S.Aureus	Should Be absent
	P. aeruginosa	Should Be absent

19.0 PRODUCT ASSESSMENT CRITERIA

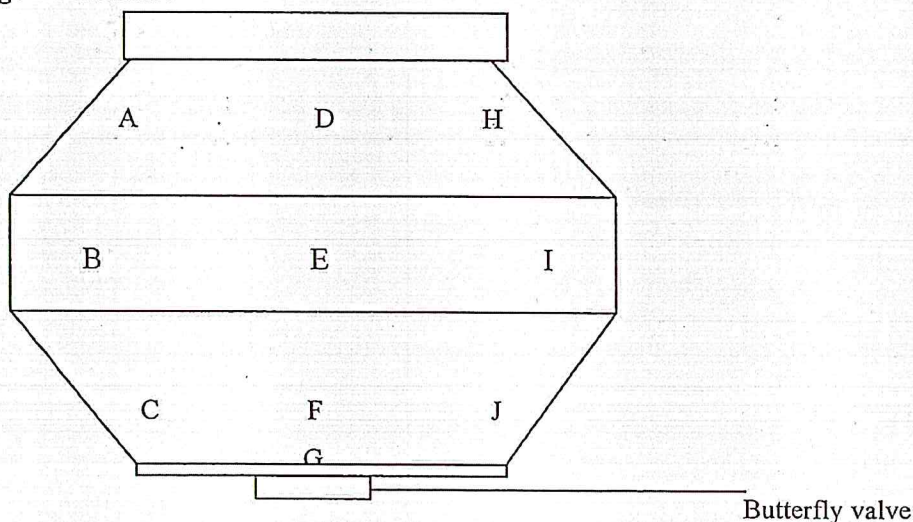
The data will be collected, summarized and a conclusion will be drawn. Any out of specification/Deviation should be investigated. The results should meet limits of acceptance specifications.

20.0 NON COMPLIANCE

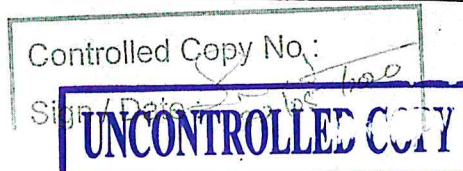
Details of deviation (including justification of acceptance if any) done to successfully carryout the validation exercise and any OOS results obtained should be recorded.

21.0 SAMPLING LOCATIONS DIAGRAMS.

1. Octagonal blender:



SYMBOL	Location	SAMPLING LOCATION DETAILS
A	Left- Top	From the left side corner near wall side of the blender approx. 2 inch below the top surface of the powder bed.
B	Left- Middle	From the left middle corner near wall side of the blender approx. 5 inch below the top surface of the powder bed.



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C	Left- Bottom	From the left side bottom wall side of the blender approx. 2 inch away from the left side of the wall.
D	Center- Top	From the center of the blender approx. 2 inch below the top surface of the powder bed.
E	Center- Middle	From the center of the blender middle surface of the powder bed.
F	Center- Bottom	From the center bottom of the blender bottom layer of the powder bed.
G	Discharge- Port	Approx. center of the discharge port of the blender.
H	Right- Middle	From the right middle corner near side of the blender approx. 2 inch below the top surface of the powder bed.
I	Right- Bottom	From the right-side bottom wall of the blender approx. 2 inch away from the right side of wall.
J	Right-Top	From the right side, corner near wall of the blender approx. 2 inch below the top surface of the powder bed.
Composite Sample		Composite sample from all location.

22.0 REFERENCE DOCUMENTS

To prepare the validation protocol current version of below mentioned documents are referred, which provide Adequate information of manufacturing & packing process.

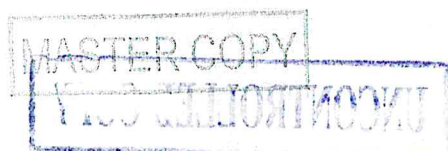
SI No	Documents	Ref. No.
1	Batch Manufacturing Record (BMR)	BMRT/107-01
2	Batch Packing Record (BPR)	BPR/T/107-01
3	Finished Product Specification (FPS)	FPS: A08
4	Process Validation SOP	QAGN/017

23.0 REVISION HISTORY

S. No.	Effective date	Version No.	Reason for changes
01	22/05/2020	00	New document

24.0 ATTACHMENTS

Analytical reports shall be attached in process validation report.



 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD		Page 13 of 13
	Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Revision No: 01
PROCESS VALIDATION PROTOCOL			Batch Size: 600000
Generic name	AMLOPERIN 5MG/5MG	Effective Date	22/05/2020
Protocol No.	PVP-A08	Ref. SOP No.	SAI/017

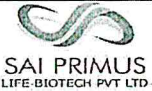
25.0 REPORT

After execution of protocol, report will be prepared and final conclusion and summary report will be drawn.

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 Sign / Date : 22-05-2020

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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 32 Revision No: 00
	PROCESS VALIDATION REPORT	
Generic name	AMLOPERIN 5MG/5MG	
Protocol No.	PVR-A08	

PROCESS VALIDATION REPORT

Generic Name	AMLODIPINE BESYLATE 5 MG AND PERINDOPRIL ERBUMINE 5MG TABLETS
Label claim	Each uncoated tablet contains: Amlodipine Besilate BP Equivalent to Amlodipine.....5 mg Perindopril Erbumine BP5 mg Excipients.....q.s
Dosage Form	Tablets
BMR No	BMR/T/107-01
Batch Size	600000
Shelf Life	36 Months
MFG. LIC. NO.	PON/DRUGS/19 13 4323
Product Code	A08





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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Revision No: 00

PROCESS VALIDATION REPORT

Batch Size: 600000

Generic name AMLOPERIN 5MG/5MG

Protocol No. PVR-A08

1.0 TABLE OF CONTENT

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2.0 OBJECTIVE

To ensure that the critical process variables are checked during validation and to demonstrate the process capability on equipment and utility ensuring that the product meets its predetermined specifications and quality attributes.

The Process validation is being taken for generation of sufficient data and establishing of standard manufacturing process. Three consecutive batches of **AMLOPERIN 5MG/5MG** have been taken up for Process Validation. If any problem is observed during manufacturing, the Process Validation shall be extended to other three consecutive batches.

3.0 SCOPE

The scope of this report is limited to the Process Validation of **AMLOPERIN 5MG/5MG**, which defines the procedural aspects to be followed while carrying out process validation activity that includes prerequisites before commencing the actual work.

This report is applicable for the process validation of **AMLOPERIN 5MG/5MG** to be manufactured at Sai Primus Life Biotech Pvt Ltd. Based on the Validation data and summary report, if required BMR will be revised.

4.0 RESPONSIBILITY

The validation group, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this report:

Functional Area	Responsibility
Production	• Execution of Process Validation Batch. • Review of Process Validation Report.
Quality Assurance	• Co-ordination with Production and QC to carryout process validation batch. • Monitoring and sampling at the different stages. • Checking and approval of Process Validation Report.
Quality Control	• Analysis of validation batch samples. • Preparation of analytical report and submit to Quality Assurance Department. • Review of Process Validation Report.
Maintenance	• To provide necessary utility and environmental condition in process equipment and area



PROCESS VALIDATION REPORT

Batch Size: 600000

Generic name AMLOPERIN 5MG/5MG

Protocol No. PVR-A08

5.0 ABBREVIATIONS

Acronym	Definition	Acronym	Definition
P	Protocol	NMT	Not more than
QA	Quality Assurance	°C	Degree Celsius
QC	Quality Control	%	Percentage
PV	Process validation	mg.	Milligram
BMR	Batch manufacturing record	RPM	Rotation per minute
TABS	Tablets	RSD	Relative standard deviation
IP	Indian pharmacopeia	OOS	Out of Specification
BP	British pharmacopeia	g.	Gram
USP	United states pharmacopeia	Kg.	Kilogram
ICH	International conference on harmonization	lt.	Litre
cGMP	Current Good Manufacturing practices	mm.	Millimeter
IH	In house	ml.	Milliliter
API	Active pharmaceutical ingredient	NLT	Not less then
PD	Production	FG	Finished goods
ID	Identification	RH	Relative humidity
S.	Serial	R-LAF	Reverse laminar Air flow
No.	Number	LOD	Loss on drying
CPP	Critical process parameter	DT	Disintegration time
CQA	Critical quality attributes	Qty.	Quantity
CPC	Critical process control	IPC	In process container
UV	Ultra violet	NA	Not applicable
HPLC	High performance liquid chromatography	MLT	Microbial limit test
Max.	Maximum	HMI	Human Machine Interface
Min.	Minimum		

PROCESS VALIDATION REPORT

Batch Size: 600000

Generic name AMLOPERIN 5MG/5MG

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6.0 PRODUCT DETAILS

Generic Name	AMLOPERIN 5MG/5MG		
Dosage Form	Oral Tablet		
Label Claim	Each uncoated tablet contains: Amlodipine Besilate BP Equivalent to Amlodipine.....5 mg Perindopril Erbumine BP5 mg Excipients.....q.s		
Average weight of coated tablet	140.00mg		
Batch number	GF200501	GF200502	GF200704
Batch size	6.0L	6.0L	6.0L
Manufacturing date	05/2020	05/2020	07/2020
Expiry date	04/2023	04/2023	06/2023
Started on	22/05/2020	22/05/2020	28/07/2020
Completed on	04/06/2020	04/06/2020	31/07/2020

7.0 PROCESS EQUIPMENT DESCRIPTION

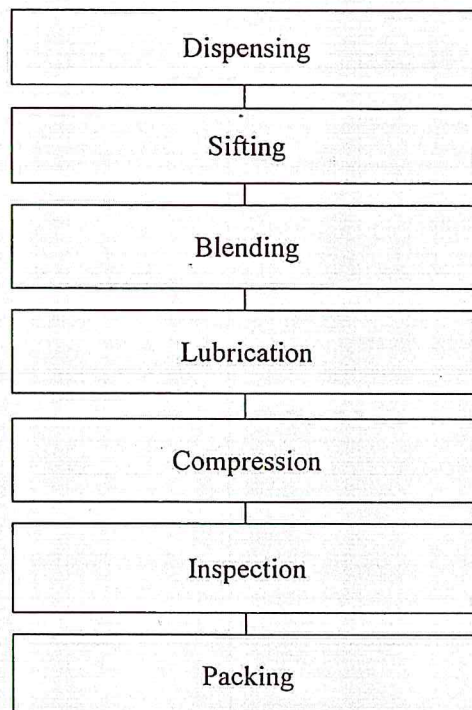
S. No.	Equipment name	Equipment ID No	Calibration/qualification status
			Next calibration due
1.	Dispensing Booth	ST/DPB/001	Qualified
2.	Vibratory sifter	PDVBS/001	Qualified
3.	Octagonal blender	PD/OCB/001	Qualified
4.	Compression machine	PD/COM/002	Qualified
5.	Packing machine (Alu Alu Packing)	PD/ALU/001	Qualified
6.	Weighing balance (IPQA)	QA/BAL/002	Calibrated
7.	Vernier caliper	QAVEC/001	Calibrated
8.	Friability apparatus	QA/FRT/001	Calibrated
9.	Hardness tester	QA/HRD/001	Calibrated
10.	Disintegration tester	QA/DTA/002	Calibrated
11.	Dissolution test apparatus	QC/DIS/001	Calibrated
12.	Sieve Shaker	QC/SSH/001	Qualified
13.	HPLC	QC/HPL/001	Calibrated
14.	UV	QC/UVS/001	Calibrated

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Generic name	AMLOPERIN 5MG/5MG	
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8.0 PROCESS FLOWCHART



9.0 BILL OF MATERIALS :

Sr. No.	Ingredients	Item code	UO M	Std. Qty.	Req. Qty.	Approved vendor	Issued Qty. Net Wt.
Dry Mixing:							
1	Amlodipine Besilate*	RAI/GH/A001	Kg	4.170	4.170	Generic health care	4.170kg
2	Perindopril Erbumine^	RAI/GH/P001	Kg	3.000	3.000	Aarti Industries	3.000
3	Microcrystalline cellulose PH 102***^	REX/GH/M002	Kg	29.694	29.694	Flexa Chem	29.694
4	Microcrystalline cellulose PH 200	REX/SP/M018	Kg	41.867	41.867	Sigachi	41.867
Lubrication:							
5	Colloidal silicon dioxide	REX/GH/C001	Kg	0.290	0.290	Cabot Sanmar	0.290
6	Croscarmellose Sodium	REX/GH/C002	Kg	2.055	2.055	DFE Pharma	2.055
7	Sodium Starch Glycolate	REX/GH/S001	Kg	1.177	1.177	DFE Pharma	1.177
8	Magnesium stearate	REX/GH/M001	Kg	3.529	3.529	S Kant Health Care	3.529



PROCESS VALIDATION REPORT

Batch Size: 600000

Generic name AMLOPERIN 5MG/5MG

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10.0 MANUFACTURING PROCESS DETAILS:

10.1. SIFTING:

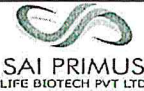
Step No.	Name of Ingredient	Specified in Approved BMR	Observation		
			Batch No.:		
			GF200501	GF200502	GF200704
1.	Sift the Amlodipine Besylate material through 80#.	Mesh size of sieve (80 #)	80#		
		Sieve Integrity Check before use	OK		
		Sieve Integrity Check after use	OK		
2	Sift the Perindopril Erbumine, through 60#	Mesh size of sieve (60 #)	60#		
		Sieve Integrity Check Before use	OK		
		Sieve Integrity Check after use	OK		
3	Sift the Microcrystalline cellulose PH 102, Croscarmellose sodium and Sodium starch Glycolate through 40#	Mesh size of sieve (40 #))	40#		
		Sieve Integrity Check Before use	OK		
		Sieve Integrity Check after use	OK		
4	Sift the Microcrystalline cellulose PH 102 and colloidal silicon dioxide through 30#	Mesh size of sieve (30 #))	30#		
		Sieve Integrity Check after use	OK		
		Sieve Integrity Check after use	OK		
5	Sift the Magnesium Stearate through 60#.	Mesh size of sieve (60 #))	60#		
		Sieve Integrity Check Before use	OK		
		Sieve Integrity Check after use	OK		

10.2 BLENDING & LUBRICATION:

Specified in approved BMR	Setting Time	Observations		
		Batch No.:		
		GF200501	GF200502	GF200704
Blending				
Load the sifted Amlodipine Besylate, Perindopril Erbumine, Microcrystalline cellulose PH 102, Purified Talc, Croscarmellose Sodium and Lake Brilliant Blue in to the blender and blend for 10 minutes at 10 RPM (To be established).	10 Min. at 10 RPM	The sifted Amlodipine Besylate, Perindopril Erbumine, Microcrystalline cellulose PH 102, Purified Talc, Croscarmellose Sodium and Lake Brilliant Blue is loaded in to the blender and blended for 10 minutes at 10 RPM.		

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Lubrication

Load the Sifted Magnesium Stearate into the above Pre-lubricated blend and mix for further 5 minutes at 10 RPM

5 min.
at
10 RPM

The Sifted Magnesium Stearate into the above Pre-lubricated blend and mixed 5 minutes at 10 RPM.

10.3 COMPRESSION: (Machine Setting)

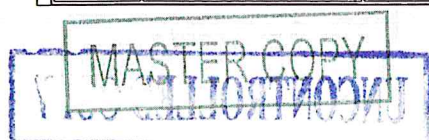
Machine Description		Setting as per Approved BMR	Batch No.:		
			GF200501	GF200502	GF200704
Compression machine type		27 Station Double Rotary	27 Station Double Rotary		
Punch Description	Upper punch	6.80 mm Circular shaped standard concave with break line on punches.	6.80 mm Circular shaped standard concave with break line on punches.		
	Lower punch	6.80 mm Circular shaped standard concave punches.	6.80 mm Circular shaped standard concave punches.		
	Dies	6.80 mm Circular shaped standard concave punches.	6.80 mm Circular shaped standard concave punches.		
Tooling Type		D-Tooling	D-Tooling		

10.3.1 PRE-COMPRESSION:

Note: As per the protocol Pre-compressed tablets analyzed 1st batch only.

10.3.2 COMPRESSION (Speed Challenge Test):

Sr. No.	Parameters	Parameters as per approved BMR	Observation			
			B. No.: GF200501			
			Low speed		High Speed	
			RPM: 10		RPM: 25	
			LHS		RHS	
1	Description	White to off white coloured, circular shaped, biconvex, uncoated tablet with breakline on one side and plain on other side	Ok	OK	OK	OK
2	Weight of 20 Tablets	2.800 g± 3.0 % (2.716 gm to 2.884 gm)	2.809gm	2.803	2.807gm	2.802gm



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3	Average weight (mg)	140.000 mg ± 3.0 % (135.800 mg – 144.200 mg)	140mg		140mg		140mg		140mg	
4	Uniformity of weight Tablets	140.00 mg ± 5.0 % (133.000 mg – 147.000 mg)	139	142	138	141	139mg	141mg	139mg	142mg
5	Hardness (KP)	NLT 4.0 Kg (To be established)	6.0kg		6.0kg		4.0kg		4.0kg	
6	Thickness (mm)	3.00 mm ±0.2 (2.80 mm – 3.20 mm) (To be established)	3.26mm		3.30mm		3.40mm		3.49mm	
7	Friability	NMT 1% w/w	0.01%		0.01%		0.01%		0.01%	
8	Disintegration Time	NMT 15 Minutes	05Min 31Sec		05Min 21Sec		05Min 12Sec		05Min 19Sec	
Sr. No.	Parameters	Parameters as per approved BMR	Observation							
			B. No.: GF200502							
			Low speed				High Speed			
			RPM:10				RPM:25			
			LHS				RHS			
1	Description	White to off white coloured, circular shaped, biconvex, uncoated tablet with breakline on one side and plain on other side	OK		OK		OK		OK	
2	Weight of 20 Tablets	3.000 g± 3.0 % (2.910 gm to 3.090 gm)	2.786gm		2.790gm		2.788gm		2.795gm	
3	Average weight (mg)	140.000 mg ± 3.0 % (133.000 mg – 147.000 mg)	139mg		139.5mg		139mg		139.7mg	
4	Uniformity of weight Tablets	140.00 mg ± 5.0 % (133.000 mg – 147.000 mg)	138	140	138	141	138	140	138	141
5	Hardness (KP)	NLT 4.0 Kg (To be established)	5kg		6kg		5kg		6kg	
6	Thickness (mm)	3.00 mm ±0.2 (2.80 mm – 3.20 mm) (To be established)	3.30mm		3.38mm		3.31mm		3.40mm	
7	Friability	NMT 1% w/w	0.02%		0.01%		0.01%		0.00%	
8	Disintegration Time	NMT 15 Minutes	03Min 49Sec		03Min 57Sec		03Min 47sec		03Min 56Sec	
Sr. No.	Parameters	Parameters as per approved BMR	Observation							
			B. No.: GF200704							
			Low speed				High Speed			
			RPM: 10				RPM: 30			

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Generic name	AMLOPERIN 5MG/5MG			
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			LHS		RHS	
1	Description	White to off white coloured, circular shaped, biconvex, uncoated tablet with breakline on one side and plain on other side	OK	OK	OK	OK
2	Weight of 20 Tablets	2.800 g± 3.0 % (2.716 gm to 2.884 gm)	2.796	2.792	2.783	2.795
3	Average weight (mg)	140.000 mg ± 3.0 % (135.800 mg – 144.200 mg)	139.8mg	139.6mg	139.15	139.75
4	Uniformity of weight Tablets	140.00 mg ± 5.0 % (133.000 mg – 147.000 mg)	137	144	137	142
5	Hardness (KP)	NLT 4.0 Kg (To be established)	4Kg	4.5Kg	4.5Kg	4.5Kg
6	Thickness (mm)	3.00 mm ±0.2 (2.80 mm – 3.20 mm) (To be established)	3.36mm	3.41mm	3.34mm	3.35mm
7	Friability	NMT 1% w/w	0.09%	0.06%	0.10%	0.08%
8	Disintegration Time	NMT 15 Minutes	04Min 26Sec	04Min 28Sec	04Min 27Sec	04Min 32Sec

10.3.3 COMPRESSION (At optimum Speed Low Hardness & High Hardness):

Sr. No.	Parameters	Parameters as per approved BMR	Observation			
			B. No.: GF200501			
			Low Hardness		High Hardness	
			RPM:20		RPM:20	
1	Description	White to off white coloured, circular shaped, biconvex, uncoated tablet with breakline on one side and plain on other side	OK	OK	OK	OK
2	Weight of 20 Tablets	2.800 g± 3.0 % (2.716 gm to 2.884 gm)	2.800gm	2.803gm	2.801gm	2.808gm
3	Average weight (mg)	140.000 mg ± 3.0 % (135.800 mg – 144.200 mg)	140mg	140mg	140mg	141mg
4	Uniformity of weight Tablets	140.00 mg ± 5.0 % (133.000 mg – 147.000 mg)	138	142	138	142
5	Hardness (KP)	NLT 4.0 Kg (To be established)	4.0kg	4.0kg	6.0kg	6.0kg

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6	Thickness (mm)	3.00 mm $\pm$ 0.2 (2.80 mm – 3.20 mm) (To be established)	3.45mm	3.44mm	3.25mm	3.29mm
7	Friability	NMT 1% w/w	0.02%	0.02%	0.00%	0.01%
8	Diameter	6.80 mm $\pm$ 0.2mm	6.80mm	6..83mm	6.80mm	6.82mm
9	Disintegration Time	NMT 15 Minutes	05Min 37Sec	05Min 42sec	05Min 52Sec	6Min 04Sec
Sr. No.	Parameters	Parameters as per approved BMR	Observation			
			B. No.: GF200502			
			Low Hardness		High Hardness	
			RPM: 20		RPM: 20	
1	Description	White to off white coloured, circular shaped, biconvex, uncoated tablet with breakline on one side and plain on other side	OK	OK	OK	OK
2	Weight of 20 Tablets	2.800 g $\pm$ 3.0 % (2.716 gm to 2.884 gm)	2.809gm	2.798gm	2.804gm	2.805gm
3	Average weight (mg)	140.000 mg $\pm$ 3.0 % (133.000 mg – 147.000 mg)	140	140mg	140mg	140mg
4	Uniformity of weight Tablets	150.00 mg $\pm$ 5.0 % (142.500 mg – 157.500 mg)	138	143	138	141
5	Hardness (KP)	NLT 4.0 Kg (To be established)	4kg	5kg	5kg	6kg
6	Thickness (mm)	3.00 mm $\pm$ 0.2 (2.80 mm – 3.20 mm) (To be established)	3.38mm	3.40mm	3.32mm	3.40mm
7	Friability	NMT 1% w/w	0.23%	0.21%	0.02%	0.01%
8	Disintegration Time	NMT 15 Minutes	03Min 46Sec	03Min 52Sec	03Min 55sec	04Min 07Sec
Sr. No.	Parameters	Parameters as per approved BMR	Observation			
			B. No.: GF200704			
			Low Hardness		High Hardness	
			RPM: 20		RPM: 20	
1	Description	White to off white coloured, circular shaped, biconvex, uncoated tablet with breakline on one side and plain on other side	Ok	Ok	Ok	Ok
2	Weight of 20 Tablets	2.800 g $\pm$ 3.0 % (2.716 gm to 2.884 gm)	2.791	2.803	2.811	2.798
3	Average weight (mg)	140.000 mg $\pm$ 3.0 % (133.000 mg – 147.000 mg)	139.55	140.15	140.55	139.9
4	Uniformity of weight Tablets	140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)	136	136	136	136
			144	142	144	144

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5	Hardness (KP)	NLT 4.0 Kg (To be established)	4.0kg	4.5kg	4.5Kg	4.5Kg
6	Thickness (mm)	3.00 mm $\pm$ 0.2 (2.80 mm – 3.20 mm) (To be established)	3.32mm	3.36mm	3.39mm	3.41mm
7	Friability	NMT 1% w/w	0.04%	0.06%	0.10%	0.12%
8	Disintegration Time	NMT 15 Minutes	04Min 25Sec	04Min 25Sec	04Min 12Sec	04Min 25Sec

10.3.4 COMPRESSION (At Optimum Speed Hopper Challenge Test):

Sr. No.	Parameters	Parameters as per approved BMR	Observation					
			B. No.: GF200501					
			RPM: 24					
			Full Hopper		Middle Hopper		Low Hopper	
1	Description	White to off white coloured, circular shaped, biconvex, uncoated tablet with breakline on one side and plain on other side	OK		OK		OK	
2	Weight of 20 Tablets	2.800 g $\pm$ 3.0 % (2.716 gm to 2.884 gm)	2.805g m	2.799g m	2.809g m	2.810g m	2.797g m	2.805g m
3	Average weight (mg)	140.000 mg $\pm$ 3.0 % (135.800 mg – 144.200 mg)	140mg		141mg		140mg	
			140mg		140.5mg		141mg	
4	Uniformity of weight Tablets	140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)	139	141	139	141	138	141
			138	141	139	142	139	141
5	Hardness (KP)	NLT 4.0 Kg (To be established)	5kg		5kg		5kg	
			6kg		6kg		6kg	
6	Thickness (mm)	3.40 mm $\pm$ 0.2 mm (3.20 mm – 3.60 mm)	3.29mm		3.28mm		3.34mm	
			3.41mm		3.39mm		3.37mm	
7	Friability	NMT 1% w/w	0.01%		0.01%		0.01%	
			0.01%		0.01%		0.01%	
8	Diameter (mm)	6.80 mm $\pm$ 0.2mm	6.80mm		6.800		6.80mm	
			6.83mm		6.83mm		6.82mm	
9	Disintegration Test	NMT 15 Minutes	05Min 20Sec		05Min 31Sec		05Min 17Sec	
			05Min 29Sec		05Min 27Sec		05Min 27Sec	

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PROCESS VALIDATION REPORT

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Generic name AMLOPERIN 5MG/5MG

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Sr. No.	Parameters	Parameters as per approved BMR	Observation					
			B. No.: GF200502					
			RPM: 25					
			Full Hopper		Middle Hopper		Low Hopper	
1	Description	White to off white coloured, circular shaped, biconvex, uncoated tablet with breakline on one side and plain on other side	OK		OK		Ok	
2	Weight of 20 Tablets	2.800 g $\pm$ 3.0 % (2.716 gm to 2.884 gm)	2.801	2.793	2.799	2.806	2.801	2.803
3	Average weight (mg)	140.000 mg $\pm$ 3.0 % (133.000 mg – 147.000 mg)	140mg		140mg		140mg	
			139.6mg		140mg		140mg	
4	Uniformity of weight Tablets	140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)	139	139	139	139	139	139
			141	141	142	142	141	141
5	Hardness (KP)	NLT 4.0 Kg (To be established)	5Kg		5kg		5Kg	
			6Kg		6kg		6kg	
6	Thickness (mm)	3.40 mm $\pm$ 0.2 mm (3.20 mm – 3.60 mm)	3.39mm		3.38mm		3.32mm	
			3.41mm		3.42mm		3.40mm	
7	Friability	NMT 1% w/w	0.00%		0.07%		0.02%	
			0.01%		0.05%		0.01%	
8	Diameter (mm)	6.80 mm $\pm$ 0.2mm	6.80mm		6.80mm		6.80mm	
			6.83mm		6.82mm		6.82mm	
9	Disintegration Test	NMT 15 Minutes	03Min 37Sec		03Min 32Sec		03Min 49sec	
			03Min 48Sec		03Min 42Sec		03Min 42Sec	

Sr. No.	Parameters	Parameters as per approved BMR	Observation		
			B. No.: GF200704		
			RPM: 24		
			Full Hopper	Middle Hopper	Low Hopper
1	Description	White to off white coloured, circular shaped, biconvex, uncoated tablet with breakline on one side and plain on other side	OK	OK	OK
2	Weight of 20 Tablets	2.800 g $\pm$ 3.0 % (2.716 gm to 2.884 gm)	2.796	2.783	2.805
			2.807	2.807	2.802

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	Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.	Revision No: 00
PROCESS VALIDATION REPORT		Batch Size: 600000
Generic name	AMLOPERIN 5MG/5MG	
Protocol No.	PVR-A08	

3	Average weight (mg)	140.00 mg ± 5.0 % (133.00 mg – 147.00 mg)	139.8		139.15		140.25	
			140.35		140.35		1401	
4	Uniformity of weight Tablets	140.00 mg ± 5.0 % (133.00 mg – 147.00 mg)	137	137	136	136	136	137
			144	144	142	144	144	144
5	Hardness (KP)	NLT 4.0 Kg (To be established)	4Kg		4.5kg		4kg	
			5Kg		5kg		4.5kg	
6	Thickness (mm)	3.40 mm ± 0.2 mm (3.20 mm – 3.60 mm)	3.31mm		3.29mm		3.36mm	
			3.37mm		3.34mm		3.39mm	
7	Friability	NMT 1% w/w	0.07%		0.07%		0.10%	
			0.09%		0.09%		0.09%	
8	Diameter (mm)	6.80 mm ± 0.2mm	6.80mm		6.80mm		6.80mm	
			6.83mm		6.83mm		6.82mm	
9	Disintegration Test	NMT 15 Minutes	4Min 03sec		04Min 20Sec		04Min 19Sec	
			4min 07sec		04Min 17Sec		4Min 20Sec	

10.4 INSPECTION

Parameter	Specified	Observation		
		Batch No.:		
		GF200501	GF200502	GF200704
Equipment Name	Inspection Machine	Inspection Machine		
Equipment ID No.	PD/INB/001	PD/INB/001		
No. of Rejected Tablets	To be recorded	566Nos	1146Nos	645Nos



PROCESS VALIDATION REPORT

Batch Size: 600000

Generic name AMLOPERIN 5MG/5MG

Protocol No. PVR-A08

10.5 PACKING PROCESS:

10.5.1 BILL OF PACKING MATERIALS:

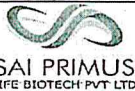
Material Name	Item code	UOM	Req. Qty. for 6.0 Lac	Issued Qty.	Approved vendor
188 mm Amloperin 5 mg /5 mg Printed Foil	PPF/GH/A001	Kg	30.600	30.600	Atharv Foil Industries
188 mm Alu/Alu Base Foil	PBF/GH/A001	Kg	91.800	91.800	Atharv Foil Industries
Ptd Carton Amloperin 5 mg / 5 mg	PPC/GH/A001	No	20400	20400	Generic health care
Amloperin packing inserts	PPI/GH/I001	No	20400	20400	Dayal & Associates Pvt Ltd
Shrink Sleeves (PVC)	PPS/GH/P001	No	1275	1275	Metro Packaging
5 Ply 390x390x260 mm C/Boxes	PUS/GH/C001	No	90	90	Anand Packaging
GHPL Ptd Bopp Tapes	PPB/GH/B001	No	18	18	NKB Enterprises
Strapping Role	NA	Mtrs	250	250	Generic health care
Shipper Label	NA	No	91	91	NA

10.5.2 PACKING VALIDATION:

Parameters	Specified	Observation			
		Batch No.:			
		GF200501	GF200502	GF200704	
		Low speed/ Low temp.	Low speed/ High temp.	High speed/ High temp.	High speed/ Low temp.
Machine Speed	To be established	10	10	35	35
Forming / Sealing Temperature	To be established	170°C	220°C	220°C	170°C
Pack Quality	Should be proper	It is Proper	It is Proper	It is Proper	It is Proper
Leak Test	Should be absent	Absent	Absent	Absent	Absent
Printing Details	Should be legible and clear	Legible and Clear	Legible and Clear	Legible and Clear	Legible and Clear
Proper Sealing	Should be proper	It is Proper	It is Proper	It is Proper	It is Proper
Horizontal cutting	Should be OK	Ok	Ok	Ok	Ok

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	Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.	Revision No: 00
PROCESS VALIDATION REPORT		Batch Size: 600000
Generic name	AMLOPERIN 5MG/5MG	
Protocol No.	PVR-A08	

Vertical cutting	Should be OK	Ok	Ok	Ok	Ok
Comments/ Remarks	Complies/does not comply with respected to standards of specification	Complies	Complies	Complies	Complies

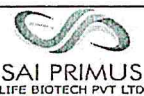
11.0 ANALYTICAL RESULTS:

11.1.1 Analytical Result of Lubricated Blend (For 03Min)

Test	Limit	Observation					
UNIFORMITY OF BLEND	90.0% to 110.0% of the label claim. RSD NMT 5.0%	Sample No.	Batch No.:				
			GF200501	GF200502	GF200704		
			Amlodipine Besylate BP			Perindopril Erbumine	
		1	101.88%	101.21%	102.64%	99.75%	100.95% 97.90%
		2	98.39%	97.22%	101.51%	99.51%	98.01% 99.53%
		3	92.23%	98.47%	97.62%	98.41%	99.72% 98.12%
		4	101.87%	102.34%	98.44%	100.40%	100.91% 97.80%
		5	94.07%	101.22%	93.81%	97.72%	98.24% 97.45%
		6	102.96%	96.74%	99.30%	97.39%	99.90% 99.22%
		7	99.77%	100.89%	97.62%	96.54%	97.62% 96.48%
		8	102.55%	103.72%	98.74%	94.62%	97.49% 99.92%
		9	92.93%	98.38%	100.23%	96.22%	96.82% 101.03%
		10	93.84%	100.41%	102.01%	101.29%	99.96% 101.21%
		Min.	92.23%	96.74%	93.81%	94.62%	96.82% 96.48%
		Max.	102.96%	103.72%	102.64%	101.29%	100.95% 101.21%
		Mean	98.05%	100.06%	99.19%	98.19%	98.96% 98.87%
		% RSD	4.43	2.27	2.62	2.11	1.51 1.58
Comments/	Complies/does not comply with respected	Complies					

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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 17 of 32 Revision No: 00
	PROCESS VALIDATION REPORT	
Generic name	AMLOPERIN 5MG/5MG	
Protocol No.	PVR-A08	

11.1.2 Analytical Result of Lubricated Blend (For 04Min)

Test	Limit	Observation					
UNIFORMITY OF BLEND	90.0% to 110.0% of the label claim. RSD NMT 5.0%	Sample No.	Batch No.:				
			GF200501	GF200502	GF200704		
			Amlodipine Besylate BP			Perindopril Erbumine	
		1	98.43%	96.95%	101.38%	97.84%	99.36%
		2	97.18%	98.67%	101.15%	97.70%	97.92%
		3	94.71%	94.22%	98.89%	97.69%	98.54%
		4	99.37%	98.60%	101.23%	98.13%	101.81%
		5	98.20%	97.90%	97.87%	97.14%	101.65%
		6	104.47%	103.10%	100.71%	101.11%	100.54%
		7	95.52%	100.96%	98.02%	98.18%	97.75%
		8	98.86%	94.09%	98.15%	94.79%	97.20%
		9	94.69%	102.97%	100.81%	99.79%	102.09%
		10	98.57%	95.20%	97.05%	96.34%	102.46%
		Min.	94.69%	94.09%	97.05%	94.79%	97.20%
		Max.	104.47%	103.10%	101.45%	101.11%	102.46%
		Mean	98.00%	98.27%	99.53%	97.87%	99.89%
		% RSD	2.91	3.35	1.69	1.76	2.07
Comments/	Complies/does not comply with respected	Complies					

11.1.3 Analytical Result of Lubricated Blend (For 05Min)

Test	Limit	Observation					
UNIFORMITY OF BLEND	90.0% to 110.0% of the label claim. RSD NMT 5.0%	Sample No.	Batch No.:				
			GF200501	GF200502	GF200704		
			Amlodipine Besylate BP			Perindopril Erbumine	
		1	93.86%	102.05%	97.40%	96.80%	100.34%
		2	92.69%	93.88%	98.25%	98.62%	101.65%
		3	91.79%	94.10%	104.12%	100.22%	97.45%

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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 32
		Revision No: 00
PROCESS VALIDATION REPORT		Batch Size: 600000
Generic name	AMLOPERIN 5MG/5MG	
Protocol No.	PVR-A08	

		4	102.43%	95.09%	98.56%	100.67%	98.94%	101.35%
		5	102.18%	105.38%	98.35%	103.09%	100.52%	100.95%
		6	101.53%	101.56%	97.78%	99.58%	101.52%	97.21%
		7	98.73%	97.95%	98.41%	103.76%	100.69%	99.55%
		8	96.24%	99.78%	98.53%	98.37%	99.33%	99.44%
		9	102.02%	102.53%	98.31%	96.98%	98.35%	97.03%
		10	91.56%	92.99%	100.39%	96.65%	98.99%	98.38%
		Min.	91.56%	92.99%	97.40%	96.65%	97.45%	97.03%
		Max.	102.43%	105.38%	104.12%	103.76%	101.69%	101.35%
		Mean	97.30%	98.53%	99.01%	99.47%	99.78%	99.04%
		% RSD	4.72	4.41	1.97	2.52	1.38	1.58
Comments/	Complies/does not comply with respected	Complies						

Sr. No.	Parameters		Acceptance Criteria	Observation	
				Batch No. GF200501	
1	Description		White colour granules.	White colour granules.	
2	LOD		Informative	3.11%	
3	Bulk Density (gm/ml)		Informative	0.3942gm/l	
4	Tapped Density (gm/ml)		Informative	0.4711gm/l	
5	Assay (%)	Amlodipine Besylate BP	90.0% to 110.0 %	100.26%	
		Perindopril Erbumine		99.72%	
6	Sieve Analysis	60#	Informative	94.26%	5.74%
		80#		84.12%	15.88%
		100#		81.04%	18.96%
		120#		61.44%	38..56%
Comments / Remarks		Complies/does not comply with respected to standards of specification		complies	
Sr. No.	Parameters		Acceptance Criteria	Observation	
				Batch No. GF200502	
1	Description		White colour granules.	White colour granules.	

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		Revision No: 00
PROCESS VALIDATION REPORT		Batch Size: 600000
Generic name	AMLOPERIN 5MG/5MG	
Protocol No.	PVR-A08	

2	LOD		Informative	3.26%	
3	Bulk Density (gm/ml)		Informative	0.3716gm/l	
4	Tapped Density (gm/ml)		Informative	0.4926gm/l	
5	Assay (%)	Amlodipine Besylate BP	90.0% to 110.0 %	99.53%	
		Perindopril Erbumine		99.56%	
6	Sieve Analysis	60#	Informative	95.92%	4.08%
		80#		85.26%	14.74%
		100#		81.45%	18.55%
		120#		60.23%	39.77%

Comments / Remarks	Complies/does not comply with respected to standards of specification	Complies
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Sr. No.	Parameters		Acceptance Criteria	Observation	
				Batch No. GF200704	
1	Description		White colour granules.	White colour granules.	
2	LOD		Informative	3.19%	
3	Bulk Density (gm/ml)		Informative	0.37369g/l	
4	Tapped Density (gm/ml)		Informative	0.5026g/l	
5	Assay (%)	Amlodipine Besylate BP	90.0% to 110.0 %	98.74%	
		Perindopril Erbumine		99.70%	
6	Sieve Analysis	60#	Informative	94.23%	5.77%
		80#		86.26%	13.74%
		100#		80.73%	19.27%
		120#		60.66%	39.34%

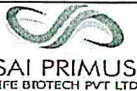
Comments / Remarks	Complies/does not comply with respected to standards of specification	Complies
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11.1.4 Analytical Result of Compression at Different Speed:

Test	Limit	Observation	
		Batch No.: GF200501	
		Low Speed	High Speed
		RPM:10	RPM: 30

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	Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.	Revision No: 00
PROCESS VALIDATION REPORT		Batch Size: 600000
Generic name	AMLOPERIN 5MG/5MG	
Protocol No.	PVR-A08	

Assay	Amlodipine Besylate BP	90.0% to 110.0 %	99.70%	100.14%
	Perindopril Erbumine		99.76%	99.37%
Comments/ Remarks	Complies/does not comply with respected to standards of specification		Complies	Complies
Test		Limit	Observation	
			Batch No.: GF200502	
			Low Speed	High Speed
			RPM:	RPM:
Assay	Amlodipine Besylate BP	90.0% to 110.0 %	99.92%	99.64%
	Perindopril Erbumine		99.93%	99.64%
Comments/ Remarks	Complies/does not comply with respected to standards of specification		Complies	Complies
Test		Limit	Observation	
			Batch No.: GF200704	
			Low Speed	High Speed
			RPM:	RPM:
Assay	Amlodipine Besylate BP	90.0% to 110.0 %	99.67%	99.54%
	Perindopril Erbumine		99.62%	99.39%
Comments/ Remarks	Complies/does not comply with respected to standards of specification		Complies	Complies

11.1.5 Analytical Result of Compression at Different Compression Pressure:

Test		Limit	Observation					
			Batch No.: GF200501					
			Low Hardness			High Hardness		
			RPM:24			RPM: 24		
Dissolution	Amlodipine Besylate BP	NLT 75.0 %	93.46%	99.63%	96.29%	93.19%	100.26%	97.79%
	Perindopril Erbumine		93.77%	98.23%	96.47%	93.63%	97.50%	95.94%
Comments/ Remarks	Complies/does not comply with respected to standards of specification		Complies			Complies		
Test			Limit	Observation				
				Batch No.: GF200502				
				Low Hardness		High Hardness		

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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 32 Revision No: 00
	PROCESS VALIDATION REPORT	
Generic name	AMLOPERIN 5MG/5MG	
Protocol No.	PVR-A08	

			RPM: 24			RPM: 24		
Dissolution	Amlodipine Besylate BP	NLT 75.0 %	91.63 %	100.9 3%	95.72 %	93.46 %	100.0 2%	97.07 %
	Perindopril Erbumine		91.84 %	96.96 %	94.15 %	94.00 %	96.99 %	95.13 %
Comments/ Remarks	Complies/does not comply with respected to standards of specification		Complies					
Test		Limit	Observation					
			Batch No.: GF200704					
			Low Hardness			High Hardness		
			RPM: 24			RPM: 24		
Dissolution	Amlodipine Besylate BP	NLT 75.0 %	98.34 %	103.0 9%	100.3 7%	97.21 %	101.9 0%	99.65 %
	Perindopril Erbumine		96.03 %	99.84 %	98.06 %	96.93 %	100.1 1%	98.23 %
Comments/ Remarks	Complies/does not comply with respected to standards of specification		Complies					

11.1.6 Analytical Result of Compression at Optimum Speed(Hopper Challenge):

Test	Limit	Observation						
UNIFORMITY OF CONTENT	85.0% to 115.0% of the label claim.	Sample No.	Batch No.: GF200501					
			Full Hopper		Middle Hopper		Low Hopper	
		1	94.07%	100.44%	103.19%	102.09%	97.76%	100.39%
		2	90.84%	98.74%	99.13%	96.63%	103.50%	98.81%
		3	99.04%	97.55%	91.61%	96.39%	91.81%	102.45%
		4	93.60%	98.38%	95.10%	102.08%	103.43%	96.26%
		5	99.60%	97.56%	102.08%	97.53%	91.79%	102.27%
		6	102.08%	102.03%	93.03%	103.01%	98.94%	100.11%
		7	99.42%	102.23	102.71%	101.69%	100.61%	98.47%
		8	102.71%	100.03%	103.27%	98.07%	99.18%	95.82%
		9	102.27%	97.33%	93.91%	98.95%	95.36%	97.66%
		10	98.25%	96.29%	105.52%	102.09%	97.55%	98.11%
		Min.	90.84%	96.29%	91.61%	96.39%	91.79%	95.82%
		Max.	102.71%	102.23%	105.52%	103.01%	103.50%	102.45%
		Mean	98.19%	99.06%	98.96%	99.85%	97.99%	99.04%
% RSD	4.13	2.05	4.14	2.58	4.20	2.28		
Comments/ Remarks	Complies / does not comply with respected to standards of specification			Complies				

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	PROCESS VALIDATION REPORT	
Generic name	AMLOPERIN 5MG/5MG	
Protocol No.	PVR-A08	

Test	Limit	Observation						
UNIFORMITY OF CONTENT	85.0% to 115.0% of the label claim.	Sample No.	Batch No.: GF200502					
			Full Hopper		Middle Hopper		Low Hopper	
			Composite		Composite		Composite	
		1	100.82%	98.24%	96.03%	98.51%	98.78%	102.26%
		2	93.75%	101.88%	95.66%	96.39%	102.67%	100.88%
		3	98.09%	101.75%	93.11%	97.23%	97.95%	98.83%
		4	94.39%	98.12%	98.87%	102.02%	101.31%	98.19%
		5	94.88%	102.08%	98.82%	99.33%	98.55%	102.00%
		6	102.79%	98.42%	93.19%	100.99%	98.94%	98.49%
		7	100.83%	100.79%	103.72%	97.26%	99.01%	98.47%
		8	94.06%	98.03%	98.55%	97.87%	103.90%	97.93%
		9	95.18%	97.33%	93.91%	99.86%	100.86%	97.54%
		10	101.63%	100.79%	99.15%	100.36%	98.72%	98.18%
		Min.	93.75%	97.33%	93.11%	96.39%	97.95%	97.54%
		Max.	102.79%	102.08%	103.72%	102.02%	103.90%	102.26%
Mean	97.64%	99.74%	97.10%	99.27%	100.07%	99.28%		
% RSD	3.66	1.88	3.44	1.70	2.00	1.76		

Comments/Remarks	Complies / does not comply with respected to standards of specification	Complies
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Test	Limit	Observation						
UNIFORMITY OF CONTENT	85.0% to 115.0% of the label claim.	Sample No.	Batch No.: GF200704					
			Full Hopper		Middle Hopper		Low Hopper	
			Composite		Composite		Composite	
		1	101.44%	100.19%	99.45%	99.32%	97.89%	100.14%
		2	100.52%	99.95%	99.32%	96.64%	98.96%	99.84%
		3	98.41%	97.53%	100.51%	96.40%	103.18%	96.81%
		4	99.30%	99.78%	96.76%	98.42%	99.71%	97.70%
		5	95.71%	99.33%	98.30%	97.51%	99.87%	100.03%
		6	98.30%	98.36%	97.56%	98.25%	98.30%	101.12%
		7	103.73%	98.21%	99.78%	100.53%	98.41%	99.51%
		8	98.96%	96.40%	99.54%	101.62%	104.96%	95.83%
		9	97.67%	100.0%	101.27%	99.62%	98.51%	99.43%
		10	98.41%	100.05%	101.89%	98.42%	100.39%	101.66%

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		Revision No: 00
PROCESS VALIDATION REPORT		Batch Size: 600000
Generic name	AMLOPERIN 5MG/5MG	
Protocol No.	PVR-A08	

		Min.	95.71%	96.40%	96.79%	96.40%	97.89%	95.83%
		Max.	103.73%	100.19%	101.89%	101.62%	104.96%	101.66%
		Mean	99.25%	98.98%	99.44%	98.67%	100.02%	99.21%
		% RSD	2.22	1.30	1.59	1.66	2.31	1.87
Comments/Remarks	Complies / does not comply with respected to standards of specification					Complies		

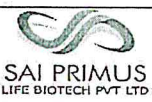
11.1.7 Analytical Result of Composite Tablets:

Parameters	Specified	Observation
		Batch No.: GF200501
		Composite Sample
Description	White to off white coloured, circular shaped, biconvex, uncoated tablet with breakline on one side and plain on other	White to off white coloured, circular shaped, biconvex, uncoated tablet with breakline on one side and plain
Weight of 20 tablets	2.800 g $\pm$ 3.0 % (2.716 gm to 2.884 gm)	2.788gm
Average weight(mg)	140.000 mg $\pm$ 3.0 % (133.000 mg – 147.000 mg)	139.4mg
Uniformity of weight	140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)	Min: -1.52% and Max: 2.05%
Thickness	3.40 mm $\pm$ 0.2 mm (3.20 mm – 3.60 mm)	Min: 3.35mm to Max: 3.45mm
Hardness (N)	NLT 4.0 Kg (To be established)	4.0kg
Friability	NMT 1% w/w	0.26%
Disintegration Time	NMT 15 Minutes	02Min 16Sec
Average Diameter	6.80 mm $\pm$ 0.2mm	6.80mm

Parameters	Specified	Observation
		Batch No.: GF200502
		Composite Sample
Description	White to off white coloured, circular shaped, biconvex, uncoated tablet with breakline on one side and plain on other side	White to off white coloured, circular shaped, biconvex, uncoated tablet with breakline on one side and plain on other side
Weight of 20 tablets	2.800 g $\pm$ 3.0 % (2.716 gm to 2.884 gm)	2.812gm
Average weight(mg)	140.000 mg $\pm$ 3.0 % (133.000 mg – 147.000 mg)	140.6mg

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Generic name	AMLOPERIN 5MG/5MG	
Protocol No.	PVR-A08	

Uniformity of weight	140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)	Min: -2.03mm; Max: 1.55mm
Thickness	3.40 mm $\pm$ 0.2 mm (3.20 mm – 3.60 mm)	Min: 3.36mm and Max: 3.40mm
Hardness (N)	NLT 4.0 Kg (To be established)	4.5Kg
Friability	NMT 1% w/w	0.30%
Disintegration Time	NMT 15 Minutes	02Min and 25Sec
Average Diameter	6.80 mm $\pm$ 0.2mm	Min: 6.80mm and Max: 6.82mm

Parameters	Specified	Observation
		Batch No.: GF200704
		Composite Sample
Description	White to off white coloured, circular shaped, biconvex, uncoated tablet with breakline on one side and plain on other side	White to off white coloured, circular shaped, biconvex, uncoated tablet with breakline on one side and plain on other side
Weight of 20 tablets	2.800 g $\pm$ 3.0 % (2.716 gm to 2.884 gm)	2.822gm
Average weight(mg)	140.000 mg $\pm$ 3.0 % (133.000 mg – 147.000 mg)	141.1mg
Uniformity of weight	140.00 mg $\pm$ 5.0 % (133.000 mg – 147.000 mg)	Min: -1.04: Max: 2.05mm
Thickness	3.40 mm $\pm$ 0.2 mm (3.20 mm – 3.60 mm)	Min: 3.29mm: Max: 3.40mm
Hardness (N)	NLT 4.0 Kg (To be established)	4.5Kg
Friability	NMT 1% w/w	0.25%
Disintegration Time	NMT 15 Minutes	2min and 30Sec
Average Diameter	6.80 mm $\pm$ 0.2mm	Min: 6.80mm to Max: 6.83mm

11.1.8 FINISHED PRODUCT REPORT:

Parameter	Specified	Observation
		Batch No: GF200501
		Composite Sample
Appearance	White to off white coloured, circular shaped, biconvex, uncoated tablet with breakline on one side and plain on other	White to off white coloured, circular shaped, biconvex, uncoated tablet with breakline on one side and plain



PROCESS VALIDATION REPORT

Batch Size: 600000

Generic name AMLOPERIN 5MG/5MG

Protocol No. PVR-A08

	side	on other side		
Identification				
Amlodipine Besylate BP	The retention time of Amlodipine peaks in the chromatogram of sample preparation should correspond to that in chromatogram of the standard preparation as obtained in the assay.	Complies		
Perindopril Erbumine BP	The retention time of Perindopril Erbumine peaks in the chromatogram of sample preparation should correspond to that in chromatogram of the standard preparation as obtained in the assay.	Complies		
Average weight	140.000 mg ± 3.0 % (135.800 mg – 144.00 mg)	143.80mg		
Uniformity of weight	140.00 mg ± 5.0 % (133.000 mg – 147.000 mg)	-1.87%	1.58%	
Dimensions:				
Thickness	3.20 mm ± 0.3 mm (2.90 mm – 3.50 mm)	3.38mm	3.46mm.	3.42mm
Hardness	NLT 4.0 kg	5.0Kg/cm ²		
Diameter	6.80 mm ± 0.2mm	6.85mm	6.87mm	6.86mm
Friability	NMT 1.0 %	0.2%		
Disintegration Time	NMT 15mins	01Min 02Sec		
Dissolution Amlodipine Besylate BP eq. to Amlodipine ...5mg Perindopril Erbumine BP 5mg	Not less than 80 % of labeled amount	101.54%	104.66%	102.85%
		96.67%	99.52%	98.13%
Uniformity of content Amlodipine Besylate BP eq. to Amlodipine ...5mg Perindopril Erbumine BP 5mg	85.0 % to 115.0 % of average value.	101.61%	103.33%	102.30%
	85.0 % to 115.0 % of average value.	98.66%	102.12%	99.69%
Assay				
Amlodipine Besylate BP equivalent to Amlodipine 5mg Perindopril Erbumine BP 5mg	NLT 90.0% and NMT 110%	100.83%		
		98.61%		
Related Substance Amlodipine Impurity A Perindopril Impurity B Perindopril Impurity C Perindopril Impurity E	NMT 1.00% NMT 1.50% NMT 0.60% NMT 0.40%	Not Detected(ND) Not Detected(ND) Not Detected(ND) Not Detected(ND)		

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				Revision No: 00	
PROCESS VALIDATION REPORT				Batch Size: 600000	
Generic name		AMLOPERIN 5MG/5MG			
Protocol No.		PVR-A08			
Perindopril Impurity F Single Maximum unknown Impurity Total Unknown Impurities Total Impurities		NMT 1.50% NMT 0.5% NMT 1.0% NMT 5.0%		Not Detected(ND) Below Detection Limit(BDL) Below Detection Limit(BDL) Below Detection Limit(BDL)	
Microbiological Limits Total Aerobic Microbial counts Total Yeasts and Mould Counts E.coli Salmonella S.Aureus P. aeruginosa		NMT 1000 cfu/g NMT 100 cfu/g Should Be absent Should Be absent Should Be absent Should Be absent		20cfu/g <10cfu/g Absent Absent Absent Absent	
Parameters		Specified		Observation	
				Batch No.: GF200502	
				Composite Sample	
Appearance		White to off white coloured, circular shaped, biconvex, uncoated tablet with breakline on one side and plain on other side		White to off white coloured, circular shaped, biconvex, uncoated tablet with breakline on one side and plain on other side	
Amlodipine Besylate BP		The retention time of Amlodipine peaks in the chromatogram of sample preparation should correspond to that in chromatogram of the standard preparation as obtained in the assay.		Complies	
Perindopril Erbumine BP		The retention time of Perindopril Erbumine peaks in the chromatogram of sample preparation should correspond to that in chromatogram of the standard preparation as obtained in the assay		Complies	
Average weight		140.000 mg $\pm$ 3.0 % (135.800 mg – 144.00 mg)		142.59gm	
Uniformity of weight		Not More Than 2 of the Individual weights deviate from the average by more than $\pm$ 7.5% and more deviate by more than $\pm$ 15.0%		Min: -1.70%	Max: 1.84%
Dimensions:					
Thickness		3.20 mm $\pm$ 0.3 mm (2.90 mm – 3.50 mm)		3.36mm	3.45mm 3.41mm
Hardness (N)		NLT 4.0 kg		4.94Kg/cm ²	
Diameter		6.80 mm $\pm$ 0.2mm		6.82mm	6.90mm 6.85mm

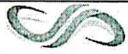
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PROCESS VALIDATION REPORT				Batch Size: 600000	
Generic name		AMLOPERIN 5MG/5MG			
Protocol No.		PVR-A08			
Friability		NMT 1.0 %		0.18%	
Disintegration Time		NMT 15mins		02Min 04Sec	
Dissolution Amlodipine Besylate BP eq. to Amlodipine ...5mg Perindopril Erbumine BP 5mg		Not less than 80 % of labeled amount.		96.99%	104.18%
				101.47%	
Uniformity of content Amlodipine Besylate BP eq. to Amlodipine ...5mg Perindopril Erbumine BP 5mg		NLT 90.0% and NMT 110%		98.07%	102.38%
		NLT 90.0% and NMT 110%		100.26%	
Assay		Amlodipine Besylate BP equivalent to Amlodipine 5mg Perindopril Erbumine BP 5mg		Not less than 80.0% of Labeled	
				101.61%	
Related Substance Amlodipine Impurity A Perindopril Impurity B Perindopril Impurity C Perindopril Impurity E Perindopril Impurity F Single Maximum unknown Impurity Total Unknown Impurities Total Impurities		Not less than 80.0% of Labeled		99.36%	
Microbiological Limits Total Aerobic Microbial counts Total Yeasts and Mould Counts E.coli Salmonella S.Aureus P. aeruginosa		NMT 1.00% NMT 1.50% NMT 0.60% NMT 0.40% NMT 1.50% NMT 0.5% NMT 1.0% NMT 5.0%		Not Detected(ND) Not Detected(ND) Not Detected(ND) Not Detected(ND) Not Detected(ND) Below Detection Limit(BDL)	
				Below Detection Limit(BDL) Below Detection Limit(BDL)	
Parameter		Specified		Observation	
				Batch No: GF200704	
Appearance		White to off white coloured, circular		Composite Sample	
				White to off white coloured, circular	

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				Revision No: 00	
PROCESS VALIDATION REPORT				Batch Size: 600000	
Generic name		AMLOPERIN 5MG/5MG			
Protocol No.		PVR-A08			
		shaped, biconvex, uncoated tablet with breakline on one side and plain on other side		shaped, biconvex, uncoated tablet with breakline on one side and plain on other side	
Identification					
Amlodipine Besylate BP		The retention time of Amlodipine peaks in the chromatogram of sample preparation should correspond to that in chromatogram of the standard preparation as obtained in the assay.		Complies	
Perindopril Erbumine BP		The retention time of Perindopril Erbumine peaks in the chromatogram of sample preparation should correspond to that in chromatogram of the standard preparation as obtained in the assay.		Complies	
Average weight		140.000 mg $\pm$ 3.0 % (135.800 mg – 144.00 mg)		141.00mg	
Uniformity of weight		Not More Than 2 of the Individual weights deviate from the average by more than $\pm$ 7.5% and more deviate by more than $\pm$ 15.0%		-1.42%	1.42%
Dimensions:					
Thickness		3.20 mm $\pm$ 0.3 mm (2.90 mm – 3.50 mm)		3.44mm	3.48mm 3.46mm
Hardness		NLT 4.0 kg		3.70kg/cm ²	
Diameter		6.80 mm $\pm$ 0.2mm		6.81mm	6.82mm 6.81mm
Friability		NMT 1.0 %		0.25%	
Disintegration Time		NMT 15mins		02min 21Sec	
Dissolution Amlodipine Besylate BP eq. to Amlodipine ...5mg Perindopril Erbumine BP 5mg		Not less than 80 % of labeled amount.		94.00%	103.48% 100.11%
				99.05%	103.64% 100.64%
Uniformity of content Amlodipine Besylate BP eq. to Amlodipine ...5mg Perindopril Erbumine BP 5mg		NLT 90.0% and NMT 110%		93.08%	103.53% 96.85%
				91.10%	102.97% 98.33%
Assay					
Amlodipine Besylate BP equivalent to Amlodipine 5mg				99.37%	
Perindopril Erbumine BP 5mg		Not less than 80.0% of Labeled		100.61%	

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	PROCESS VALIDATION REPORT	
Generic name	AMLOPERIN 5MG/5MG	
Protocol No.	PVR-A08	

Related Substance		
Amlodipine Impurity A	NMT 1.00%	Not Detected(ND)
Perindopril Impurity B	NMT 1.50%	Not Detected(ND)
Perindopril Impurity C	NMT 0.60%	Not Detected(ND)
Perindopril Impurity E	NMT 0.40%	Not Detected(ND)
Perindopril Impurity F	NMT 1.50%	Not Detected(ND)
Single Maximum unknown Impurity	NMT 0.5%	Below Detection Limit(BDL)
Total Unknown Impurities	NMT 1.0%	Below Detection Limit(BDL)
Total Impurities	NMT 5.0%	Below Detection Limit(BDL)
Microbiological Limits		
Total Aerobic Microbial counts	NMT 1000 cfu/g	10cfu/g
Total Yeasts and Mould Counts	NMT 100 cfu/g	<10cfu/g
E.coli	Should Be absent	Absent
Salmonella	Should Be absent	Absent
S.Aureus	Should Be absent	Absent
P. aeruginosa	Should Be absent	Absent

12.0 PROCESS YIELD STATEMENT:

Sr. No.	Stage	Observation (%)		
		Batch No.:		
		GF200501	GF200502	GF200704
1.	Blending & Lubrication	99.52%	99.76%	99.89%
2.	Compression	98.84%	99.77%	100.10%
3.	Inspection	98.52%	99.39%	99.95%
4.	Packing	97.96%	98.70%	96.94%

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Revision No: 00

PROCESS VALIDATION REPORT

Batch Size: 600000

Generic name AMLOPERIN 5MG/5MG

Protocol No. PVR-A08

13.0 Deviation and Justification/Corrective Action:

Sr. No.	Deviation details	Justification(s) / Corrective Action(s)	Remarks Acceptable / Not acceptable
1.			
2.			
3.		nil	
4.			
5.			

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PROCESS VALIDATION REPORT

Batch Size: 600000

Generic name AMLOPERIN 5MG/5MG

Protocol No. PVR-A08

14.0 SUMMARY:

The process validation of Amloperin 515 has been carried out as per pre determined procedure and found satisfactory

15.0 CONCLUSION:

The process of Amloperin 515 batch no GF200501, GF200502 and GF200704 have been validated and the result obtained from lubrication, compression and packing found well within the limit. Hence the process stand validated and recommended to follow same procedure for further batches.

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PROCESS VALIDATION REPORT		Batch Size: 600000
Generic name	AMLOPERIN 5MG/5MG	
Protocol No.	PVR-A08	

16.0 REPORT APPROVAL:

The process Validation Report of batch "AMLOPERIN 5MG/5MG" having batch size of 6, 00,000 Tablets has been reviewed and complies with requirements.

Prepared By:	
Name: <u>R. Stephen</u>	
Sign / Date: <u>[Signature]</u> Quality Assurance	
Checked and Reviewed By:	
Name: <u>A. VALLABHARANI</u>	Name: <u>BAVAJURAM ANANDARAJ</u>
Sign/Date: <u>[Signature]</u> Quality Control	Sign/Date: <u>[Signature]</u> Production 15/06/2020
Name: <u>K. V. BAKKAMURTHY</u>	
Sign/Date: <u>[Signature]</u> PROD Quality Assurance	

Comments: We certify that the process Validation report for "AMLOPERIN 5MG/5MG" having batch size of 6, 00,000 Tablets has been accepted.

Report Approved By:
Name: <u>T. SIVAPATHIA</u>
Sign / Date: <u>[Signature]</u> President

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