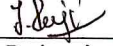
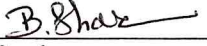


 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PRIVATE LIMITED R.S. No. 4/3, plot No. 33, Kurumbapet Industrial Estate, Villianur Commune, Pondicherry- 605009				Page 1 of 2	
QUALITY CONTROL	CERTIFICATE OF ANALYSIS				Format No: F/QCGN/022/08	
	FINISHED PRODUCT					
Product Name	:	Amloperin 5 mg / 5 mg (Amlodipine Besilate & Perindopril Erbumine Tablet)				
A.R.No.	:	FP/280420/01				
Batch No.	:	GF200405	Batch Size	:	6.0 L	
Mfg. Date	:	Apr-2020	Exp. Date	:	Mar-2023	
Sampling Date	:	27.04.2020	Sample Qty	:	120 Tablets	
Analysis Date	:	27.04.2020	Release Date	:	06.05.2020	

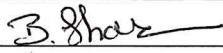
S.No.	TEST	RESULTS	LIMITS
01.	Description	Off white, round, biconvex,uncoated tablet with breakline on one side and plain on other side.	Off white, round, biconvex,uncoated tablet with breakline on one side and plain on other side.
02.	Identification Amlodipine Besylate BP Perindopril Erbumine BP	Complies Complies	The retention time of Amlodipine & perindopril erbumine peak in the chromatogram of sample preparation should correspond to that in chromatogram of the standard preparation as obtained in the assay.
03.	Average weight of tablets	141.65 mg	140 mg $\pm$ 5.0 % (133.0 mg to 147.0 mg)
04.	Uniformity of weight	+2.12 % to -1.41 %	Not more than 2 of the individual weights deviate from the average weight by more than $\pm$ 7.5 % and none deviate by more than $\pm$ 15 % .
05.	Diameter	Min Max Avg. 6.85 mm 6.86 mm 6.85 mm	6.60 mm to 7.00 mm
06.	Thickness	Min Max Avg. 3.35 mm 3.43mm 3.38 mm	2.9 mm to 3.50 mm
07.	Hardness	4.22 kg/cm ²	NLT 3.0 kg/cm ²
08.	Friability	0.07 %	Not More than 1.0 %
09.	Disintegration Time	02 minutes 12 seconds	Not more than 15 minutes
10.	Content Uniformity:		
	Amlodipine Besylate BP equivalent to Amlodipine-5 mg	Min Max Avg. 95.76 % 102.15 % 99.39 %	Not less than 85.0 % and Not more than 115.0 % of labeled claim.
	Perindopril Erbumine BP-5 mg	Min Max Avg. 96.85 % 104.04 % 100.33 %	Not less than 85.0 % and Not more than 115.0 % of labeled claim.

	Tested By	Checked By	Approved By
Sign			
Name	Rajarajeswari	Sankar	Vallarasan
Date	06/05/2020	06/05/2020	06/05/2020

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PRIVATE LIMITED R.S. No. 4/3, plot No. 33, Kurumbapet Industrial Estate, Villianur Commune, Pondicherry- 605009				Page 2 of 2	
QUALITY CONTROL	CERTIFICATE OF ANALYSIS					Format No: F/QCGN/022/08
	FINISHED PRODUCT					
Product Name	:	Amloperin 5 mg / 5 mg (Amlodipine Besilate & Perindopril Erbumine Tablet)				
A.R.No.	:	FP/280420/01				
Batch No.	:	GF200405	Batch Size	:	6.0 L	
Mfg. Date	:	Apr-2020	Exp. Date	:	Mar-2023	
Sampling Date	:	27.04.2020	Sample Qty	:	120 Tablets	
Analysis Date	:	27.04.2020	Release Date	:	06.05.2020	

11.	Dissolution:				
	Amlodipine Besylate BP equivalent to Amlodipine-5 mg	Min 92.92 %	Max 101.47 %	Avg. 95.12 %	Not less than 80.0 % of labeled amount.
	Perindopril Erbumine BP-5 mg	Min 97.46 %	Max 102.12 %	Avg. 98.49 %	Not less than 80 % of labeled amount.
12.	Related substances:				
	Amlodipine Impurity A	Not Detected(ND)			Not more than 1.0 %
	Perindopril Impurity B	Not Detected(ND)			Not more than 1.5 %
	Perindopril Impurity C	Not Detected(ND)			Not more than 0.60 %
	Perindopril Impurity E	Not Detected(ND)			Not more than 0.40 %
	Perindopril Impurity F	Not Detected(ND)			Not more than 1.50 %
	Single maximum unknown impurity	Below Detection Limit(BDL)			Not more than 0.50 %
	Total unknown impurity	Below Detection Limit(BDL)			Not more than 1.0 %
	Total impurities	Below Detection Limit(BDL)			Not more than 5.0 %
13.	Assay: Each uncoated tablet contains:				
	Amlodipine Besylate BP equivalent to Amlodipine-5 mg	100.29 %			Not less than 90.0 % and Not more than 110.0 %
	Perindopril Erbumine BP-5 mg	101.03 %			Not less than 90.0 % and Not more than 110.0 %
14.	Microbiological limits:				
	Total Aerobic Microbial count	20 cfu /g			NMT 1000 cfu/g
	Total Yeasts and mould counts	<10 cfu/g			NMT 100 cfu/g
	E.Coli	Absent			Should be Absent
	Salmonella	Absent			Should be Absent
	S.aureus	Absent			Should be Absent
	P.aeruginosa	Absent			Should be Absent

Remark : The product complies/~~not complies~~ with the prescribed standard of quality with reference to BP/USP and In-house Specification.

	Tested By	Checked By	Approved By
Sign			
Name	Rajarajeswari	Sankar	Vallarasan
Date	06/05/2020	06/05/2020	06/05/2020

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S.No. 4/3, Plot No.3, kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.	Page 1 of 1	Issued by (QA): Date: <u>28/12/19</u>
	TESTING AND RELEASE OF INTERMEDIATE AND FINISHED PRODUCTS	Format No.: F/QCGN/022/04	Revision No.: 00
TITLE:	CHECK LIST OF FINISHED PRODUCT	Review Period: 02 Years	Effective Date: <u>22/05/19</u>

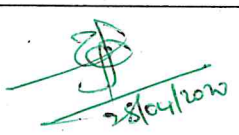
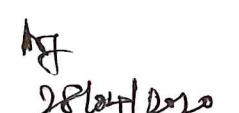
Name of the Product: <u>Amloperin 5mg/5mg</u>	
Analytical Report No. <u>FP/280420/01</u>	Batch No. <u>G1F200405</u>

Log entry Verification (Put ✓ mark on verified)	CONTENTS	S.No.	No. of Pages
Balance log entry ✓	Check list- Finished product	1	1
WS log entry ✓	Test request form	2 to 3	2
WS validity entry ✓	Observation during sampling form	NA	NA
HPLC Column entry ✓	Certificate of analysis	4 to 5	2
HPLC Ins. log entry ✓	Result of analysis (Analytical work record)	NA	NA
Dissolution log entry ✓	Physical parameter sheet Tablet / Capsule / Sachet	6 to 7	2
UV-VIS log entry NA	Graph of UV-VIS spectrophotometer	NA	NA
pH meter log entry ✓	Graph of IR spectrophotometer	NA	NA
IR log entry NA	LC chromatogram	8 to 67	60
	Tapped density test report	NA	NA
	KF-Autotitra report	NA	NA
	Microbiological test report	68 to 73	6
	Outside laboratory testing report	74 to 99	26
	Additional test report if any	100 to 101	2
	The above product consist of -----101----- pages		Total pages-----101-----

MASTER COPY	
--	--

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.3, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.	Page 1 of 1	Issued by <i>Mauli</i> QA/Date: <i>28/04/2020</i>
	SAMPLING POLICY		No.: F/QAGN/026/01
TITLE	TEST REQUEST FORM	Revision No: 00	
		Review Period: 2 years	
		Effective Date: <i>27/04/19</i>	

Date: <i>28/04/2020</i>	
From (Dept): <i>Packing</i>	To: Q.C. DEPARTMENT
Name of the Item/ Product/ Previous Product* : <i>Amlopenin 5mg/5mg.</i>	Quantity sampled
Batch No.* : <i>G1F200405</i>	1. <i>Finished products</i>
Batch Size* : <i>6.0L</i>	2. <i>4x3x10's</i>
Mfg. Date* : <i>04/2020</i>	3.
Exp. Date* : <i>03/2023.</i>	4.
Stage* : <i>Finished Goods.</i>	Sampled on: <i>28/04/2020</i>
	Sampled by: <i>Ramkumar</i>
	Analyzed By: <i>Raji</i>
	Analytical Reference No.
	<i>FP/280420/01</i>

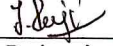
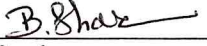
Tests:		
1. <i>As per Specification.</i>		
2. <i>1</i>		
3.		
4.		
<i>84/28/04/2020</i>		
<i>84/28/04/2020</i>	 <i>28/04/2020</i>	 <i>28/04/2020</i>
TRF raised by Sign/Date	TRF given to QC by QA Sign/Date	Head of QC Sign/Date

*wherever not applicable write NA

MASTER COPY	
--	--

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PRIVATE LIMITED R.S. No. 4/3, plot No. 33, Kurumbapet Industrial Estate, Villianur Commune, Pondicherry- 605009				Page 1 of 2	
QUALITY CONTROL	CERTIFICATE OF ANALYSIS				Format No: F/QCGN/022/08	
	FINISHED PRODUCT					
Product Name	:	Amloperin 5 mg / 5 mg (Amlodipine Besilate & Perindopril Erbumine Tablet)				
A.R.No.	:	FP/280420/01				
Batch No.	:	GF200405	Batch Size	:	6.0 L	
Mfg. Date	:	Apr-2020	Exp. Date	:	Mar-2023	
Sampling Date	:	27.04.2020	Sample Qty	:	120 Tablets	
Analysis Date	:	27.04.2020	Release Date	:	06.05.2020	

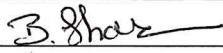
S.No.	TEST	RESULTS	LIMITS
01.	Description	Off white, round, biconvex,uncoated tablet with breakline on one side and plain on other side.	Off white, round, biconvex,uncoated tablet with breakline on one side and plain on other side.
02.	Identification Amlodipine Besylate BP Perindopril Erbumine BP	Complies Complies	The retention time of Amlodipine & perindopril erbumine peak in the chromatogram of sample preparation should correspond to that in chromatogram of the standard preparation as obtained in the assay.
03.	Average weight of tablets	141.65 mg	140 mg $\pm$ 5.0 % (133.0 mg to 147.0 mg)
04.	Uniformity of weight	+2.12 % to -1.41 %	Not more than 2 of the individual weights deviate from the average weight by more than $\pm$ 7.5 % and none deviate by more than $\pm$ 15 % .
05.	Diameter	Min Max Avg. 6.85 mm 6.86 mm 6.85 mm	6.60 mm to 7.00 mm
06.	Thickness	Min Max Avg. 3.35 mm 3.43mm 3.38 mm	2.9 mm to 3.50 mm
07.	Hardness	4.22 kg/cm ²	NLT 3.0 kg/cm ²
08.	Friability	0.07 %	Not More than 1.0 %
09.	Disintegration Time	02 minutes 12 seconds	Not more than 15 minutes
10.	Content Uniformity:		
	Amlodipine Besylate BP equivalent to Amlodipine-5 mg	Min Max Avg. 95.76 % 102.15 % 99.39 %	Not less than 85.0 % and Not more than 115.0 % of labeled claim.
	Perindopril Erbumine BP-5 mg	Min Max Avg. 96.85 % 104.04 % 100.33 %	Not less than 85.0 % and Not more than 115.0 % of labeled claim.

	Tested By	Checked By	Approved By
Sign			
Name	Rajarajeswari	Sankar	Vallarasan
Date	06/05/2020	06/05/2020	06/05/2020

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PRIVATE LIMITED R.S. No. 4/3, plot No. 33, Kurumbapet Industrial Estate, Villianur Commune, Pondicherry- 605009				Page 2 of 2	
QUALITY CONTROL	CERTIFICATE OF ANALYSIS					Format No: F/QCGN/022/08
	FINISHED PRODUCT					
Product Name	:	Amloperin 5 mg / 5 mg (Amlodipine Besilate & Perindopril Erbumine Tablet)				
A.R.No.	:	FP/280420/01				
Batch No.	:	GF200405	Batch Size	:	6.0 L	
Mfg. Date	:	Apr-2020	Exp. Date	:	Mar-2023	
Sampling Date	:	27.04.2020	Sample Qty	:	120 Tablets	
Analysis Date	:	27.04.2020	Release Date	:	06.05.2020	

11.	Dissolution:				
	Amlodipine Besylate BP equivalent to Amlodipine-5 mg	Min 92.92 %	Max 101.47 %	Avg. 95.12 %	Not less than 80.0 % of labeled amount.
	Perindopril Erbumine BP-5 mg	Min 97.46 %	Max 102.12 %	Avg. 98.49 %	Not less than 80 % of labeled amount.
12.	Related substances:				
	Amlodipine Impurity A	Not Detected(ND)			Not more than 1.0 %
	Perindopril Impurity B	Not Detected(ND)			Not more than 1.5 %
	Perindopril Impurity C	Not Detected(ND)			Not more than 0.60 %
	Perindopril Impurity E	Not Detected(ND)			Not more than 0.40 %
	Perindopril Impurity F	Not Detected(ND)			Not more than 1.50 %
	Single maximum unknown impurity	Below Detection Limit(BDL)			Not more than 0.50 %
	Total unknown impurity	Below Detection Limit(BDL)			Not more than 1.0 %
	Total impurities	Below Detection Limit(BDL)			Not more than 5.0 %
13.	Assay: Each uncoated tablet contains:				
	Amlodipine Besylate BP equivalent to Amlodipine-5 mg	100.29 %			Not less than 90.0 % and Not more than 110.0 %
	Perindopril Erbumine BP-5 mg	101.03 %			Not less than 90.0 % and Not more than 110.0 %
14.	Microbiological limits:				
	Total Aerobic Microbial count	20 cfu /g			NMT 1000 cfu/g
	Total Yeasts and mould counts	<10 cfu/g			NMT 100 cfu/g
	E.Coli	Absent			Should be Absent
	Salmonella	Absent			Should be Absent
	S.aureus	Absent			Should be Absent
	P.aeruginosa	Absent			Should be Absent

Remark : The product complies/~~not complies~~ with the prescribed standard of quality with reference to BP/USP and In-house Specification.

	Tested By	Checked By	Approved By
Sign			
Name	Rajarajeswari	Sankar	Vallarasan
Date	06/05/2020	06/05/2020	06/05/2020

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S No. 4/3, Plot No.3, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.	Page 1 of 2 Issued by (QA): Date: <u>14/04/2020</u>
	TESTING AND RELEASE OF INTERMEDIATE AND FINISHED PRODUCTS	SOP No.: F/QCGN/022/05 Revision No.: 00
TITLE:	PHYSICAL PARAMETER OF TABLETS	Review Period: 02 years Effective Date: <u>22/05/19</u>

Name of the Product: <u>Amloperin 5/5</u>	B.No: <u>CR 200405</u>
Appearance: <u>off-white, round, biconvex, uncoated tablet with breakline on one side and plain on other side.</u>	
Weight of 20 tablets: <u>2.833 gm.</u> Average Weight: <u>0.14165 gm</u> Eqv. To: <u>141.65mg</u>	
Weight of individual units:	
1. <u>0.139</u> 2. <u>0.139</u> 3. <u>0.142</u> 4. <u>0.142</u> 5. <u>0.139</u> 6. <u>0.142</u> 7. <u>0.144</u> 8. <u>0.143</u> 9. <u>0.141</u> 10. <u>0.143</u>	11. <u>0.141</u> 12. <u>0.139</u> 13. <u>0.140</u> 14. <u>0.140</u> 15. <u>0.141</u> 16. <u>0.142</u> 17. <u>0.140</u> 18. <u>0.141</u> 19. <u>0.140</u> 20. <u>0.143</u>
Weight of Highest: <u>0.144</u>	Weight of Lowest: <u>0.139</u>
Tablet No: <u>7</u>	Tablet No: <u>1</u>
Percentage: <u>2.12%</u>	Percentage: <u>-1.41%</u>
The tablets <u>complies</u> with the limits to <u>±7.5%</u> of Average Weight.	
Disintegration Time: <u>02</u> Minutes <u>12</u> Seconds.	
Hardness: 1. <u>4.0</u> 2. <u>4.5</u> 3. <u>4.0</u> 4. <u>4.0</u> 5. <u>4.6</u> (In Kg)	
(Limit: _____ Kg to _____ Kg) Average: <u>4.22kg</u>	

MASTER COPY	
--------------------	--

	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S No. 4/3, Plot No.3, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.	Page 2 of 2 Issued by (QA): Date: <u>16/04/2020</u>
	TESTING AND RELEASE OF INTERMEDIATE AND FINISHED PRODUCTS	SOP No.: F/QCGN/022/05 Revision No.: 00
TITLE:	PHYSICAL PARAMETER OF TABLETS	Review Period: 02 years Effective Date: <u>22/05/19</u>

Thickness: 1. <u>3.41</u> 2. <u>3.35</u> 3. <u>3.36</u> 4. <u>3.43</u> 5. <u>3.38</u> (In mm) (Limit: _____ mm to _____ mm) Average: <u>3.38 mm</u>
Diameter: 1. <u>6.85</u> 2. <u>6.85</u> 3. <u>6.86</u> 4. <u>6.85</u> 5. <u>6.86</u> (In mm) (Limit: _____ mm to _____ mm) Average: <u>6.85 mm</u>
Length: 1. <u>NA</u> 2. _____ 3. _____ 4. _____ 5. _____ (In mm) (Limit: <u>NA</u> mm to <u>NA</u> mm) Average: <u>NA</u>
Width: 1. <u>NA</u> 2. _____ 3. _____ 4. _____ 5. _____ (In mm) (Limit: <u>NA</u> mm to <u>NA</u> mm) Average: <u>NA</u>
Friability: A. Weight of Tablets: <u>6.617</u> (Before Operation) B. Weight of Tablets: <u>6.612</u> (After Operation) C. Weight Loss: <u>0.005</u>
(Note: For tablets with an average weight of 0.65 g or less, take a sample of whole tablets corresponding to about 6.5 g and for tablets with an average weight of more than 0.65 g, take a sample of 10 whole tablets)
Calculation: $C/A \times 100 = \frac{0.005}{6.617} \times 100 = 0.07\%$
Limit: (NMT 1.0%)
Analysed By: <u>J. Subh.</u>
Date: <u>29/04/2020</u>
Checked By: <u>D. Shree</u>
Date: <u>30/04/2020</u>

MASTER COPY	
--------------------	--

Vial	Inj Vol (uL)	# of Injs	SampleName	Function	Method Set / Report Method	Run Time (Minutes)
25	10.0	1	BLANK	Inject Samples	AMLOPERIN ASSAY FP_MSET	10.00
26	10.0	5	STD SOLUTION	Inject Standards	AMLOPERIN ASSAY FP_MSET	10.00
27	10.0	1	SPL SOLUTION GF200405(1)	Inject Samples	AMLOPERIN ASSAY FP_MSET	10.00
28	10.0	1	SPL SOLUTION GF200405(2)	Inject Samples	AMLOPERIN ASSAY FP_MSET	10.00
26	10.0	1	STD SOLUTION(B)	Inject Standards	AMLOPERIN ASSAY FP_MSET	10.00
29	10.0	1	GF200405 CU_1	Inject Samples	AMLOPERIN ASSAY FP_MSET	10.00
30	10.0	1	GF200405 CU_2	Inject Samples	AMLOPERIN ASSAY FP_MSET	10.00
31	10.0	1	GF200405 CU_3	Inject Samples	AMLOPERIN ASSAY FP_MSET	10.00
32	10.0	1	GF200405 CU_4	Inject Samples	AMLOPERIN ASSAY FP_MSET	10.00
33	10.0	1	GF200405 CU_5	Inject Samples	AMLOPERIN ASSAY FP_MSET	10.00
26	10.0	1	STD SOLUTION(B)	Inject Standards	AMLOPERIN ASSAY FP_MSET	10.00
34	10.0	1	GF200405 CU_6	Inject Samples	AMLOPERIN ASSAY FP_MSET	10.00
35	10.0	1	GF200405 CU_7	Inject Samples	AMLOPERIN ASSAY FP_MSET	10.00
36	10.0	1	GF200405 CU_8	Inject Samples	AMLOPERIN ASSAY FP_MSET	10.00
37	10.0	1	GF200405 CU_9	Inject Samples	AMLOPERIN ASSAY FP_MSET	10.00
38	10.0	1	GF200405 CU_10	Inject Samples	AMLOPERIN ASSAY FP_MSET	10.00
26	10.0	1	STD SOLUTION(B)	Inject Standards	AMLOPERIN ASSAY FP_MSET	10.00
				Condition Column	WASHING SOLUTION_A_MSET	30.00
				Condition Column	WASHING SOLUTION_B_MSET	30.00
				Condition Column	WASHING SOLUTION_C_MSET	30.00
				Equilibrate	SHUTDOWN_MSET	1.00

B. Shauz
28/04/2020

D. Shauz
28/04/2020



INSTRUMENT METHOD



Instrument Method: AMLOPERIN ASSAY FP_IM

Stored: 4/18/2020 16:13:53 IST

Method Information

Method Comments

Method Modified User RAJI

Method Locked No

Method Id 2527

Old Id

Method Version 1

Method Edit User

Source S/W Info Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505

W2487 Instrument Setup

Type W2487

Instrument Status On

Dual Wavelength False

Pulse Period Seconds 1.0

Pulse Repeat Period Seconds 1.0

W2487 Channel Information

Channel Name 2487Channel 1

Description 210

Use Channels On

Wavelength 210

Output Mode Absorbance A (Ch1)

Data Mode Absorbance A (Ch1)

Sampling Rate 1

Filter Type Hamming

Aufs 2.0000

Time Constant 1.0

AU Offset 0.000

Voltage Offset 0

Polarity +

AutoZero Wavelength True

AutoZero Keypad True

AutoZeroEvent Input True

AutoZero Inject True

Chart Mark Enable True

Ratio AuMinimum 0.1000

Minimum Ratio 0.00

Maximum Ratio 2.00

W2690/5 Instrument Setup

Type W2690/5

Instrument Status On

Channel Name 2690/5

Description 210

Use Channel Monitor On

Monitor Parameter System Pressure

Stroke Volume 50uL (flow rates <= 1.23 mL/min)

Chart Out %A

Syringe Draw Rate Normal

Depth Of Needle 0.0

Degas Mode On

Analysed by: B8haz

Date: 28/04/2020

Checked by: D. Shree
Date: 28/04/2020

Pump Mode Isocratic
 Flow 1.000
 %A 0.0
 %B 0.0
 %C 0.0
 %D 100.0
 High Limit 5000.0
 Low Limit 0.0
 Enable Sample Temp False
 Enable Column Temp True
 Bubble Detect True
 Pre Column Volume 0.0
 Sample Temp Target -1.0
 Sample Temp Range 5.0
 Spurge A 0.0
 Spurge B 0.0
 Spurge C 0.0
 Spurge D 0.0
 Column Temp Target 40.0
 Column Temp Range 5.0
 Flow Ramp 2.00
 Column choice No Change
 Column Equil Minutes 0.00
 Needle Wash Normal
 Switch 1 No Change
 Switch 2 No Change
 Switch 3 No Change
 Switch 4 No Change
 Use Events False
 Solvent A
 Solvent B
 Solvent C
 Solvent D

Revision History

Version 1 4/18/2020 16:13:53 IST User RAJI Created method 'AMLOPERIN ASSAY FP_IM'.

Method Version Summaries

	Method Name	Method Type	Method Comments	Method Date	Method Modified User	Method Locked	Method Id	Old Id
1	AMLOPERIN ASSAY FP_IM	Instrument		4/18/2020 16:13:53 IST	RAJI	No	2527	

Method Version Summaries

Method Version	Source S/W Info
1	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505

Analysed by: *B. Shaz*
 Date: *28/04/2020*

Checked by: *D. Shaz*
 Date: *28/04/2020*

Method Version Summaries

Method Version		Source S/W Info
1	2	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505
2	1	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505

Analysed by: B. Shar
Date: 28/04/2020

Checked by: D. Shar
Date: 28/04/2020

Sample Set Method: 29042020_AMLOPERIN DISSO_SS

	Vial	Inj Vol (uL)	# of Injs	SampleName	Function	Method Set / Report Method	Run Time (Minutes)
1	97	50.0	1	BLANK	Inject Samples	AMLOPERIN_FP_MSET	10.00
2	98	50.0	5	DISSO STANDARD	Inject Standards	AMLOPERIN_FP_MSET	10.00
3	97	50.0	1	BLANK	Inject Samples	AMLOPERIN_FP_MSET	10.00
4	99	50.0	1	GF200405 JAR_1	Inject Samples	AMLOPERIN_FP_MSET	10.00
5	100	50.0	1	GF200405 JAR_2	Inject Samples	AMLOPERIN_FP_MSET	10.00
6	101	50.0	1	GF200405 JAR_3	Inject Samples	AMLOPERIN_FP_MSET	10.00
7	102	50.0	1	GF200405 JAR_4	Inject Samples	AMLOPERIN_FP_MSET	10.00
8	103	50.0	1	GF200405 JAR_5	Inject Samples	AMLOPERIN_FP_MSET	10.00
9	104	50.0	1	GF200405 JAR_6	Inject Samples	AMLOPERIN_FP_MSET	10.00
10	98	50.0	1	DISSO STANDARD(B)	Inject Standards	AMLOPERIN_FP_MSET	10.00
11					Condition Column	WASHING SOLUTION_A_MSET	30.00
12					Condition Column	WASHING SOLUTION_B_MSET	30.00
13					Condition Column	WASHING SOLUTION_C_MSET	30.00
14					Equilibrate	SHUTDOWN_MSET	1.00

B. Ghaz
28/04/2020

D. Ghaz
28/04/2020

	Vial	Inj Vol (uL)	# of Injs	SampleName	Function	Method Set / Report Method	Run Time (Minutes)
1	73	20.0	1	BLANK	Inject Controls	AMLOPERIN_RS_FP_MSET	30.00
2	74	20.0	6	STD SOLUTION	Inject Standards	AMLOPERIN_RS_FP_MSET	10.00
3	73	20.0	1	BLANK	Inject Controls	AMLOPERIN_RS_FP_MSET	30.00
4	75	20.0	1	PLACEBOSOLUTION	Inject Controls	AMLOPERIN_RS_FP_MSET	30.00
5	73	20.0	1	BLANK	Inject Controls	AMLOPERIN_RS_FP_MSET	30.00
6	76	20.0	1	SAMPLE SOLUTION GF200405	Inject Samples	AMLOPERIN_RS_FP_MSET	30.00
7	74	20.0	1	STD SOLUTION (B)	Inject Standards	AMLOPERIN_RS_FP_MSET	10.00
8					Condition Column	WASHING SOLUTION_A_MSET	20.00
9					Condition Column	WASHING SOLUTION_A_MSET	20.00
10					Equilibrate	SHUTDOWN_MSET	0.01

B. Shae
28/04/2020

D. Shae
28/04/2020



INSTRUMENT METHOD



Instrument Method: AMLOPERIN_RS_FP_IM

Stored: 4/28/2020 12:51:40 IST

Method Information

Method Comments

Method Modified User Sankar

Method Locked No

Method Id 5290

Old Id

Method Version 5

Method Edit User

Source S/W Info Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505

W2690/5 Instrument Setup

Type W2690/5
Instrument Status On
Channel Name 2690/5
Description 215
Use Channel Monitor On
Monitor Parameter System Pressure
Stroke Volume 100uL (flow rates <= 3.030 mL/min)
Chart Out %A
Syringe Draw Rate Normal
Depth Of Needle 0.0
Degas Mode On
Pump Mode Isocratic
Flow 2.000
%A 0.0
%B 0.0
%C 0.0
%D 100.0
High Limit 5000.0
Low Limit 0.0
Enable Sample Temp False
Enable Column Temp True
Bubble Detect True
Pre Column Volume 0.0
Sample Temp Target -1.0
Sample Temp Range 5.0
Spurge A 0.0
Spurge B 0.0
Spurge C 0.0
Spurge D 0.0
Column Temp Target 60.0

Analysed by: B. Shari

Date: 28/04/2020

Checked by: D. Shari

Date: 28/04/2020

Column Temp Range 5.0
 Flow Ramp 2.00
 Column choice No Change
 Column Equil Minutes 0.00
 Needle Wash Normal
 Switch 1 No Change
 Switch 2 No Change
 Switch 3 No Change
 Switch 4 No Change
 Use Events False
 Solvent A
 Solvent B
 Solvent C
 Solvent D

W2487 Instrument Setup

Type W2487
 Instrument Status On
 Dual Wavelength False
 Pulse Period Seconds 1.0
 Pulse Repeat Period Seconds 1.0

W2487 Channel Information

Channel Name	2487Channel 1	Voltage Offset	0
Description	215	Polarity	+
Use Channels	On	AutoZero Wavelength	True
Wavelength	215	AutoZero Keypad	True
Output Mode	Absorbance A (Ch1)	AutoZeroEvent Input	True
Data Mode	Absorbance A (Ch1)	AutoZero Inject	True
Sampling Rate	1	Chart Mark Enable	True
Filter Type	Hamming	Ratio AuMinimum	0.1000
Aufs	2.0000	Minimum Ratio	0.00
Time Constant	1.0	Maximum Ratio	2.00
AU Offset	0.000		

Revision History

Version 5 4/28/2020 12:51:40 IST User Sankar
 Version 4 4/28/2020 13:57:10 IST User RAJI
 Version 3 4/28/2020 13:53:57 IST User RAJI
 Version 2 4/27/2020 12:48:08 IST User RAJI
 Version 1 4/23/2020 15:32:34 IST User Sankar Created method 'AMLOPERIN_RS_FP_IM'.

Method Version Summaries

	Method Name	Method Type	Method Comments	Method Date	Method Modified User	Method Locked	Method Id	Old Id
1	AMLOPERIN_RS_FP_IM	Instrument		4/28/2020 12:51:40 IST	Sankar	No	5290	
2	AMLOPERIN_RS_FP_IM	Instrument		4/28/2020 13:57:10 IST	RAJI	No	4744	
3	AMLOPERIN_RS_FP_IM	Instrument		4/28/2020 13:53:57 IST	RAJI	No	4742	
4	AMLOPERIN_RS_FP_IM	Instrument		4/27/2020 12:48:08 IST	RAJI	No	4429	
5	AMLOPERIN_RS_FP_IM	Instrument		4/23/2020 15:32:34 IST	Sankar	No	4019	

Analysed by: B. Shaz
 Date: 28/04/2020

Checked by: D. Shaz
 Date: 28/04/2020

Method Version Summaries

	Method Version	Source S/W Info
1	5	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505
2	4	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505
3	3	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505
4	2	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505
5	1	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505

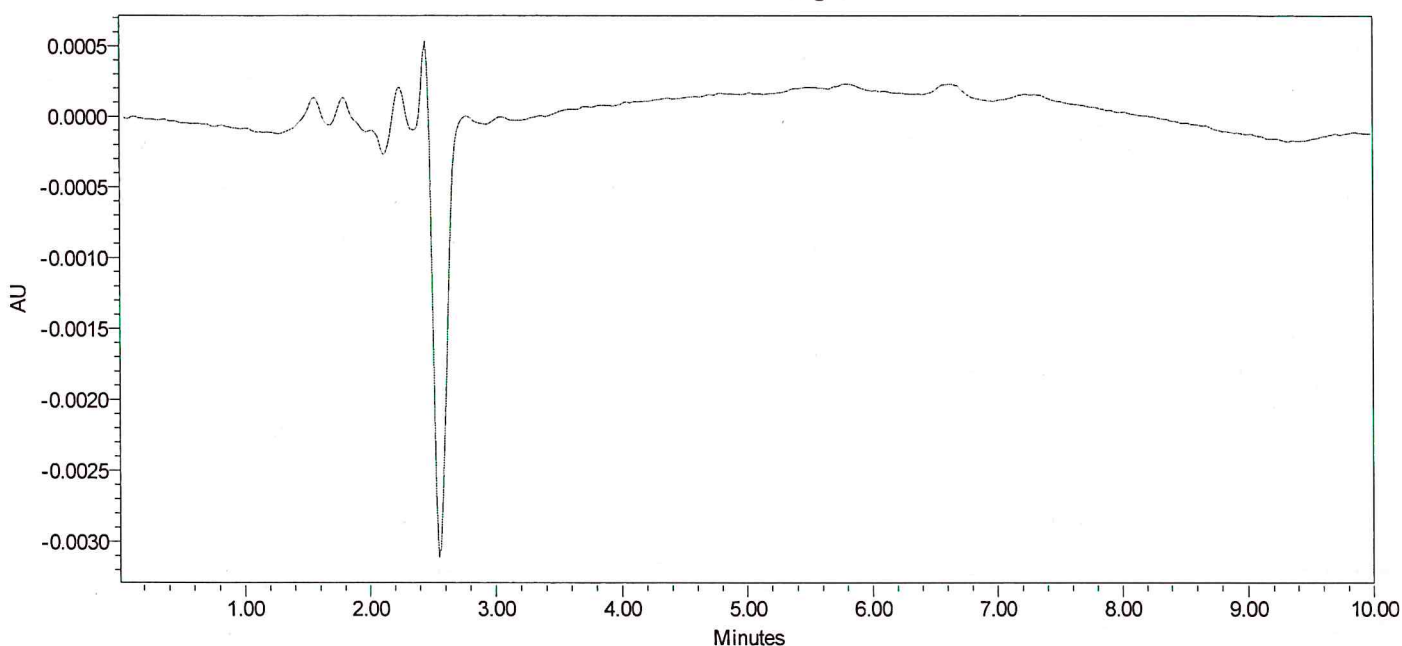
Analysed by: B. Shree
Date: 28/04/2020

Checked by: D. Shree
Date: 28/04/2020

SAMPLE INFORMATION

Sample Name:	BLANK	Acquired By:	Sankar
Sample Type:	Unknown	Sample Set Name	28042020_AMLOPIRIN_FP_ASSAY_SS
Vial:	25	Acq. Method Set:	AMLOPERIN ASSAY FP_MSET
Injection #:	1	Processing Method	AMLOPERIN_10_10_FP_PM
Injection Volume:	10.00 ul	Channel Name:	2487Channel 1
Run Time:	10.0 Minutes	Proc. Chnl. Descr.:	210
Date Acquired:	4/28/2020 12:58:20 IST		
Date Processed:	4/28/2020 14:11:22 IST		

Auto-Scaled Chromatogram



Peak Results

	Name	RT	Area	% Area
1	PERINDOPRIL ERBUMINE	3.820		
2	AMLODIPINE BESYLATE	5.674		

Analysed by: *B. Shau*
Date: *29/04/2020*

Checked by: *D. Jey*
Date: *30/04/2020*



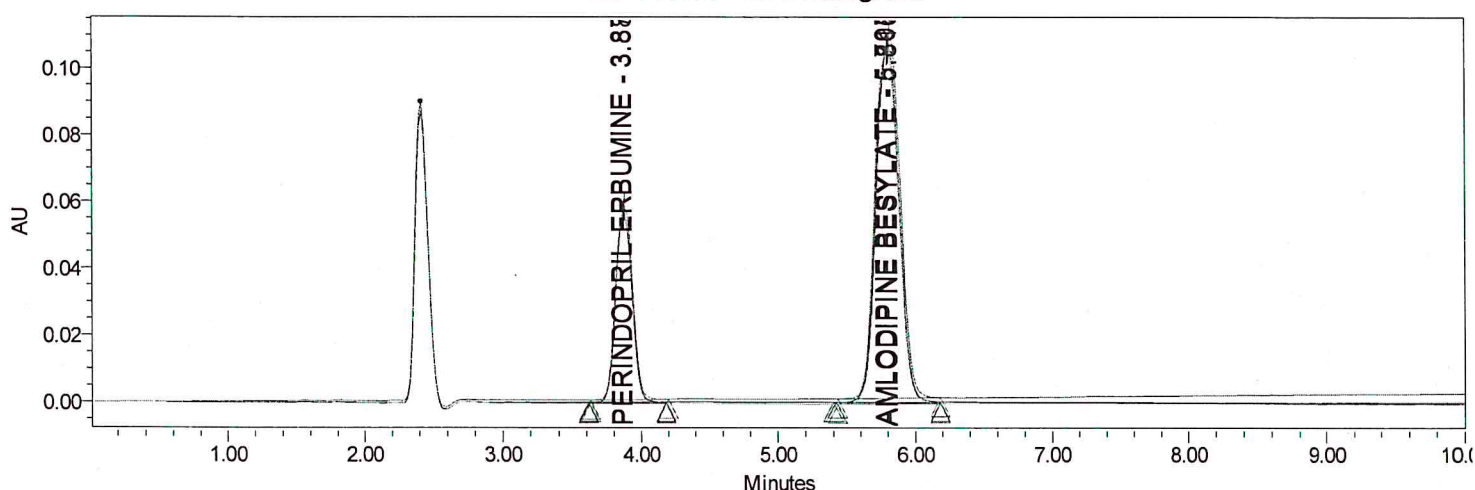
RSD REPORT



SAMPLE INFORMATION

Sample Name: STD SOLUTION
 Sample Type: Standard
 Vial: 26
 Injection #: 1, 2, 4, 5, 3
 Injection Volume: 10.00 ul
 Run Time: 10.0 Minutes
 Acquired By: Sankar
 Sample Set Name: 28042020 AMLOPIRIN FP ASSAY SS
 Acq. Method Set: AMLOPERIN ASSAY FP_MSET
 Processing Method: AMLOPERIN_10_10_FP_PM
 Channel Name: 2487Channel 1
 Proc. Chnl. Descr.: 210
 Date Acquired: 4/28/2020 13:09:11 IST, 4/28/2020 13:19:58 IST, 4/28/2020 13:30:45 IST, 4/28/2020
 Date Processed: 4/28/2020 14:09:34 IST, 4/28/2020 14:09:44 IST, 4/28/2020 14:09:52 IST, 4/28/2020

Auto-Scaled Chromatogram



Peak Name: AMLODIPINE BESYLATE

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count	USP Resolution
1	AMLODIPINE BESYLATE	1	5.816	1283254	0.99	5963	7.44
2	AMLODIPINE BESYLATE	2	5.808	1276175	0.99	5816	7.41
3	AMLODIPINE BESYLATE	3	5.807	1277508	0.99	5747	7.38
4	AMLODIPINE BESYLATE	4	5.803	1281701	1.00	5712	7.34
5	AMLODIPINE BESYLATE	5	5.797	1278400	1.00	5742	7.31
Mean			5.806	1279408	0.99	5796.02	7.38
Std. Dev.			0.007	2963.587	0.01	100.64	0.05
% RSD			0.117	0.232	0.59	1.74	0.69

Analysed by: *B. Shan*
 Date: *29/04/2020*

Checked by: *D. Dhan*
 Date: *30/04/2020*

Peak Name: PERINDOPRIL ERBUMINE

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count
1	PERINDOPRIL ERBUMINE	1	3.881	481300	1.02	5106
2	PERINDOPRIL ERBUMINE	2	3.877	478170	1.03	4916
3	PERINDOPRIL ERBUMINE	3	3.877	478673	1.03	4885
4	PERINDOPRIL ERBUMINE	4	3.875	480383	1.03	4867
5	PERINDOPRIL ERBUMINE	5	3.872	478614	1.03	4926
Mean			3.876	479428	1.03	4940.07
Std. Dev.			0.003	1344.583	0.01	95.66
% RSD			0.081	0.280	0.59	1.94

Analysed by: *B.ghar*
Date: 29/04/2020

Checked by: *D.ghar*
Date: 30/04/2020



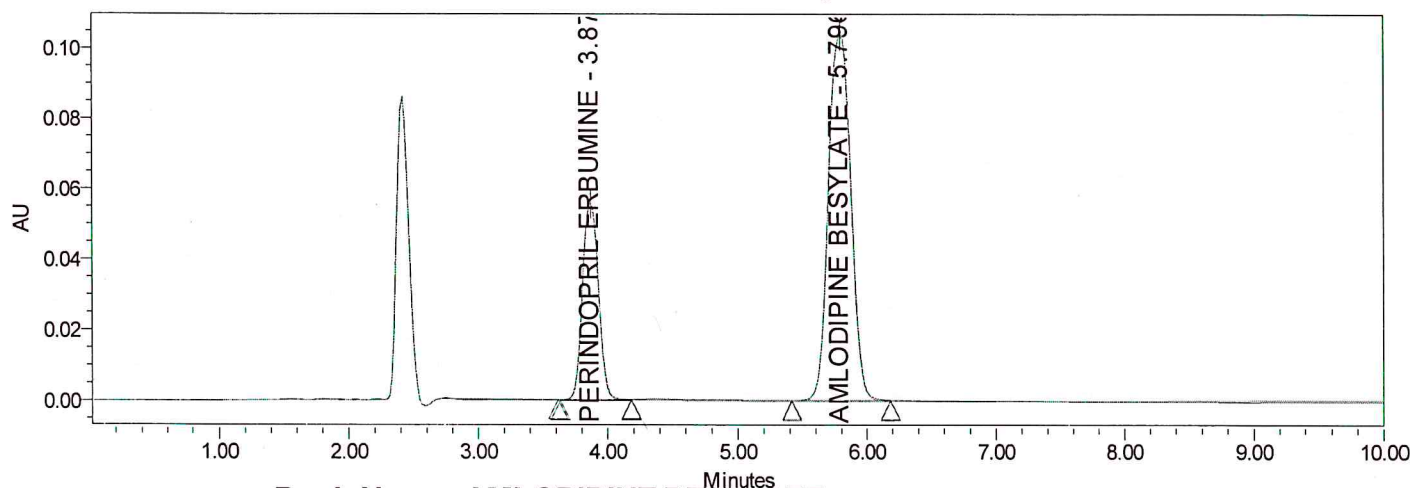
RSD REPORT



SAMPLE INFORMATION

Sample Name: SPL SOLUTION GF200405(2), SPL SOLUTION Acquired By: Sankar
 Sample Type: Unknown Sample Set Name 28042020 AMLOPIRIN FP ASSAY SS
 Vial: 28, 27 Acq. Method Set: AMLOPERIN ASSAY FP_MSET
 Injection #: 1 Processing Method AMLOPERIN_10_10_FP_PM
 Injection Volume: 10.00 ul Channel Name: 2487Channel 1
 Run Time: 10.0 Minutes Proc. Chnl. Descr.: 210
 Date Acquired: 4/28/2020 14:03:25 IST, 4/28/2020 14:14:16 IST
 Date Processed: 4/28/2020 14:25:15 IST, 4/28/2020 14:25:28 IST

Auto-Scaled Chromatogram



Peak Name: AMLODIPINE BESYLATE

	Peak Name	Injection	RT	Area
1	AMLODIPINE BESYLATE	1	5.796	1274415
2	AMLODIPINE BESYLATE	1	5.794	1273060
Mean			5.795	1273738
Std. Dev.			0.001	958.324
% RSD			0.0	0.1

Peak Name: PERINDOPRIL ERBUMINE

	Peak Name	Injection	RT	Area
1	PERINDOPRIL ERBUMINE	1	3.872	477972
2	PERINDOPRIL ERBUMINE	1	3.872	477627
Mean			3.872	477799
Std. Dev.			0.000	244.115
% RSD			0.0	0.1

Analysed by: B. Shree
 Date: 29/04/2020

Checked by: D. Shree
 Date: 30/04/2020



RSD REPORT

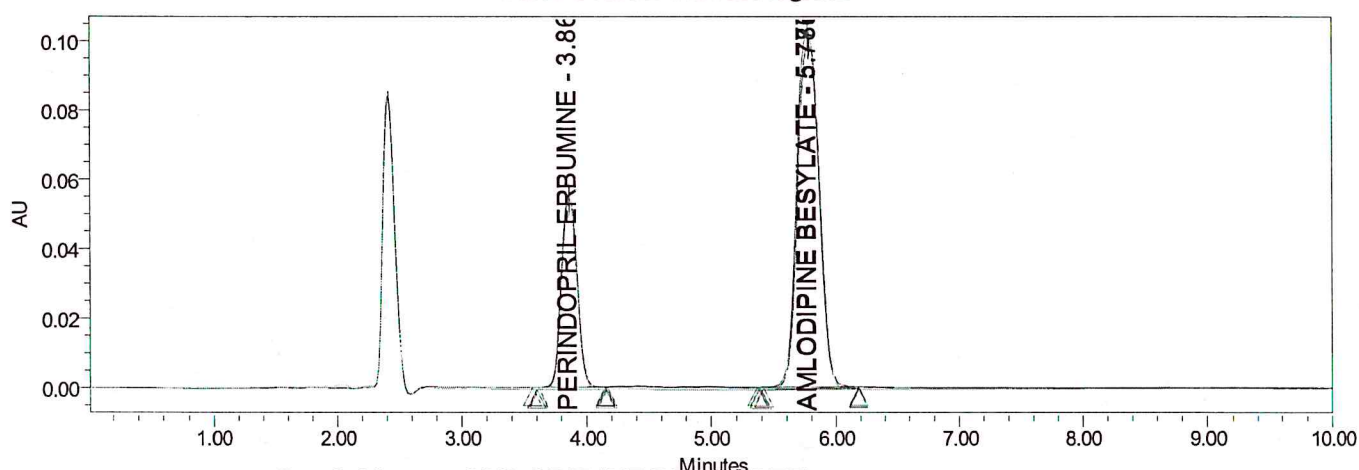


SAMPLE INFORMATION

Sample Name: GF200405 CU_2, GF200405 CU_1, GF200405 Acquired By: Sankar
 Sample Type: Unknown Sample Set Name 28042020 AMLOPIRIN FP ASSAY SS
 Vial: 29, 31, 33, 32, 30 Acq. Method Set: AMLOPERIN ASSAY FP_MSET
 Injection #: 1 Processing Method AMLOPERIN_10_10_FP_PM
 Injection Volume: 10.00 ul Channel Name: 2487Channel 1
 Run Time: 10.0 Minutes Proc. Chnl. Descr.: 210

Date Acquired: 4/28/2020 14:36:02 IST, 4/28/2020 14:46:53 IST, 4/28/2020 14:57:46 IST, 4/28/2020
 Date Processed: 4/28/2020 16:41:39 IST, 4/28/2020 16:41:44 IST, 4/28/2020 16:41:48 IST, 4/28/2020

Auto-Scaled Chromatogram



Peak Name: AMLODIPINE BESYLATE

	Peak Name	Injection	RT	Area
1	AMLODIPINE BESYLATE	1	5.786	1230328
2	AMLODIPINE BESYLATE	1	5.777	1278293
3	AMLODIPINE BESYLATE	1	5.789	1235435
4	AMLODIPINE BESYLATE	1	5.780	1246034
5	AMLODIPINE BESYLATE	1	5.775	1284837
Mean			5.781	1254985
Std. Dev.			0.006	25023.776
% RSD			0.1	2.0

Peak Name: PERINDOPRIL ERBUMINE

	Peak Name	Injection	RT	Area
1	PERINDOPRIL ERBUMINE	1	3.863	480539
2	PERINDOPRIL ERBUMINE	1	3.864	479198
3	PERINDOPRIL ERBUMINE	1	3.867	462420

Analysed by: B. Shave
 Date: 29/04/2020

Checked by: D. Shave
 Date: 30/04/2020

Peak Name: PERINDOPRIL ERBUMINE

	Peak Name	Injection	RT	Area
4	PERINDOPRIL ERBUMINE	1	3.869	469413
5	PERINDOPRIL ERBUMINE	1	3.864	463263
Mean			3.865	470966
Std. Dev.			0.003	8576.049
% RSD			0.1	1.8

Analysed by: B. Shave
Date: 29/04/2020

Checked by: D. Shave
Date: 30/04/2020



RSD REPORT

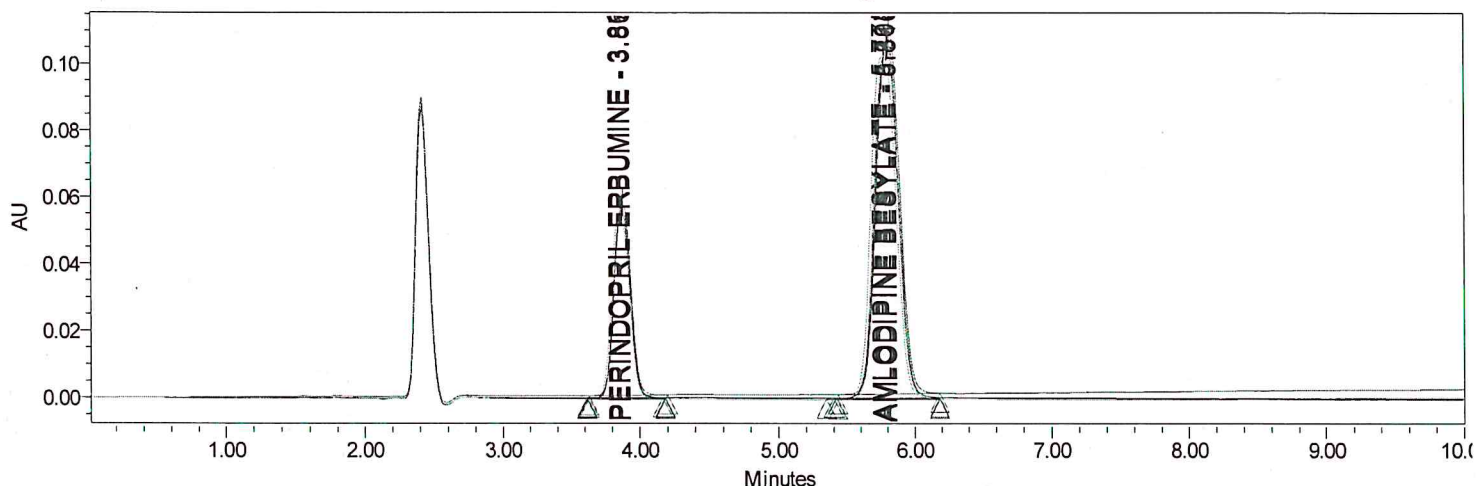


SAMPLE INFORMATION

Sample Name: STD SOLUTION, STD SOLUTION(B) Acquired By: Sankar
 Sample Type: Standard Sample Set Name 28042020 AMLOPIRIN FP ASSAY SS
 Vial: 26 Acq. Method Set: AMLOPERIN ASSAY FP_MSET
 Injection #: 1, 2, 4, 5, 3 Processing Method AMLOPERIN_10_10_FP_PM
 Injection Volume: 10.00 ul Channel Name: 2487Channel 1
 Run Time: 10.0 Minutes Proc. Chnl. Descr.: 210

Date Acquired: 4/28/2020 13:09:11 IST, 4/28/2020 13:19:58 IST, 4/28/2020 13:30:45 IST, 4/28/2020
 Date Processed: 4/28/2020 14:09:34 IST, 4/28/2020 14:09:44 IST, 4/28/2020 14:09:52 IST, 4/28/2020

Auto-Scaled Chromatogram



Peak Name: AMLODIPINE BESYLATE

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count	USP Resolution
1	AMLODIPINE BESYLATE	1	5.775	1311121	1.03	5347	7.09
2	AMLODIPINE BESYLATE	1	5.816	1283254	0.99	5963	7.44
3	AMLODIPINE BESYLATE	2	5.808	1276175	0.99	5816	7.41
4	AMLODIPINE BESYLATE	3	5.807	1277508	0.99	5747	7.38
5	AMLODIPINE BESYLATE	4	5.803	1281701	1.00	5712	7.34
6	AMLODIPINE BESYLATE	5	5.797	1278400	1.00	5742	7.31
Mean			5.801	1284693	1.00	5721.18	7.33
Std. Dev.			0.014	13215.369	0.02	204.23	0.12
% RSD			0.245	1.029	1.60	3.57	1.70

Analysed by: B. Shari
 Date: 29/04/2020

Checked by: D. Shari
 Date: 30/04/2020

Peak Name: PERINDOPRIL ERBUMINE

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count
1	PERINDOPRIL ERBUMINE	1	3.881	481300	1.02	5106
2	PERINDOPRIL ERBUMINE	1	3.862	492955	1.05	4632
3	PERINDOPRIL ERBUMINE	2	3.877	478170	1.03	4916
4	PERINDOPRIL ERBUMINE	3	3.877	478673	1.03	4885
5	PERINDOPRIL ERBUMINE	4	3.875	480383	1.03	4867
6	PERINDOPRIL ERBUMINE	5	3.872	478614	1.03	4926
Mean			3.874	481682	1.03	4888.68
Std. Dev.			0.007	5651.753	0.01	152.20
% RSD			0.169	1.173	1.05	3.11

Analysed by: B. Shaw
Date: 29/01/2020

Checked by: D. Singh
Date: 30/01/2020



RSD REPORT

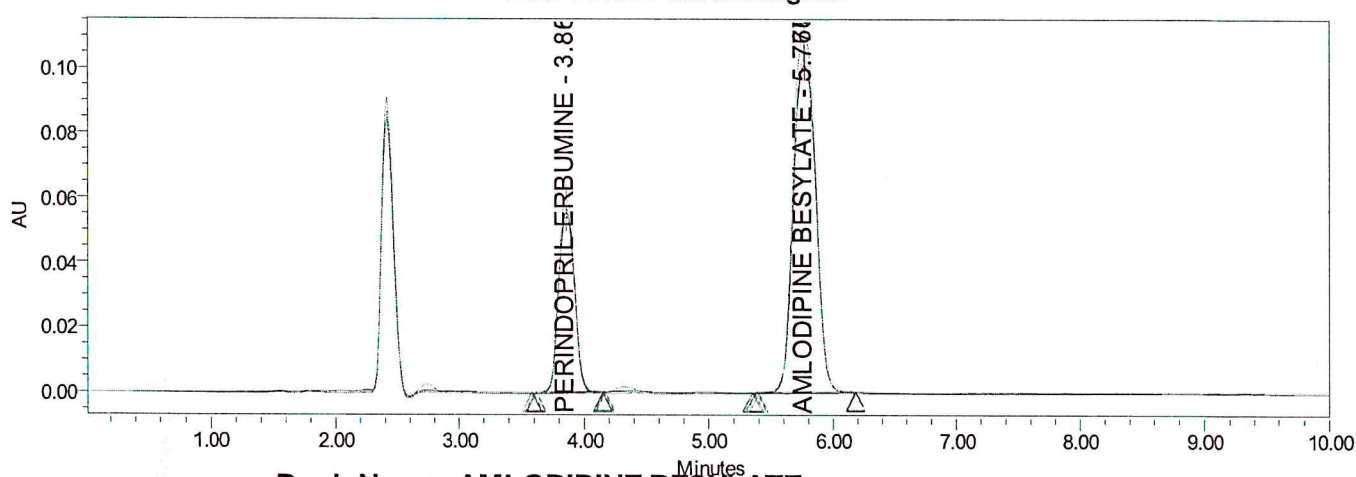


SAMPLE INFORMATION

Sample Name: GF200405 CU_7, GF200405 CU_8, GF200405 Acquired By: Sankar
 Sample Type: Unknown Sample Set Name 28042020 AMLOPIRIN FP ASSAY SS
 Vial: 36, 37, 38, 34, 35 Acq. Method Set: AMLOPERIN ASSAY FP_MSET
 Injection #: 1 Processing Method AMLOPERIN_10_10_FP_PM
 Injection Volume: 10.00 ul Channel Name: 2487Channel 1
 Run Time: 10.0 Minutes Proc. Chnl. Descr.: 210

Date Acquired: 4/28/2020 15:41:12 IST, 4/28/2020 15:52:03 IST, 4/28/2020 16:02:54 IST, 4/28/2020
 Date Processed: 4/28/2020 16:41:58 IST, 4/28/2020 16:42:01 IST, 4/28/2020 16:42:05 IST, 4/28/2020

Auto-Scaled Chromatogram



Peak Name: AMLODIPINE BESYLATE

	Peak Name	Injection	RT	Area
1	AMLODIPINE BESYLATE	1	5.770	1312458
2	AMLODIPINE BESYLATE	1	5.767	1290117
3	AMLODIPINE BESYLATE	1	5.771	1282710
4	AMLODIPINE BESYLATE	1	5.771	1297133
5	AMLODIPINE BESYLATE	1	5.768	1311857
Mean			5.770	1298855
Std. Dev.			0.002	13172.63
% RSD			0.0	1.01

Peak Name: PERINDOPRIL ERBUMINE

	Peak Name	Injection	RT	Area
1	PERINDOPRIL ERBUMINE	1	3.859	486011
2	PERINDOPRIL ERBUMINE	1	3.859	482262
3	PERINDOPRIL ERBUMINE	1	3.860	496742

Analysed by: B. Shiva
 Date: 29/04/2020

Checked by: D. Shiva
 Date: 30/04/2020

Peak Name: PERINDOPRIL ERBUMINE

	Peak Name	Injection	RT	Area
4	PERINDOPRIL ERBUMINE	1	3.861	482384
5	PERINDOPRIL ERBUMINE	1	3.860	489583
Mean			3.860	487396
Std. Dev.			0.001	6031.729
% RSD			0.0	1.2

Analysed by: B. Shan
Date: 29/04/2020

Checked by: Jyoti
Date: 30/04/2020



RSD REPORT

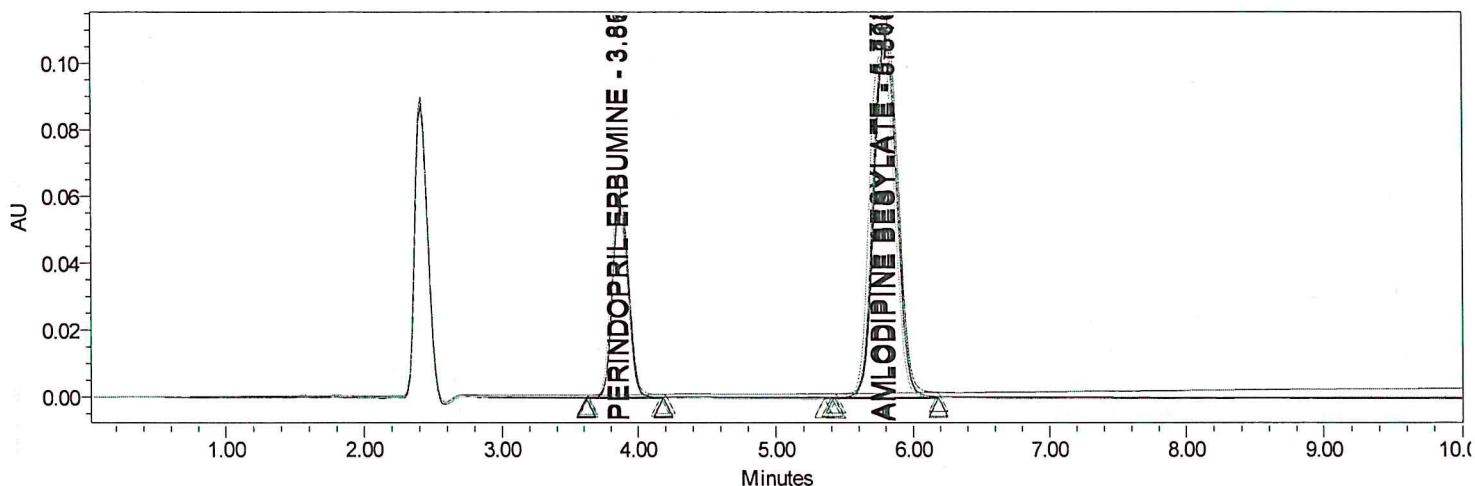


SAMPLE INFORMATION

Sample Name: STD SOLUTION, STD SOLUTION(B) Acquired By: Sankar
 Sample Type: Standard Sample Set Name 28042020 AMLOPIRIN FP ASSAY SS
 Vial: 26 Acq. Method Set: AMLOPERIN ASSAY FP_MSET
 Injection #: 1, 2, 4, 5, 3 Processing Method AMLOPERIN_10_10_FP_PM
 Injection Volume: 10.00 ul Channel Name: 2487Channel 1
 Run Time: 10.0 Minutes Proc. Chnl. Descr.: 210

Date Acquired: 4/28/2020 13:09:11 IST, 4/28/2020 13:19:58 IST, 4/28/2020 13:30:45 IST, 4/28/2020
 Date Processed: 4/28/2020 14:09:34 IST, 4/28/2020 14:09:44 IST, 4/28/2020 14:09:52 IST, 4/28/2020

Auto-Scaled Chromatogram



Peak Name: AMLODIPINE BESYLATE

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count	USP Resolution
1	AMLODIPINE BESYLATE	1	5.775	1311121	1.03	5347	7.09
2	AMLODIPINE BESYLATE	1	5.816	1283254	0.99	5963	7.44
3	AMLODIPINE BESYLATE	2	5.808	1276175	0.99	5816	7.41
4	AMLODIPINE BESYLATE	3	5.807	1277508	0.99	5747	7.38
5	AMLODIPINE BESYLATE	4	5.803	1281701	1.00	5712	7.34
6	AMLODIPINE BESYLATE	5	5.797	1278400	1.00	5742	7.31
Mean			5.801	1284693	1.00	5721.18	7.33
Std. Dev.			0.014	13215.369	0.02	204.23	0.12
% RSD			0.245	1.029	1.60	3.57	1.70

Analysed by: B. Shave
 Date: 29/04/2020

Checked by: D. Shave
 Date: 30/04/2020

Peak Name: PERINDOPRIL ERBUMINE

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count
1	PERINDOPRIL ERBUMINE	1	3.881	481300	1.02	5106
2	PERINDOPRIL ERBUMINE	1	3.862	492955	1.05	4632
3	PERINDOPRIL ERBUMINE	2	3.877	478170	1.03	4916
4	PERINDOPRIL ERBUMINE	3	3.877	478673	1.03	4885
5	PERINDOPRIL ERBUMINE	4	3.875	480383	1.03	4867
6	PERINDOPRIL ERBUMINE	5	3.872	478614	1.03	4926
Mean			3.874	481682	1.03	4888.68
std. Dev.			0.007	5651.753	0.01	152.20
% RSD			0.169	1.173	1.05	3.11

Analysed by: *B. Shree*
Date: *29/04/2020*

Checked by: *D. Shree*
Date: *30/04/2020*



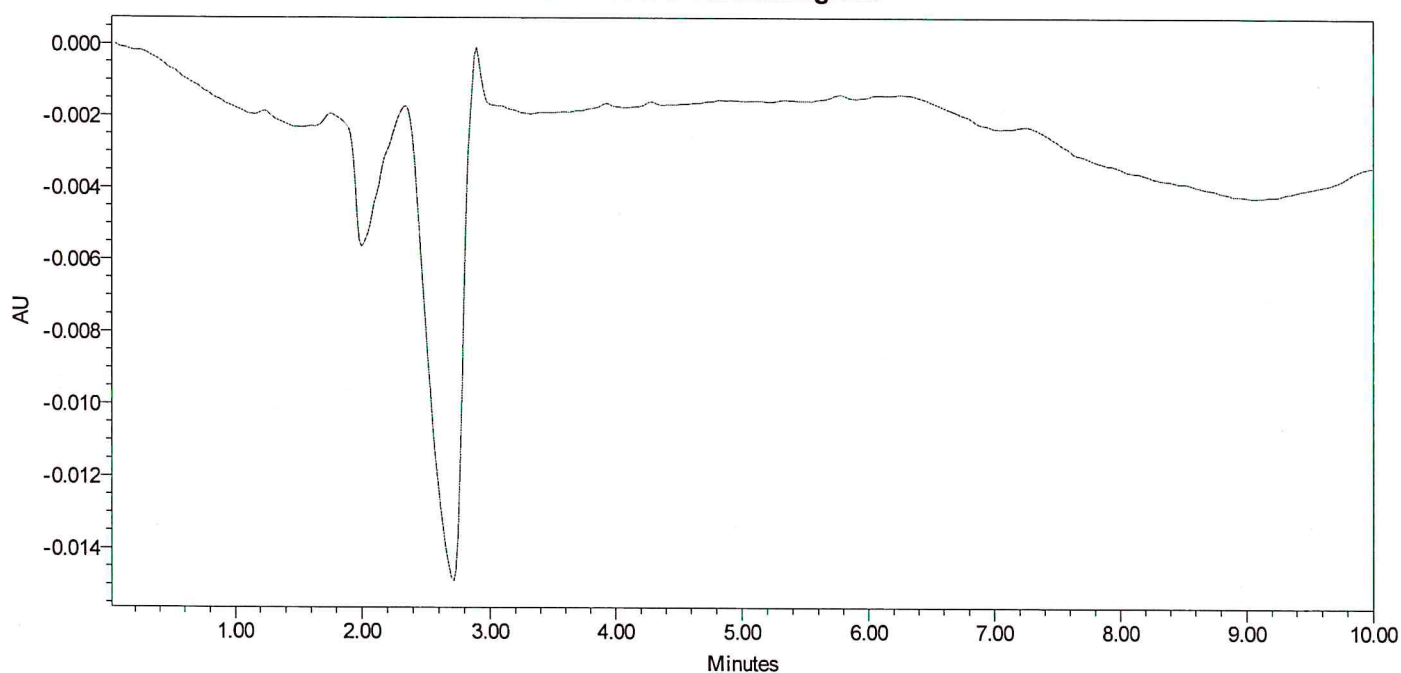
CHROMATOGRAPHIC DATA



SAMPLE INFORMATION

Sample Name:	BLANK	Acquired By:	RAJI
Sample Type:	Unknown	Sample Set Name	29042020_AMILOPERIN DISSO_SS
Vial:	97	Acq. Method Set:	AMLOPERIN_FP_MSET
Injection #:	1	Processing Method	AMLOPERIN_FP_PM
Injection Volume:	50.00 ul	Channel Name:	2487Channel 1
Run Time:	10.0 Minutes	Proc. Chnl. Descr.:	210
Date Acquired:	4/29/2020 14:22:20 IST		
Date Processed:	4/29/2020 16:01:01 IST		

Auto-Scaled Chromatogram



Peak Results

	Name	RT	Area	% Area
1	PERINDOPRIL ERBUMINE	3.919		
2	AMLODIPINE BESYLATE	5.764		

Analysed by: *B. Shave*
Date: 29/04/2020

Checked by: *J. Shave*
Date: 30/04/2020

Reported by User: RAJARAJESWARI (RAJI)
Report Method: CHROMATOGRAPHIC DATA
Report Method ID5069
Page: 1 of 1

Project Name: 2020\QC-HPL-001\APR-2020
Printed Date: 4/29/2020
Printed Time: 16:07:25 Asi



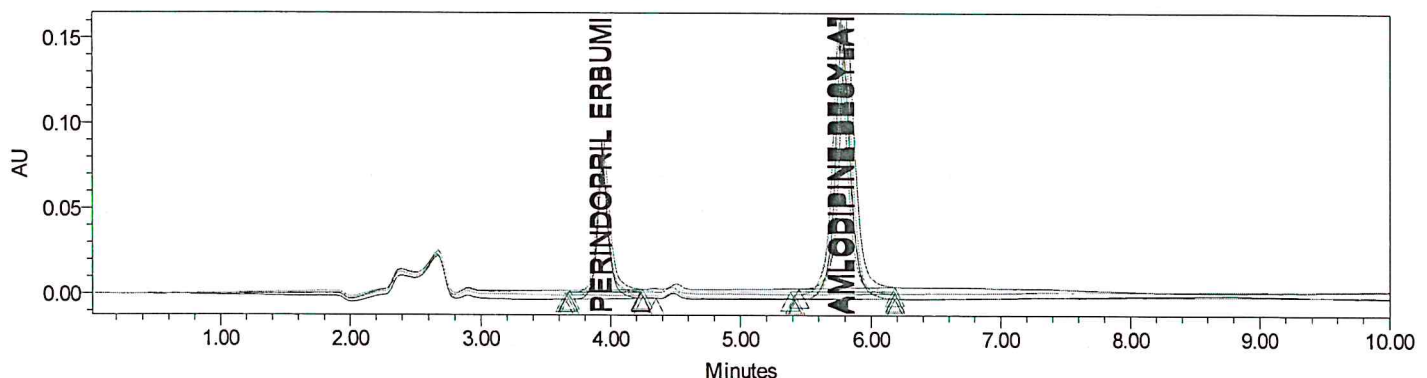
RSD REPORT



SAMPLE INFORMATION

Sample Name: DISSO STANDARD
 Sample Type: Standard
 /ial: 98
 Injection #: 1, 2, 4, 5, 3
 Injection Volume: 50.00 ul
 Run Time: 10.0 Minutes
 Acquired By: RAJI
 Sample Set Name: 29042020_AMLOPERIN DISSO_SS
 Acq. Method Set: AMLOPERIN_FP_MSET
 Processing Method: AMLOPERIN_FP_PM
 Channel Name: 2487Channel 1
 Proc. Chnl. Descr.: 210
 Date Acquired: 4/29/2020 13:26:43 IST, 4/29/2020 13:37:46 IST, 4/29/2020 13:48:49 IST, 4/29/2020 14:00:06 IST, 4/29/2020 14:11:09 IST
 Date Processed: 4/29/2020 14:27:06 IST, 4/29/2020 14:27:10 IST, 4/29/2020 14:27:13 IST, 4/29/2020 14:27:18 IST, 4/29/2020 14:27:22 IST

Auto-Scaled Chromatogram



Peak Name: AMLODIPINE BESYLATE

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count	USP Resolution
1	AMLODIPINE BESYLATE	1	5.815	1297240	1.02	11955	9.83
2	AMLODIPINE BESYLATE	2	5.796	1298443	1.03	12025	9.68
3	AMLODIPINE BESYLATE	3	5.781	1297197	1.02	11948	9.72
4	AMLODIPINE BESYLATE	4	5.770	1298316	1.04	12224	9.71
5	AMLODIPINE BESYLATE	5	5.758	1291328	1.04	12287	9.55
Mean			5.784	1296505	1.03	12087.83	9.70
Std. Dev.			0.022	2952.006	0.01	157.74	0.10
% RSD			0.4	0.2	0.87	1.30	1.05

Peak Name: PERINDOPRIL ERBUMINE

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count
1	PERINDOPRIL ERBUMINE	1	3.951	513568	1.12	9616

Analysed by: *[Signature]*
 Date: 29/04/2020

Checked by: *[Signature]*
 Date: 30/04/2020

Peak Name: PERINDOPRIL ERBUMINE

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count
2	PERINDOPRIL ERBUMINE	2	3.944	512552	1.14	9670
3	PERINDOPRIL ERBUMINE	3	3.937	516200	1.12	9636
4	PERINDOPRIL ERBUMINE	4	3.933	512687	1.12	9673
5	PERINDOPRIL ERBUMINE	5	3.929	512705	1.13	9658
Mean			3.939	513542	1.13	9650.35
Std. Dev.			0.009	1539.291	0.01	24.38
% RSD			0.2	0.3	0.95	0.25

Analysed by: *[Signature]*
Date: 29/04/2020

Checked by: *[Signature]*
Date: 30/04/2020



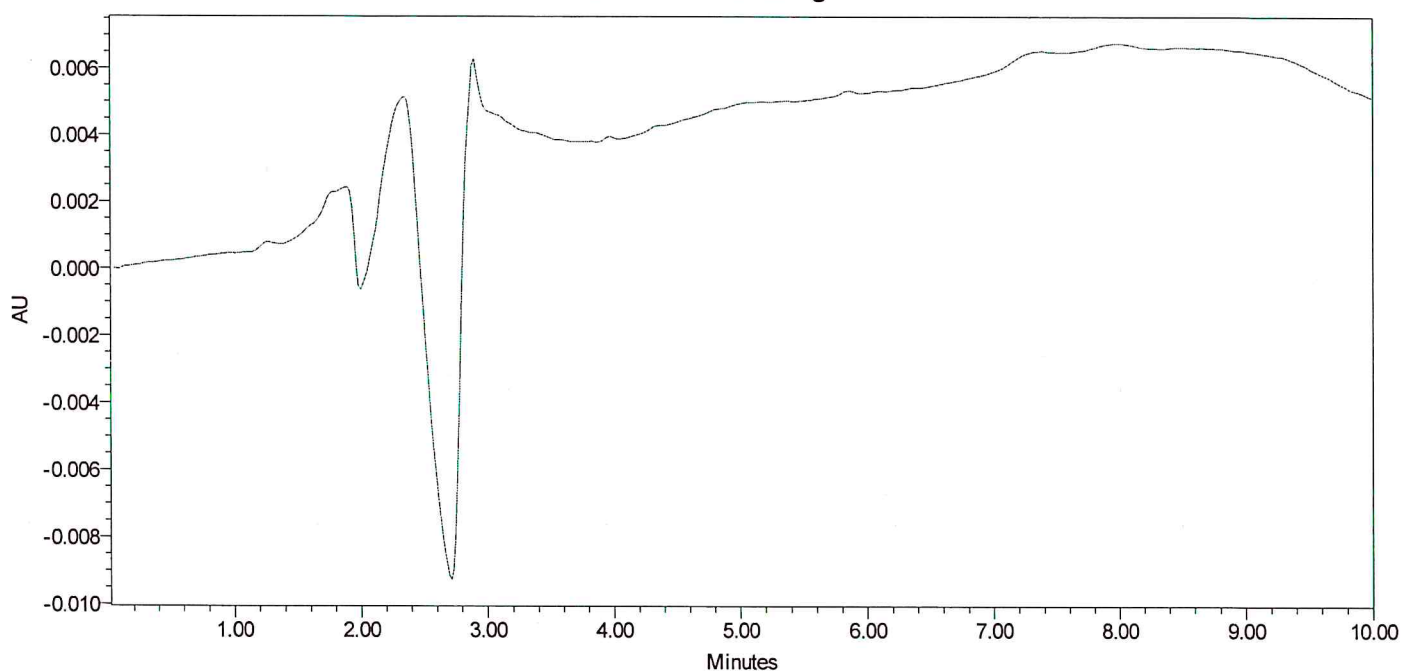
CHROMATOGRAPHIC DATA



SAMPLE INFORMATION

Sample Name:	BLANK	Acquired By:	RAJI
Sample Type:	Unknown	Sample Set Name	29042020_AMILOPERIN DISSO_SS
Vial:	97	Acq. Method Set:	AMLOPERIN_FP_MSET
Injection #:	1	Processing Method	AMLOPERIN_FP_PM
Injection Volume:	50.00 ul	Channel Name:	2487Channel 1
Run Time:	10.0 Minutes	Proc. Chnl. Descr.:	210
Date Acquired:	4/29/2020 13:20:07 IST		
Date Processed:	4/29/2020 14:26:42 IST		

Auto-Scaled Chromatogram



Peak Results

	Name	RT	Area	% Area
1	PERINDOPRIL ERBUMINE	3.919		
2	AMLODIPINE BESYLATE	5.764		

Analysed by: *[Signature]*
Date: 29/04/2020

Checked by: *[Signature]*
Date: 30/04/2020



RSD REPORT



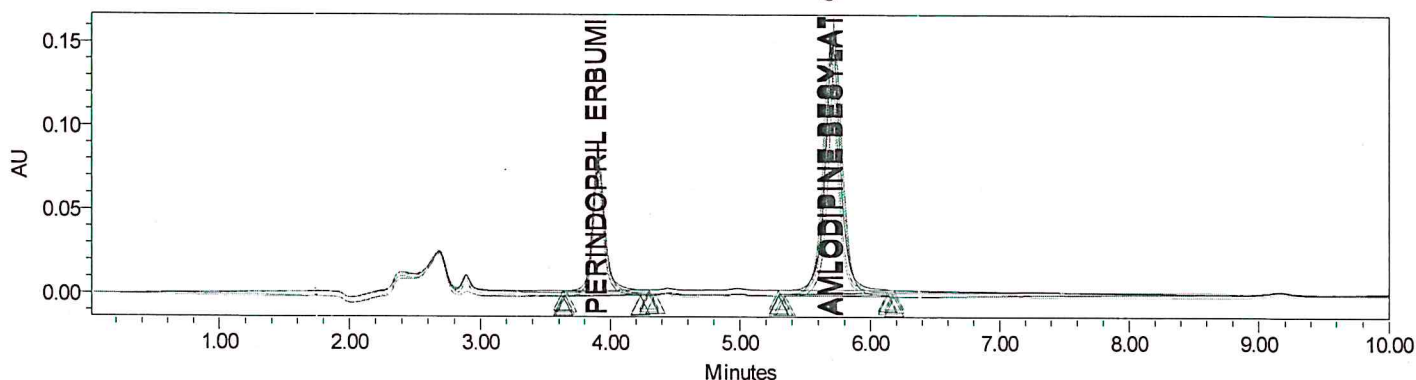
SAMPLE INFORMATION

Sample Name: GF200405 JAR_2, GF200405 JAR_6, GF200405 Acquired By: RAJI
 Sample Type: Unknown Sample Set Name 29042020_AMILOPERIN DISSO_SS
 Vial: 99, 101, 100, 102, 103, 104 Acq. Method Set: AMLOPERIN_FP_MSET
 Injection #: 1 Processing Method: AMLOPERIN_FP_PM
 Injection Volume: 50.00 ul Channel Name: 2487Channel 1
 Run Time: 10.0 Minutes Proc. Chnl. Descr.: 210

Date Acquired: 4/29/2020 14:33:27 IST, 4/29/2020 14:44:34 IST, 4/29/2020 14:55:55 IST, 4/29/2020 15:07:16 IST, 4/29/2020 15:18:37 IST, 4/29/2020 15:29:59 IST

Date Processed: 4/29/2020 16:01:30 IST, 4/29/2020 16:01:34 IST, 4/29/2020 16:01:38 IST, 4/29/2020 16:01:42 IST, 4/29/2020 16:01:45 IST, 4/29/2020 16:01:48 IST

Auto-Scaled Chromatogram



Peak Name: AMLODIPINE BESYLATE

	Peak Name	Injection	RT	Area
1	AMLODIPINE BESYLATE	1	5.710	1236254
2	AMLODIPINE BESYLATE	1	5.695	1218643
3	AMLODIPINE BESYLATE	1	5.700	1225166
4	AMLODIPINE BESYLATE	1	5.685	1211739
5	AMLODIPINE BESYLATE	1	5.719	1323197
6	AMLODIPINE BESYLATE	1	5.733	1227510
Mean			5.707	1240418
Std. Dev.			0.017	41389.875
% RSD			0.3	3.3

Analysed by: *[Signature]*
 Date: 29/04/2020

Checked by: *[Signature]*
 Date: 30/04/2020

Peak Name: PERINDOPRIL ERBUMINE

	Peak Name	Injection	RT	Area
1	PERINDOPRIL ERBUMINE	1	3.901	510830
2	PERINDOPRIL ERBUMINE	1	3.907	511038
3	PERINDOPRIL ERBUMINE	1	3.912	534432
4	PERINDOPRIL ERBUMINE	1	3.897	510036
5	PERINDOPRIL ERBUMINE	1	3.902	512065
6	PERINDOPRIL ERBUMINE	1	3.917	514096
Mean			3.906	515416
Std. Dev.			0.008	9420.498
% RSD			0.2	1.8

Analysed by: *[Signature]*
Date: 29/04/2020

Checked by: *[Signature]*
Date: 30/04/2020



RSD REPORT



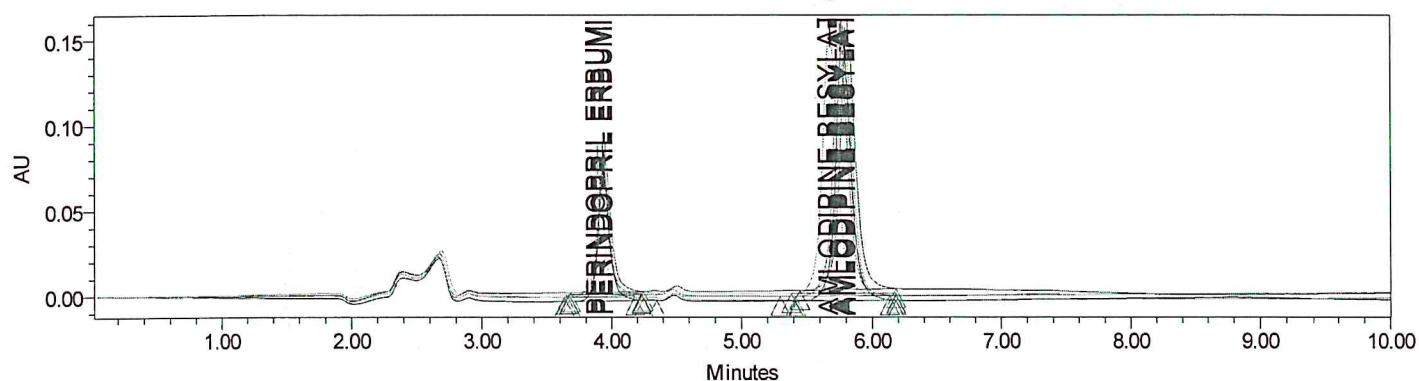
SAMPLE INFORMATION

Sample Name: DISSO STANDARD(B), DISSO STANDARD Acquired By: RAJI
 Sample Type: Standard Sample Set Name 29042020_AMLOPERIN DISSO_SS
 Vial: 98 Acq. Method Set: AMLOPERIN_FP_MSET
 Injection #: 1, 2, 4, 5, 3 Processing Method: AMLOPERIN_FP_PM
 Injection Volume: 50.00 ul Channel Name: 2487Channel 1
 Run Time: 10.0 Minutes Proc. Chnl. Descr.: 210

Date Acquired: 4/29/2020 13:26:43 IST, 4/29/2020 13:37:46 IST, 4/29/2020 13:48:49 IST, 4/29/2020 14:00:06 IST
 4/29/2020 14:11:09 IST, 4/29/2020 15:41:08 IST

Date Processed: 4/29/2020 14:27:06 IST, 4/29/2020 14:27:10 IST, 4/29/2020 14:27:13 IST, 4/29/2020 14:27:18 IST,
 4/29/2020 14:27:22 IST, 4/29/2020 16:02:11 IST

Auto-Scaled Chromatogram



Peak Name: AMLODIPINE BESYLATE

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count	USP Resolution
1	AMLODIPINE BESYLATE	1	5.679	1295506	1.03	12019	9.51
2	AMLODIPINE BESYLATE	1	5.815	1297240	1.02	11955	9.83
3	AMLODIPINE BESYLATE	2	5.796	1298443	1.03	12025	9.68
4	AMLODIPINE BESYLATE	3	5.781	1297197	1.02	11948	9.72
5	AMLODIPINE BESYLATE	4	5.770	1298316	1.04	12224	9.71
6	AMLODIPINE BESYLATE	5	5.758	1291328	1.04	12287	9.55
Mean			5.767	1296338	1.03	12076.42	9.67
Std. Dev.			0.047	2671.657	0.01	143.83	0.12
% RSD			0.8	0.2	0.81	1.19	1.23

Analysed by: *[Signature]*
 Date: 29/04/2020

Checked by: *[Signature]*
 Date: 30/04/2020

Peak Name: PERINDOPRIL ERBUMINE

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count
1	PERINDOPRIL ERBUMINE	1	3.951	513568	1.12	9616
2	PERINDOPRIL ERBUMINE	1	3.895	511841	1.12	9857
3	PERINDOPRIL ERBUMINE	2	3.944	512552	1.14	9670
4	PERINDOPRIL ERBUMINE	3	3.937	516200	1.12	9636
5	PERINDOPRIL ERBUMINE	4	3.933	512687	1.12	9673
6	PERINDOPRIL ERBUMINE	5	3.929	512705	1.13	9658
Mean			3.931	513259	1.13	9684.81
Std. Dev.			0.020	1542.136	0.01	87.17
% RSD			0.5	0.3	0.88	0.90

Analysed by: *[Signature]*
Date: 29/04/2020.

Checked by: *[Signature]*
Date: 30/04/2020



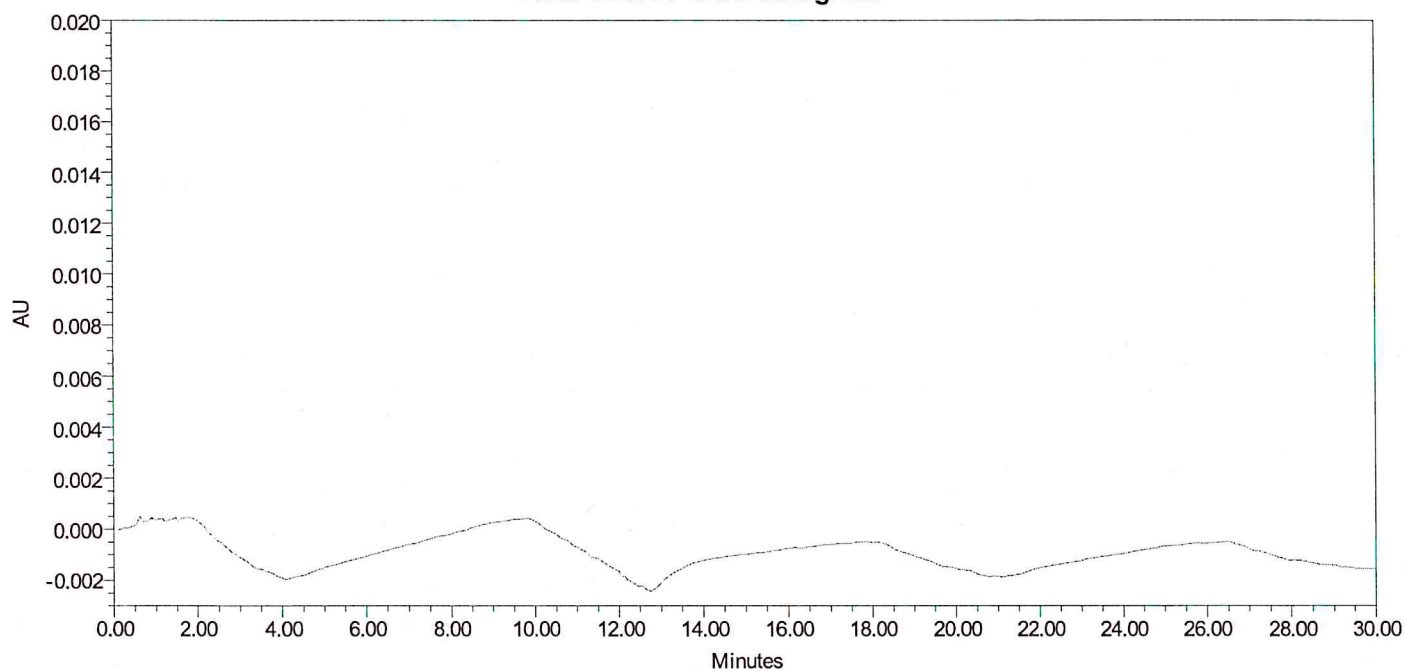
CHROMATOGRAPHIC DATA



SAMPLE INFORMATION

Sample Name:	BLANK	Acquired By:	RAJI
Sample Type:	Control	Sample Set Name:	28042020_AMLO_5_5_RS_FP_SS
Vial:	73	Acq. Method Set:	AMLOPERIN_RS_FP_MSET
Injection #:	1	Processing Method:	AMLOPERIN_FP_RS_STD_PM
Injection Volume:	20.00 ul	Channel Name:	2487Channel 1
Run Time:	30.0 Minutes	Proc. Chnl. Descr.:	215
Date Acquired:	4/28/2020 15:43:03 IST		
Date Processed:	4/29/2020 19:45:50 IST		

Auto-Scaled Chromatogram



Peak Results

	Name	RT	Area	% Area
1	PERINDOPRIL	5.100		

Analysed by: B. Shave
Date: 30/04/2020

Checked by: D. Shave
Date: 30/04/2020



RSD REPORT



SAMPLE INFORMATION

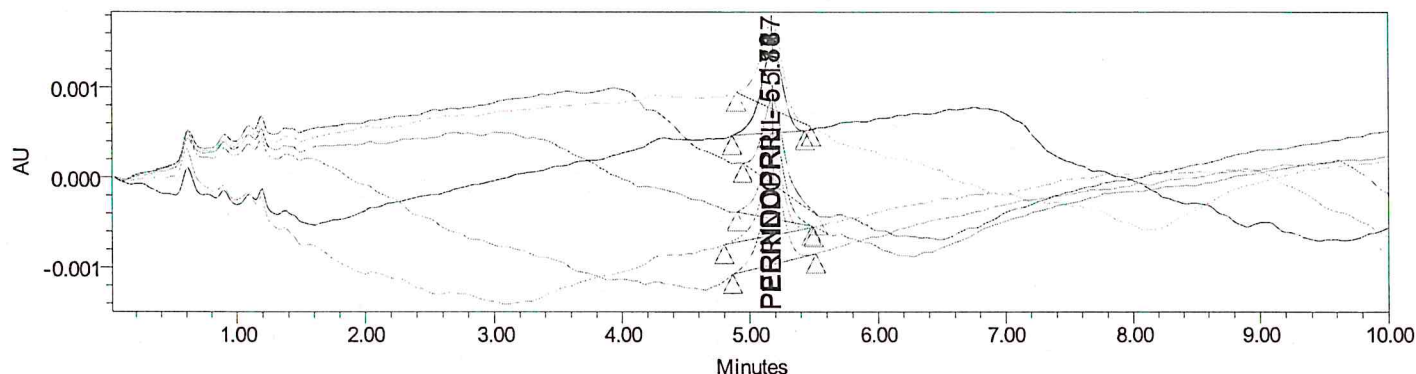
Sample Name: STD SOLUTION
 Sample Type: Standard
 Vial: 74
 Injection #: 1, 6, 2, 4, 5, 3
 Injection Volume: 20.00 ul
 Run Time: 10.0 Minutes

Acquired By: RAJI
 Sample Set Name: 28042020_AMLO_5_5_RS_FP_SS
 Acq. Method Set: AMLOPERIN_RS_FP_MSET
 Processing Method: AMLOPERIN_FP_RS_STD_PM
 Channel Name: 2487Channel 1
 Proc. Chnl. Descr.: 215

Date Acquired: 4/28/2020 16:13:58 IST, 4/28/2020 16:24:49 IST, 4/28/2020 16:35:40 IST, 4/28/2020 16:46:31 IST, 4/28/2020 16:57:22 IST, 4/28/2020 17:08:13 IST

Date Processed: 4/29/2020 19:53:17 IST, 4/29/2020 19:53:42 IST, 4/29/2020 19:54:01 IST, 4/29/2020 19:54:27 IST, 4/29/2020 19:54:44 IST, 4/29/2020 19:55:24 IST

Auto-Scaled Chromatogram



Peak Name: PERINDOPRIL

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count
1	PERINDOPRIL	1	5.181	11118	1.42	4572
2	PERINDOPRIL	2	5.187	11872	0.82	4204
3	PERINDOPRIL	3	5.187	11354	0.85	4498
4	PERINDOPRIL	4	5.178	11802	1.05	4190
5	PERINDOPRIL	5	5.185	11782	1.02	4500
6	PERINDOPRIL	6	5.186	11168	0.77	4436
Mean			5.184	11516	0.99	4400.12
Std. Dev.			0.004	342.021	0.24	163.20
% RSD			0.1	3.0	24.32	3.71

Analysed by: B. Shaya
 Date: 30/04/2020

Checked by: J. Shaya
 Date: 30/04/2020

Reported by User: sankar (sankar)
 Report Method: RSD REPORT STD
 Report Method I4966
 Page: 1 of 1

Project Name: 2020\QC-HPL-001\APR-2020
 Printed Date: 4/30/2020
 Printed Time: 10:00:01 Asi



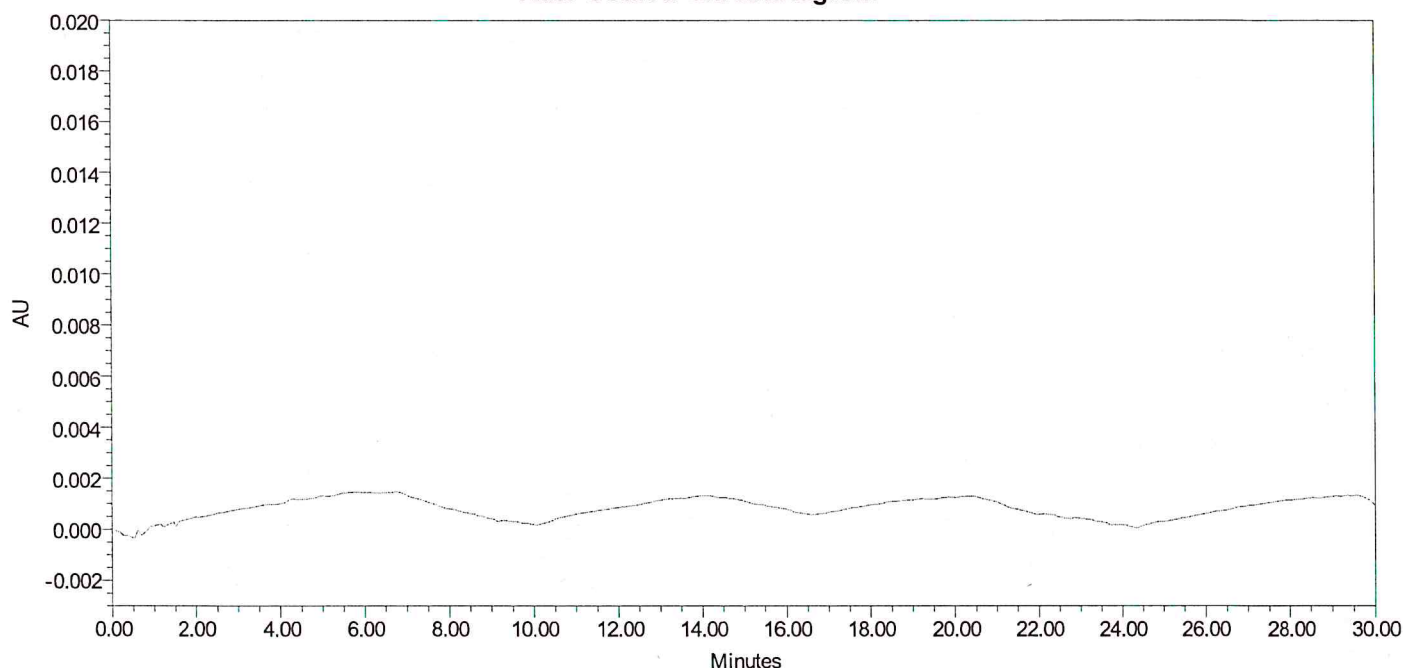
CHROMATOGRAPHIC DATA



SAMPLE INFORMATION

Sample Name:	BLANK	Acquired By:	RAJI
Sample Type:	Control	Sample Set Name	28042020_AMLO_5_5_RS_FP_SS
Vial:	73	Acq. Method Set:	AMLOPERIN_RS_FP_MSET
Injection #:	1	Processing Method	AMLOPERIN_FP_RS_STD_PM
Injection Volume:	20.00 ul	Channel Name:	2487Channel 1
Run Time:	30.0 Minutes	Proc. Chnl. Descr.:	215
Date Acquired:	4/28/2020 17:19:10 IST		
Date Processed:	4/29/2020 19:56:17 IST		

Auto-Scaled Chromatogram



Peak Results

	Name	RT	Area	% Area
1	PERINDOPRIL	5.100		

Analysed by: B. Shari
Date: 30/04/2020

Checked by: D. Shari
Date: 30/04/2020



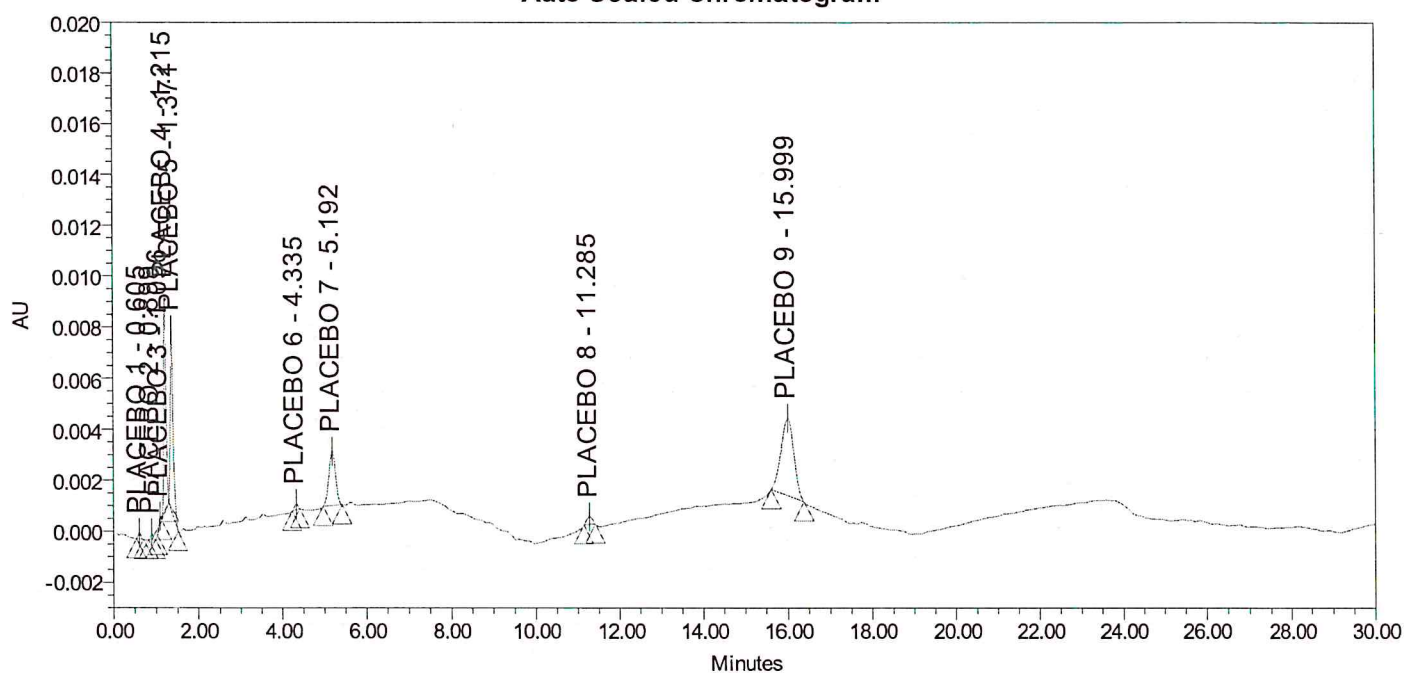
CHROMATOGRAPHIC DATA



SAMPLE INFORMATION

Sample Name:	PLACEBOSOLUTION	Acquired By:	RAJI
Sample Type:	Control	Sample Set Name	28042020_AMLO_5_5_RS_FP_SS
Vial:	75	Acq. Method Set:	AMLOPERIN_RS_FP_MSET
Injection #:	1	Processing Method	AMLOPERIN_FP_RS_PLACEBO_PM
Injection Volume:	20.00 ul	Channel Name:	2487Channel 1
Run Time:	30.0 Minutes	Proc. Chnl. Descr.:	215
Date Acquired:	4/28/2020 17:50:05 IST		
Date Processed:	4/29/2020 20:02:37 IST		

Auto-Scaled Chromatogram



Peak Results

	Name	RT	Area	% Area
1	PLACEBO 1	0.605	1085	0.70
2	PLACEBO 2	0.899	966	0.62
3	PLACEBO 3	1.096	1393	0.89
4	PLACEBO 4	1.215	32134	20.62
5	PLACEBO 5	1.371	29913	19.20
6	PLACEBO 6	4.335	1392	0.89
7	PLACEBO 7	5.192	23418	15.03
8	PLACEBO 8	11.285	2824	1.81
9	PLACEBO 9	15.999	62688	40.23

Analysed by: B. Shaz
Date: 30/04/2020

Checked by: D. Shaz
Date: 30/04/2020



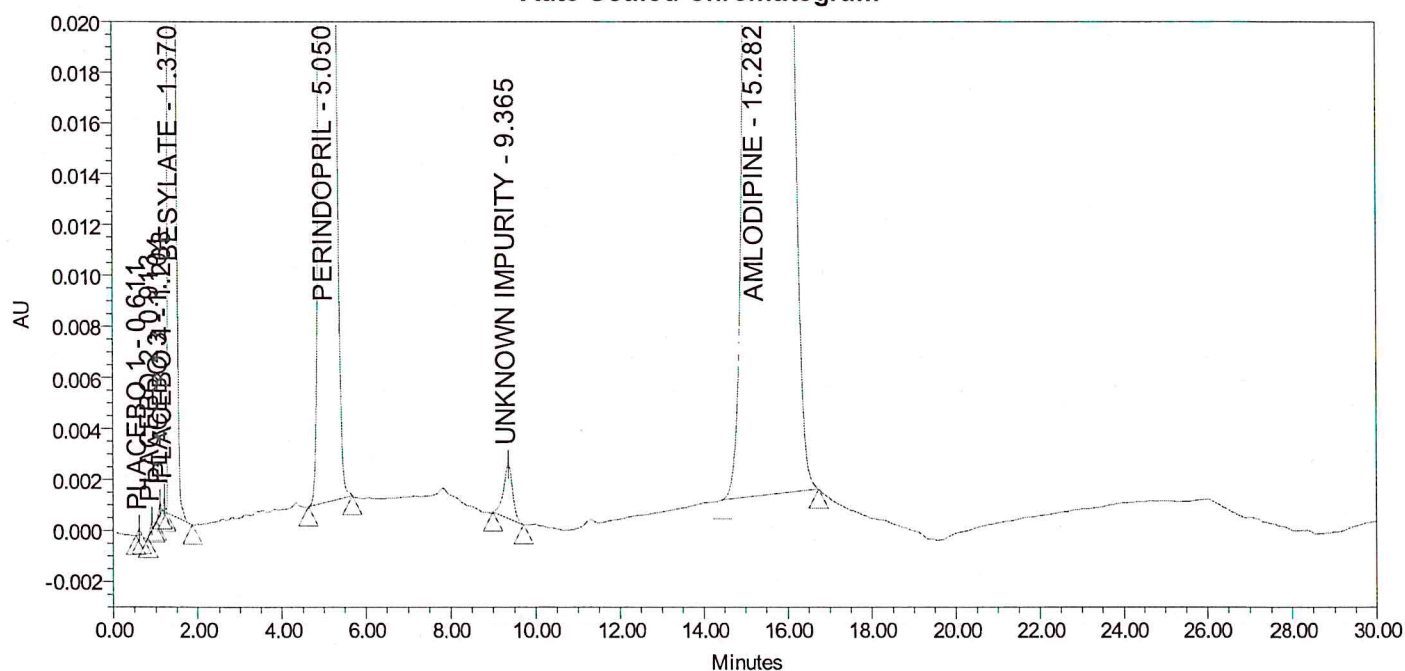
CHROMATOGRAPHIC DATA



SAMPLE INFORMATION

Sample Name:	SAMPLE SOLUTION GF200405	Acquired By:	RAJI
Sample Type:	Unknown	Sample Set Name	28042020_AMLO_5_5_RS_FP_SS
Vial:	76	Acq. Method Set:	AMLOPERIN_RS_FP_MSET
Injection #:	1	Processing Method	AMLOPERIN_FP_RS_SPL_PM
Injection Volume:	20.00 ul	Channel Name:	2487Channel 1
Run Time:	30.0 Minutes	Proc. Chnl. Descr.:	215
Date Acquired:	4/28/2020 18:51:58 IST		
Date Processed:	4/29/2020 9:02:13 IST		

Auto-Scaled Chromatogram



Peak Results

	Name	RT	Area	% Area
1	PLACEBO 1	0.611	955	0.00
2	PLACEBO 2	0.913	1665	0.01
3	PLACEBO 3	1.104	1662	0.01
4	PLACEBO 4	1.203	1406	0.01
5	BESYLATE	1.370	4965056	25.16
6	PERINDOPRIL	5.050	3774204	19.12
7	UNKNOWN IMPURITY	9.365	32012	0.16
8	AMLODIPINE	15.282	10958267	55.53

Analysed by: B. Shree
Date: 30/04/2020

Checked by: D. Shree
Date: 30/04/2020



RSD REPORT



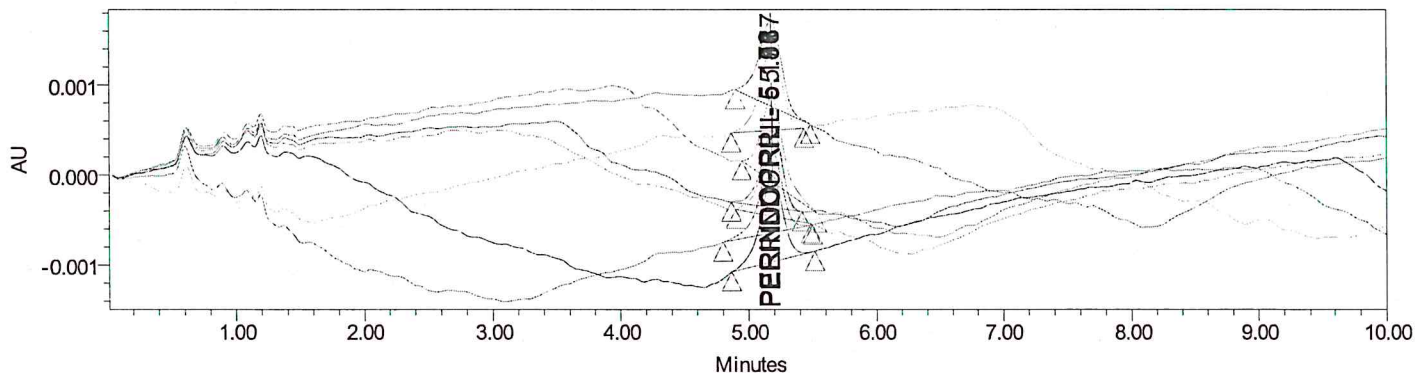
SAMPLE INFORMATION

Sample Name: STD SOLUTION, STD SOLUTION (B) Acquired By: RAJI
 Sample Type: Standard Sample Set Name: 28042020_AMLO_5_5_RS_FP_SS
 Vial: 74 Acq. Method Set: AMLOPERIN_RS_FP_MSET
 Injection #: 1, 6, 2, 4, 5, 3 Processing Method: AMLOPERIN_FP_RS_STD_PM_
 Injection Volume: 20.00 ul Channel Name: 2487Channel 1
 Run Time: 10.0 Minutes Proc. Chnl. Descr.: 215

Date Acquired: 4/28/2020 16:13:58 IST, 4/28/2020 16:24:49 IST, 4/28/2020 16:35:40 IST, 4/28/2020 16:46:31 IST,
 4/28/2020 16:57:22 IST, 4/28/2020 17:08:13 IST, 4/28/2020 19:22:55 IST

Date Processed: 4/29/2020 8:35:39 IST, 4/29/2020 19:53:17 IST, 4/29/2020 19:53:42 IST, 4/29/2020 19:54:01 IST,
 4/29/2020 19:54:27 IST, 4/29/2020 19:54:44 IST, 4/29/2020 19:55:24 IST

Auto-Scaled Chromatogram



Peak Name: PERINDOPRIL

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count
1	PERINDOPRIL	1	5.181	11118	1.42	4572
2	PERINDOPRIL	1	5.191	11120	0.89	4698
3	PERINDOPRIL	2	5.187	11872	0.82	4204
4	PERINDOPRIL	3	5.187	11354	0.85	4498
5	PERINDOPRIL	4	5.178	11802	1.05	4190
6	PERINDOPRIL	5	5.185	11782	1.02	4500
7	PERINDOPRIL	6	5.186	11168	0.77	4436
Mean			5.185	11459	0.97	4442.68
Std. Dev.			0.004	346.278	0.22	186.74
% RSD			0.1	3.02	22.83	4.20

Analysed by: B. Shave
 Date: 30/04/2020

Checked by: D. Shave
 Date: 30/04/2020



PROCESSING METHOD



Processing Method: AMLOPERIN_10_10_FP_PM

Type: LC

Stored: 4/28/2020 14:09:38 IST

Method Information

Method Comments	
Method Modified User	Sankar
Method Locked	No
Method Id	4309
Old Id	3666
Method Version	3
Method Edit User	
Source S/W Info	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505
Integration Algorithm	Traditional
Search Depth	3
Retention Time Presearch	No
RT Presearch Window	10.0
Start Mass Limit	(m/z)
End Mass Limit	(m/z)
PBM Search Mode	Pure
Duplicate Spectra	No
PBM Reference Sets	SET1
Search Threshold	50.000(%)
Noise Baseline	(min)
Peak Separation	1.0000(Da)
Baseline Multiplier	1.000
Spectra To Average	5
Noise Threshold	0.000(%)
Combine Type	Average
Expected Mass Peak Separation	1.00(Da)
Expected Mass Calculation Type	None
Include the uncorrected Target or Base Mass in the list of expected masses	No
Expected Mass Base Value	100.00(Da)
Expected Mass Base Intensity	80.0(%)
Centroid Center Type	Centroid Top(%)
Centroid Top (%)	80.00
Centroid Intensity	Heights
Min. Peak Width at Half-Height	0.500(Da)
Smoothing Type	None
Average By	None
RT Window %	5.00
Update RT	Never
CCalRef1	
Include Internal Standard Amounts in Amount Calculation	Yes
Analysed by: B. Shave	
Date: 29/04/2020	
	Checked by: J. Shave
	Date: 30/04/2020

Vial/Default Value Type
RT Reference Used to Name Unnamed Peaks by RRT

Amount

System Suitability Information

Void Volume Time	1.000(min)
Calculate Suitability	Yes
Flag Outside	Yes
Calculate Unknowns	Yes
Pharmacopoeia	All
Tangent Percent (USP Plate Count)	61
Tangent Percent (USP Resolution)	50
Calculate USP, EP, and JP s/n	No
Use noise centered on peak region in blank injection	Yes
Half Height Multiplier for USP s/n Noise Region	
Half Height Multiplier for EP s/n Noise Region	
Half Height Multiplier for JP s/n Noise Region	
Noise Value for s/n	
% Runtime	5.0
Maximum Noise	
Maximum Drift	
Baseline Noise Minimum	30 Seconds
Baseline Start	(min)
Baseline End	(min)

Integration Parameters

Minimum Area	50000($\mu V \cdot sec$)
Minimum Height	0(μV)
Threshold	50.000($\mu V/sec$)
Peak Width	50.00(sec)

Integration Events

	Time (min)	Type	Value	Stop (min)
1	0.000	Valley to Valley		10.000
2	0.000	Inhibit Integration		3.000
3	4.500	Inhibit Integration		5.000
4	6.200	Inhibit Integration		10.000

Component Table

	Name	Component Type	Peak Label	Retention Time (min)	RT Window (min)	Peak Match	Calculate Suit Results	Flag Outside Limits
1	PERINDOPRIL ERBUMINE			3.820	0.191	Closest	Yes	Yes
2	AMLODIPINE BESYLATE			5.674	0.284	Closest	Yes	Yes

Component Table

	dn/dc (ml/g)	A2 ($10e-4 \cdot ml \cdot mol/g^2$)	3D Channel Name (Description)	Channel	Y Value	X Value	Fit	Weighting	Internal Std	RT Reference
1		0.000		2487Channel 1	Area	Amount	Linear	None		
2		0.000		2487Channel 1	Area	Amount	Linear	None		

Analysed by: B. Shan
Date: 29/04/2020

Checked by: D. Shan
Date: 30/04/2020

Reported by User: Sankar (Sankar)
Report Method: PROCESSING METHOD
Report Method ID1566
Page: 2 of 4

Project Name: 2020\QC-HPL-002\APR-2020
Printed Date: 4/29/2020
Printed Time: 9:27:20 Asia/

Component Table

	Rel RT Reference	RRT	Rel Resol Reference	Curve Reference	Relative Response	Must	Default Pk	Default Pk Start (min)	Default Pk End (min)	Default Units	MW Fit	Type	Impurity Type
1					1.000000	No	No				1st Order	Single	
2					1.000000	No	No				1st Order	Single	

Component Table

	CCompRef1	CCompRef2	CCompRef3	Structure 1 Name	Structure 1 Description	Structure 1 Mol Wt	Structure 1 Formula	Structure 1 Structure	Structure 2 Name	Structure 2 Description
1										
2										

Component Table

	Structure 2 Mol Wt	Structure 2 Formula	Structure 2 Structure	Structure 3 Name	Structure 3 Description	Structure 3 Mol Wt	Structure 3 Formula	Structure 3 Structure	CConst1	CConst2	CConst3
1											
2											

Component Table

	CConst4	CConst5	CConst6	CConst7
1				
2				

Processing Method Group 'Name Groups' table contains no data.

Processing Method Group 'Time Groups' table contains no data.

Processing Method Group 'Suit Limits-'PERINDOPRIL ERBUMINE'' table contains no data.

Processing Method Group 'Relative Limits-'PERINDOPRIL ERBUMINE'' table contains no data.

Processing Method Group 'Def Amts-'PERINDOPRIL ERBUMINE'' table contains no data.

Processing Method Group 'Suit Limits-'AMLODIPINE BESYLATE'' table contains no data.

Processing Method Group 'Relative Limits-'AMLODIPINE BESYLATE'' table contains no data.

Processing Method Group 'Def Amts-'AMLODIPINE BESYLATE'' table contains no data.

Processing Method Group 'Primary Peaks (Primary MS Ions)' table contains no data.

Noise and Drift Parameters

Calculate Detector Noise and Drift No
 Detector Noise and Drift Start Time (Minutes)
 Detector Noise and Drift End Time (Minutes)
 Detector Noise and Drift Segment Width 60(sec)

Concentration Smoothing/Offset Parameters

Time Offset 0.000(Minutes)
 Smoothing Type None
 Smoothing Level None
 Empty parameters supersede the derived channel's smoothing and offset parameters No

LS Smoothing/Offset Parameters

Time Offset 0.000(Minutes)

Analysed by: B. Shaw
 Date: 29/04/2020

Checked by: J. Shaw
 Date: 30/04/2020

Smoothing Type None
 Smoothing Level None
 Empty parameters supersede the derived channel's smoothing and offset parameters No

Impurity Parameters

Calculate Total Impurities	No	Qualification Threshold
Impurity Response		Total Impurities Threshold
w Value		Maximum Impurity Threshold
Main Component		
Reporting Threshold	0.05	
Identification Threshold		

Excluded Component Types

Internal Standard Peaks

Revision History

Version 3 4/28/2020 14:09:38 IST User Sankar

Version 2 4/25/2020 17:08:57 IST User Sankar

Version 1 4/24/2020 9:05:06 IST User RAJI Created method 'AMLOPERIN_10_10_FP_PM'.

Method Version Summaries

	Method Name	Method Type	Method Comments	Method Date	Method Modified User	Method Locked	Method Id	Old Id
1	AMLOPERIN_10_10_FP_PM	Processing		4/29/2020 9:21:30 IST	Sankar	No	4451	4309
2	AMLOPERIN_10_10_FP_PM	Processing		4/28/2020 14:09:38 IST	Sankar	No	4309	3666
3	AMLOPERIN_10_10_FP_PM	Processing		4/25/2020 17:08:57 IST	Sankar	No	3666	3141
4	AMLOPERIN_10_10_FP_PM	Processing		4/24/2020 9:05:06 IST	RAJI	No	3141	

Method Version Summaries

Method Version	Source SW Info
1	4 Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505
2	3 Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505
3	2 Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505
4	1 Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505

Analysed by: B. Shaz
 Date: 29/04/2020

Checked by: D. Shaz
 Date: 30/04/2020

Reported by User: Sankar (Sankar)
 Report Method: PROCESSING METHOD
 Report Method ID 1566
 Page: 4 of 4

Project Name: 2020\QC-HPL-002\APR-2020
 Printed Date: 4/29/2020
 Printed Time: 9:27:20 Asia/



PROCESSING METHOD



Processing Method: AMLOPERIN_FP_PM

Type: LC

Stored: 4/28/2020 11:31:52 IST

Method Information

Method Comments	
Method Modified User	RAJI
Method Locked	No
Method Id	4664
Old Id	4362
Method Version	6
Method Edit User	
Source S/W Info	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505
Integration Algorithm	Traditional
Search Depth	3
Retention Time Presearch	No
RT Presearch Window	10.0
Start Mass Limit	(m/z)
End Mass Limit	(m/z)
PBM Search Mode	Pure
Duplicate Spectra	No
PBM Reference Sets	SET1
Search Threshold	50.000(%)
Noise Baseline	(min)
Peak Separation	1.0000(Da)
Baseline Multiplier	1.000
Spectra To Average	5
Noise Threshold	0.000(%)
Combine Type	Average
Expected Mass Peak Separation	1.00(Da)
Expected Mass Calculation Type	None
Include the uncorrected Target or Base Mass in the list of expected masses	No
Expected Mass Base Value	100.00(Da)
Expected Mass Base Intensity	80.0(%)
Centroid Center Type	Centroid Top(%)
Centroid Top (%)	80.00
Centroid Intensity	Heights
Min. Peak Width at Half-Height	0.500(Da)
Smoothing Type	None
Average By	None
RT Window %	5.00
Update RT	Never

Analysed by: *[Signature]*
Date: 29/04/2020

Checked by: *[Signature]*
Date: 30/04/2020

CCalRef1

Include Internal Standard Amounts in Amount Calculation

Vial/Default Value Type

RT Reference Used to Name Unnamed Peaks by RRT

Yes

Amount

System Suitability Information

Void Volume Time 1.000(min)
 Calculate Suitability Yes
 Flag Outside Yes
 Calculate Unknowns Yes
 Pharmacopoeia All
 Tangent Percent (USP Plate Count) 61
 Tangent Percent (USP Resolution) 50
 Calculate USP, EP, and JP s/n No
 Use noise centered on peak region in blank injection Yes
 Half Height Multiplier for USP s/n Noise Region
 Half Height Multiplier for EP s/n Noise Region
 Half Height Multiplier for JP s/n Noise Region
 Noise Value for s/n
 % Runtime 5.0
 Maximum Noise
 Maximum Drift
 Baseline Noise Minimum 30 Seconds
 Baseline Start (min)
 Baseline End (min)

Integration Parameters

Minimum Area 50000($\mu\text{V}\cdot\text{sec}$)
 Minimum Height 0(μV)
 Threshold 100.000($\mu\text{V}/\text{sec}$)
 Peak Width 50.00(sec)

Integration Events

	Time (min)	Type	Value	Stop (min)
1	0.000	Valley to Valley		10.000
2	0.000	Inhibit Integration		3.200
3	4.300	Inhibit Integration		5.000
4	6.200	Inhibit Integration		10.000

Component Table

	Name	Component Type	Peak Label	Retention Time (min)	RT Window (min)	Peak Match	Calculate Suit Results
1	PERINDOPRIL ERBUMINE		1	3.919	0.196	Closest	Yes
2	AMLODIPINE BESYLATE		2	5.764	0.288	Closest	Yes

Component Table

	Flag Outside Limits	dn/dc (ml/g)	A2 ($10e-4\cdot\text{ml}\cdot\text{mol}/\text{g}^2$)	3D Channel Name (Description)	Channel	Y Value	X Value	Fit	Weighting
1	Yes		0.000		2487Channel 1	Area	Amount	Linear	None
2	Yes		0.000		2487Channel 1	Area	Amount	Linear	None

Analysed by: *J. Duj*
 Date: 29/04/2020

Checked by: *J. Duj*
 Date: 30/04/2020

Component Table

	Internal Std	RT Reference	Rel RT Reference	RRT	Rel Resol Reference	Curve Reference	Relative Response	Must	Default Pk	Default Pk Start (min)	Default Pk End (min)	Default Units	MW Fit
1							1.000000	No	No				1st Order
2							1.000000	No	No				1st Order

Component Table

	Type	Impurity Type	CCompRef1	CCompRef2	CCompRef3	Structure 1 Name	Structure 1 Description	Structure 1 Mol Wt	Structure 1 Formula	Structure 1 Structure
1	Single									
2	Single									

Component Table

	Structure 2 Name	Structure 2 Description	Structure 2 Mol Wt	Structure 2 Formula	Structure 2 Structure	Structure 3 Name	Structure 3 Description	Structure 3 Mol Wt	Structure 3 Formula
1									
2									

Component Table

	Structure 3 Structure	CConst1	CConst2	CConst3	CConst4	CConst5	CConst6	CConst7
1								
2								

Processing Method Group 'Name Groups' table contains no data.

Processing Method Group 'Time Groups' table contains no data.

Processing Method Group 'Suit Limits-'PERINDOPRIL ERBUMINE'' table contains no data.

Processing Method Group 'Relative Limits-'PERINDOPRIL ERBUMINE'' table contains no data.

Processing Method Group 'Def Amts-'PERINDOPRIL ERBUMINE'' table contains no data.

Processing Method Group 'Suit Limits-'AMLODIPINE BESYLATE'' table contains no data.

Processing Method Group 'Relative Limits-'AMLODIPINE BESYLATE'' table contains no data.

Processing Method Group 'Def Amts-'AMLODIPINE BESYLATE'' table contains no data.

Processing Method Group 'Primary Peaks (Primary MS Ions)' table contains no data.

Noise and Drift Parameters

Calculate Detector Noise and Drift No
 Detector Noise and Drift Start Time (Minutes)
 Detector Noise and Drift End Time (Minutes)
 Detector Noise and Drift Segment Width 60(sec)

Concentration Smoothing/Offset Parameters

Time Offset 0.000(Minutes)
 Smoothing Type None
 Smoothing Level None
 Empty parameters supersede the derived channel's smoothing and offset parameters No

LS Smoothing/Offset Parameters

Time Offset 0.000(Minutes)

Analysed by: *[Signature]*
 Date: 29/04/2020

Checked by: *[Signature]*
 Date: 30/04/2020

Smoothing Type None
 Smoothing Level None
 Empty parameters supersede the derived channel's smoothing and offset parameters No

Impurity Parameters

Calculate Total Impurities No Qualification Threshold
 Impurity Response Total Impurities Threshold
 w Value Maximum Impurity Threshold
 Main Component
 Reporting Threshold 0.05
 Identification Threshold

Excluded Component Types

Internal Standard Peaks

Revision History

Version 6 4/28/2020 11:31:52 IST User RAJI
 Version 5 4/27/2020 9:25:04 IST User RAJI
 Version 4 4/27/2020 9:13:22 IST User RAJI
 Version 3 4/22/2020 17:35:23 IST User RAJI
 Version 2 4/17/2020 9:08:07 IST User RAJI
 Version 1 4/16/2020 17:11:23 IST User VALLARASAN Created method 'AMLOPERIN_FP_PM'.

Method Version Summaries

	Method Name	Method Type	Method Comments	Method Date	Method Modified User	Method Locked	Method Id	Old Id
1	AMLOPERIN_FP_PM	Processing		4/28/2020 11:31:52 IST	RAJI	No	4664	4362
2	AMLOPERIN_FP_PM	Processing		4/27/2020 9:25:04 IST	RAJI	No	4362	4313
3	AMLOPERIN_FP_PM	Processing		4/27/2020 9:13:22 IST	RAJI	No	4313	3661
4	AMLOPERIN_FP_PM	Processing		4/22/2020 17:35:23 IST	RAJI	No	3661	3406
5	AMLOPERIN_FP_PM	Processing		4/17/2020 9:08:07 IST	RAJI	No	3406	2533
6	AMLOPERIN_FP_PM	Processing		4/16/2020 17:11:23 IST	VALLARASAN	No	2533	

Method Version Summaries

Method Version	Source S/W Info
1	6 Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505
2	5 Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505
3	4 Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505
4	3 Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505
5	2 Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505
6	1 Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505

Analysed by: *RAJI*
 Date: 29/04/2020

Checked by: *D. J. Raji*
 Date: 30/04/2020

Reported by User: RAJARAJESWARI (RAJI)
 Report Method: PROCESSING METHOD
 Report Method ID1555
 Page: 4 of 4

Project Name: 2020\QC-HPL-001\APR-202
 Printed Date: 4/29/2020
 Printed Time: 16:08:33 Asi



PROCESSING METHOD



Processing Method: AMLOPERIN_FP_RS_PLACEBO_PM

Type: LC

Stored: 4/29/2020 20:02:46 IST

Method Information

Method Comments	
Method Modified User	Sankar
Method Locked	No
Method Id	5159
Old Id	4832
Method Version	5
Method Edit User	
Source S/W Info	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505
Integration Algorithm	Traditional
Search Depth	3
Retention Time Presearch	No
RT Presearch Window	10.0
Start Mass Limit	(m/z)
End Mass Limit	(m/z)
PBM Search Mode	Pure
Duplicate Spectra	No
PBM Reference Sets	SET1
Search Threshold	50.000(%)
Noise Baseline	(min)
Peak Separation	1.0000(Da)
Baseline Multiplier	1.000
Spectra To Average	5
Noise Threshold	0.000(%)
Combine Type	Average
Expected Mass Peak Separation	1.00(Da)
Expected Mass Calculation Type	None
Include the uncorrected Target or Base Mass in the list of expected masses	No
Expected Mass Base Value	100.00(Da)
Expected Mass Base Intensity	80.0(%)
Centroid Center Type	Centroid Top(%)
Centroid Top (%)	80.00
Centroid Intensity	Heights
Min. Peak Width at Half-Height	0.500(Da)
Smoothing Type	None
Average By	None
RT Window %	5.00
Update RT	Never

Analysed by: B. Shree
Date: 29/04/2020

Checked by: D. Shree
Date: 30/04/2020

CCalRef1

Include Internal Standard Amounts in Amount Calculation

Yes

Vial/Default Value Type

Amount

RT Reference Used to Name Unnamed Peaks by RRT

System Suitability Information

Void Volume Time	(min)
Calculate Suitability	No
Flag Outside	Yes
Calculate Unknowns	Yes
Pharmacopoeia	All
Tangent Percent (USP Plate Count)	61
Tangent Percent (USP Resolution)	50
Calculate USP, EP, and JP s/n	No
Use noise centered on peak region in blank injection	Yes
Half Height Multiplier for USP s/n Noise Region	
Half Height Multiplier for EP s/n Noise Region	
Half Height Multiplier for JP s/n Noise Region	
Noise Value for s/n	
% Runtime	5.0
Maximum Noise	
Maximum Drift	
Baseline Noise Minimum	30 Seconds
Baseline Start	(min)
Baseline End	(min)

Integration Parameters

Minimum Area	0(μ V*sec)
Minimum Height	0(μ V)
Threshold	50.000(μ V/sec)
Peak Width	20.00(sec)

Integration Events

	Time (min)	Type	Value	Stop (min)
1	0.000	Valley to Valley		30.000

Component Table

	Name	Component Type	Peak Label	Retention Time (min)	RT Window (min)	Peak Match	Calculate Suit Results	Flag Outside Limits	dn/dc (ml/g)
1	PLACEBO 1		1	0.587	0.029	Closest	Yes	Yes	
2	PLACEBO 2		2	0.901	0.045	Closest	Yes	Yes	
3	PLACEBO 3		3	1.070	0.054	Closest	Yes	Yes	
4	PLACEBO 4		4	1.200	0.060	Closest	Yes	Yes	
5	PLACEBO 5		5	1.370	0.099	Closest	Yes	Yes	
6	PLACEBO 6			4.300	0.215	Closest	Yes	Yes	
7	PLACEBO 7			5.200	0.260	Closest	Yes	Yes	
8	PLACEBO 8			11.300	0.565	Closest	Yes	Yes	
9	PLACEBO 9			16.000	0.800	Closest	Yes	Yes	

Analysed by: B. Shaz
 Date: 29/04/2020

Checked by: D. Shaz
 Date: 30/04/2020

Reported by User: Sankar (Sankar)
 Report Method: PROCESSING METHOD
 Report Method ID1555
 Page: 2 of 6

Project Name: 2020\QC-HPL-001\APR-202
 Printed Date: 4/29/2020
 Printed Time: 8:42:19 Asia

Component Table

	A2 (10e-4*ml*mol/g^2)	3D Channel Name (Description)	Channel	Y Value	X Value	Fit	Weighting	Internal Std	RT Reference	Rel RT Reference
1	0.000			Area	Amount	Linear	None			
2	0.000			Area	Amount	Linear	None			
3	0.000			Area	Amount	Linear	None			
4	0.000			Area	Amount	Linear	None			
5	0.000			Area	Amount	Linear	None			
6	0.000			Area	Amount	Linear	None			
7	0.000			Area	Amount	Linear	None			
8	0.000			Area	Amount	Linear	None			
9	0.000			Area	Amount	Linear	None			

Component Table

	RRT	Rel Resol Reference	Curve Reference	Relative Response	Must	Default Pk	Default Pk Start (min)	Default Pk End (min)	Default Units	MW Fit	Type	Impurity Type	CCompRef1
1				1.000000	No	No				1st Order	Single		
2				1.000000	No	No				1st Order	Single		
3				1.000000	No	No				1st Order	Single		
4				1.000000	No	No				1st Order	Single		
5				1.000000	No	No				1st Order	Single		
6				1.000000	No	No				1st Order	Single		
7				1.000000	No	No				1st Order	Single		
8				1.000000	No	No				1st Order	Single		
9				1.000000	No	No				1st Order	Single		

Component Table

	CCompRef2	CCompRef3	Structure 1 Name	Structure 1 Description	Structure 1 Mol Wt	Structure 1 Formula	Structure 1 Structure	Structure 2 Name	Structure 2 Description
1									
2									
3									
4									
5									
6									
7									
8									
9									

Component Table

	Structure 2 Mol Wt	Structure 2 Formula	Structure 2 Structure	Structure 3 Name	Structure 3 Description	Structure 3 Mol Wt	Structure 3 Formula	Structure 3 Structure	CConst1	CConst2
1										
2										
3										

Analysed by: B. Shaz
Date: 29/04/2020

Checked by: J. Shaz
Date: 30/04/2020

Component Table

	Structure 2 Mol Wt	Structure 2 Formula	Structure 2 Structure	Structure 3 Name	Structure 3 Description	Structure 3 Mol Wt	Structure 3 Formula	Structure 3 Structure	CConst1	CConst2
4										
5										
6										
7										
8										
9										

Component Table

	CConst3	CConst4	CConst5	CConst6	CConst7
1					
2					
3					
4					
5					
6					
7					
8					
9					

Processing Method Group 'Name Groups' table contains no data.

Processing Method Group 'Time Groups' table contains no data.

Processing Method Group 'Suit Limits-'PLACEBO 1'' table contains no data.

Processing Method Group 'Relative Limits-'PLACEBO 1'' table contains no data.

Processing Method Group 'Def Amts-'PLACEBO 1'' table contains no data.

Processing Method Group 'Suit Limits-'PLACEBO 2'' table contains no data.

Processing Method Group 'Relative Limits-'PLACEBO 2'' table contains no data.

Processing Method Group 'Def Amts-'PLACEBO 2'' table contains no data.

Processing Method Group 'Suit Limits-'PLACEBO 3'' table contains no data.

Processing Method Group 'Relative Limits-'PLACEBO 3'' table contains no data.

Processing Method Group 'Def Amts-'PLACEBO 3'' table contains no data.

Processing Method Group 'Suit Limits-'PLACEBO 4'' table contains no data.

Processing Method Group 'Relative Limits-'PLACEBO 4'' table contains no data.

Processing Method Group 'Def Amts-'PLACEBO 4'' table contains no data.

Processing Method Group 'Suit Limits-'PLACEBO 5'' table contains no data.

Processing Method Group 'Relative Limits-'PLACEBO 5'' table contains no data.

Processing Method Group 'Def Amts-'PLACEBO 5'' table contains no data.

Processing Method Group 'Suit Limits-'PLACEBO 6'' table contains no data.

Processing Method Group 'Relative Limits-'PLACEBO 6'' table contains no data.

Analysed by: B. Shan
Date: 22/04/2020

Checked by: D. Shafiq
Date: 30/04/2020

Processing Method Group 'Def Amts-'PLACEBO 6'' table contains no data.

Processing Method Group 'Suit Limits-'PLACEBO 7'' table contains no data.

Processing Method Group 'Relative Limits-'PLACEBO 7'' table contains no data.

Processing Method Group 'Def Amts-'PLACEBO 7'' table contains no data.

Processing Method Group 'Suit Limits-'PLACEBO 8'' table contains no data.

Processing Method Group 'Relative Limits-'PLACEBO 8'' table contains no data.

Processing Method Group 'Def Amts-'PLACEBO 8'' table contains no data.

Processing Method Group 'Suit Limits-'PLACEBO 9'' table contains no data.

Processing Method Group 'Relative Limits-'PLACEBO 9'' table contains no data.

Processing Method Group 'Def Amts-'PLACEBO 9'' table contains no data.

Processing Method Group 'Primary Peaks (Primary MS Ions)' table contains no data.

Noise and Drift Parameters

Calculate Detector Noise and Drift	No
Detector Noise and Drift Start Time	(Minutes)
Detector Noise and Drift End Time	(Minutes)
Detector Noise and Drift Segment Width	60(sec)

Concentration Smoothing/Offset Parameters

Time Offset	0.000(Minutes)
Smoothing Type	None
Smoothing Level	None
Empty parameters supersede the derived channel's smoothing and offset parameters	No

LS Smoothing/Offset Parameters

Time Offset	0.000(Minutes)
Smoothing Type	None
Smoothing Level	None
Empty parameters supersede the derived channel's smoothing and offset parameters	No

Impurity Parameters

Calculate Total Impurities	No	Qualification Threshold
Impurity Response		Total Impurities Threshold
w Value		Maximum Impurity Threshold
Main Component		
Reporting Threshold	0.05	
Identification Threshold		

Excluded Component Types

Internal Standard Peaks

Revision History

Version 5	4/29/2020 20:02:46 IST	User Sankar	
Version 4	4/28/2020 16:07:01 IST	User RAJI	
Version 3	4/28/2020 16:06:28 IST	User RAJI	
Version 2	4/28/2020 16:00:27 IST	User RAJI	Created method 'AMLOPERIN_FP_RS_PLACEBO_PM'.
Version 1	4/28/2020 15:40:02 IST	User RAJI	Created method 'AMLOPERIN_FP_RS_PLACEBO_PM'.

Analysed by: B. Shari
Date: 29/04/2020

Checked by: D. Shari
Date: 30/04/2020

Method Version Summaries

	Method Name	Method Type	Method Comments	Method Date	Method Modified User	Method Locked
1	AMLOPERIN_FP_RS_PLACEBO_PM	Processing		4/29/2020 20:02:46 IST	Sankar	No
2	AMLOPERIN_FP_RS_PLACEBO_PM	Processing		4/28/2020 16:07:01 IST	RAJI	No
3	AMLOPERIN_FP_RS_PLACEBO_PM	Processing		4/28/2020 16:06:28 IST	RAJI	No
4	AMLOPERIN_FP_RS_PLACEBO_PM	Processing		4/28/2020 16:00:27 IST	RAJI	No
5	AMLOPERIN_FP_RS_PLACEBO_PM	Processing		4/28/2020 15:40:02 IST	RAJI	No

Method Version Summaries

	Method Id	Old Id	Method Version	Source S/W Info
1	5159	4832	5	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505
2	4832	4821	4	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505
3	4821	4817	3	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505
4	4817	4780	2	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505
5	4780		1	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505

Analysed by: B. Shan
Date: 29/04/2020

Checked by: D. Sankar
Date: 30/04/2020



PROCESSING METHOD



Processing Method: AMLOPERIN_FP_RS_SPL_PM

Type: LC

Stored: 4/29/2020 20:13:27 IST

Method Information

Method Comments	
Method Modified User	Sankar
Method Locked	No
Method Id	5166
Old Id	4904
Method Version	6
Method Edit User	
Source S/W Info	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505
Integration Algorithm	Traditional
Search Depth	3
Retention Time Presearch	No
RT Presearch Window	10.0
Start Mass Limit	(m/z)
End Mass Limit	(m/z)
PBM Search Mode	Pure
Duplicate Spectra	No
PBM Reference Sets	SET1
Search Threshold	50.000(%)
Noise Baseline	(min)
Peak Separation	1.0000(Da)
Baseline Multiplier	1.000
Spectra To Average	5
Noise Threshold	0.000(%)
Combine Type	Average
Expected Mass Peak Separation	1.00(Da)
Expected Mass Calculation Type	None
Include the uncorrected Target or Base Mass in the list of expected masses	No
Expected Mass Base Value	100.00(Da)
Expected Mass Base Intensity	80.0(%)
Centroid Center Type	Centroid Top(%)
Centroid Top (%)	80.00
Centroid Intensity	Heights
Min. Peak Width at Half-Height	0.500(Da)
Smoothing Type	None
Average By	None
RT Window %	5.00
Update RT	Never

Analysed by: B. Shave
Date: 29/04/2020

Checked by: D. Shave
Date: 30/04/2020

CCalRef1

Include Internal Standard Amounts in Amount Calculation

Vial/Default Value Type

RT Reference Used to Name Unnamed Peaks by RRT

Yes

Amount

System Suitability Information

Void Volume Time (min)
 Calculate Suitability No
 Flag Outside Yes
 Calculate Unknowns Yes
 Pharmacopoeia All
 Tangent Percent (USP Plate Count) 61
 Tangent Percent (USP Resolution) 50
 Calculate USP, EP, and JP s/n No
 Use noise centered on peak region in blank injection Yes
 Half Height Multiplier for USP s/n Noise Region
 Half Height Multiplier for EP s/n Noise Region
 Half Height Multiplier for JP s/n Noise Region
 Noise Value for s/n
 % Runtime 5.0
 Maximum Noise
 Maximum Drift
 Baseline Noise Minimum 30 Seconds
 Baseline Start (min)
 Baseline End (min)

Integration Parameters

Minimum Area 0(μ V*sec)
 Minimum Height 0(μ V)
 Threshold 50.000(μ V/sec)
 Peak Width 20.00(sec)

Integration Events

	Time (min)	Type	Value	Stop (min)
1	0.000	Valley to Valley		30.000

Component Table

	Name	Component Type	Peak Label	Retention Time (min)	RT Window (min)	Peak Match	Calculate Suit Results	Flag Outside Limits
1	PLACEBO 1			0.610	0.031	Closest	Yes	Yes
2	PLACEBO 2			0.930	0.047	Closest	Yes	Yes
3	PLACEBO 3			1.100	0.054	Closest	Yes	Yes
4	PLACEBO 4			1.200	0.060	Closest	Yes	Yes
5	BESYLATE		1	1.370	0.069	Closest	Yes	Yes
6	PERINDOPRIL		2	5.000	0.250	Closest	Yes	Yes
7	UNKNOWN IMPURITY			9.200	0.460	Closest	Yes	Yes
8	AMLODIPINE		3	15.300	0.765	Closest	Yes	Yes

Analysed by: B. Shau
 Date: 29/04/2020

Checked by: D. Shau
 Date: 30/04/2020

Reported by User: Sankar (Sankar)
 Report Method: PROCESSING METHOD
 Report Method ID1555
 Page: 2 of 6

Project Name: 2020\QC-HPL-001\APR-202
 Printed Date: 4/29/2020
 Printed Time: 8:42:47 Asia

Component Table

	dn/dc (ml/g)	A2 (10e-4*ml*mol/g^2)	3D Channel Name (Description)	Channel	Y Value	X Value	Fit	Weighting	Internal Std	RT Reference
1		0.000			Area	Amount	Linear	None		
2		0.000			Area	Amount	Linear	None		
3		0.000			Area	Amount	Linear	None		
4		0.000			Area	Amount	Linear	None		
5		0.000			Area	Amount	Linear	None		
6		0.000			Area	Amount	Linear	None		
7		0.000			Area	Amount	Linear	None		
8		0.000			Area	Amount	Linear	None		

Component Table

	Rel RT Reference	RRT	Rel Resol Reference	Curve Reference	Relative Response	Must	Default Pk	Default Pk Start (min)	Default Pk End (min)	Default Units	MW Fit	Type	Impurity Type
1					1.000000	No	No				1st Order	Single	
2					1.000000	No	No				1st Order	Single	
3					1.000000	No	No				1st Order	Single	
4					1.000000	No	No				1st Order	Single	
5					1.000000	No	No				1st Order	Single	
6					1.000000	No	No				1st Order	Single	
7					1.000000	No	No				1st Order	Single	
8					1.000000	No	No				1st Order	Single	

Component Table

	CCompRef1	CCompRef2	CCompRef3	Structure 1 Name	Structure 1 Description	Structure 1 Mol Wt	Structure 1 Formula	Structure 1 Structure	Structure 2 Name
1									
2									
3									
4									
5									
6									
7									
8									

Component Table

	Structure 2 Description	Structure 2 Mol Wt	Structure 2 Formula	Structure 2 Structure	Structure 3 Name	Structure 3 Description	Structure 3 Mol Wt	Structure 3 Formula	Structure 3 Structure	CConst1
1										
2										
3										
4										
5										
6										

Analysed by: B. Shave
Date: 29/04/2020

Checked by: D. Shave
Date: 30/04/2020

Component Table

	Structure 2 Description	Structure 2 Mol Wt	Structure 2 Formula	Structure 2 Structure	Structure 3 Name	Structure 3 Description	Structure 3 Mol Wt	Structure 3 Formula	Structure 3 Structure	CConst1
7										
8										

Component Table

	CConst2	CConst3	CConst4	CConst5	CConst6	CConst7
1						
2						
3						
4						
5						
6						
7						
8						

Processing Method Group 'Name Groups' table contains no data.

Processing Method Group 'Time Groups' table contains no data.

Processing Method Group 'Suit Limits-'PLACEBO 1'' table contains no data.

Processing Method Group 'Relative Limits-'PLACEBO 1'' table contains no data.

Processing Method Group 'Def Amts-'PLACEBO 1'' table contains no data.

Processing Method Group 'Suit Limits-'PLACEBO 2'' table contains no data.

Processing Method Group 'Relative Limits-'PLACEBO 2'' table contains no data.

Processing Method Group 'Def Amts-'PLACEBO 2'' table contains no data.

Processing Method Group 'Suit Limits-'PLACEBO 3'' table contains no data.

Processing Method Group 'Relative Limits-'PLACEBO 3'' table contains no data.

Processing Method Group 'Def Amts-'PLACEBO 3'' table contains no data.

Processing Method Group 'Suit Limits-'PLACEBO 4'' table contains no data.

Processing Method Group 'Relative Limits-'PLACEBO 4'' table contains no data.

Processing Method Group 'Def Amts-'PLACEBO 4'' table contains no data.

Processing Method Group 'Suit Limits-'BESYLATE'' table contains no data.

Processing Method Group 'Relative Limits-'BESYLATE'' table contains no data.

Processing Method Group 'Def Amts-'BESYLATE'' table contains no data.

Processing Method Group 'Suit Limits-'PERINDOPRIL'' table contains no data.

Processing Method Group 'Relative Limits-'PERINDOPRIL'' table contains no data.

Processing Method Group 'Def Amts-'PERINDOPRIL'' table contains no data.

Processing Method Group 'Suit Limits-'UNKNOWN IMPURITY'' table contains no data.

Processing Method Group 'Relative Limits-'UNKNOWN IMPURITY'' table contains no data.

Processing Method Group 'Def Amts-'UNKNOWN IMPURITY'' table contains no data.

Processing Method Group 'Suit Limits-'AMLODIPINE'' table contains no data.

Analysed by: B. Shau

Date: 29/04/2020

Checked by: D. Shau

Date: 30/04/2020

Processing Method Group 'Relative Limits-'AMLODIPINE'' table contains no data.

Processing Method Group 'Def Amts-'AMLODIPINE'' table contains no data.

Processing Method Group 'Primary Peaks (Primary MS Ions)' table contains no data.

Noise and Drift Parameters

Calculate Detector Noise and Drift No
 Detector Noise and Drift Start Time (Minutes)
 Detector Noise and Drift End Time (Minutes)
 Detector Noise and Drift Segment Width 60(sec)

Concentration Smoothing/Offset Parameters

Time Offset 0.000(Minutes)
 Smoothing Type None
 Smoothing Level None
 Empty parameters supersede the derived channel's smoothing and offset parameters No

LS Smoothing/Offset Parameters

Time Offset 0.000(Minutes)
 Smoothing Type None
 Smoothing Level None
 Empty parameters supersede the derived channel's smoothing and offset parameters No

Impurity Parameters

Calculate Total Impurities No Qualification Threshold
 Impurity Response Total Impurities Threshold
 w Value Maximum Impurity Threshold
 Main Component
 Reporting Threshold 0.05
 Identification Threshold

Excluded Component Types

Internal Standard Peaks

Revision History

Version 6 4/29/2020 20:13:27 IST User Sankar
 Version 5 4/28/2020 17:49:14 IST User RAJI
 Version 4 4/28/2020 17:46:51 IST User RAJI
 Version 3 4/28/2020 17:45:38 IST User RAJI
 Version 2 4/28/2020 16:20:15 IST User RAJI Created method 'AMLOPERIN_FP_RS_SPL_PM'.
 Version 1 4/28/2020 15:38:18 IST User RAJI Created method 'AMLOPERIN_FP_RS_SPL_PM'.

Method Version Summaries

	Method Name	Method Type	Method Comments	Method Date	Method Modified User	Method Locked
1	AMLOPERIN_FP_RS_SPL_PM	Processing		4/29/2020 20:13:27 IST	Sankar	No
2	AMLOPERIN_FP_RS_SPL_PM	Processing		4/28/2020 17:49:14 IST	RAJI	No
3	AMLOPERIN_FP_RS_SPL_PM	Processing		4/28/2020 17:46:51 IST	RAJI	No
4	AMLOPERIN_FP_RS_SPL_PM	Processing		4/28/2020 17:45:38 IST	RAJI	No
5	AMLOPERIN_FP_RS_SPL_PM	Processing		4/28/2020 16:20:15 IST	RAJI	No
6	AMLOPERIN_FP_RS_SPL_PM	Processing		4/28/2020 15:38:18 IST	RAJI	No

Analysed by: B. Shaz
 Date: 29/04/2020

Checked by: D. Shaz
 Date: 30/04/2020

Reported by User: Sankar (Sankar)
 Report Method: PROCESSING METHOD
 Report Method ID1555
 Page: 5 of 6

Project Name: 2020\QC-HPL-001\APR-202
 Printed Date: 4/29/2020
 Printed Time: 8:42:47 Asia

Method Version Summaries

	Method Id	Old Id	Method Version	Source S/W Info
1	5166	4904	6	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505
2	4904	4893	5	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505
3	4893	4881	4	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505
4	4881	4849	3	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505
5	4849	4779	2	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505
6	4779		1	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2299089505

Analysed by: B. Shax
Date: 29/04/2020

Checked by: D. Shax
Date: 30/04/2020

		EXCEL SHEET FOR UNIFORMITY OF CONTENT					
Name of Product		AMLOPERIN 5/5 TABLETS (PERINDOPRIL ERBUMINE)					
Date of Analysis		28-04-2020		Batch No.		GF200405	
Mfg. Date		Apr-20		Exp. Date		Mar-23	
WS No.		NA		% Purity		99.3	
WS Weight (WS)		50.56		WS Validity		NA	
Sample Weight (SW)		1		Label Claim (LC)		5	
Std. Dilution		50.56	5	1	1	1	1
		100	50	1	1	1	1
Sample Dilution		1	1	1	1	1	1
		100	1	1	1	1	1
Calculation Formula		Smp. Area	99.3	100	Conversion Factor1	Conversion Factor3	% Assay
		Std. Area	100	5	Conversion Factor2	Conversion Factor4	
Sr. No.		Standard Area	Standard RT	Sample			
1	481300	3.881	UC	Smp. Weight	%	mg	Minimum %
2	478170	3.877	UC1	1	100.64	5.03	96.85
3	478673	3.877	UC2	1	100.36	5.02	
4	480383	3.875	UC3	1	96.85	4.84	
5	478614	3.872	UC4	1	98.31	4.92	
6			UC5	1	97.03	4.85	Maximum %
7			UC6	1	101.79	5.09	104.04
8			UC7	1	101.01	5.05	
Average	479428	3.876	UC8	1	104.04	5.20	
SD	1344.581162	0.00328634	UC9	1	101.03	5.05	
RSD	0.3	0.1	UC10	1	102.54	5.13	
Analysed By		B.8 Jay		Checked By		D. D. D. D.	
Date		29/04/2020		Date		30/04/2020	

		EXCEL SHEET FOR UNIFORMITY OF CONTENT					
Name of Product		AMLOPERIN 5/5 TABLETS (AMLODIPINE BESYLATE)					
Date of Analysis		28-04-2020		Batch No.		GF200405	
Mfg. Date		Apr-20		Exp. Date		Mar-23	
WS No.		NA		% Purity		99.3	
WS Weight (WS)		69.64		WS Validity		NA	
Sample Weight (SW)		1		Label Claim (LC)		5	
Std. Dilution		69.64 100		5 50		1 1	
Sample Dilution		1 100		1 1		1 1	
Calculation Formula		Smp. Area Std. Area		Std Dilution Sample Dilution		99.3 100	
				Conversion Factor1 Conversion Factor2		100 5	
				Conversion Factor3 Conversion Factor4		95.76 102.15	
						% Assay	
Sr. No.		Standard Area		Standard RT		Sample	
1		1283254		5.816		UC	
2		1276175		5.808		UC1	
3		1277508		5.807		UC2	
4		1281701		5.803		UC3	
5		1278400		5.797		UC4	
6						UC5	
7						UC6	
8						UC7	
Average		1279408		5.806		UC8	
SD		2963.44045		0.00697854		UC9	
RSD		0.2		0.1		UC10	
Analysed By		B. Shree		Checked By		D. Shree	
Date		29/04/2020		Date		20/04/2020	

SAI PRIMUS LIFE BIOTECH PVT LTD		EXCEL SHEET FOR ASSAY CALCULATION FP									
Name of Product		AMLOPERIN 5/5 TABLETS (AMLODIPINE BESYLATE)									
Date of Analysis		28-04-2020		Batch No.		GF200405					
Mfg. Date		APR-2020		Exp. Date		MAR-2023					
WS No.		NA		% Purity		99.3					
WS Weight (WS)		69.64		WS Validity		NA					
Sample Weight (SW)		1400.17		Label Claim (LC)		5					
CF1		0.72		CF2		1		CF3		1	
Std. Dilution		69.64		5		1		1		1	
		100		50		1		1		1	
Sample Dilution		1400.17		5		1		1		1	
		100		50		1		1		1	
Calculation Formula		Smp. Area/Abs		Std Dilution		99.3		141.65		CF1	
		Std. Area/Abs		Sample Dilution		100		CF2		CF3	
								CF4			
Sr. No.		Standard Area/Abs		Standard RT				Sr. No.		Sample Area/Abs	
1		1283254		5.816				1		1274415	
2		1276175		5.808				2		1273060	
3		1277508		5.807				3			
4		1281701		5.803				4			
5		1278400		5.797				5			
6								6			
Average		1279408		5.806				Average		1273738	
SD		2963.44		0.01							
RSD		0.23		0.12							
Assay (mg)		5.0147						Assay (%)		100.29	
Analysed By B. Shave								Checked By D. D. Shave			
Date 29/04/2020								Date 30/04/2020			



EXCEL SHEET FOR ASSAY CALCULATION FP

Name of Product		AMLOPERIN 5/5 TABLETS (PERINDOPRIL ERBUMINE)									
Date of Analysis		28-04-2020		Batch No.		GF200405					
Mfg. Date		APR-2020		Exp. Date		MAR-2023					
WS No.		NA		% Purity		99.1					
WS Weight (WS)		50.56		WS Validity		NA					
Sample Weight (SW)		1400.17		Label Claim (LC)		5					
CF1		1		CF2		1		CF4		1	
Std. Dilution		50.56		5		1		1		1	
		100		50		1		1		1	
Sample Dilution		1400.17		5		1		1		1	
		100		50		1		1		1	
Calculation Formula		Smp. Area/Abs		Std Dilution		99.1		141.65		CF1	
		Std. Area/Abs		Sample Dilution		100		CF2		CF3	
								CF4			
Sr. No.		Standard Area/Abs		Standard RT				Sr. No.		Sample Area/Abs	
1		481300		3.881				1		477972	
2		478170		3.877				2		477627	
3		478673		3.877				3			
4		480383		3.875				4			
5		478614		3.872				5			
6								6			
Average		479428		3.876				Average		477800	
SD		1344.58		0.00							
RSD		0.28		0.08							
Assay (mg)		5.052						Assay (%)		101.03	
Analysed By B. Shree								Checked By D. Shree			
Date 29/04/2020								Date 30/04/2020			



EXCEL SHEET FOR DISSOLUTION CALCULATION

Name of Product	AMLOPERIN 5/5 TABLETS (PERINDOPRIL ERBUMINE)				
Date of Analysis	29-04-2020	Batch No.	GF200405		
Mfg. Date	APR-2020	Exp. Date	MAR-2023		
WS No.	NA	% Purity	99.1		
WS Weight (WS)	49.51	WS Validity	NA		
Sample Weight (SW)	1	Label Claim (LC)	5		

Std. Dilution	49.51	5	5	1	1	1
	50	50	50	1	1	1

CF1	1
CF2	1
CF3	1
CF4	1

Sample Dilution	1	1	1	1	1	1
	500	1	1	1	1	1

Calculation	Smp. Area/Abs	Std Dilution	99.1	100	CF1	CF3
Formula	Std. Area/Abs	Sample Dilution	100	5	CF2	CF4

Sr. No.	Standard Area/Abs	Standard RT
1	513568	3.951
2	512552	3.944
3	516200	3.937
4	512687	3.933
5	512705	3.929
6		
Average	513542	3.939
SD	1539.263883	0.008786353
%RSD	0.3	0.2

Tablet	Area/Abs.
Tab1	510830
Tab2	511038
Tab3	534432
Tab4	510036
Tab5	512065
Tab6	514096
Average	
Minimum	
Maximum	

Result %	Result mg
97.61	4.88
97.65	4.88
102.12	5.11
97.46	4.87
97.85	4.89
98.23	4.91
98.49	4.92
97.46	4.87
102.12	5.11

Analysed By: *[Signature]*
Date: 29/04/2020

Checked By: *[Signature]*
Date: 29/04/2020



EXCEL SHEET FOR DISSOLUTION CALCULATION

Name of Product	AMLOPERIN 5/5 TABLETS (AMLODIPINE)				
Date of Analysis	29-04-2020	Batch No.	GF200405		
Mfg. Date	APR-2020	Exp. Date	MAR-2023		
WS No.	NA	% Purity	99.3		
WS Weight (WS)	69.53	WS Validity	NA		
Sample Weight (SW)	1	Label Claim (LC)	5		

Std. Dilution	69.53	5	5	1	1	1
	50	50	50	1	1	1
Sample Dilution	1	1	1	1	1	1
	500	1	1	1	1	1
						CF1
						CF2
						CF3
						CF4

Calculation Formula	Smp. Area/Abs	Std Dilution	99.3	100	CF1	CF3
	Std. Area/Abs	Sample Dilution	100	5	CF2	CF4

Sr. No.	Standard Area/Abs	Standard RT
1	1297240	5.815
2	1298443	5.796
3	1297197	5.781
4	1298316	5.770
5	1291328	5.758
6		
Average	1296505	5.784
SD	2951.947781	0.02228228
%RSD	0.2	0.4

Tablet	Area/Abs.
Tab1	1236254
Tab2	1218643
Tab3	1225166
Tab4	1211739
Tab5	1323197
Tab6	1227510
Average	
Minimum	
Maximum	

Result %	Result mg
94.80	4.74
93.45	4.67
93.95	4.70
92.92	4.65
101.47	5.07
94.13	4.71
95.12	4.76
92.92	4.65
101.47	5.07

Analysed By *[Signature]*
Date 24/04/2020

Checked By *[Signature]*
Date 20/04/2020

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009	Page 1 of 6	Issued by QA/Date: <i>EB</i> 23/04/2020
	MICROBIAL LIMIT TEST	No.: F/QCMB/006/02	
TITLE:	MICROBIAL LIMIT TEST REPORT	Revision No.: 00	
		Review Period: 02 years	
		Effective Date: 24/04/19	

MICROBIOLOGICAL TEST REPORT

Name of Product:	Amleperin 5mg / 5mg tablets		
Type of Product	Finished product		
Batch No./ Lot No.	GF200405	A.R. No.	FP/280420/01
Mfg. Date	April-2020	Exp.Date	March-2023
Date of Analysis	28/04/2020	Date of Completion	05/05/2020

S.No:	Test Required	Result	Specification
1.	Total aerobic microbial count	20 cfm	Not more than 1000 cfu g or ml
2.	Total yeast and mould count	<10 cfm	Not more than 100 cfu g or ml
3.	Pathogens		
	a.E.coli	Absent	Should be absent in g or ml
	b.Salmonella sp.	Absent	Should be absent in 10g or 10ml
	c.Pseudomonas aeruginosa	Absent	Should be absent in g or ml
	d.Staphylococcus aureus	Absent	Should be absent in g or ml
	e.Shigella sp.	NA	Should be absent in 10g or 10ml
	f.Enterobacteriace	NA	Should be absent in g or ml

Analysed by: <i>A. Vsb</i> 28/04/2020	Reported by: <i>A. Vsb</i> 05/05/2020	Checked by: <i>B. Shree</i> 05/05/2020
--	--	---

MASTER COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009	Page 2 of 6	Issued by QA/Date: 23/04/2020
	MICROBIAL LIMIT TEST	No.: F/QCMB/006/02	
TITLE:	MICROBIAL LIMIT TEST REPORT	Revision No.: 00	
		Review Period: 02 years	
		Effective Date: 24/04/19	

Name of Product:	Batch No./ Lot No.	A.R. No.	Ref. Specification No.
Amlopin 5mg/5mg tablets	GTF200405	FP/280420/01	
Type of Product	Sample Received on	Date of Analysis	Date of Completion
Finished product	28/04/2020	28/04/2020	05/05/2020

Media and Accessories used:

Autoclave Id. No: MB/MCE/001

Micropipette Id. No: MB/MOP/003

S. No.	Name of the Media	Media Preparation Details		Media Batch No.
		Date	Sterilization cycle No.	
1	SCDM	25/04/2020	MS-20-0182	MP/20/0408
2	SCDA	28/04/2020	MS-20-0186	MP/20/0418
3	SDA	28/04/2020	MS-20-0186	MP/20/0419
4	MCB	24/04/2020	MS-20-0180	MP/20/0399
5	MCA	28/04/2020	MS-20-0186	MP/20/0424
6	RVSE	NA	NA	NA
7	XLDA	28/04/2020	NA	MP/20/0422
8	MSA	24/04/2020	MS-20-0180	MP/20/0401
9	CA	24/04/2020	MS-20-0180	MP/20/0400
10	EE			
11	VRBGA			
12	GN			
13	XLDA			

Note: Rappaport Vassiliadis Salmonella Enrichment Broth (Readymade form):

Media Mfg.: 14/06/2023 Media Lot No: RVSEB-1934 Expiry at: 10/06/2025

A. Uth
28/04/2020

MASTER COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009	Page 3 of 6	Issued by QA/Date:  23/04/2020
	MICROBIAL LIMIT TEST	No.: F/QCMB/006/02	
TITLE:	MICROBIAL LIMIT TEST REPORT	Revision No.: 00	
		Review Period: 02 years	
		Effective Date: 24/04/19	

S. No.	Temperature	Incubator Id. No.
1	30-35°C	MB/BOT/002
2	20-25°C	MB/BOD/001
3	42-44°C	MB/BOT/003

Procedure:

LAF Id. No: MB/LAF/001

BSC Id. No: MB/BSC/001

a) Sample preparation:

Taken 2-9.1602 g/ml of sample and dissolve in 90/100 mL of SCDM aseptically.
 Culture enrichment for the detection of *E. coli*, *S. aureus* & *P. aeruginosa* Inoculate 10mL of diluted sample in to 90mL of SCDM (**Enrichment II**) aseptically & incubate at 30 -35°C for not less than 18-24 hours

b) Sample preparation for salmonella abony :

Taken 2-9.1601 g/ml of sample and dissolve in 90mL of SCDM aseptically.
 Incubate at 30 -35°C for not less than 18-24 hours

Method of analysis: Pipette out 1ml of diluted sample in one set of petriplate and aseptically add 15-20 mL of media respectively, rotate and allow to solidify and incubate at appropriate conditions

TAMC & TYMC :							
Tested for	Incubation details		Incubated on		Observed on		Observed by
	Temp. (°C)	Duration (days)	Date	Time	Date	Time	
TAMC	30-35	3-5	28/04/2020	17:50	04/05/2020	14:05	A. Uth 28/04/2020 04/05/2020
TYMC	20-25	5-7	28/04/2020	17:55	04/05/2020	14:15	A. Uth 28/04/2020 04/05/2020

MASTER COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009	Page 4 of 6 Issued by QA/Date: <u>EB</u> <u>23/04/2020</u>
	MICROBIAL LIMIT TEST	No.: F/QCMB/006/02
TITLE:	MICROBIAL LIMIT TEST REPORT	Revision No.: 00
		Review Period: 02 years
		Effective Date: <u>24/04/19</u>

Enrichment :								
Tested for	Incubation details		Incubated on		Observed on		Done by	Observed by
	Temp. (°C)	Duration (hours)	Date	Time	Date	Time		
Pre enrichment for <i>E. coli</i> , <i>P. aeruginosa</i> , <i>S. aureus</i> & <i>Shigella</i> Species	30-35	18-24	28/04/2020	17:50	29/04/2020	14:05	A.Us 28/04/2020	A.Us 29/04/2020
Pre enrichment for <i>Salmonella</i> abony	30-35	18-24	28/04/2020	17:50	29/04/2020	14:05	A.Us 28/04/2020	A.Us 29/04/2020
Pre enrichment for Bile tolerant gram negative bacteria	20-25	2-5					NA	

Test for Specified Microorganisms

- E. coli*:** Add 1 ml of the above sample preparation to 100 ml of MCB and incubate at appropriate conditions. After incubation, streak a loopful of suspension in MCA and incubate at appropriate conditions.
- Salmonella* sp.:** Add 10 gm or 10 ml sample in 100/90 ml Soyabean Casein Digest medium. Add 0.1 ml of the sample preparation to 10 mL of RVSE broth and incubate at appropriate conditions. After incubation, streak a loopful of suspension in XLDA and incubate at appropriate conditions.
- Pseudomonas aeruginosa*:** Streak a loopful of sample preparation in CA and incubate at appropriate conditions.
- Staphylococcus aureus*:** Streak a loopful of sample preparation in MSA and incubate at appropriate conditions.
- Bile tolerant gram negative bacteria:** Inoculate 10 ml of enriched sample in 100ml Enterobacteria enrichment broth mossel and incubate at appropriate

MASTER COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009	Page 5 of 6	Issued by QA/Date: EP 23/04/2020
	MICROBIAL LIMIT TEST	No.: F/QCMB/006/02	
TITLE:	MICROBIAL LIMIT TEST REPORT	Revision No.: 00	
		Review Period: 02 years	
		Effective Date: 24/04/19	

conditions. After incubation, streak a loopful of suspension in Violet Red bile glucose agar and incubate at appropriate conditions.

6. **Shigella Species:** Add 1 ml of the above sample preparation to 100 ml of GN broth and incubate at appropriate conditions. After incubation, streak a loopful of suspension in XLDA and incubate at appropriate conditions.

Test for Specified Microorganisms:

Tested for	Method of analysis	Incubation Details		Incubated on		Observed on		Done by	Observed by
		Temp (°C)	Duration (Hours)	Date	Time	Date	Time		
<i>E. coli</i>	MCB	42 -44	24 - 48	29/04/2020	15:35	02/05/2020	14:09	A. Uz 29/04/2020	A. Uz 02/05/2020
	MCA	30 -35	18 - 72	02/05/2020	15:35	05/05/2020	14:10	A. Uz 02/05/2020	A. Uz 05/05/2020
<i>Salmonella</i> Species.	RVSE	30 -35	18 -24	29/04/2020	15:30	30/04/2020	14:10	A. Uz 29/04/2020	A. Uz 30/04/2020
	XLDA	30 -35	24 - 48	30/04/2020	15:30	02/05/2020	14:04	A. Uz 30/04/2020	A. Uz 02/05/2020
<i>S. aureus</i>	MSA	30 -35	18 -72	29/04/2020	15:30	02/05/2020	14:04	A. Uz 29/04/2020	A. Uz 02/05/2020
<i>P. aeruginosa</i>	CA	30 -35	18 -72	29/04/2020	15:30	02/05/2020	14:04	A. Uz 29/04/2020	A. Uz 02/05/2020
<i>Bile tolerant gram negative bacteria</i>	EE	30-35	24-48	NA					
	VRBGA	30-35	18-24						
<i>Shigella</i> Species.	GN	30-35	24-48						
	XLDA	30-35	24-48						

A. Uz
29/04/2020

MASTER COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009	Page 6 of 6 Issued by QA/Date: <u>23/04/2020</u>
	MICROBIAL LIMIT TEST	No.: F/QCMB/006/02
TITLE:	MICROBIAL LIMIT TEST REPORT	Revision No.: 00
		Review Period: 02 years
		Effective Date: <u>24/04/19</u>

Observation:

Parameter	TAMC		TYMC	
	Plate 1	Plate 2	Plate 1	Plate 2
Count per plate	01	02	21	21
Average	02		21	

Calculation:

TAMC: Average Count X Dilution factor = 02 Countx10 = 20 cfu/gm/ml.

TYMC: Average Count X Dilution factor = 21 Countx10 = 210 cfu/gm/ml

Test for Specified Microorganisms
--

Pre - Enrichment test: Samples shown growth/Not shown growth ✓

Enrichment and Conformation Test:

MCB	MCA	RVS	XLDA	MSA	CA	EE	VRBGA	GN Broth	XLDA
X	X	X	X	X	X	NA	NA	NA	NA

- 1) Positive Control: Shown growth / not shown growth. ✓
- 2) Negative Control: Shown growth / not shown growth. ✓

Note: ✓ - Shown Growth, X - Not Shown Growth

Result: The above sample complies/does not comply with the Specification No.

_____ as per USP/IP.

Analysed by: <u>A. Uth</u> <u>28/04/2020</u>	Reported by: <u>A. Uth</u> <u>05/05/2020</u>	Checked by: <u>B. Shree</u> <u>05/05/2020</u>
---	---	--

MASTER COPY	
--------------------	--

Certificate Of Analysis

Certificate number	20/05/05/21		
Name & Address of Customer	ALFA BIOMED LTD 38 Dublin Road, Sutton, Dublin, D13 H9K3 Ireland.		
Sample Name	AMLOPERIN 5 mg/5 mg TABLETS	Batch No	GF200405
Date of Manufacture	APR 2020	Expiry Date	MAR 2023
Date of Receipt	05 MAY 2020	Date of Analysis	06 MAY 2020
Received Quantity	1 CARTON	Reference Number	20/05/05/21
Manufacturing Lic. No.	-		
Name of Original Manufacturer/Supplier	GHPL / GHPL		
Analysis Required	Related substance		

The Undersigned Hereby Certifies The Following Data To Be True Specification Of The Results As Per The Drugs And Cosmetics Act 1940 And The Rules Thereunder Form 39[See Rule 150-E (f)].

Test	Limit	Result
Appearance	Off-White, round, biconvex, uncoated tablet plain on both sides.	Complies
Average weight of tablets	140 mg $\pm$ 5.0 % (133.0 mg to 147.0 mg)	139.23 mg
Related substance		
Amlodipine impurity A	NMT 1.00 %	Not detected

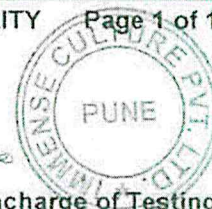
OPINION IN THE OPINION OF THE UNDERSIGNED THE SAMPLE REFERRED TO ABOVE IS OF STANDARD QUALITY AS DEFINED IN THE ACT OF AND RULES THEREUNDER FOR THE REASONS GIVEN BELOW

ABOVE PERFORMED TESTS COMPLIES AS PER SPECIFICATION NO.GHPL/FPS/E/T/002/01

The opinion is in respect of the tests carried out the sample, as mentioned above.

- Legal Liability is limited to the value in the invoice for testing.
- Sampling was not done by IMMENSE CULTURE PVT. LTD.
- This analysis report shall not be reproduced except in full, without written approval of IMMENSE CULTURE PVT. LTD.

[Signature]
06 MAY 2020



Person Incharge of Testing

 Immense Culture	Immense Culture Pvt. Ltd. Sr.No. 14, Dhadge Industrial Estate, Nanded, Pune-411041
RAW DATA SHEET FOR FINISHED PRODUCT	
Name of Product: AMLOPERIN 5 MG/ 5 MG	
Batch No: GF200405	A.R. Number: 20/05/05/21
Sample Qty.: 01 CARTON	Stage: NA
Analysis Start On: 06 MAY 2020	Specification no: 4 HPL / FPS / E17 / 002 / 01
Analysis Completed On: 06 MAY 2020	

1) Description: off-white, round, biconvex, uncoated tablet plain on both sides

2) Identification:

3) Avg. weight of tablet:

$$\text{Avg. weight of tablet} = \frac{2784.6 \text{ mg}}{20} = 139.23 \text{ mg}$$

4) Uniformity of Wt. of tablets:

No.	Weight in mg	No.	Weight in mg	No.	Weight in mg	No.	Weight in mg
1		6		11		16	
2		7		12		17	
3		8		13		18	
4		9		14		19	
5		10		15		20	

5) Friability:

i) Weight of tablets before test: gm.

ii) Weight of tablets after test: gm.

iii) Weight difference: gm.

$$\text{Friability} = \frac{\text{Weight difference}}{\text{Weight of tablets before test}} \times 100 =$$

Analyzed By:  Date: 06 MAY 2020	Checked by:  Date: 06 MAY 2020
---	--

 Immense Culture	Immense Culture Pvt. Ltd. Sr.No. 14, Dhadge Industrial Estate, Nanded, Pune-411041	
RAW DATA SHEET FOR FINISHED PRODUCT		
Name of Product: AMLOPERIN 5 MG/ 5 MG		
Batch No: GF200405	A.R. Number: 20/05/05/21	
Sample Qty.: 01 CARTON	Stage: NA	
Analysis Start On: 06 MAY 2020	Specification no: 4HP4FPS1E171002101	
Analysis Completed On: 06 MAY 2020		

13) Related Substances/ Impurities: Amlodipine Impurity A.

Chromatographic Condition:

Column Description	:	cg, 4.6mm x 250 mm, 5µm K80 mosil
Column No.	:	IC11C-01
Flow Rate	:	1 mL/minute
Wavelength	:	237 nm
Injection Volume	:	20 µL
Column Oven Temperature	:	40°C

Preparation of buffer for Mobile phase:

3.75 mL triethylamine → 500 mL H₂O -
 adjust pH 3.0 with OPA

Mobile phase preparation:

450 mL buffer solution + 1800 methanol + 750 ACN.

Resolution/ impurity preparation:

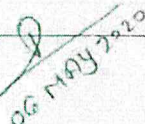
Standard/ Reference Preparation:

Placebo solution →
 0.6582 gm of placebo → 50 mL diluent (MP)

Sample Preparation:

0.7049 gm 20105105121 sample → 50 mL mobile phase

Calculation and Results: Refter excel

Analyzed By:  Date: 06 MAY 2020	Checked by:  Date: 06 MAY 2020
---	--

Balance Printout Sheet



Product Name	Amlodipine 515 mg	Batch No.	GF200405
AR No.	20105105121	Specification No.	GHPL1FP91E171002101
Test Name	Related Substances		

06.05.2020 10:57
Balance Type ME204/A04
SNR 2736361113

N 0.6582 g

Signature

[Signature]
06 MAY 2020

wt. of placebo

Test - RS

Impurity A

20105105121

06.05.2020 11:09
Balance Type ME204/A04
SNR 2736361113

N 0.7049 g

Signature

[Signature]
06 MAY 2020

wt. of Sample

Test - RS

Impurity A

20105105121

Analysed By	<i>[Signature]</i> 06 MAY 2020	Checked By	<i>[Signature]</i> 06 MAY 2020
-------------	-----------------------------------	------------	-----------------------------------

78

Sequence: 20_05_05_17 Amlodipine Amloperin_RS
Operator: Administrator

Page 1 of 1
Printed: 5/6/2020 9:04:13 AM

Title: Gradient 3D 06-04-16 11
Datasource: DATA_2020
Location: GHPLIMAYAmlo RS
Timebase: uhplc_01
#Samples: 24

Created: 5/6/2020 8:53:38 AM by Administrator
Last Update: 5/6/2020 9:04:05 AM by Administrator

No.	Name	Type	Pot	Inj. Vol	Program	Method	Status	Inj. Date/Time	Weight	Dil. Factor	ISTD Amount	Sample ID	Replicate ID	Comment
1	Blank	Unknown	GA1	20.000	AMLODIPINE-10min	AMLODIPINE	Single		1.0000	1.0000	1.0000		1	
2	System suitability solution	Standard	GA2	20.000	AMLODIPINE-10min	AMLODIPINE	Single		1.0000	1.0000	1.0000		1	
3	Blank	Unknown	GA1	20.000	AMLODIPINE-10min	AMLODIPINE	Single		1.0000	1.0000	1.0000		1	
4	Impurity A Standard Solution 1	Standard	GA3	20.000	AMLODIPINE-10min	AMLODIPINE	Single		1.0000	1.0000	1.0000		1	
5	Impurity A Standard Solution 2	Standard	GA3	20.000	AMLODIPINE-10min	AMLODIPINE	Single		1.0000	1.0000	1.0000		2	
6	Impurity A Standard Solution 3	Standard	GA3	20.000	AMLODIPINE-10min	AMLODIPINE	Single		1.0000	1.0000	1.0000		3	
7	Impurity A Standard Solution 4	Standard	GA3	20.000	AMLODIPINE-10min	AMLODIPINE	Single		1.0000	1.0000	1.0000		4	
8	Impurity A Standard Solution 5	Standard	GA3	20.000	AMLODIPINE-10min	AMLODIPINE	Single		1.0000	1.0000	1.0000		4	
9	Impurity A Standard Solution 6	Standard	GA3	20.000	AMLODIPINE-10min	AMLODIPINE	Single		1.0000	1.0000	1.0000		5	
10	Blank	Unknown	GA1	20.000	AMLODIPINE-10min	AMLODIPINE	Single		1.0000	1.0000	1.0000		1	
11	Placebo 5-5 mg Amloperin	Unknown	GA4	20.000	AMLODIPINE-30min	AMLODIPINE	Single		1.0000	1.0000	1.0000		1	
12	Blank	Unknown	GA1	20.000	AMLODIPINE-30min	AMLODIPINE	Single		1.0000	1.0000	1.0000		1	
13	5-5 mg GF200405 RS SPL	Unknown	GA5	20.000	AMLODIPINE-30min	AMLODIPINE	Single		1.0000	1.0000	1.0000		1	
14	Impurity A Standard (BKT)	Standard	GA3	20.000	AMLODIPINE-10min	AMLODIPINE	Single		1.0000	1.0000	1.0000		1	
15	Placebo 10-10 mg Amlodipine	Unknown	GA6	20.000	AMLODIPINE-30min	AMLODIPINE	Single		1.0000	1.0000	1.0000		1	
16	Blank	Unknown	GA1	20.000	AMLODIPINE-30min	AMLODIPINE	Single		1.0000	1.0000	1.0000		1	
17	10-10 mg GF200402 RS SPL 1	Unknown	GA7	20.000	AMLODIPINE-30min	AMLODIPINE	Single		1.0000	1.0000	1.0000		1	
18	10-10 mg GF200403 RS SPL 1	Unknown	GA8	20.000	AMLODIPINE-30min	AMLODIPINE	Single		1.0000	1.0000	1.0000		1	
19	10-10 mg GF200404 RS SPL 1	Unknown	GB1	20.000	AMLODIPINE-30min	AMLODIPINE	Single		1.0000	1.0000	1.0000		1	
20	Impurity A Standard (BKT)	Standard	GA3	20.000	AMLODIPINE-10min	AMLODIPINE	Single		1.0000	1.0000	1.0000		1	
21	Placebo 5-10 mg Amlodipine	Unknown	GB2	20.000	AMLODIPINE-30min	AMLODIPINE	Single		1.0000	1.0000	1.0000		1	
22	Blank	Unknown	GA1	20.000	AMLODIPINE-30min	AMLODIPINE	Single		1.0000	1.0000	1.0000		1	
23	5-10 mg GF200401 RS SPL 1	Unknown	GB3	20.000	AMLODIPINE-30min	AMLODIPINE	Single		1.0000	1.0000	1.0000		1	
24	Impurity A Standard (BKT)	Standard	GA3	20.000	AMLODIPINE-10min	AMLODIPINE	Single		1.0000	1.0000	1.0000		1	

B.L.
06 MAY 2020

OG MAY 2020

Title: AMLODIPINE

Datasource: DATA_2020

Created: 8/25/2018 3:33:43 PM by Administrator

Location: GHPL\MAY\Amlo RS\20_05_05_17 Amlodipine Amloperin_RS.SEQ

Timebase: UHPLC_01

Changed: 1/10/2019 12:20:02 PM by Administrator

```
Sampler.TempCtrl = On
Sampler.Temperature.Nominal = 25.0 [°C] ✓
Sampler.Temperature.LowerLimit = 8.0 [°C]
Sampler.Temperature.UpperLimit = 45.0 [°C]
Sampler.ReadyTempDelta = 1.0 [°C]
ColumnOven.TempCtrl = On
ColumnOven.Temperature.Nominal = 40.0 [°C] ✓
ColumnOven.Temperature.LowerLimit = 0.0 [°C]
ColumnOven.Temperature.UpperLimit = 50.0 [°C]
EquilibrationTime = 0.5 [min] ✓
ColumnOven.ReadyTempDelta = 5.0 [°C]
Pressure.LowerLimit = 10 [bar]
Pressure.UpperLimit = 620 [bar]
MaximumFlowRampDown = 6.000 [ml/min²]
MaximumFlowRampUp = 6.000 [ml/min²]
%A.Equate = "150:600:250" ✓
Buffer:MeOH:ACN" ✓
DrawSpeed = 5.000 [µl/s]
DrawDelay = 3000 [ms]
DispSpeed = 10.000 [µl/s]
DispenseDelay = 3000 [ms]
WasteSpeed = 50.000 [µl/s]
WashSpeed = 50.000 [µl/s]
LoopWashFactor = 2.000
SampleHeight = 1.000 [mm]
WashVolume = 250.000 [µl]
SyncWithPump = On
PumpDevice = "Pump" ✓
PunctureOffset = 0.0 [mm]
InjectMode = Partial
FlushVolume = 80.000 [µl]
ColumnOven_Temp.Step = Auto
ColumnOven_Temp.Average = On
Pump_Pressure.Step = 0.01 [s]
Pump_Pressure.Average = On
Data_Collection_Rate = 5 [Hz]
ResponseTime = 2.000 [s]
UV_VIS_1.Wavelength = 237.0 [nm] ✓
UV_VIS_1.Bandwidth = 1 [nm]
UV_VIS_1.RefWavelength = Off
UV_VIS_1.RefBandwidth = 1 [nm]
3DFIELD.RefWavelength = Off
3DFIELD.RefBandwidth = 1 [nm]
Flow = 1.000 [ml/min] ✓
```

3-1
06 MAY 2020

06 MAY 2020

Program File: AMLODIPINE-30min

Operator: Administrator

Commands, Page 2 of 2

Printed: 5/6/2020 9:10:00 AM

Title: AMLODIPINE

Datasource: DATA_2020

Created: 8/25/2018 3:33:43 PM by Administrator

Location: GHPL\MAY\Amlo RS\20_05_05_17 Amlodipine Amloperin_RS.SEQ

Timebase: UHPLC_01

Changed: 1/10/2019 12:20:02 PM by Administrator

%B = 0.0 [%]
%C = 0.0 [%]
%D = 0.0 [%]
Curve = 5
3DFIELD.MinWavelength = 200.0 [nm]
3DFIELD.MaxWavelength = 360.0 [nm]
3DFIELD.BunchWidth = 1 [nm]

0.000 Autozero
Wait UV.Ready and Pump.Ready
and ColumnOven.Ready and Sampler.Ready and PumpModule.Ready
Inject
ColumnOven_Temp.AcqOn
Pump_Pressure.AcqOn
UV_VIS_1.AcqOn
Temp_Lamphouse.AcqOn
3DFIELD.AcqOn

30.000 ColumnOven_Temp.AcqOff
Pump_Pressure.AcqOff
UV_VIS_1.AcqOff
Temp_Lamphouse.AcqOff
3DFIELD.AcqOff
End

8-1
06 May 2020

06 May 2020

Program File: AMLODIPINE-10min
Operator: Administrator

Commands, Page 1 of 2
Printed: 5/6/2020 9:09:42 AM

Title: AMLODIPINE

Datasource: DATA_2020

Location: GHPL\MAY\Amlo RS\20_05_05_17 Amlo dipine Amloperin_RS.SEQ

Timebase: UHPLC_01

Created: 8/25/2018 3:29:46 PM by Administrator

Changed: 1/10/2019 12:19:20 PM by Administrator

Sampler.TempCtrl = On
Sampler.Temperature.Nominal = 25.0 [°C]
Sampler.Temperature.LowerLimit = 8.0 [°C]
Sampler.Temperature.UpperLimit = 45.0 [°C]
Sampler.ReadyTempDelta = 1.0 [°C]
ColumnOven.TempCtrl = On
ColumnOven.Temperature.Nominal = 40.0 [°C]
ColumnOven.Temperature.LowerLimit = 0.0 [°C]
ColumnOven.Temperature.UpperLimit = 50.0 [°C]
EquilibrationTime = 0.5 [min]
ColumnOven.ReadyTempDelta = 5.0 [°C]
Pressure.LowerLimit = 10 [bar]
Pressure.UpperLimit = 620 [bar]
MaximumFlowRampDown = 6.000 [ml/min²]
MaximumFlowRampUp = 6.000 [ml/min²]
%A.Equate = "150:600:250"
Buffer:MeOH:ACN"
DrawSpeed = 5.000 [µl/s]
DrawDelay = 3000 [ms]
DispSpeed = 10.000 [µl/s]
DispenseDelay = 3000 [ms]
WasteSpeed = 50.000 [µl/s]
WashSpeed = 50.000 [µl/s]
LoopWashFactor = 2.000
SampleHeight = 1.000 [mm]
WashVolume = 250.000 [µl]
SyncWithPump = On
PumpDevice = "Pump"
PunctureOffset = 0.0 [mm]
InjectMode = Partial
FlushVolume = 80.000 [µl]
ColumnOven_Temp.Step = Auto
ColumnOven_Temp.Average = On
Pump_Pressure.Step = 0.01 [s]
Pump_Pressure.Average = On
Data_Collection_Rate = 5 [Hz]
ResponseTime = 2.000 [s]
UV_VIS_1.Wavelength = 237.0 [nm]
UV_VIS_1.Bandwidth = 1 [nm]
UV_VIS_1.RefWavelength = Off
UV_VIS_1.RefBandwidth = 1 [nm]
3DFIELD.RefWavelength = Off
3DFIELD.RefBandwidth = 1 [nm]
Flow = 1.000 [ml/min]

06 MAY 2020

06 MAY 2020

Program File: AMLODIPINE-10min
Operator: Administrator

Commands, Page 2 of 2
Printed: 5/6/2020 9:09:42 AM

Title: AMLODIPINE
Datasource: DATA_2020 Created: 8/25/2018 3:29:46 PM by Administrator
Location: GHPLAMAY\Amlodipine Amloperin_RS.SEQ
Timebase: UHPLC_01 Changed: 1/10/2019 12:19:20 PM by Administrator

%B = 0.0 [%]
%C = 0.0 [%]
%D = 0.0 [%]
Curve = 5
3DFIELD.MinWavelength = 200.0 [nm]
3DFIELD.MaxWavelength = 360.0 [nm]
3DFIELD.BunchWidth = 1 [nm]

0.000 Autozero
Wait UV.Ready and Pump.Ready
and ColumnOven.Ready and Sampler.Ready and PumpModule.Ready
Inject
ColumnOven_Temp.AcqOn
Pump_Pressure.AcqOn
UV_VIS_1.AcqOn
Temp_Lamphouse.AcqOn
3DFIELD.AcqOn

10.000 / ColumnOven_Temp.AcqOff/
Pump_Pressure.AcqOff /
UV_VIS_1.AcqOff
Temp_Lamphouse.AcqOff
3DFIELD.AcqOff
End

8-1-20
06 MAY 2020

06 MAY 2020

Method File: AMLODIPINE
Operator: Administrator

Page 1 of 2
Printed: 5/6/2020 6:47:05 PM

Title:
Datasource: DATA_2020 Created: 5/31/2018 10:36:27 PM by Administrator
Location: GHPLMAYAmlo RS\20_05_05_17 AMLODIPINE AMLOPERIN_R Last Update: 5/6/2020 6:46:55 PM by Administrator

Blank Run Subtraction: No Blank Run Subtraction

Detection Table:

No.	Ret. Time [min]	Param. Name	Param. Value	Channel
1	0.000	Minimum Area	50.0 "[Signal]"*min"	All Channels
2	0.000	Valley to Valley	On	All Channels
3	0.000	Fronting Sensitivity Factor	8.0	All Channels
4	0.000	Tailing Sensitivity Factor	8.0	All Channels
5	2.500	Inhibit Integration	Off	All Channels

Method File: AMLODIPINE
Operator: Administrator

Page 2 of 2
Printed: 5/6/2020 6:47:05 PM

Title:
Datasource: DATA_2020 Created: 5/31/2018 10:36:27 PM by Administrator
Location: GHPL\MAY\Amlo RS\20_05_05_17 AMLODIPINE AMLOPERIN_RS Last Update: 5/6/2020 6:46:55 PM by Administrator

Peak Table:

Use Recently Detected Retention Times: Off
Peak Retention Time Determination: Absolute
Dead time:
Delay Time of 2'nd Detector: <None>
Delay Time of 3'rd Detector: <None>

No.	Peak Name	Ret.Time	Window	Standard	Int.Type	Cal.Type	Peak Type	Group	Comment
1	Placebo	2.640 min	0.100 AG	External	Area	Lin	Auto		
2	Amlodipine	3.137 min	0.100 AG	External	Area	Lin	Auto		
3	Placebo	3.240 min	0.100 AG	External	Area	Lin	Auto		
4	Placebo	3.643 min	0.100 AG	External	Area	Lin	Auto		
5	Blank	3.823 min	0.100 AG	External	Area	Lin	Auto		
6	Placebo	4.270 min	0.100 AG	External	Area	Lin	Auto		
7	Placebo	4.620 min	0.100 AG	External	Area	Lin	Auto		
8	Placebo	4.953 min	0.100 AG	External	Area	Lin	Auto		
9	Placebo	5.313 min	0.100 AG	External	Area	Lin	Auto		
10	Amlodipine IMP A	5.553 min	0.100 AG	External	Area	Lin	Auto		
11	Placebo	7.147 min	0.100 AG	External	Area	Lin	Auto		
12	Placebo	8.253 min	0.100 AG	External	Area	Lin	Auto		
13	Placebo	13.453 min	0.100 AG	External	Area	Lin	Auto		
14	Blank	14.370 min	0.100 AG	External	Area	Lin	Auto		

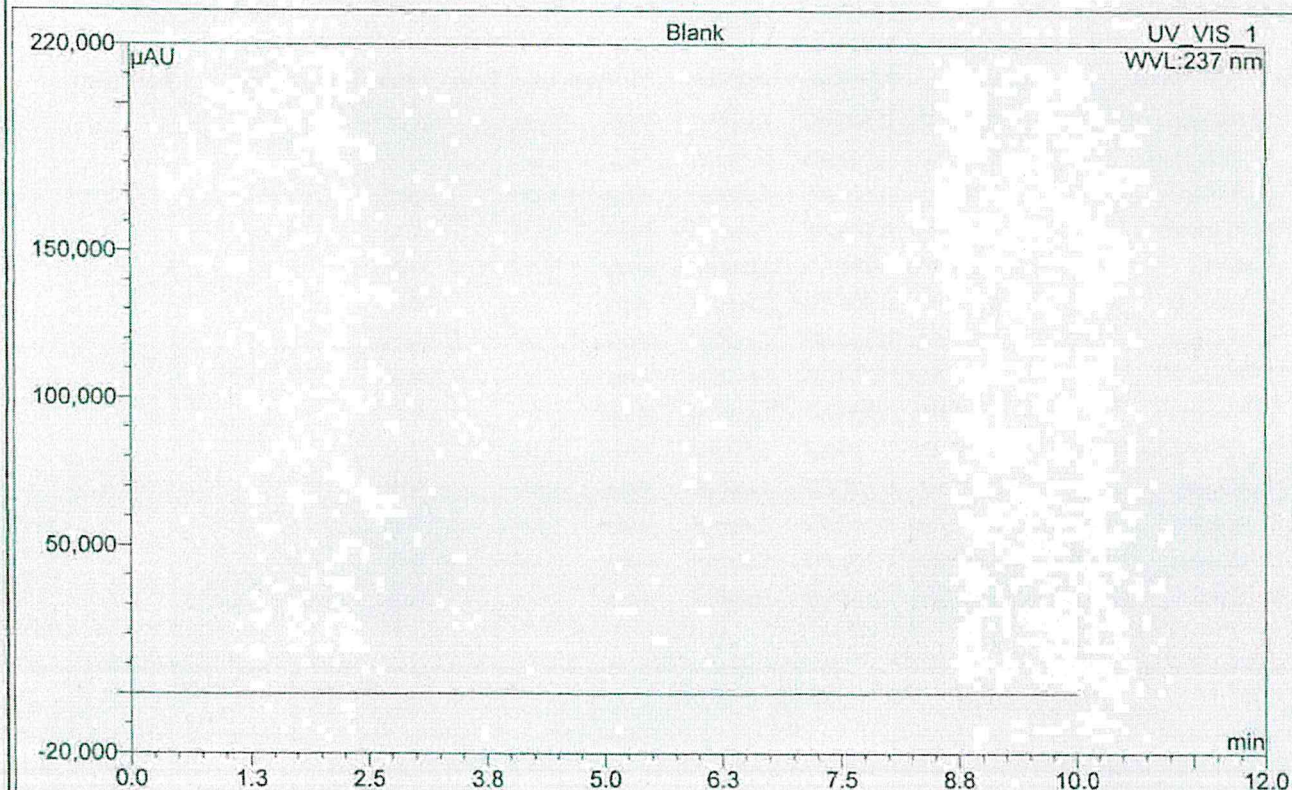
32
06 MAY 2020

P
06 MAY 2020

IMMENSE CULTURE PVT. LTD., PUNE

HPLC CHROMATOGRAM

Sample Name:	Blank	Injection Volume:	20.0
Vial Number:	GA1	Channel:	UV_VIS_1
Sample Type:	unknown	Wavelength:	237.0
Control Program:	AMLODIPINE-10min		
Quantif. Method:	AMLODIPINE	Run Time:	10.00
Recording Time:	5/6/2020 9:12	Sample Weight:	1.0000



Peak No.	Ret.Time min	Peak Name	Area μAU*min	Area %	Asymmetry	Plates	Resolution
Total:			0	0.00	0.00	0	

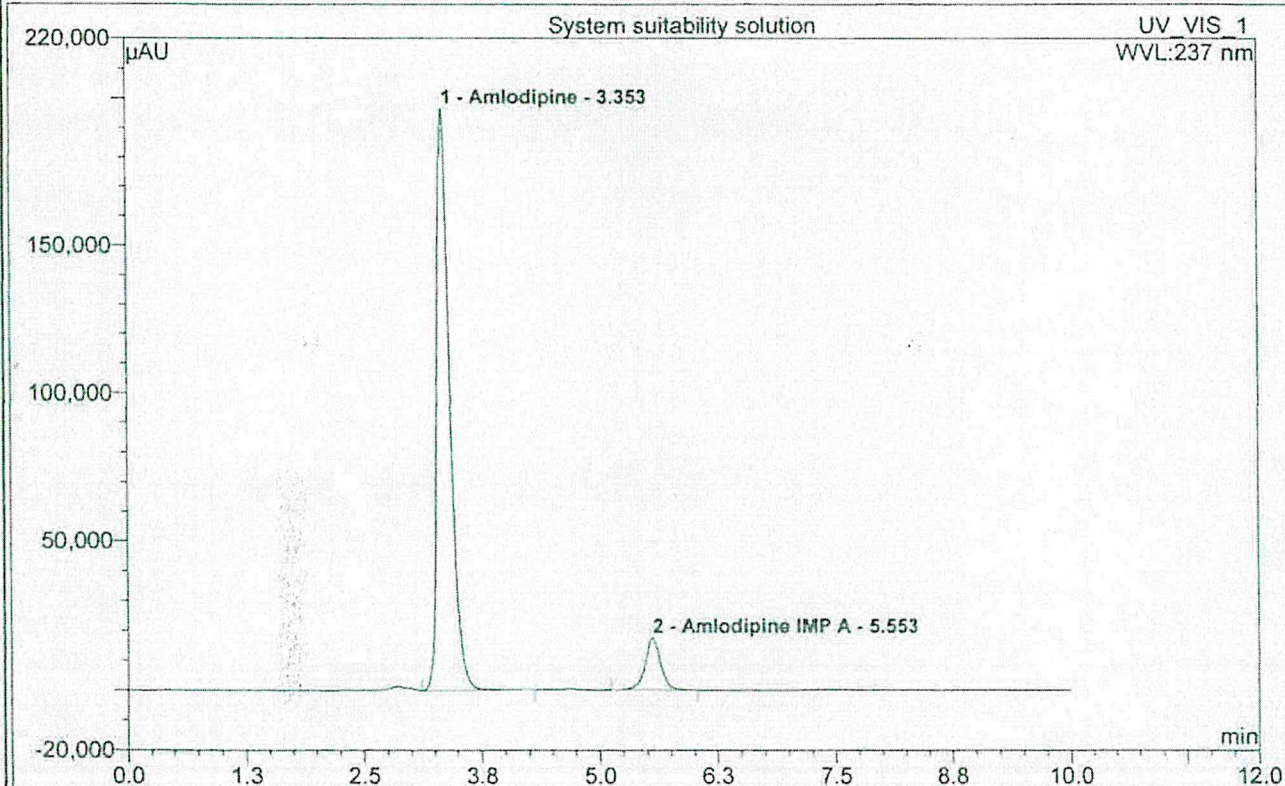
Analysed By/Date

Checked By/Date

IMMENSE CULTURE PVT. LTD., PUNE

HPLC CHROMATOGRAM

Sample Name:	System suitability solution	Injection Volume:	20.0
Vial Number:	GA2	Channel:	UV_VIS_1
Sample Type:	standard	Wavelength:	237.0
Control Program:	AMLODIPINE-10min		
Quantif. Method:	AMLODIPINE	Run Time:	10.00
Recording Time:	5/6/2020 9:23	Sample Weight:	1.0000



Peak No.	Ret.Time min	Peak Name	Area $\mu\text{AU} \cdot \text{min}$	Area %	Asymmetry	Plates	Resolution
1	3.353	Amlodipine	1991531	90.56	1.36	2933	8.39
2	5.553	Amlodipine IMP A	207588	9.44	0.99	6442	n.a.
Total:			2199119	100.00	2.36	9375	

3-1-1
06 MAY 2020

Analysed By/Date

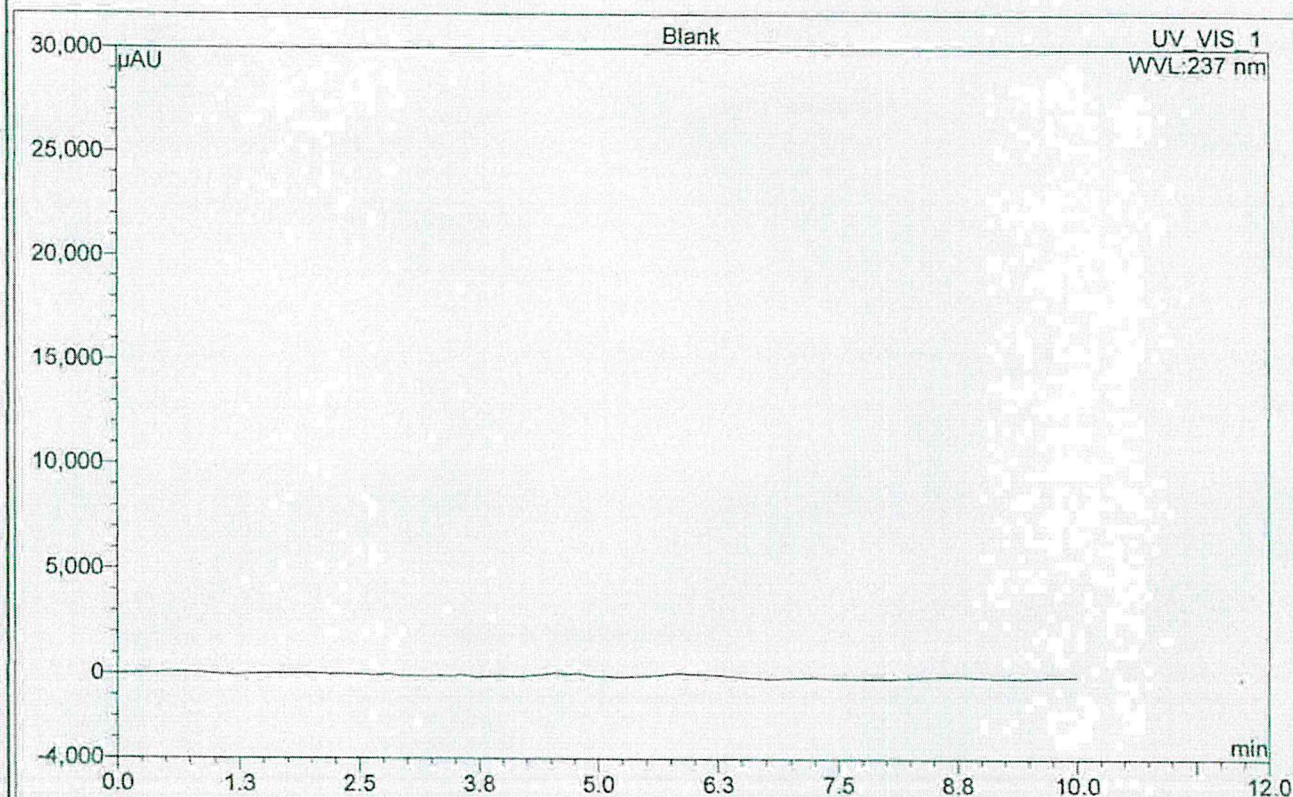
D
06 MAY 2020

Checked By/Date

IMMENSE CULTURE PVT. LTD., PUNE

HPLC CHROMATOGRAM

Sample Name:	Blank	Injection Volume:	20.0
Vial Number:	GA1	Channel:	UV_VIS_1
Sample Type:	unknown	Wavelength:	237.0
Control Program:	AMLODIPINE-10min		
Quantif. Method:	AMLODIPINE	Run Time:	10.00
Recording Time:	5/6/2020 9:34	Sample Weight:	1.0000



Peak No.	Ret.Time min	Peak Name	Area μAU*min	Area %	Asymmetry	Plates	Resolution
Total:			0	0.00	0.00	0	

[Signature]
06 MAY 2020

Analysed By/Date

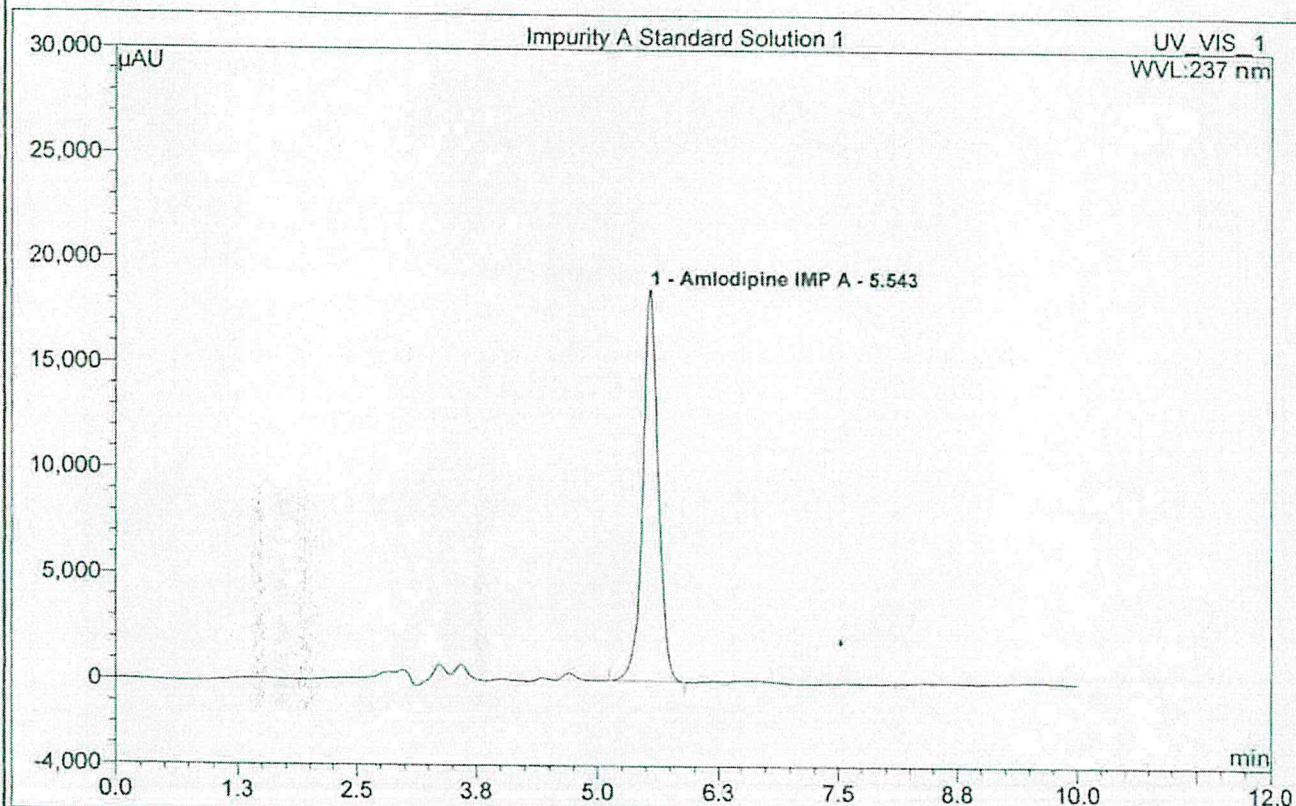
[Signature]
06 MAY 2020

Checked By/Date

IMMENSE CULTURE PVT. LTD., PUNE

HPLC CHROMATOGRAM

Sample Name:	Impurity A Standard Solution 1	Injection Volume:	20.0
Vial Number:	GA3	Channel:	UV_VIS_1
Sample Type:	standard	Wavelength:	237.0
Control Program:	AMLODIPINE-10min		
Quantif. Method:	AMLODIPINE	Run Time:	10.00
Recording Time:	5/6/2020 9:44	Sample Weight:	1.0000



Peak No.	Ret.Time min	Peak Name	Area $\mu\text{AU} \cdot \text{min}$	Area %	Asymmetry	Plates	Resolution
1	5.543	Amlodipine IMP A	215993	100.00	0.98	6498	n.a.
Total:			215993	100.00	0.98	6498	

21/1
06 MAY 2020

Analysed By/Date

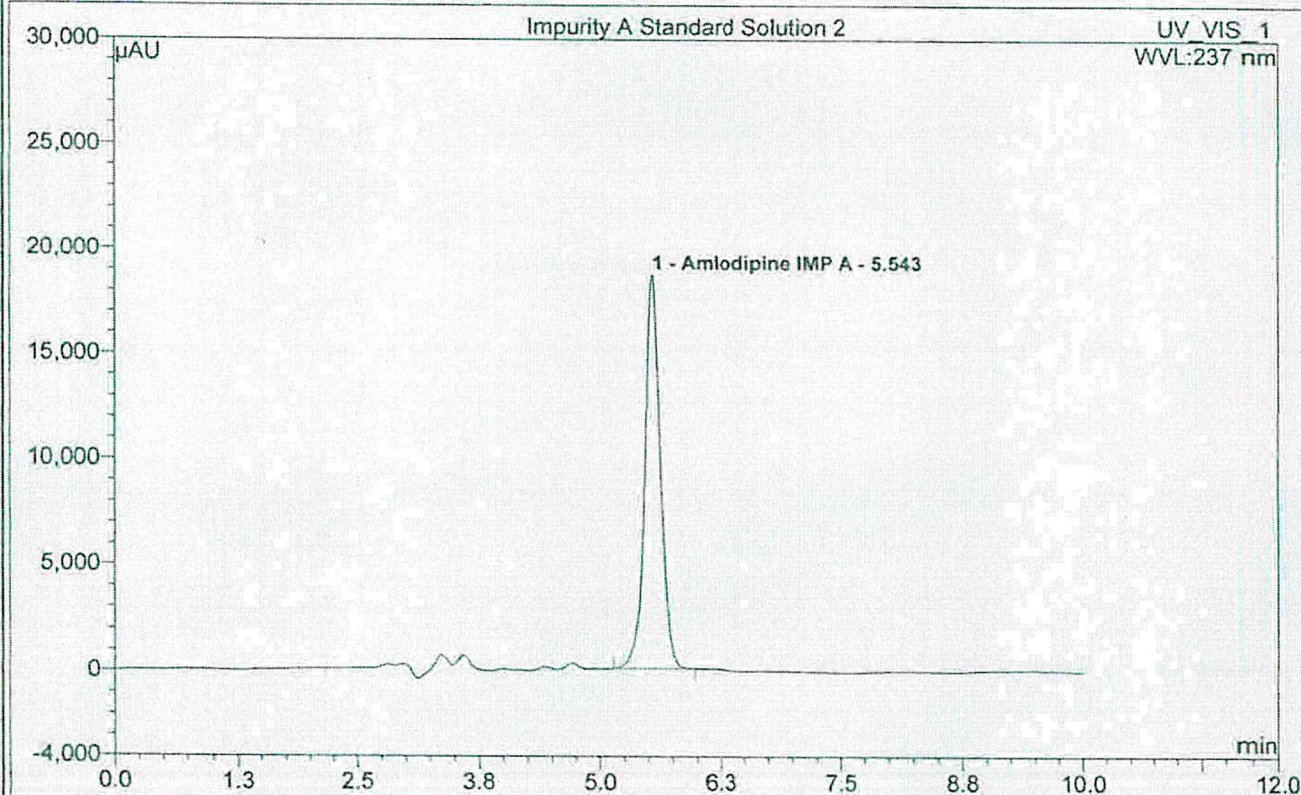
06 MAY 2020

Checked By/Date

IMMENSE CULTURE PVT. LTD., PUNE

HPLC CHROMATOGRAM

Sample Name:	Impurity A Standard Solution 2	Injection Volume:	20.0
Vial Number:	GA3	Channel:	UV_VIS_1
Sample Type:	standard	Wavelength:	237.0
Control Program:	AMLODIPINE-10min		
Quantif. Method:	AMLODIPINE	Run Time:	10.00
Recording Time:	5/6/2020 9:55	Sample Weight:	1.0000



Peak No.	Ret.Time min	Peak Name	Area $\mu\text{AU} \cdot \text{min}$	Area %	Asymmetry	Plates	Resolution
1	5.543	Amlodipine IMP A	217924	100.00	0.98	6418	n.a.
Total:			217924	100.00	0.98	6418	

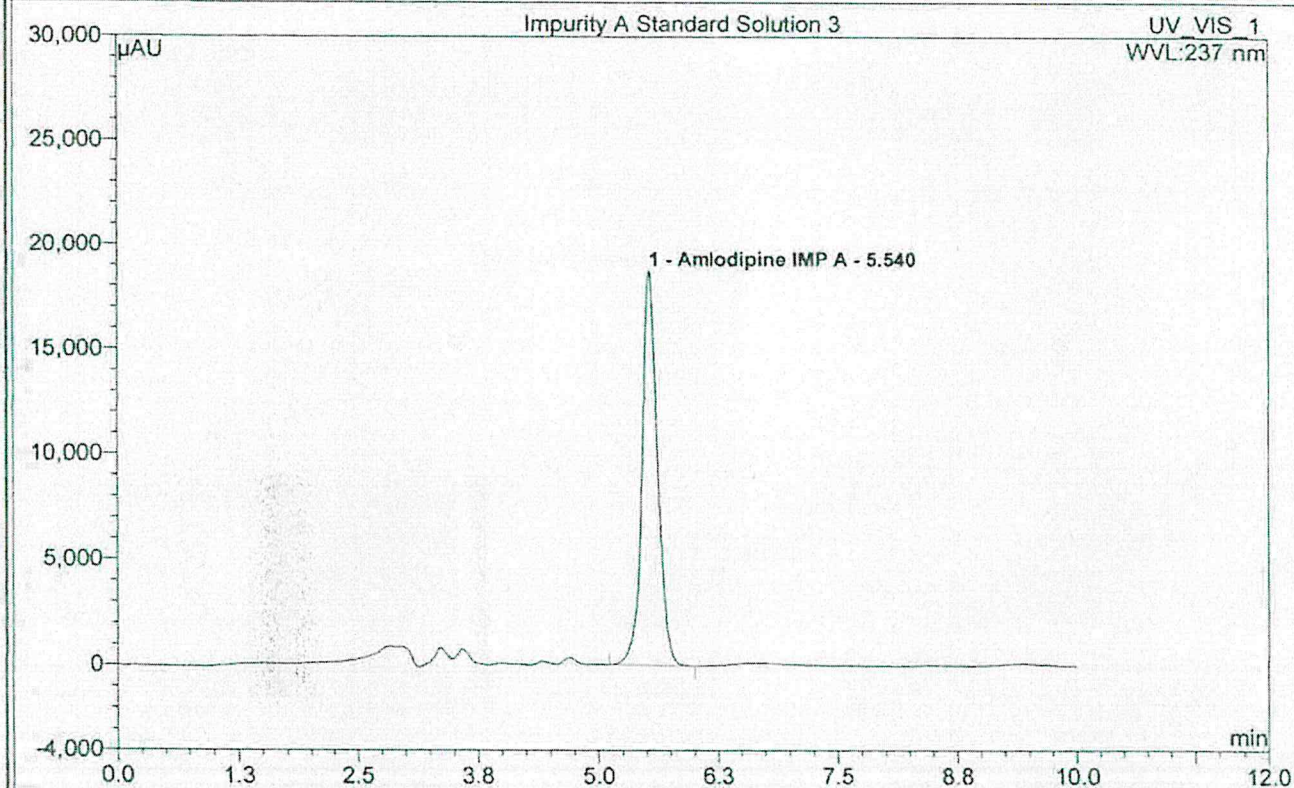
8-
06 MAY 2020
Analysed By/Date

06 MAY 2020
Checked By/Date

IMMENSE CULTURE PVT. LTD., PUNE

HPLC CHROMATOGRAM

Sample Name: Impurity A Standard Solution 3 Injection Volume: 20.0
 Vial Number: GA3 Channel: UV_VIS_1
 Sample Type: standard Wavelength: 237.0
 Control Program: AMLODIPINE-10min
 Quantif. Method: AMLODIPINE Run Time: 10.00
 Recording Time: 5/6/2020 10:06 Sample Weight: 1.0000



Peak No.	Ret. Time min	Peak Name	Area $\mu\text{AU} \cdot \text{min}$	Area %	Asymmetry	Plates	Resolution
1	5.540	Amlodipine IMP A	219834	100.00	0.99	6398	n.a.
Total:			219834	100.00	0.99	6398	

06 MAY 2020

Analysed By/Date

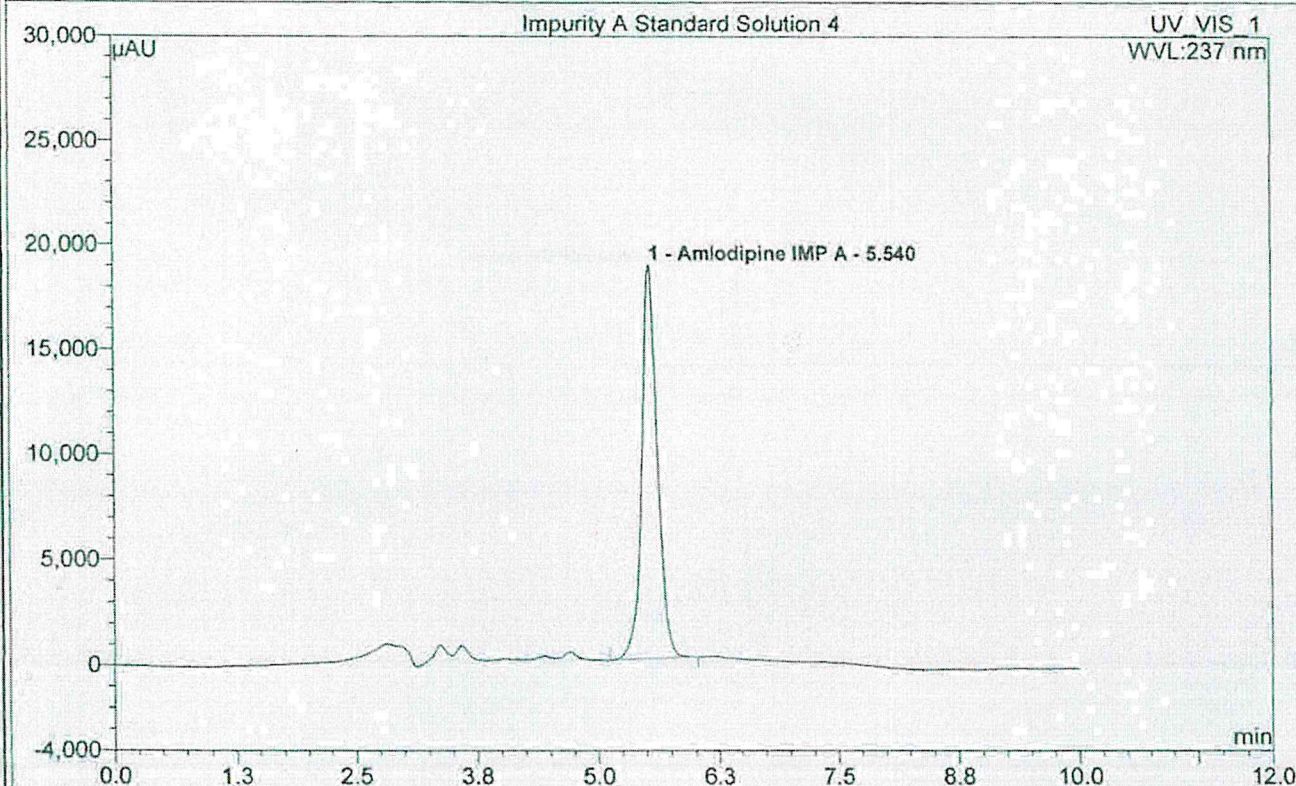
06 MAY 2020

Checked By/Date

IMMENSE CULTURE PVT. LTD., PUNE

HPLC CHROMATOGRAM

Sample Name:	Impurity A Standard Solution 4	Injection Volume:	20.0
Vial Number:	GA3	Channel:	UV_VIS_1
Sample Type:	standard	Wavelength:	237.0
Control Program:	AMLODIPINE-10min		
Quantif. Method:	AMLODIPINE	Run Time:	10.00
Recording Time:	5/6/2020 10:17	Sample Weight:	1.0000



Peak No.	Ret. Time min	Peak Name	Area μ AU*min	Area %	Asymmetry	Plates	Resolution
1	5.540	Amlodipine IMP A	218843	100.00	0.99	6438	n.a.
Total:			218843	100.00	0.99	6438	

[Signature]
06 MAY 2020

Analysed By/Date

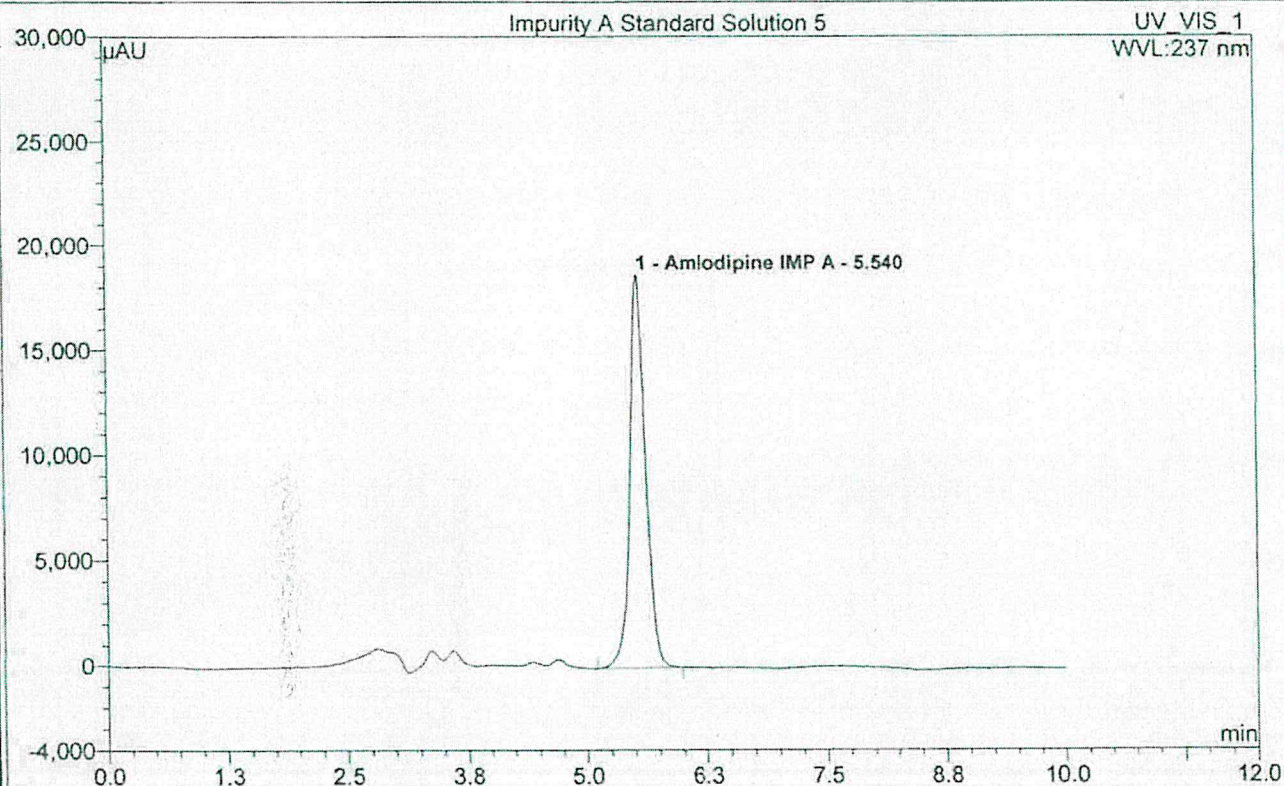
[Signature]
06 MAY 2020

Checked By/Date

IMMENSE CULTURE PVT. LTD., PUNE

HPLC CHROMATOGRAM

Sample Name:	Impurity A Standard Solution 5	Injection Volume:	20.0
Vial Number:	GA3	Channel:	UV_VIS_1
Sample Type:	standard	Wavelength:	237.0
Control Program:	AMLODIPINE-10min	Run Time:	10.00
Quantif. Method:	AMLODIPINE	Sample Weight:	1.0000
Recording Time:	5/6/2020 10:27		



Peak No.	Ret.Time min	Peak Name	Area μAU*min	Area %	Asymmetry	Plates	Resolution
1	5.540	Amlodipine IMP A	218862	100.00	0.99	6451	n.a.
Total:			218862	100.00	0.99	6451	

9/2/20
06 MAY 2020

Analysed By/Date

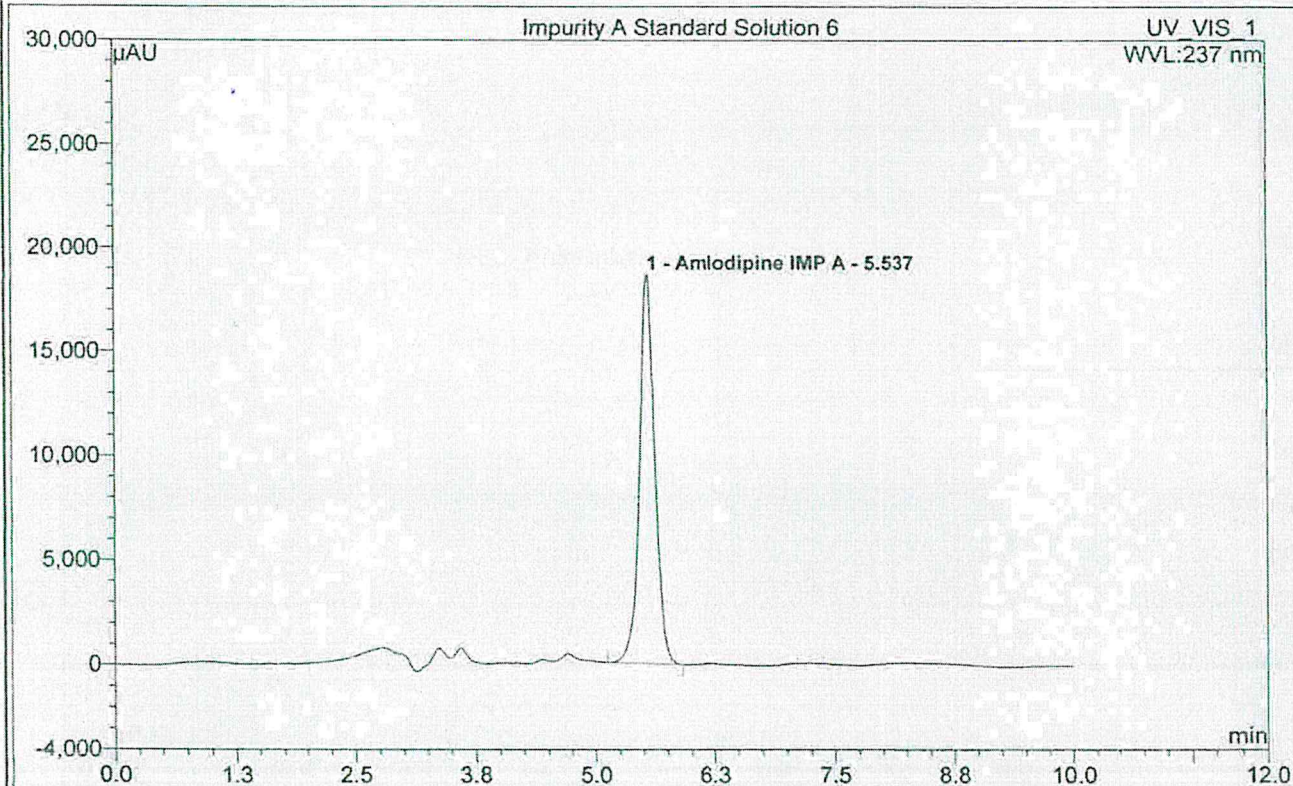
9/2/20
06 MAY 2020

Checked By/Date

IMMENSE CULTURE PVT. LTD., PUNE

HPLC CHROMATOGRAM

Sample Name:	Impurity A Standard Solution 6	Injection Volume:	20.0
Vial Number:	GA3	Channel:	UV_VIS_1
Sample Type:	standard	Wavelength:	237.0
Control Program:	AMLODIPINE-10min		
Quantif. Method:	AMLODIPINE	Run Time:	10.00
Recording Time:	5/6/2020 10:38	Sample Weight:	1.0000



Peak No.	Ret. Time min	Peak Name	Area $\mu\text{AU} \cdot \text{min}$	Area %	Asymmetry	Plates	Resolution
1	5.537	Amlodipine IMP A	215364	100.00	1.00	6496	n.a.
Total:			215364	100.00	1.00	6496	

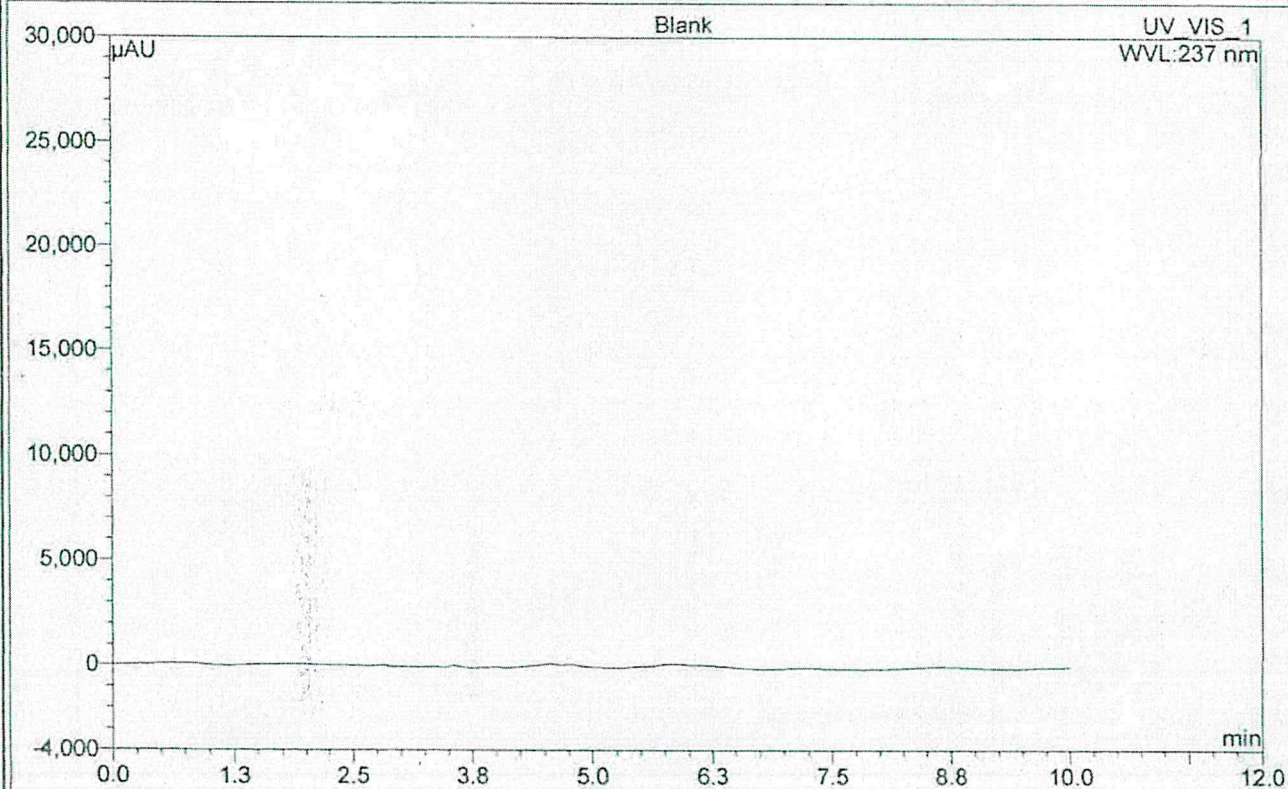
Analysed By/Date

Checked By/Date

IMMENSE CULTURE PVT. LTD., PUNE

HPLC CHROMATOGRAM

Sample Name:	Blank	Injection Volume:	20.0
Vial Number:	GA1	Channel:	UV_VIS_1
Sample Type:	unknown	Wavelength:	237.0
Control Program:	AMLODIPINE-10min		
Quantif. Method:	AMLODIPINE	Run Time:	10.00
Recording Time:	5/6/2020 10:49	Sample Weight:	1.0000



Peak No.	Ret.Time min	Peak Name	Area μAU*min	Area %	Asymmetry	Plates	Resolution
Total:			0	0.00	0.00	0	

Analysed By/Date

Checked By/Date

Format N° IC/FI/GEN/57

Date of implementation:

Approved by: Mr. Amir Yabari

Version N° 01

Ref. SOP N° IC/SOP/GEN/10

02 JUN 16

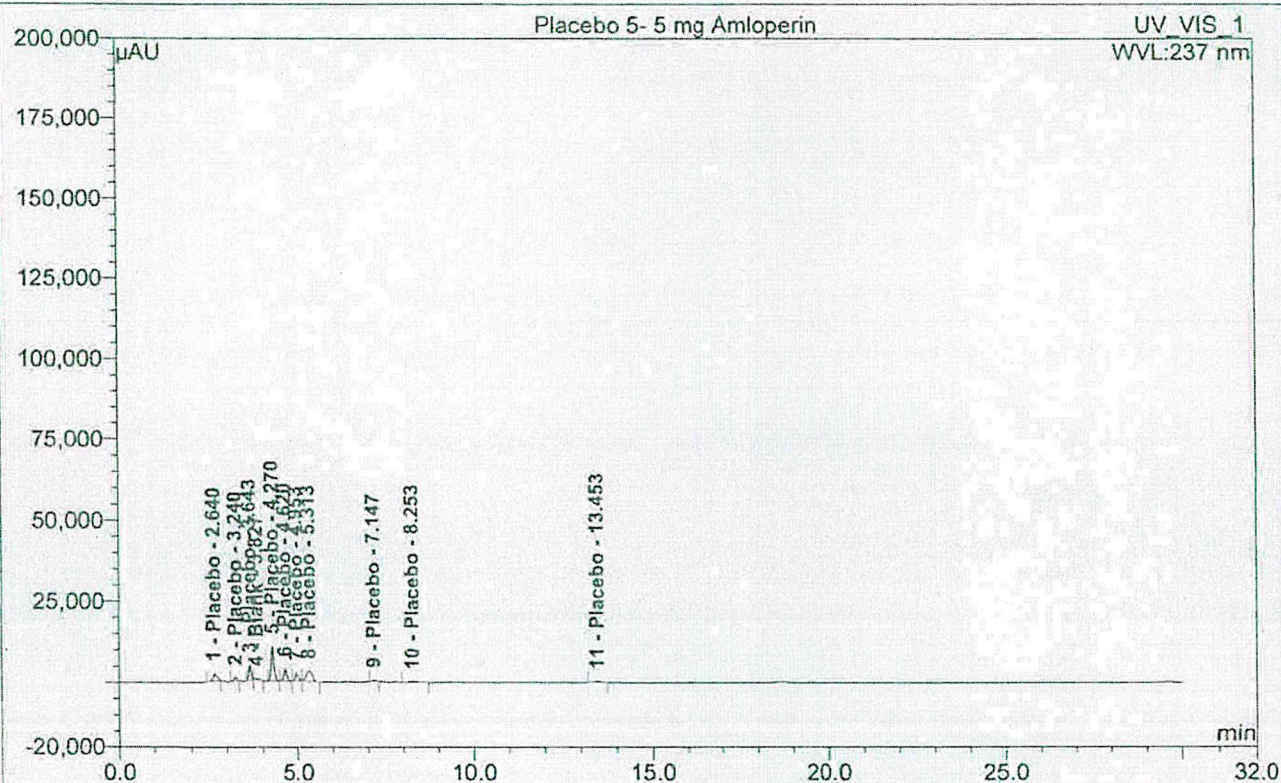
SOP



HPLC CHROMATOGRAM

Sample Name: Placebo 5- 5 mg Amloperin
 Vial Number: GA4
 Sample Type: unknown
 Control Program: AMLODIPINE-30min
 Quantif. Method: AMLODIPINE
 Recording Time: 5/6/2020 11:00

Injection Volume: 20.0
 Channel: UV_VIS_1
 Wavelength: 237.0
 Run Time: 30.00
 Sample Weight: 1.0000



Peak No.	Ret.Time min	Peak Name	Area μAUseC	Area %	Asymmetry	Plates	Resolution
1	2.640	Placebo	18872	8.81	1.01	3579	3.62
2	3.240	Placebo	7809	3.65	0.86	7060	2.90
3	3.643	Placebo	22415	10.47	1.11	14051	1.04
4	3.827	Blank	3781	1.77	1.63	4447	2.35
5	4.270	Placebo	64322	30.04	1.26	13568	2.28
6	4.620	Placebo	25117	11.73	1.33	13266	1.97
7	4.953	Placebo	19243	8.99	1.27	12599	1.45
8	5.313	Placebo	39417	18.41	1.11	4433	7.17
9	7.147	Placebo	3859	1.80	1.08	22292	3.72
10	8.253	Placebo	5033	2.35	1.26	6713	13.87
11	13.453	Placebo	4227	1.97	1.03	24270	n.a.
Total:			214095	100.00	12.96	126278	

Analysed By/Date

Checked By/Date

OG MAY 2020

Format N° IC/GEN-67
Version N° 01
Ref. SOP N° IC/SOP/GEN-10

Date of implementation:

Approved by: Mr. Amit Yadav

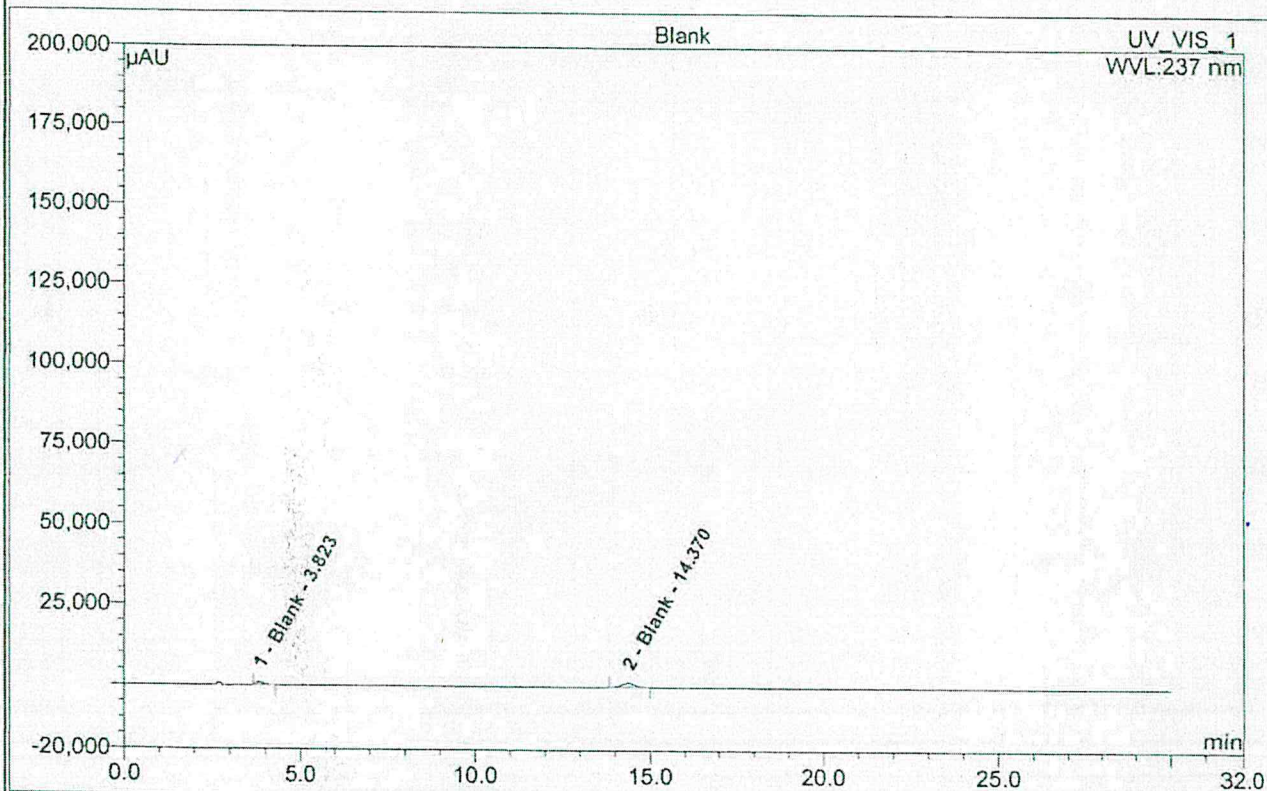
02 JUN 16

Scn

Immense Culture

HPLC CHROMATOGRAM

Sample Name:	Blank	Injection Volume:	20.0
Vial Number:	GA1	Channel:	UV_VIS_1
Sample Type:	unknown	Wavelength:	237.0
Control Program:	AMLODIPINE-30min		
Quantif. Method:	AMLODIPINE	Run Time:	30.00
Recording Time:	5/6/2020 11:31	Sample Weight:	1.0000



Peak No.	Ret. Time min	Peak Name	Area μAUsec	Area %	Asymmetry	Plates	Resolution
1	3.823	Blank	13418	25.74	1.87	2445	20.46
2	14.370	Blank	38715	74.26	1.05	6381	n.a.
Total:			52133	100.00	2.91	8825	

2/1/20
06 MAY 2020

Analysed By/Date

06 MAY 2020
Checked By/Date

Formet N° IC/F/GEN/57

Date of Implementation:

Approved by: Mr. Amit Yadav

Version N°: 01

Ref. SOP N° IC/SOP/GEN/10

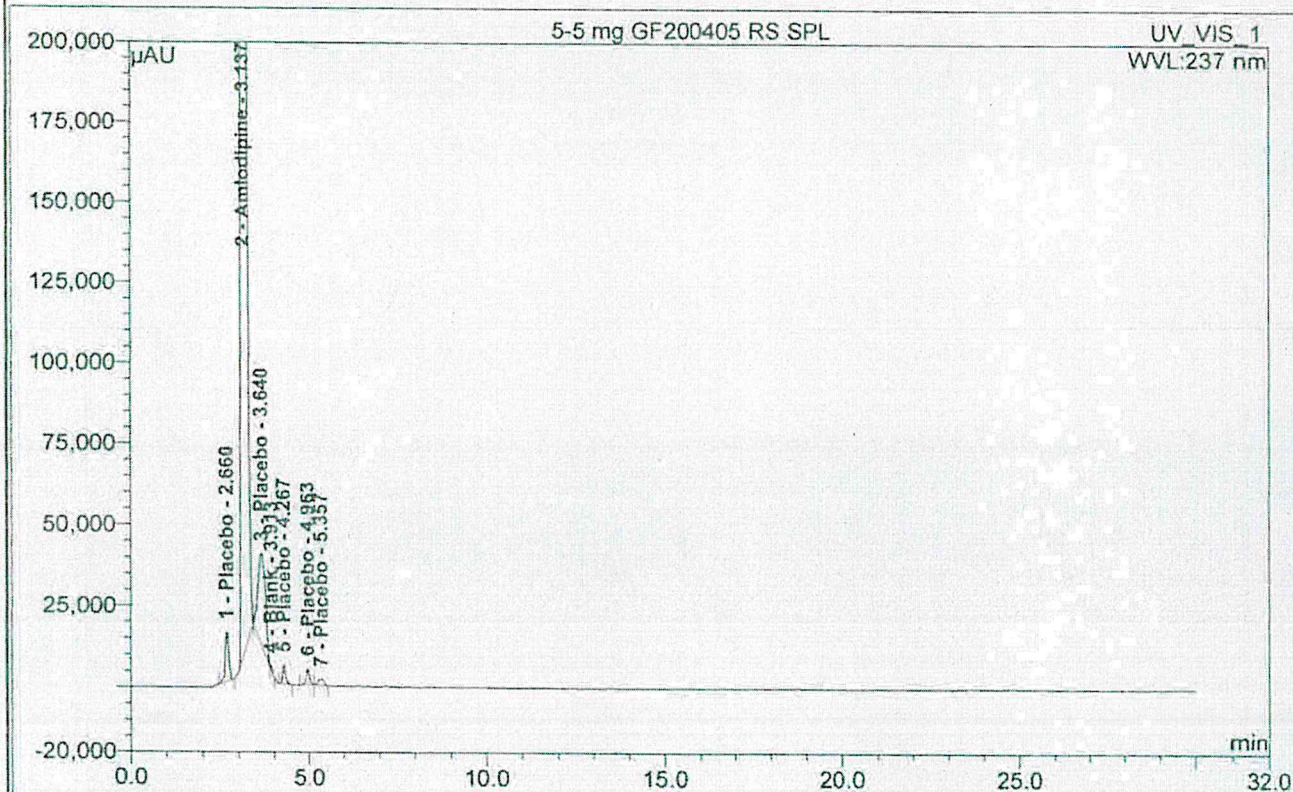
02 JUN 16

5.05

 Immense Culture

HPLC CHROMATOGRAM

Sample Name:	5-5 mg GF200405 RS SPL	Injection Volume:	20.0
Vial Number:	GA5	Channel:	UV_VIS_1
Sample Type:	unknown	Wavelength:	237.0
Control Program:	AMLODIPINE-30min		
Quantif. Method:	AMLODIPINE	Run Time:	30.00
Recording Time:	5/6/2020 12:02	Sample Weight:	1.0000



Peak No.	Ret. Time min	Peak Name	Area μAUseC	Area %	Asymmetry	Plates	Resolution
1	2.660	Placebo	116099	0.49	0.89	3070	2.71
2	3.137	Amlodipine	22935481	97.23	1.46	6202	1.75
3	3.640	Placebo	427790	1.81	1.00	1224	1.05
4	3.913	Blank	6195	0.03	1.43	23778	2.83
5	4.267	Placebo	37013	0.16	1.37	13393	4.16
6	4.963	Placebo	41987	0.18	0.92	11311	1.57
7	5.357	Placebo	24326	0.10	0.92	4652	n.a.
Total:			23588892	100.00	7.98	63631	

8/1/20
06 May 2020
Analysed By/Date

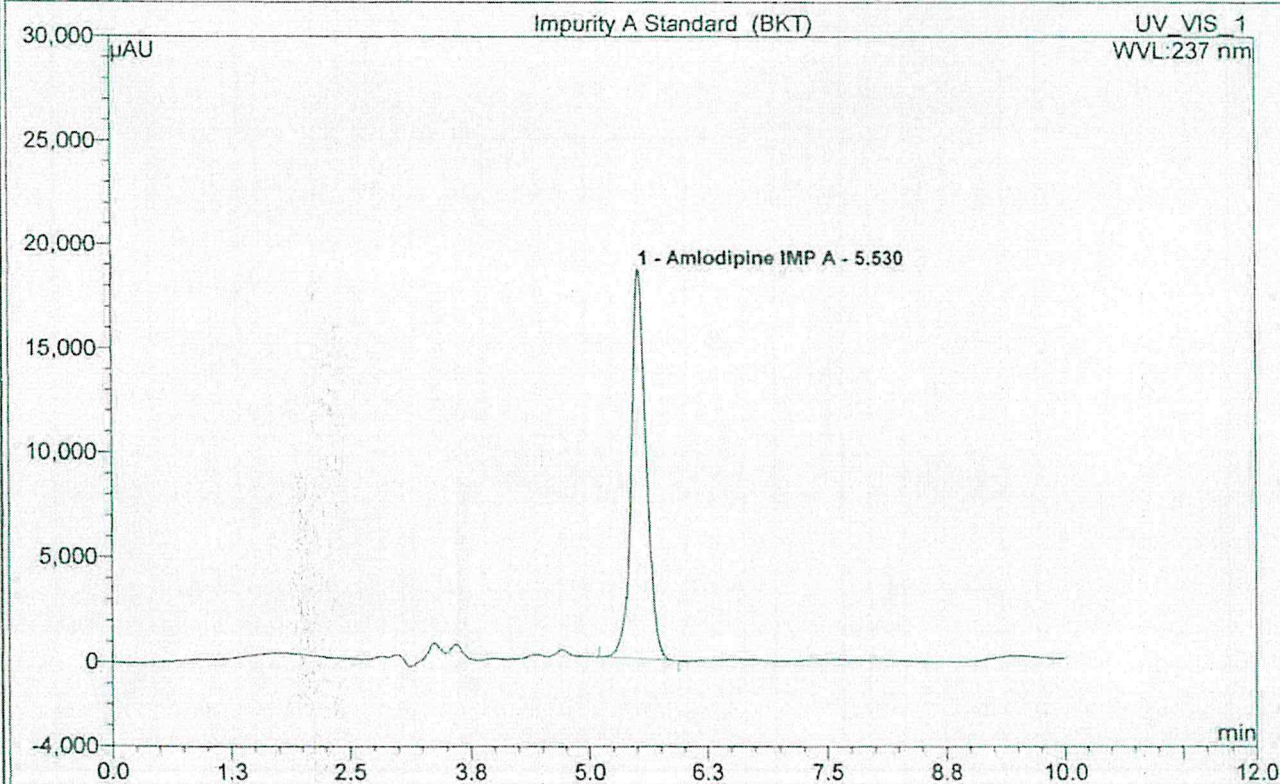
06 May 2020
Checked By/Date

78

IMMENSE CULTURE PVT. LTD., PUNE

HPLC CHROMATOGRAM

Sample Name:	Impurity A Standard (BKT)	Injection Volume:	20.0
Vial Number:	GA3	Channel:	UV_VIS_1
Sample Type:	standard	Wavelength:	237.0
Control Program:	AMLODIPINE-10min		
Quantif. Method:	AMLODIPINE	Run Time:	10.00
Recording Time:	5/6/2020 12:32	Sample Weight:	1.0000



Peak No.	Ret.Time min	Peak Name	Area μ AU*min	Area %	Asymmetry	Plates	Resolution
1	5.530	Amlodipine IMP A	213949	100.00	1.00	6507	n.a.
Total:			213949	100.00	1.00	6507	

8-1-1
06 MAY 2020

Analysed By/Date

D
06 MAY 2020

Checked By/Date

Immense Culture

Amlopressin 5 mg / 5 mg

Batch No.	GP200405	A.R Number	20/05/05/21
Test Name	Related Substance By HPLC	Worksheet ID	IC/WS/ACH/20/05/05/21
Analyst Name	Sachal	Date of Analysis	06 MAY 2020
Wt of Standard (mg)	50.3	Potency Of Amlopressin	99.39
Wt Of Sample (1) mg	704.9	LC Of Amlopressin	5
		Av wt (mg)	139.23

Standard details		Amlopressin	
Injection No.	RT (min)	Peak Area Of Standard	Plates
1	5.543	215993	6498
2	5.543	217924	6418
3	5.540	219834	6398
4	5.540	218843	6438
5	5.540	218862	6451
6	5.537	215364	6496
Mean	5.541	217803	6450
SD	0.002	1764.51	0.99
%RSD	0.04	0.81	
LIMIT	NMT 1.0%	NMT 5.0%	NMT 2.00

FORMULA

$$\% \text{ Unknown Impurity} = \frac{\text{Peak Area Unknown Impurity}}{\text{Mean Peak Area of STD}} \times \frac{\text{Wt of STD (mg)}}{\text{Wt of Sample (mg)}} \times \frac{\text{STD Potency}}{\text{X Avg. wt.}}$$

Amlopressin		
Sample No.	Peak Area Of Unknown Impurity in sample 1	Mean
1	Not Detected	Not Detected
Limit		1.00%

Analysed by

Reviewed by

20 MAY 2020

06 MAY 2020



SAI PRIMUS
LIFE BIOTECH PVT LTD

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

Page 1 of 1

Issued by QA
Sign/Date: *[Signature]* 28/04/2020

No.: F/QCGN/003/01

GOOD LABORATORY PRACTICES

Revision No.: 00

TITLE:

ANALYTICAL DATA SHEET

Review Period: 02 years

Effective Date: 18/05/19

Assay spl.

SPL BIOTECH
Model: AUM2200
S/N: D450041599
ID: QC/ABL/002
Date: 28/04/2020
Time: 11:53:47

1400.23 m9

[Signature]
28/04/2020

Assay std s/s
Amlodipine

SPL BIOTECH
Model: AUM2200
S/N: D450041599
ID: QC/ABL/002
Date: 28/04/2020
Time: 09:37:02

69.64 m9

[Signature]
28/04/2020

Dissol Std: Amlodipine

SPL BIOTECH
Model: AUM2200
S/N: D450041599
ID: QC/ABL/002
Date: 29/04/2020
Time: 10:44:31

69.53 m9

[Signature]
29/04/2020

SPL BIOTECH
Model: AUM2200
S/N: D450041599
ID: QC/ABL/002
Date: 28/04/2020
Time: 11:57:34

1400.12 m9

[Signature]
28/04/2020

Assay std s/s
perindopril

SPL BIOTECH
Model: AUM2200
S/N: D450041599
ID: QC/ABL/002
Date: 28/04/2020
Time: 09:41:12

59.56 m9

[Signature]
28/04/2020

Dissol std: perindopril.

SPL BIOTECH
Model: AUM2200
S/N: D450041599
ID: QC/ABL/002
Date: 29/04/2020
Time: 10:59:05

49.51 m9

[Signature]
29/04/2020

Analysed by: *[Signature]*
Date: 29/04/2020

Checked by: *[Signature]*
Date: 20/04/2020

MASTER COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.3, Kurumbapet Industrial Estate, Villianur Commune, Puducherry- 605009.	Page 1 of 1	Issued by QA Sign/Date: <i>Mallu 24/04/2020</i>
	GOOD LABORATORY PRACTICES	No.: F/QCGN/003/01	Revision No.: 00
TITLE:	ANALYTICAL DATA SHEET	Review Period: 02 years	
		Effective Date: 18/05/19	

Sample

RS std Amloperin 5/5

SPL BIOTECH
Model: RUM2200
S/N: 0450041599
ID: QC/ABL/002
Date: 28/04/2020
Time: 12:23:31

50.32 mg

Mallu
28/04/2020
Signature

SPL BIOTECH
Model: JE383
S/N: 2739321070
ID: QC/ABL/001
Date: 28/04/2020
Start: 10:32:01

001 0.702 g

End: 10:32:19

Mallu
28/04/2020
Signature

placebo

SPL BIOTECH
Model: JE383
S/N: 2739321070
ID: QC/ABL/001
Date: 28/04/2020
Start: 10:33:16

001 0.651 g

End: 10:33:54

Mallu
28/04/2020
Signature

Analysed by: *J. Day*
Date: 28/04/2020

Checked by: *D. Dinesh*
Date: 30/04/2020

MASTER COPY

		SAI PRIMUS LIFE BIOTECH PRIVATE LIMITED R.S. No. 4/3, plot No. 33, Kurumbapet Industrial Estate, Villianur Commune, Pondicherry- 605009		Page 1 of 2	
QUALITY CONTROL		CERTIFICATE OF ANALYSIS			Format No: F/QCGN/022/08
		FINISHED PRODUCT			
Product Name		: Amloperin 5 mg / 5 mg (Amlodipine Besilate & Perindopril Erbumine Tablet)			
A.R.No.		: FP/250520/03			
Batch No.		: GF200501		Batch Size : 6.0 L	
Mfg. Date		: May-2020		Exp. Date : Apr-2023	
Sampling Date		: 23.05.2020		Sample Qty : 120 Tablets	
Analysis Date		: 23.05.2020		Release Date : 04.06.2020	

S.No.	TEST	RESULTS			LIMITS
01.	Description	Off white, round, biconvex,uncoated tablet with breakline on one side and plain on other side.			Off white, round, biconvex,uncoated tablet with breakline on one side and plain on other side.
02.	Identification Amlodipine Besylate BP Perindopril Erbumine BP	Complies Complies			The retention time of Amlodipine & perindopril erbumine peak in the chromatogram of sample preparation should correspond to that in chromatogram of the standard preparation as obtained in the assay.
03.	Average weight of tablets	143.80 mg			140 mg $\pm$ 5.0 % (133.0 mg to 147.0 mg)
04.	Uniformity of weight	+1.58 % to -1.87 %			Not more than 2 of the individual weights deviate from the average weight by more than $\pm$ 7.5 % and none deviate by more than $\pm$ 15 % .
05.	Diameter	Min 6.85 mm	Max 6.87 mm	Avg. 6.86 mm	6.60 mm to 7.00 mm
06.	Thickness	Min 3.38 mm	Max 3.46mm	Avg. 3.42 mm	2.9 mm to 3.50 mm
07.	Hardness	5.0 kg/cm ²			NLT 3.0 kg/cm ²
08.	Friability	0.2 %			Not More than 1.0 %
09.	Disintegration Time	01 minutes 02 seconds			Not more than 15 minutes
10.	Content Uniformity:				
	Amlodipine Besylate BP equivalent to Amlodipine-5 mg	Min 101.61 %	Max 103.33 %	Avg. 102.30 %	Not less than 85.0 % and Not more than 115.0 % of labeled claim.
	Perindopril Erbumine BP-5 mg	Min 98.66 %	Max 102.12 %	Avg. 99.69 %	Not less than 85.0 % and Not more than 115.0 % of labeled claim.

	Tested By	Checked By	Approved By
Sign			
Name	Rajarajeswari	Ramesh	Vallarasan
Date	04/06/2020	04/06/2020	04/06/2020

		SAI PRIMUS LIFE BIOTECH PRIVATE LIMITED R.S. No. 4/3, plot No. 33, Kurumbapet Industrial Estate, Villianur Commune, Pondicherry- 605009		Page 2 of 2	
QUALITY CONTROL		CERTIFICATE OF ANALYSIS			Format No: F/QCGN/022/08
		FINISHED PRODUCT			
Product Name		: Amloperin 5 mg / 5 mg (Amlodipine Besilate & Perindopril Erbumine Tablet)			
A.R.No.		: FP/250520/03			
Batch No.		: GF200501		Batch Size : 6.0 L	
Mfg. Date		: May-2020		Exp. Date : Apr-2023	
Sampling Date		: 23.05.2020		Sample Qty : 120 Tablets	
Analysis Date		: 23.05.2020		Release Date : 04.06.2020	

11.	Dissolution:		
	Amlodipine Besylate BP equivalent to Amlodipine-5 mg	Min 101.54 % Max 104.66 % Avg. 102.85 %	Not less than 80.0 % of labeled amount.
	Perindopril Erbumine BP-5 mg	Min 96.67 % Max 99.52 % Avg. 98.13 %	Not less than 80 % of labeled amount.
12.	Related substances:		
	Amlodipine Impurity A	Not Detected(ND)	Not more than 1.0 %
	Perindopril Impurity B	Not Detected(ND)	Not more than 1.5 %
	Perindopril Impurity C	Not Detected(ND)	Not more than 0.60 %
	Perindopril Impurity E	Not Detected(ND)	Not more than 0.40 %
	Perindopril Impurity F	Not Detected(ND)	Not more than 1.50 %
	Single maximum unknown impurity	Below Detection Limit(BDL)	Not more than 0.50 %
	Total unknown impurity	Below Detection Limit(BDL)	Not more than 1.0 %
	Total impurities	Below Detection Limit(BDL)	Not more than 5.0 %
13.	Assay: Each uncoated tablet contains:		
	Amlodipine Besylate BP equivalent to Amlodipine-5 mg	100.83 %	Not less than 90.0 % and Not more than 110.0 %
	Perindopril Erbumine BP-5 mg	98.61 %	Not less than 90.0 % and Not more than 110.0 %
14.	Microbiological limits:		
	Total Aerobic Microbial count	20 cfu /g	NMT 1000 cfu/g
	Total Yeasts and mould counts	<10 cfu/g	NMT 100 cfu/g
	E.Coli	Absent	Should be Absent
	Salmonella	Absent	Should be Absent
	S.aureus	Absent	Should be Absent
	P.aeruginosa	Absent	Should be Absent

Remark : The product complies/~~not complies~~ with the prescribed standard of quality with reference to BP/USP and In-house Specification.

	Tested By	Checked By	Approved By
Sign			
Name	Rajarajeswari	Ramesh	Vallarasan
Date	04/06/2020	04/06/2020	04/06/2020

**QUALITY
CONTROL**

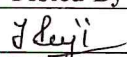
CERTIFICATE OF ANALYSIS

Format No:
F/QCGN/022/08

FINISHED PRODUCT

Product Name	:	Amloperin 5 mg / 5 mg (Amlodipine Besilate & Perindopril Erbumine Tablet)			
A.R.No.	:	FP/270520/02			
Batch No.	:	GF200502	Batch Size	:	6.0 L
Mfg. Date	:	May-2020	Exp. Date	:	Apr-2023
Sampling Date	:	23.05.2020	Sample Qty	:	120 Tablets
Analysis Date	:	23.05.2020	Release Date	:	04.06.2020

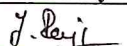
S.No.	TEST	RESULTS			LIMITS
01.	Description	Off white, round, biconvex,uncoated tablet with breakline on one side and plain on other side.			Off white, round, biconvex,uncoated tablet with breakline on one side and plain on other side.
02.	Identification Amlodipine Besylate BP Perindopril Erbumine BP	Complies Complies			The retention time of Amlodipine & perindopril erbumine peak in the chromatogram of sample preparation should correspond to that in chromatogram of the standard preparation as obtained in the assay.
03.	Average weight of tablets	142.59 mg			140 mg $\pm$ 5.0 % (133.0 mg to 147.0 mg)
04.	Uniformity of weight	+1.84 % to -1.70 %			Not more than 2 of the individual weights deviate from the average weight by more than $\pm$ 7.5 % and none deviate by more than $\pm$ 15 % .
05.	Diameter	Min 6.82 mm	Max 6.90 mm	Avg. 6.85 mm	6.60 mm to 7.00 mm
06.	Thickness	Min 3.36 mm	Max 3.45 mm	Avg. 3.41 mm	2.9 mm to 3.50 mm
07.	Hardness	4.94 kg/cm ²			NLT 3.0 kg/cm ²
08.	Friability	0.18 %			Not More than 1.0 %
09.	Disintegration Time	02 minutes 04 seconds			Not more than 15 minutes
10.	Content Uniformity:				
	Amlodipine Besylate BP equivalent to Amlodipine-5 mg	Min 98.07 %	Max 102.38 %	Avg. 100.26 %	Not less than 85.0 % and Not more than 115.0 % of labeled claim.
	Perindopril Erbumine BP-5 mg	Min 99.63 %	Max 101.48 %	Avg. 100.31 %	Not less than 85.0 % and Not more than 115.0 % of labeled claim.

	Tested By	Checked By	Approved By
Sign			
Name	Rajarajeswari	Ramesh	Vallarasan
Date	04/06/2020	04/06/2020	04/06/2020

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PRIVATE LIMITED R.S. No. 4/3, plot No. 33, Kurumbapet Industrial Estate, Villianur Commune, Pondicherry- 605009				Page 2 of 2	
QUALITY CONTROL	CERTIFICATE OF ANALYSIS				Format No: F/QCGN/022/08	
	FINISHED PRODUCT					
Product Name	:	Amloperin 5 mg / 5 mg (Amlodipine Besilate & Perindopril Erbumine Tablet)				
A.R.No.	:	FP/270520/02				
Batch No.	:	GF200502	Batch Size	:	6.0 L	
Mfg. Date	:	May-2020	Exp. Date	:	Apr-2023	
Sampling Date	:	23.05.2020	Sample Qty	:	120 Tablets	
Analysis Date	:	23.05.2020	Release Date	:	04.06.2020	

11.	Dissolution:				
	Amlodipine Besylate BP equivalent to Amlodipine-5 mg	Min 96.99 %	Max 104.18 %	Avg. 101.47 %	Not less than 80.0 % of labeled amount.
	Perindopril Erbumine BP-5 mg	Min 95.28 %	Max 97.71 %	Avg. 96.46 %	Not less than 80 % of labeled amount.
12.	Related substances:				
	Amlodipine Impurity A	Not Detected(ND)			Not more than 1.0 %
	Perindopril Impurity B	Not Detected(ND)			Not more than 1.5 %
	Perindopril Impurity C	Not Detected(ND)			Not more than 0.60 %
	Perindopril Impurity E	Not Detected(ND)			Not more than 0.40 %
	Perindopril Impurity F	Not Detected(ND)			Not more than 1.50 %
	Single maximum unknown impurity	Below Detection Limit(BDL)			Not more than 0.50 %
	Total unknown impurity	Below Detection Limit(BDL)			Not more than 1.0 %
	Total impurities	Below Detection Limit(BDL)			Not more than 5.0 %
13.	Assay: Each uncoated tablet contains:				
	Amlodipine Besylate BP equivalent to Amlodipine-5 mg	101.61 %			Not less than 90.0 % and Not more than 110.0 %
	Perindopril Erbumine BP-5 mg	99.36 %			Not less than 90.0 % and Not more than 110.0 %
14.	Microbiological limits:				
	Total Aerobic Microbial count	20 cfu /g			NMT 1000 cfu/g
	Total Yeasts and mould counts	<10 cfu/g			NMT 100 cfu/g
	E.Coli	Absent			Should be Absent
	Salmonella	Absent			Should be Absent
	S.aureus	Absent			Should be Absent
	P.aeruginosa	Absent			Should be Absent

Remark : The product complies/~~not complies~~ with the prescribed standard of quality with reference to BP/USP and In-house Specification.

	Tested By	Checked By	Approved By
Sign			
Name	Rajarajeswari	Ramesh	Vallarasan
Date	04/06/2020	04/06/2020	04/06/2020