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 7
		No.: FPS: A08
	FINISHED PRODUCT SPECIFICATION	Revision No.: 02
Title:	AMLOPERIN 5 mg / 5 mg (Amlodipine Besylate & Perindopril Erbumine Tablet)	Review Period: 3 Years
	Product Code: A08	Effective Date: 06/02/2024

01	**GENERAL**	**Pharmacopoeial Reference**	**INHOUSE**
02	**Composition**	**Label Claim**	
	Each uncoated tablet contains:		
	Amlodipine Besylate BP equivalent to Amlodipine	5 mg	
	Perindopril Erbumine BP	5 mg	
03	**Shelf life**	36 months	
04	**Quantity of sample taken for analysis**	Lubricated granules: 100 gm Bulk sample : 120'S (For complete analysis) Finished product: 12 X 10'S (For Physical parameter & Microbial Limit test only)	
05	**Control sample**	7 [3 X 10'S]	
06	**Storage of Finished pack**	Store in a cool and dry place.protect from light and moisture.	

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature			
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Department: Quality Control		Date of Issue: 06/02/2024	

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	Product Code: A08	Effective Date: 06/02/2024

BULK GRANULES SPECIFICATION

S.No.	TEST	LIMIT	METHOD
01	DESCRIPTION	Off white coloured granular powder.	Follow section I of Method of analysis
02	ASSAY (By HPLC)		Follow section IX of Method of analysis
	Each 140 mg Granules Contains:		
	Amlodipine Besylate BP equivalent to Amlodipine	Not Less than 90.0 % and Not more than 110.0 %	
	Perindopril Erbumine BP	Not Less than 90.0 % and Not more than 110.0 %	

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature			
Date	06/02/2024	06/02/2024	06/02/2024
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		No.: FPS: A08
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	Product Code: A08	Effective Date: 06/02/2024

BULK PRODUCT SPECIFICATION

S.No.	TEST	LIMIT	METHOD
01	**DESCRIPTION**	Off white, round, biconvex, uncoated tablet with breakline on one side and plain on other sides.	Follow section I of Method of analysis
02	**AVERAGE WEIGHT**	140 mg ± 5 % (133.0 mg to 147.0 mg)	Follow section III of Method of analysis
03	**UNIFORMITY OF WEIGHT**	Not more than 2 of the individual weights deviate from the average weight by more than ± 7.5 % and none deviate by more than ± 15.0 %.	Follow section IV of Method of analysis
04	**DIMENSIONS** Diameter Thickness	 6.60 mm to 7.00 mm 2.90 mm to 3.50 mm	Follow section V of Method of analysis
05	**HARDNESS**	Not Less than 3.0 kg	Follow section VI of Method of analysis
06	**FRIABILITY**	Not more than 1.0 %	Follow section VII of Method of analysis
07	**DISINTEGRATION TIME**	Not more than 15 minutes	Follow section VIII of Method of analysis
08	**ASSAY (By HPLC)** **Each uncoated tablets contains:** Amlodipine Besylate BP equivalent to Amlodipine Perindopril Erbumine BP	 Not less than 90.0 % to Not more than 110.0 % Not less than 90.0 % to Not more than 110.0 %	Follow section IX of Method of analysis
09	**DISSOLUTION(By HPLC)** Amlodipine Besylate BP equivalent to Amlodipine Perindopril Erbumine BP	 Not less than 80.0 % of the labeled amount Not less than 80.0 % of the labeled amount	Follow section X of Method of analysis

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Designation	Executive QC	Sr.Executive QC	Manager QC
Signature			
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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 7
		No.: FPS: A08
	FINISHED PRODUCT SPECIFICATION	Revision No.: 02
Title:	AMLOPERIN 5 mg / 5 mg (Amlodipine Besylate & Perindopril Erbumine Tablet)	Review Period: 3 Years
	Product Code: A08	Effective Date: 06/02/2024

RELEASE SPECIFICATION

S.No.	TEST	LIMIT	METHOD
01	**DESCRIPTION**	Off white, round, biconvex, uncoated tablet with breakline on one side and plain on other sides.	Follow section I of Method of analysis
02	**IDENTIFICATION (By HPLC)** Amlodipine Besylate BP & Perindopril Erbumine BP	The retention time of Amlodipine & Perindopril Erbumine peaks in the chromatogram of sample preparation should correspond to that in chromatogram of the standard preparation as obtained in the assay.	Follow section II of Method of analysis
03	**AVERAGE WEIGHT**	140 mg ± 5 % (133.0 mg to 147.0 mg)	Follow section III of Method of analysis
04	**UNIFORMITY OF WEIGHT**	Not more than 2 of the individual weights deviate from the average weight by more than ± 7.5 % and none deviate by more than ± 15.0 %.	Follow section IV of Method of analysis
05	**DIMENSIONS** Diameter Thickness	6.60 mm to 7.00 mm 2.90 mm to 3.50 mm	Follow section V of Method of analysis
06	**HARDNESS**	Not Less than 3.0 kg	Follow section VI of Method of analysis
07	**FRIABILITY**	Not more than 1.0 %	Follow section VII of Method of analysis
08	**DISINTEGRATION TIME**	Not more than 15 minutes	Follow section VIII of Method of analysis
09	**ASSAY (By HPLC)** **Each uncoated tablets contains:** Amlodipine Besylate BP equivalent to Amlodipine	Not less than 90.0 % to Not more than 110.0 %	Follow section IX of Method of analysis
	Perindopril Erbumine BP	Not less than 90.0 % to Not more than 110.0 %	

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature	J. Lang		
Date	06/02/2024	06/02/2024	06/02/2024
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	Product Code: A08	Effective Date: 06/02/2024

S.No.	TEST	LIMIT	METHOD
	UNIFORMITY OF CONTENT		
	Amlodipine Besylate BP equivalent to Amlodipine	Not less than 85.0 % to Not more than 115.0 % of labeled claim	
	Perindopril Erbumine BP	Not less than 85.0 % to Not more than 115.0 % of labeled claim	
10	**DISSOLUTION (By HPLC)**		Follow section X of Method of analysis
	Amlodipine Besylate BP equivalent to Amlodipine	Not less than 80.0 % of the labeled amount	
	Perindopril Erbumine BP	Not less than 80.0 % of the labeled amount	
11	**RELATED SUBSTANCES**		Follow section XI of Method of analysis
	Amlodipine Impurity-A	Not more than 1.00 %	
	Perindopril Impurity-B	Not more than 1.50 %	
	Perindopril Impurity-C	Not more than 0.60 %	
	Perindopril Impurity-E	Not more than 0.40 %	
	Perindopril Impurity-F	Not more than 1.50 %	
	Single maximum unknown impurity	Not more than 0.50 %	
	Total unknown impurity	Not more than 1.00 %	
	Total impurities	Not more than 5.00%	
12	**MICROBIOLOGICAL LIMITS**		
	Total Aerobic Microbial count	NMT 1000 cfu/g	Follow section XII of Method of analysis
	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	

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature			
Date	06/02/2024	06/02/2024	06/02/2024
Department: Quality Control		Date of Issue: 06/02/2024	

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		No.: FPS: A08
	FINISHED PRODUCT SPECIFICATION	Revision No.: 02
Title:	AMLOPERIN 5 mg / 5 mg (Amlodipine Besylate & Perindopril Erbumine Tablet)	Review Period: 3 Years
	Product Code: A08	Effective Date: 06/02/2024

SHELF LIFE SPECIFICATION

S.No.	TEST	LIMIT	METHOD
01	**DESCRIPTION**	Off white, round, biconvex, uncoated tablet with breakline on one side and plain on other sides.	Follow section I of Method of analysis
02	**AVERAGE WEIGHT**	140 mg ± 5 % (133.0 mg to 147.0 mg)	Follow section III of Method of analysis
03	**HARDNESS**	Not Less than 3.0 kg	Follow section VI of Method of analysis
04	**FRIABILITY**	Not more than 1.0 %	Follow section VII of Method of analysis
05	**DISINTEGRATION TIME**	Not more than 15 minutes	Follow section VIII of Method of analysis
06	**ASSAY (By HPLC)** **Each uncoated tablets contains:** Amlodipine Besylate BP equivalent to Amlodipine Perindopril Erbumine BP	 Not less than 90.0 % to Not more than 110.0 % Not less than 90.0 % to Not more than 110.0 %	Follow section IX of Method of analysis
07	**DISSOLUTION (By HPLC)** Amlodipine Besylate BP equivalent to Amlodipine Perindopril Erbumine BP	 Not less than 80.0 % of the labeled amount Not less than 80.0 % of the labeled amount	Follow section X of Method of analysis
08	**RELATED SUBSTANCES:** Amlodipine Impurity-A Perindopril Impurity-B Perindopril Impurity-C Perindopril Impurity-E Perindopril Impurity-F Single maximum unknown impurity Total unknown impurity Total impurities	 Not more than 1.00 % Not more than 1.50 % Not more than 0.60 % Not more than 0.40 % Not more than 1.50 % Not more than 0.50 % Not more than 1.00 % Not more than 5.00%	Follow section XI of Method of analysis

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature			
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	Product Code: A08	Effective Date: 06/02/2024

S.No.	TEST	LIMIT	METHOD
09	**MICROBIOLOGICAL LIMITS:**		
	Total Aerobic Microbial count	NMT 1000 cfu/g	Follow section XII of Method of analysis
	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	

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New Specification No: A08
2	Revision No.: 01	Periodic Revision
3	Revision No.: 02	Incorporated Bulk Granules Specification, Bulk product Specification.

END OF DOCUMENT

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature			
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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 17
		No.: FPSTP:A08
	FINISHED PRODUCT STANDARD TEST PROCEDURE	Revision No.: 02
Title:	AMLOPERIN 5 mg/5 mg (Amlodipine Besylate & Perindopril Erbumine tablet)	Review Period: 3 Years
	Product Code :A08	Effective Date: 06/02/2024

METHOD OF ANALYSIS

SECTION – I

DESCRIPTION: (By Visual Inspection)

Check physical aspects – Colour and appearance of granules, shape and nature of tablets, presence of foreign material, mottling etc.,

SECTION – II

IDENTIFICATION (By HPLC)

Amlodipine Besylate & Perindopril Erbumine

The retention time of Amlodipine & Perindopril Erbumine peaks in the chromatogram of sample preparation should correspond to that in chromatogram of the standard preparation as obtained in the assay.

SECTION – III

AVERAGE WEIGHT

Weigh 20 tablets and note down weight in g. Determine the average weight. Report the result of average weight in mg.

$$\text{Average weight} = \frac{\text{Weight of 20 tablets in g}}{20} \times 1000 = \_\_\_\_\_ \text{ mg}$$

SECTION – IV

UNIFORMITY OF WEIGHT

Weigh individually 20 tablets taken for average weight. Calculate the percentage of highest and lowest variation of the tablets with maximum and minimum weight from the average weight of tablets by the following expression..

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Signature	J. kayal		for
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Calculation

$$\left(\frac{\text{Lowest Wt. of Tablet}}{\text{Avg. Wt of Tablet}} \times 100 - 100 = - \right) \%$$

$$\left(\frac{\text{Highest Wt. of Tablet}}{\text{Avg. Wt. of Table}} \times 100 - 100 = + \right) \%$$

SECTION – V

DIMENSIONS

Measure individually diameter and thickness of 10 tablets with Digital Vernier Calipers. It should be within the specified limits.

SECTION – VI

HARDNESS

Measure the hardness of 10 tablets on a suitable hardness tester. It should be within the specified limits.

SECTION – VII

FRIABILITY

Weigh accurately about 6.5 g of tablets note down the mass in grams (a).Place weighed tablets in friability test apparatus and operate the instrument as per SOP for tablet friability test apparatus, for 100 rotations. After completion of test collect the tablets from the sample collector carefully. Remove broken particles, chipped pieces (if any) by means of gentle brushing. Weigh the tablet and record the mass in grams (b).

Calculate the weight loss (c= a-b).

Calculate the percentage as follows:

Calculation

$$\frac{c \times 100}{a} = \quad \% \text{ w/w}$$

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Designation	Executive QC	Sr.Executive QC	Manager QC
Signature			
Date	06/02/2024	06/02/2024	06/02/2024
Department: Quality Control		Date of Issue: 06/02/2024	

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 17
		No.: FPSTP:A08
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	Product Code :A08	Effective Date: 06/02/2024

SECTION – VIII

DISINTEGRATION TIME

Introduce one tablet into each tube disintegrating testing apparatus. Add disc to each tube. Suspend the assembly in the beaker containing water .Maintained at $37^0C \pm 2^0C$ and operate the apparatus for 15 minutes. Observe all the tablets, if all the tablets are disintegrated completely within 15 minutes, life the basket from the fluid and note down the time required. If 1 or 2 tablets fails to disintegrate completely repeat the test on 12 additional tablets. The requirement is met if not fewer than 16 of total of 18 tablets tested are disintegrated.

SECTION –IX

ASSAY AND CONTENT UNIFORMITY(By HPLC)

Chromatographic Conditions:

Column type	: C8,4.6 mm x 250 mm, 5 µL
Flow rate	: 1.0 ml/minute
Detector wavelength	: 210 nm
Column oven temperature	: 40^0C
Injection volume	: 10 µL
Diluent	: Mobile phase

Preparation of Buffer solution:

Weight accurately about 6.8 g of potassium dihydrogen orthophosphate to 1000 ml glass beaker. Add about 500 ml of water, shake and sonicate to dissolve completely and finally make the solution 1000 ml with water.

Preparation of Mobile phase:

Mix 590 ml of buffer solution and 410 ml acetonitrile. Sonicate with stirring and adjust the pH to 2.6 with orthophosphoric acid. Filter through 0.20 micron membrane filter and degas.

Preparation of Standard solution:

Weigh accurately about 69 mg of amlodipine besylate standard and 50 mg of Perindopril erbumine standard into a 100 ml volumetric flask. Add about 70 ml of diluents, Sonicate to dissolve and dilute up to mark with diluents and Mix. Further dilute 5 ml of this solution to 50 ml with mobile phase and Mix. (Concentration:0.05 mg/ ml)

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Designation	Executive QC	Sr.Executive QC	Manager QC
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Preparation of sample solution:
Weigh accurately 10 intact tablets into 100 ml volumetric flask. Add about 50 ml of diluent, sonicate for 10 minute with intermediate shaking to dissolve and dilute up to the mark with diluents and Mix. Filter sufficient amount of this solution through 0.45 micron syringe filter. Further dilute 5 ml of filtered solution to 50 ml with mobile phase and inject.(Concentration: Amlodipine and Perindopril 0.05 mg/ml)

Note: Prepare sample solution in duplicates.

Preparation of sample solution content uniformity:
Take 1 tablet into 100 ml volumetric flask. Add about 5 ml of purified water and shake gently to disperse the tablet completely. Add about 60 ml of diluent, sonicate for 10 minutes with intermediate shaking and dilute up to the volume with diluents. Filter the sufficient amount of this solution through 0.45 micron syringe filter and inject. Repeat the same procedure for another 9 tablets. (Concentration: Amlodipine and Perindopril 0.05 mg/ml)

Procedure:
Equilibrate the chromatographic system with mobile phase till a stable baseline is obtained . Separately inject equal volume (10 µL) of solution as per sequence of injections into the chromatograph and record the peak area responses for the major peaks and check for the system suitability requirements.

Sequence of Injections:

Name		# Injections
Blank	:	1
Standard preparation	:	5
Blank	:	1
Sample preparation-1	:	1
Sample preparation-2	:	1
Standard preparation(Bracketing)	:	1
Content Uniformity-1	:	1
Content Uniformity-2	:	1
Content Uniformity-3	:	1
Content Uniformity-4	:	1
Content Uniformity-5	:	1
Standard preparation(Bracketing)	:	1
Content Uniformity-6	:	1
Content Uniformity-7	:	1
Content Uniformity-8	:	1

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Content Uniformity-9	:	1
Content Uniformity-10	:	1
Standard preparation(Bracketing)	:	1

System suitability requirement:

1) The Resolution between the peaks corresponding to Amlodipine and Perindopril obtained with standard solution should not be less than 2.0.
2) The tailing factor for the peak of Amlodipine and Perindopril obtained with standard solution should not more than 2.0.
3) The column efficiency for the peak of Amlodipine and Perindopril obtained in the chromatogram of Standard solution should not less than 2000.
4) The % RSD for the peak area response of Amlodipine and Perindopril peak obtained with the replicate injections of standard solution should not more than 2.00
5) The % RSD for the peak area response of Amlodipine and Perindopril peak obtained with the replicate injections of standard solution and bracketing standard solution should not more than 2.00

Calculation:(ASSAY)

1)Calculated the content of Amlodipine besylate equivalent to amlodipine by using following formula,

$$= \frac{A}{B} \times \frac{W1}{100} \times \frac{5}{50} \times \frac{100}{W2} \times \frac{50}{5} \times Av \times F \times \frac{P}{100} \times \frac{100}{5}$$

Where,
A = Peak area response of Amlodipine peak obtained with sample solution
B = Average peak area response of Amlodipine peak obtained with replicate injection standard solution
W1 = Weight of Amlodipine standard in mg
W2 = weight of sample in g
Av = Average weight of sample in g
P = Purity of Amlodipine working standard in %
F = Equivalent factor (i.e. 0.72)

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Signature	J. Ieyd		
Date	06/02/2024	06/02/2024	06/02/2024
Department: Quality Control		Date of Issue: 06/02/2024	

2)Calculated the content of Perindopril by using following formula,

$$= \frac{A}{B} \times \frac{W1}{100} \times \frac{5}{50} \times \frac{100}{W2} \times \frac{50}{5} \times Av \times \frac{P}{100} \times \frac{100}{5}$$

Where,
A = Peak area response of Perindopril peak obtained with sample solution
B = Average peak area response of Perindopril peak obtained with replicate injection standard solution
W1 = Weight of Perindopril standard in mg
W2 = weight of sample in g
Av = Average weight of sample in g
P = Purity of Perindopril working standard in %

Calculation:(Content Uniformity)
1)Calculated the content of Amlodipine besylate equivalent to amlodipine in each tablet by using following formula,

$$= \frac{A}{B} \times \frac{W1}{100} \times \frac{5}{50} \times \frac{100}{1} \times F \times \frac{P}{100} \times \frac{100}{5}$$

Where,
A = Peak area response of Amlodipine peak obtained with sample solution
B = Average peak area response of Amlodipine peak obtained with replicate injection standard solution
W1 = Weight of Amlodipine standard in mg
P = Purity of Amlodipine working standard in %
F = Equivalent factor (i.e. 0.72)

2)Calculated the content of Perindopril in each by using following formula,

$$= \frac{A}{B} \times \frac{W1}{100} \times \frac{5}{50} \times \frac{100}{1} \times \frac{P}{100} \times \frac{100}{5}$$

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Where,
A = Peak area response of Perindopril peak obtained with sample solution
B = Average peak area response of Perindopril peak obtained with replicate injection standard solution
W1 = Weight of Perindopril standard in mg
P = Purity of Perindopril working standard in %

3)Calculate the average content of assay by using following formula,

$$= \frac{\text{Assay value obtained with sample- 1} + \text{Assay value obtained with sample-2}}{2}$$

Reporting: Report the average assay values in % of Amlodipine and Perindopril

SECTION –X

DISSOLUTION (By HPLC)

Chromatographic Conditions:

Column type	: C8,(4.6 mm x 250 mm, 5 µ)
Flow rate	: 1.0 ml/minute
Detector wavelength	: 210 nm
Column oven temperature	: 40°C
Injection volume	: 50 µL

Dissolution Parameters:

Medium	: 0.01 M Hydrochloric acid
Volume	: 500 ml
Apparatus	: Type II (Paddle)
RPM	: 100
Temperature	: 37°C ± 0.5°C
Time	: 45 min

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Designation	Executive QC	Sr.Executive QC	Manager QC
Signature			
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		No.: FPSTP:A08
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Title:	AMLOPERIN 5 mg/5 mg (Amlodipine Besylate & Perindopril Erbumine tablet)	Review Period: 3 Years
	Product Code :A08	Effective Date: 06/02/2024

Preparation of Buffer solution:
Weight accurately about 6.8 g of potassium dihydrogen orthophosphate to 1000 ml glass beaker. Add about 500 ml of water, shake and sonicate to dissolve completely and finally make the solution 1000 ml with water.

Preparation of Mobile phase:
Mix 590 ml of buffer solution and 410 ml acetonitrile. Sonicate with stirring and adjust the pH to 2.6 with orthophosphoric acid. Filter through 0.20 micron membrane filter and degas.

Preparation of Dissolution medium (0.01 M HCl):
Dilute 8.5 ml of Hydrochloric acid to 10 liter purified water, mix well and degas.

Preparation of Standard solution:
Weigh accurately and transfer about 69 mg of amlodipine besylate standard and 50 mg of Perindopril erbumine standard into 50 ml volumetric flask. Add about 30 ml of mobile phase, Sonicate to dissolve and dilute up to mark with mobile phase. Further dilute 5 ml of this solution to 50ml with dissolution medium and Mix. Further dilute 5 ml of this solution to 50 ml with dissolution medium and mix.
(Concentration: Amlodipine and Perindopril 0.01 mg/ ml)

Preparation of Sample solution:
Place the stated volume of dissolution medium of each vessels of the dissolution apparatus. Warm the dissolution medium at $37^0C \pm 0.5^0C$. Transfer 1 tablet in to each Vessels. Immediately operate the apparatus at specified speed. At the end of specified time interval, withdraw 10 ml of aliquot from each specimen. Filter through 0.45 micron syringe filter and inject.(Concentration: Amlodipine and Perindopril 0.01 mg/ ml)
(Aliquot withdrawal position: from the midway zone between the top surface of dissolution medium and top of rotating paddle and 1 cm away from vessel wall.)

Procedure:
Equilibrate the chromatographic system with mobile phase till a stable baseline is obtained. Separately inject volumes (50 µl) of solution as per sequence of injections into the chromatograph and record the peak area response for the major peaks and check for the system suitability requirements.
Sequence of Injections:

Name		# Injections
Blank	:	1
Standard preparation	:	5
Blank	:	1

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature	T. Kavya		
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Sample solution-1	:	1
Sample solution -2	:	1
Sample solution -3	:	1
Sample solution -4	:	1
Sample solution -5	:	1
Sample solution -6	:	1
Standard preparation(Bracketing)	:	1

System suitability requirement:

1) The Resolution between the peaks corresponding to Amlodipine and Perindopril obtained with standard solution should not be less than 2.0.
2) The tailing factor for the peak of Amlodipine and Perindopril obtained with standard solution should not more than 2.0.
3) The column efficiency for the peak of Amlodipine and Perindopril obtained in the chromatogram of Standard solution should not less than 2000.
4) The % RSD for the peak area response of Amlodipine and Perindopril peak obtained with the replicate injections of standard solution should not more than 2.00.
5) The % RSD for the peak area response of Amlodipine and Perindopril peak obtained with the replicate injections of standard solution and bracketing standard solution should not more than 2.00

Calculation:(Dissolution)
1)Calculated the content released of Amlodipine besylate equivalent to amlodipine in each tablet by using following formula,

$$= \frac{A}{B} \times \frac{W1}{50} \times \frac{5}{50} \times \frac{5}{50} \times \frac{500}{1} \times F \times \frac{P}{100} \times \frac{100}{5}$$

Where,
A = Peak area response of Amlodipine peak obtained with sample solution
B = Average peak area response of Amlodipine peak obtained with replicate injection standard solution
W1 = Weight of Amlodipine standard in mg
P = Purity of Amlodipine working standard in %
F = Equivalent factor (i.e. 0.72)

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2)Calculated the content released of Perindopril in each by using following formula,

$$= \frac{A}{B} \times \frac{W1}{50} \times \frac{5}{50} \times \frac{5}{50} \times \frac{500}{1} \times \frac{P}{100} \times \frac{100}{5}$$

Where,
A = Peak area response of Perindopril peak obtained with sample solution
B = Average peak area response of Perindopril peak obtained with replicate injection standard solution
W1 = Weight of Perindopril standard in mg
P = Purity of Perindopril working standard in %

Reporting: Report the results of minimum, maximum and average value in %

SECTION –XI

RELATED SUBSTANCES :(By HPLC)

a)Amlodipine Impurity A:

Chromatographic Conditions:

Column type	: C8,4.6 mm x 250 mm, 5 µL
Flow rate	: 1.0 ml/minute
Detector wavelength	: 237 nm
Column oven temperature	: 40°C
Injection volume	: 20 µL

Preparation of Buffer solution:
Mix about 7.5 ml of Triethylamine to 1000 ml of water. Adjust the PH to 3.0 with Orthophosphoric acid.

Preparation of mobile phase:
Mix 150 ml of buffer solution 600 ml methanol and 250 ml acetonitrile. Filter through 0.20 micron membrane filter and dages.

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		No.: FPSTP:A08
	FINISHED PRODUCT STANDARD TEST PROCEDURE	Revision No.: 02
Title:	AMLOPERIN 5 mg/5 mg (Amlodipine Besylate & Perindopril Erbumine tablet)	Review Period: 3 Years
	Product Code :A08	Effective Date: 06/02/2024

Preparation of Diluent:
Use mobile phase as a diluents.

Preparation of Blank solution:
Injection diluents as such.

Preparation of Amlodipine standard stock solution:
Weigh accurately and transfer about 50 mg of Amlodipine standard into 100 ml volumetric flask. Add about 50 ml of diluent, sonicate to dissolve and dilute up to mark with diluent. (Concentration: 0.5 mg/ ml).

Preparation of standard Impurity A stock solution:
Weigh accurately and transfer about 10 mg of Impurity A RS into 100 ml volumetric flask. Add about 30 ml of diluents, sonicate to dissolve and dilute up to mark with diluent. (Concentration: 0.1 mg/ ml)

Preparation of standard Impurity A solution:
Dilute 5 ml of above standard Impurity A stock solution to 100 ml with diluent, mix well and inject.(Concentration:0.005 mg/ml)

Preparation of System Suitability solution:
Dilute 10 ml Amlodipine standard stock solution and 5 ml of standard Impurity A stock solution 100 ml with diluent,. Mix well and inject. (concentration: Amlodipine:0.05 mg/ ml and Impurity A: 0.005 mg/ ml)

Preparation of placebo solution:
Weigh accurately and transfer about 0.650 g of placebo into 50 ml volumetric flack. Add about 30 ml of diluent, sonicate for 10 minutes with intermediate shaking to dissolve and dilute up to the volume with diluent. Centrifuge sufficient quantity of this solution until final clear solution appears and inject.

Preparation of sample solution:

Weigh accurately and transfer about 0.700 g of sample powder into 50 ml volumetric flack. Add about 30 ml of diluent, sonicate for 10 minutes with intermediate shaking to dissolve and dilute up to the volume with diluent. Centrifuge sufficient quantity of this solution until final clear solution appears and inject.
(Concentration: 0.5 mg /ml of Amlodipine)

Note: Inject all solution freshly prepared.

	Prepared by	Checked by	Approved By
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		No.: FPSTP:A08
	FINISHED PRODUCT STANDARD TEST PROCEDURE	Revision No.: 02
Title:	AMLOPERIN 5 mg/5 mg (Amlodipine Besylate & Perindopril Erbumine tablet)	Review Period: 3 Years
	Product Code :A08	Effective Date: 06/02/2024

Procedure:

Equilibrate the chromatographic system with mobile phase till a stable baseline is obtained. Separately inject volumes (20 µl) of solution as per sequence of injections into the chromatograph and record the peak area response for the major peaks and check for the system suitability requirements.

Disregard any peak with an area less than the area of the sample preparation area normalisation (0.05 %).

Sequence of Injections:

Name		# Injections
Blank	:	1
System suitability solution	:	1
Blank	:	1
Impurity A standard solution	:	6
Blank	:	1
Placebo solution	:	1
Blank	:	1
Sample solution	:	1
Impurity A standard solution (Bracketing)	:	1

System suitability requirement:

1) The Resolution between the peaks corresponding to Amlodipine and Impurity A obtained with system suitability solution should not be less than 4.0
2) The tailing factor for the peak of Impurity A obtained with chromatogram of standard Impurity A solution should not more than 2.0.
3) The theoretical plates for the peak of Impurity A obtained with the chromatogram of standard Impurity A solution should not less than 2000.
4) The % RSD for the peak area response of Impurity A peak obtained with the replicate injections of standard Impurity A solution should not be more than 5.0.
5) The % RSD for the peak area response of Impurity A peak obtained with the replicate injections of standard Impurity A solution and bracketing standard Impurity A solution should not be more than 5.0.

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature	J. kayal		
Date	06/02/2024	06/02/2024	06/02/2024
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Calculation:

1)Calculated the % content of Impurity A by using following formula,

$$= \frac{A}{B} \times \frac{W1}{100} \times \frac{5}{100} \times \frac{50}{W2} \times \frac{P}{100} \times Av \times \frac{100}{5}$$

Where,

A = Peak area response of Impurity A obtained with sample solution

B = Average peak area response of Impurity A obtained with replicate injection standard Impurity A solution

W1 = Weight of standard Impurity A taken in mg

W2 = Weight of sample taken in g

Av = Average weight of sample in g

P = Purity of Impurity A RS in %

Reporting: Report the average values in %

RELATED SUBSTANCES :(By HPLC)

b)Perindopril Impurity :

Chromatographic Conditions:

Column type	: C8,(4.6 mm x 250 mm, 5 µ)
Flow rate	: 2.0 ml/minute
Detector wavelength	: 215 nm
Column oven temperature	: 60°C
Injection volume	: 20 µL
Diluent	: Mobile phase

Preparation of Buffer solution:

Weight accurately about 6.8 g of potassium dihydrogen orthophosphate to 1000 ml glass beaker. Add about 500 ml of water, shake and sonicate to dissolve completely and finally make the solution 1000 ml with water.

Preparation of Mobile phase:

Mix 710 ml of buffer solution and 290 ml acetonitrile. Sonicate with stirring and adjust the pH to 2.6 with orthophosphoric acid. Filter through 0.20 micron membrane filter and degas.

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature	J. Kapil	CH	
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Department: Quality Control		Date of Issue: 06/02/2024	

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FINISHED PRODUCT STANDARD TEST PROCEDURE	Revision No.: 02
Title: AMLOPERIN 5 mg/5 mg (Amlodipine Besylate & Perindopril Erbumine tablet)	Review Period: 3 Years
Product Code :A08	Effective Date: 06/02/2024

Preparation of Blank solution:
Injection diluents as such.

Preparation of standard solution:
Weigh accurately and transfer about 50 mg of Perindopril standard into 100 ml volumetric flask. Add about 50 ml of diluent, sonicate to dissolve and dilute up to mark with diluent. Dilute 5 ml of this solution to 100 ml diluents. Further dilute 5 ml of this solution to 100 ml with diluents. Mix well and inject.
(Concentration: 0.00125 mg/ ml and 0.25 % w.r.t Perindopril concentration in sample solution i.e 0.5 mg/ ml).

Preparation of placebo solution:
Weigh accurately and transfer about 0.650 g of placebo into 50 ml volumetric flack. Add about 30 ml of diluent, sonicate for 10 minutes with intermediate shaking to dissolve and dilute up to the volume with diluent. Centrifuge sufficient quantity of this solution until final clear solution appears and inject.

Preparation of sample solution:
Weigh accurately and transfer about 0.700 g of sample powder into 50 ml volumetric flack. Add about 30 ml of diluent, sonicate for 10 minutes with intermediate shaking to dissolve and dilute up to the volume with diluent. Centrifuge sufficient quantity of this solution until final clear solution appears and inject.
(Concentration: 0.5 mg /ml of Perindopril)
Note: Inject all solution freshly prepared.
Procedure:
Equilibrate the chromatographic system with mobile phase till a stable baseline is obtained. Separately inject volumes (20 µl) of solution as per sequence of injections into the chromatograph and record the peak area response for the major peaks and check for the system suitability requirements.

Disregard any peak with an area less than the area of the sample preparation area normalisation (0.05 %).

Sequence of Injections:

Name		# Injections
Blank	:	1
Standard solution	:	6
Blank	:	1
Placebo solution	:	1
Blank	:	1
Sample solution	:	1
standard solution (Bracketing)	:	1

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature			
Date	06/02/2024	06/02/2024	06/02/2024
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		No.: FPSTP:A08
	FINISHED PRODUCT STANDARD TEST PROCEDURE	Revision No.: 02
Title:	AMLOPERIN 5 mg/5 mg (Amlodipine Besylate & Perindopril Erbumine tablet)	Review Period: 3 Years
	Product Code :A08	Effective Date: 06/02/2024

System suitability requirement:

1) The tailing factor for the peak of Perindopril obtained with chromatogram of standard low load solution should not be more than 2.0.
2) The theoretical plates for peak of Perindopril obtained with the chromatogram of standard solution should not less than 2000.
3) The % RSD for the peak area response of Perindopril peak obtained with the replicate injections of standard solution should not be more than 5.0.
4) The % RSD for the peak area response of Perindopril peak obtained with the replicate injections of standard solution and bracketing standard solution should not be more than 5.0.

Relative response factor for all impurities:

Name of impurity	RRT	RRF
Impurity-B	0.35	0.79
Impurity-E	1.61	0.79
Impurity-C	1.71	1.00
Impurity-F	4.47	0.69
Perindopril	1.00	-----

Calculation:

1)Calculate the % content of known impurities by using following formula,

$$= \frac{A}{B} \times \frac{W1}{100} \times \frac{5}{100} \times \frac{5}{100} \times \frac{50}{W2} \times \frac{P}{100} \times \frac{100}{Av} \times \frac{}{5} \times RRF$$

Where,
A = Peak area response of individual known impurities obtained with sample solutions.
B = Average peak area response of Perindopril obtained with replicate injection of standard solution
W1 = Weight of Perindopril standard taken in mg
W2 = Weight of sample taken in g
Av = Average weight of sample in g
P = Purity of Perindopril working standard in %
RRF= Relative response factor of individual impurities.

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature			
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Department: Quality Control		Date of Issue: 06/02/2024	

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		No.: FPSTP:A08
	FINISHED PRODUCT STANDARD TEST PROCEDURE	Revision No.: 02
Title:	AMLOPERIN 5 mg/5 mg (Amlodipine Besylate & Perindopril Erbumine tablet)	Review Period: 3 Years
	Product Code :A08	Effective Date: 06/02/2024

2) Calculate the % content of single maximum unknown impurities by using following formula,

$$= \frac{A}{B} \times \frac{W1}{100} \times \frac{5}{100} \times \frac{5}{100} \times \frac{50}{W2} \times \frac{P}{100} \times Av \times \frac{100}{5}$$

Where,
A = Peak area response of single maximum impurity obtained with sample solutions.
B = Average peak area response of Perindopril obtained with replicate injection of standard solution
W1 = Weight of Perindopril standard taken in mg
W2 = Weight of sample taken in g
Av = Average weight of sample in g
P = Purity of Perindopril working standard in %

3) Calculate the % content of total unknown impurities by using following formula,

$$= \frac{A}{B} \times \frac{W1}{100} \times \frac{5}{100} \times \frac{5}{100} \times \frac{50}{W2} \times \frac{P}{100} \times Av \times \frac{100}{5}$$

Where,
A = Peak area response of total unknown impurities obtained with sample solutions.
B = Average peak area response of Perindopril obtained with replicate injection of standard solution
W1 = Weight of Perindopril standard taken in mg
W2 = Weight of sample taken in g
Av = Average weight of sample in g
P = Purity of Perindopril working standard in %

4) Calculate the % content of total impurities by using following formula,

= Total known impurities + Total unknown impurities.

Reporting: Report the values in %

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature	J.kay		
Date	06/02/2024	06/02/2024	06/02/2024
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		No.: FPSTP:A08
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Title:	AMLOPERIN 5 mg/5 mg (Amlodipine Besylate & Perindopril Erbumine tablet)	Review Period: 3 Years
	Product Code :A08	Effective Date: 06/02/2024

SECTION –XII

MICROBIOLOGICAL LIMIT

Refer to SOP No. QCMB 006.

HISTORY

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New FPSTP No: A08
2	Revision No.: 01	Periodic Revision
3	Revision No.: 02	Incorporated Bulk Granules Specification, Bulk product Specification.

END OF DOCUMENT

	Prepared by	Checked by	Approved By
Designation	Executive QC	Sr.Executive QC	Manager QC
Signature			
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