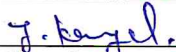


 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PRIVATE LIMITED R.S. No. 4/3, plot No. 33, Kurumbapet Industrial Estate, Villianur Commune, Pondicherry- 605009				Page 1 of 2
QUALITY CONTROL	CERTIFICATE OF ANALYSIS				Format No: F/QCGN/022/08
	FINISHED PRODUCT				
Product Name	:	Ramithiazide 5 mg/12.5 mg (Ramipril and Hydrochlorothiazide Tablets)			
A.R.No.	:	BS/150922/01			
Batch No.	:	G1822115	Batch Size	:	6.0 L
Mfg. Date	:	Sep-2022	Exp. Date	:	Aug-2025
Sampling Date	:	15.09.2022	Sample Qty	:	120 Tablets
Analysis Date	:	15.09.2022	Release Date	:	26.09.2022

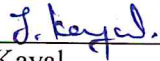
S.No.	TEST	RESULTS	LIMITS
01.	Description	Pink coloured, flat, round, beveled edged uncoated tablet with break line on one side and plain on other side.	Pink coloured, flat, round, beveled edged uncoated tablet with break line on one side and plain on other side.
02.	Identification By HPLC a. Ramipril BP b. Hydrochlorothiazide BP	Complies Complies	The retention time of one of the major peak in the chromatogram of sample preparation corresponds to the peak due to Ramipril in standard preparation as obtained in assay. The retention time of one of the major peak in the chromatogram of sample preparation corresponds to the peak due to Hydrochlorothiazide in standard preparation as obtained in assay.
03.	Average weight of tablets	198.40 mg	200.0 mg $\pm$ 5.0 % (Limit:190.0 mg to 210.0 mg)
04.	Uniformity of weight	+0.71 % to -1.81 %	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 $\pm$ 15.0 %
05.	Dimensions		
	Diameter	Min Max Avg. 7.99 mm 8.03 m 8.01 mm	7.70 mm to 8.10 mm
	Thickness	Min Max Avg. 2.95 mm 3.03 mm 2.98 mm	2.60 mm to 3.20 mm
06.	Hardness	3.75 kg/cm ²	Not less than 3.0 kg/cm ² .
07.	Friability	0.15 %	Not more than 1.0%
08.	Disintegration time	02 minutes 10 seconds	Not more than 15 minutes

	Tested By	Checked By	Approved By
Sign			
Name	Kayal	Ramesh	Vallarasan
Date	26/09/2022	26/09/2022	26/09/2022

 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	:	Ramithiazide 5 mg/12.5 mg (Ramipril and Hydrochlorothiazide Tablets)				
A.R.No.	:	BS/150922/01				
Batch No.	:	G1822115	Batch Size	:	6.0 L	
Mfg. Date	:	Sep-2022	Exp. Date	:	Aug-2025	
Sampling Date	:	15.09.2022	Sample Qty	:	120 Tablets	
Analysis Date	:	15.09.2022	Release Date	:	26.09.2022	

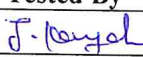
09.	Content Uniformity:				
	Ramipril BP-5mg	Min 99.18 %	Max 103.29 %	Avg. 101.29 %	Not less than 85.0 % and Not more than 115.0 % of labeled claim.
	Hydrochlorothiazide BP-12.5mg	Min 101.18 %	Max 106.32 %	Avg. 103.57 %	Not less than 85.0 % and Not more than 115.0 % of labeled claim.
10.	Dissolution:				
	Ramipril BP-5 mg	Min 98.94 %	Max 103.88 %	Avg. 100.57 %	Not less than 75.0 % of labeled amount.
	Hydrochlorothiazide BP-12.5mg	Min 97.40 %	Max 99.75 %	Avg. 98.55 %	Not less than 75.0 % of labeled amount.
11.	Related substances:				
	Impurity A	Not Detected			Not more than 2.0%
	Impurity D	Not Detected			Not more than 6.0%
	Impurity E	Not Detected			Not more than 2.0%
	Single maximum unknown impurity	Not Detected			Not more than 0.5%
	Total impurities	Not Detected			Not more than 6.0%
12.	Assay: Each uncoated tablet contains:				
	Ramipril BP -5 mg	100.48 %			Not less than 90.0 % and Not more than 110.0 %
	Hydrochlorothiazide BP-12.5mg	100.17 %			Not less than 90.0 % and Not more than 110.0 %
13.	Microbiological limits:				
	Total Aerobic Microbial count	<10 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	Kayal	Ramesh	Vallarasan
Date	26/09/2022	26/09/2022	26/09/2022

 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 :		Ramithiazide 5 mg/12.5 mg (Ramipril and Hydrochlorothiazide Tablets)			
A.R.No. :		BS/020921/01			
Batch No. :		GF210918		Batch Size : 6.0 L	
Mfg. Date :		Sep-2021		Exp. Date : Aug-2024	
Sampling Date :		02.09.2021		Sample Qty : 120 Tablets	
Analysis Date :		02.09.2021		Release Date : 09.09.2021	

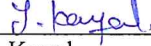
S.No.	TEST	RESULTS	LIMITS
01.	Description	Pink coloured, flat, round, beveled edged uncoated tablet with break line on one side and plain on other side.	Pink coloured, flat, round, beveled edged uncoated tablet with break line on one side and plain on other side.
02.	Identification By HPLC		
	a. Ramipril BP	Complies	The retention time of one of the major peak in the chromatogram of sample preparation corresponds to the peak due to Ramipril in standard preparation as obtained in assay.
	b. Hydrochlorothiazide BP	Complies	The retention time of one of the major peak in the chromatogram of sample preparation corresponds to the peak due to Hydrochlorothiazide in standard preparation as obtained in assay.
03.	Average weight of tablets	199.15 mg	200.0 mg $\pm$ 5.0 % (Limit:190.0 mg to 210.0 mg)
04.	Uniformity of weight	+0.93 % to -1.08 %	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 $\pm$ 15.0 %
05.	Dimensions:		
	Thickness	Min 3.09 mm Max 3.14 mm Avg. 3.11 mm	2.60 mm to 3.20 mm
	Diameter	Min 7.99 mm Max 8.01 mm Avg. 8.00 mm	7.70 mm to 8.10 mm
06.	Hardness	4.39 kg/cm ²	Not less than 3.0 kg/cm ² .
07.	Friability	0.17 %	Not more than 1.0%
08.	Disintegration time	01 minutes 46 seconds	Not more than 15 minutes

	Tested By	Checked By	Approved By
Sign			
Name	Kayal	Ramesh	Vallarasan
Date	09/09/2021	09/09/2021	09/09/2021

 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	:	Ramithiazide 5 mg/12.5 mg (Ramipril and Hydrochlorothiazide Tablets)				
A.R.No.	:	BS/020921/01				
Batch No.	:	GF210918	Batch Size	:	6.0 L	
Mfg. Date	:	Sep-2021	Exp. Date	:	Aug-2024	
Sampling Date	:	02.09.2021	Sample Qty	:	120 Tablets	
Analysis Date	:	02.09.2021	Release Date	:	09.09.2021	

09.	Content Uniformity:				
	Ramipril BP-5mg	Min 98.67 %	Max 101.57 %	Avg. 100.34 %	Not less than 85.0 % and Not more than 115.0 % of labeled claim.
	Hydrochlorothiazide BP-12.5mg	Min 98.78 %	Max 100.93 %	Avg. 99.58 %	Not less than 85.0 % and Not more than 115.0 % of labeled claim.
10.	Dissolution:				
	Ramipril BP-5 mg	Min 96.47 %	Max 98.19 %	Avg. 97.19 %	Not less than 75.0 % of labeled amount.
	Hydrochlorothiazide BP-12.5mg	Min 98.32 %	Max 100.50 %	Avg. 99.48 %	Not less than 75.0 % of labeled amount.
11.	Related substances:				
	Impurity A	Not Detected			Not more than 2.0%
	Impurity D	Not Detected			Not more than 6.0%
	Impurity E	Not Detected			Not more than 2.0%
	Single maximum unknown impurity	Not Detected			Not more than 0.5%
	Total impurities	Not Detected			Not more than 6.0%
12.	Assay: Each uncoated tablet contains:				
	Ramipril BP -5 mg	100.65 %			Not less than 90.0 % and Not more than 110.0 %
	Hydrochlorothiazide BP-12.5mg	100.40 %			Not less than 90.0 % and Not more than 110.0 %
13.	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	Kayal	Ramesh	Vallarasan
Date	09/09/2021	09/09/2021	09/09/2021

 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	:	Ramithiazide 5 mg/12.5 mg (Ramipril and Hydrochlorothiazide Tablets)				
A.R.No.	:	FP/161120/01				
Batch No.	:	GF201004	Batch Size	:	6.0 L	
Mfg. Date	:	Oct-2020	Exp. Date	:	Sep-2023	
Sampling Date	:	31.10.2020	Sample Qty	:	120 Tablets	
Analysis Date	:	31.10.2020	Release Date	:	23.11.2020	

S.No.	TEST	RESULTS	LIMITS
01.	Description	Pink coloured, flat, round, beveled edged uncoated tablet with break line on one side and plain on other side.	Pink coloured, flat, round, beveled edged uncoated tablet with break line on one side and plain on other side.
02.	Identification By HPLC a. Ramipril BP	Complies	The retention time of one of the major peak in the chromatogram of sample preparation corresponds to the peak due to Ramipril in standard preparation as obtained in assay.
	b. Hydrochlorothiazide BP	Complies	The retention time of one of the major peak in the chromatogram of sample preparation corresponds to the peak due to Hydrochlorothiazide in standard preparation as obtained in assay.
03.	Average weight of tablets	200.35 mg	200.0 mg $\pm$ 5.0 % (Limit:190.0 mg to 210.0 mg)
04.	Uniformity of weight	+2.82 % to -1.17 %	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 $\pm$ 15.0 %
05.	Dimensions:		
	Thickness	Min Max Avg. 3.09 mm 3.14 mm 3.11 mm	2.60 mm to 3.20 mm
	Diameter	Min Max Avg. 8.01 mm 8.04 mm 8.02 mm	7.70 mm to 8.10 mm
06.	Hardness	4.29 kg/cm ²	Not less than 3.0 kg/cm ² .
07.	Friability	0.22 %	Not more than 1.0%
08.	Disintegration time	01 minutes 25 seconds	Not more than 15 minutes

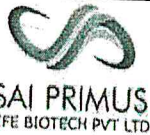
	Tested By	Checked By	Approved By
Sign			
Name	Sriramprasath	Ramesh	Vallarasan
Date	23/11/2020	23/11/2020	23/11/2020

 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	:	Ramithiazide 5 mg/12.5 mg (Ramipril and Hydrochlorothiazide Tablets)				
A.R.No.	:	FP/161120/01				
Batch No.	:	GF201004	Batch Size	:	6.0 L	
Mfg. Date	:	Oct-2020	Exp. Date	:	Sep-2023	
Sampling Date	:	31.10.2020	Sample Qty	:	120 Tablets	
Analysis Date	:	31.10.2020	Release Date	:	23.11.2020	

09.	Content Uniformity:				
	Ramipril BP-5mg 	Min 99.64 %	Max 103.94 %	Avg. 101.61 %	Not less than 85.0 % and Not more than 115.0 % of labeled claim.
	Hydrochlorothiazide BP-12.5mg 	Min 98.32 %	Max 100.02 %	Avg. 99.30 %	Not less than 85.0 % and Not more than 115.0 % of labeled claim.
10.	Dissolution:				
	Ramipril BP-5 mg 	Min 97.73 %	Max 103.76 %	Avg. 100.44 %	Not less than 75.0 % of labeled amount.
	Hydrochlorothiazide BP-12.5mg 	Min 93.72 %	Max 102.01 %	Avg. 99.59 %	Not less than 75.0 % of labeled amount.
11.	Related substances:				
	Impurity A	Not Detected			Not more than 2.0%
	Impurity D	0.24 %			Not more than 6.0%
	Impurity E	Not Detected			Not more than 2.0%
	Single maximum unknown impurity	Not Detected			Not more than 0.5%
	Total impurities	0.24 %			Not more than 6.0%
12.	Assay: Each uncoated tablet contains:				
	Ramipril BP -5 mg 	101.59 %			Not less than 90.0 % and Not more than 110.0 %
	Hydrochlorothiazide BP-12.5mg 	101.18 %			Not less than 90.0 % and Not more than 110.0 %
13.	Microbiological limits:				
	Total Aerobic Microbial count	10 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	Sriramprasath	Ramesh	Vallarasan
Date	23/11/2020	23/11/2020	23/11/2020

	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>Ramithiazide 5/12.5</u>	
Analytical Report No. <u>Fp/16/120/01</u>	Batch No. <u>GF201004</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 88	61
	Tapped density test report	NA	NA
	KF-Autotitra report	NA	NA
	Microbiological test report	69 to 74	6
	Outside laboratory testing report	NA	NA
	Additional test report if any	75	1
	The above product consist of <u>75</u> pages		Total pages <u>75</u>

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.3, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.	Page 1 of 1 Issued by: <i>[Signature]</i> QA/Date: <i>26/10/2020</i>
	SAMPLING POLICY	No.: F/QAGN/026/01 Revision No: 00
TITLE	TEST REQUEST FORM	Review Period: 2 years Effective Date: 27/04/19

Date: 31/10/2020	
From (Dept): <i>Production</i>	To: Q.C. DEPARTMENT
Name of the Item/ Product/ Previous Product* : <i>Kamithi 250 5/12.5</i>	Quantity sampled
Batch No.* : <i>C7F201004</i>	1. <i>Hopper uniformity 1.50 tabs</i>
Batch Size* : <i>6.02</i>	2. <i>RPM challenge 100 tabs</i>
Mfg. Date* : <i>10/2020</i>	3. <i>Hardness challenge 100 tabs</i>
Exp. Date* : <i>09/2023</i>	4. <i>Compress 100 tabs</i>
Stage* : <i>Compressed tablets</i>	Sampled on: <i>31/10/2020</i>
	Sampled by: <i>Prabhadharan</i>
	Analyzed By: <i>Sri ram</i>
	Analytical Reference No. <i>B313102010</i>

Tests:
1. <i>As per P.V.P.</i>
2. <i>[Line]</i>
3. <i>[Line]</i>
4. <i>[Line]</i>

<i>[Signature]</i> 31/10/2020	<i>[Signature]</i> 31/10/2020	<i>[Signature]</i> 31/10/2020
TRF raised by Sign/Date	TRF given to QC by QA Sign/Date	Head of QC Sign/Date

*wherever not applicable write NA

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 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: <i>16/11/2020</i>
	SAMPLING POLICY	No.: F/QAGN/026/01 Revision No: 00
TITLE	TEST REQUEST FORM	Review Period: 2 years Effective Date: 27/04/19

Date: 16/11/2020		
From (Dept): <i>Packing</i>		To: Q.C. DEPARTMENT
Name of the Item/ Product/ Previous Product*	<i>RAMOTHIAZIDE 5/12.5</i>	Quantity sampled
Batch No.*	<i>GF201004</i>	1. <i>Finished Product</i>
Batch Size*	<i>6.0L</i>	2. <i>12.0 Tabs</i>
Mfg. Date*	<i>10/2020</i>	3. <i>NA</i>
Exp. Date*	<i>09/2023</i>	4. <i>NA</i>
Stage*	<i>Finished product</i>	Sampled on: <i>16/11/2020</i>
		Sampled by: <i>Pam Kumar</i>
		Analyzed By: <i>Sriram</i>
		Analytical Reference No. <i>FP/161120/01</i>

Tests:
1. <i>As per Specification</i>
2. <i>NA</i>
3. <i>NA</i>
4. <i>NA</i>

 TRF raised by Sign/Date	 TRF given to QC by QA Sign/Date	 Head of QC Sign/Date
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*wherever not applicable write NA

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	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>May 31/05/2020</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: Ramithiamide 5/12.5 **B.No:** GF201004

Appearance: Pink coloured, flat, round, beveled edged uncoated tablet with break line on one side and plain on other side.

Weight of 20 tablets: 4.007 gm. **Average Weight:** 0.20035 gm **Eqv. To:** 200.35 mg

Weight of individual units:

1. <u>0.200</u>	11. <u>0.200</u>
2. <u>0.201</u>	12. <u>0.201</u>
3. <u>0.204</u>	13. <u>0.202</u>
4. <u>0.199</u>	14. <u>0.206</u>
5. <u>0.203</u>	15. <u>0.199</u>
6. <u>0.199</u>	16. <u>0.204</u>
7. <u>0.204</u>	17. <u>0.202</u>
8. <u>0.199</u>	18. <u>0.201</u>
9. <u>0.202</u>	19. <u>0.202</u>
10. <u>0.198</u>	20. <u>0.206</u>

Weight of Highest: 0.206 **Weight of Lowest:** 0.198

Tablet No: 14 **Tablet No:** 10

Percentage: 2.82% **Percentage:** -1.17%

The tablets Complies with the limits to ± 7.5% of Average Weight.

Disintegration Time: 01 Minutes 25 Seconds.

Hardness: 1. 4.27 2. 3.98 3. 4.56 4. 4.67 5. 3.98

(In Kg)

(Limit: — Kg to NLT 3.6 Kg) **Average:** 4.29

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	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>21/05/2020</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>3.12</u> 2. <u>3.14</u> 3. <u>3.10</u> 4. <u>3.10</u> 5. <u>3.09</u> (In mm) (Limit: <u>2.60</u> mm to <u>3.20</u> mm) Average: <u>3.11 mm</u>
Diameter: 1. <u>8.01</u> 2. <u>8.04</u> 3. <u>8.01</u> 4. <u>8.04</u> 5. <u>8.01</u> (In mm) (Limit: <u>7.70</u> mm to <u>8.10</u> mm) Average: <u>8.02 mm</u>
Length: 1. 2. 3. 4. 5. (In mm) (Limit: <u>NA</u> mm to <u>NA</u> mm) Average: <u>NA</u>
Width: 1. 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>6.603</u> (Before Operation) B. Weight of Tablets: <u>6.588</u> (After Operation) C. Weight Loss: <u>0.015</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: $C/A \times 100 = 0.22\%$ Limit: (NMT 1.0%)
Analysed By: <u>[Signature]</u> Checked By: <u>[Signature]</u> Date: <u>03/11/2020</u> Date: <u>23/11/2020</u>

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SAI PRIMUS LIFE BIOTECH PVT. LTD.		EXCEL SHEET FOR UNIFORMITY OF CONTENT					
Name of Product		RAMITHIAZIDE 5 mg/12.5 mg (RAMIPRIL)					
Date of Analysis		03-11-2020		Batch No.		GF201004	
Mfg. Date		OCT-2020		Exp. Date		SEP-2023	
WS No.		NA		% Purity		99.3	
WS Weight (WS)		25.02		WS Validity		NA	
Sample Weight (SW)		1		Label Claim (LC)		5	
Std. Dilution		25.02	2	1	1	1	1
		25	100	1	1	1	1
Sample Dilution		1	1	1	1	1	1
		250	1	1	1	1	1
Calculation Formula		Smp. Area		Std Dilution	99.3	100	5
		Std. Area		Sample Dilution	100	5	5
					Conversion Factor1	Conversion Factor3	% Assay
					Conversion Factor2	Conversion Factor4	
Sr. No.		Standard Area	Standard RT	Sample			
1	408270	4.856	UC				Minimum %
2	402821	4.859	UC1				101.84
3	401938	4.859	UC2				99.64
4	402785	4.859	UC3				101.18
5	404232	4.854	UC4				101.75
6			UC5				99.95
7			UC6				103.94
8			UC7				100.41
Average	404009	4.857	UC8				103.84
SD	2520.139421	0.00230217	UC9				103.50
RSD	0.6	0.1	UC10				100.09
			AVG				101.61
			423201				
Analysed By	P. Bhat		Checked By		J. A. 23/11/2020		
Date	04/11/2020		Date				



EXCEL SHEET FOR ASSAY CALCULATION FP

Name of Product		RAMITTHIAZIDE 5mg/12.5mg TAB(HYDROCHLOROTHIAZIDE)									
Date of Analysis		03/11/2020				Batch No.		GF201004			
Mfg. Date		OCT-2020				Exp. Date		SEP-2023			
WS No.		NA				% Purity		100.1			
WS Weight (WS) *		24.88 ¹				WS Validity		NA			
Sample Weight (SW)		1012.29				Label Claim (LC)		12.5			
CF1		1		CF2		1		CF3		1	
Std. Dilution		24.88		5		1		1		1	
		25		100		1		1		1	
Sample Dilution		1012.29		5		1		1		1	
		250		25		1		1		1	
Calculation Formula		Smp. Area/Abs		Std Dilution		100.1		200.35		CF1	
		Std. Area/Abs		Sample Dilution		100				CF2	
Sr. No.		Standard Area/Abs		Standard RT						CF3	
1		1639190		2.108						CF4	
2		1620577		2.110							
3		1610230		2.109							
4		1622507		2.109							
5		1627135		2.108							
Average		1623928		2.109							
SD		10536.81		0.00							
RSD		0.7		0.0							
Assay (mg)		12.6476									

Assay (%)	101.18
-----------	--------

Sr. No.	Sample Area/Abs
1	1648372
2	1685099
3	
4	
5	
6	
Average	1666736

Analysed By	D. S. S. S.
Date	04/11/2020

Checked By	A. S. S. S.
Date	04/23/11/2020



EXCEL SHEET FOR ASSAY CALCULATION FP

Name of Product		RAMITHIAZIDE 5mg/12.5mg TAB(RAMIPRIL)									
Date of Analysis		03/11/2020				Batch No.		GF201004			
Mfg. Date		OCT-2020				Exp. Date		SEP-2023			
WS No.		NA				% Purity		99.3			
WS Weight (WS)		25.02				WS Validity ³		NA			
Sample Weight (SW)		1012.29				Label Claim (LC)		5			
CF1		1		CF2		1		CF3		1	
Std. Dilution		25.02		2		1		1		1	
		25		100		1		1		1	
Sample Dilution		1012.29		5		1		1		1	
		250		25		1		1		1	
Calculation Formula		Smp. Area/Abs		Std Dilution		99.3		200.35		CF1	
		Std. Area/Abs		Sample Dilution		100				CF2	
										CF3	
										CF4	
Sr. No.		Standard Area/Abs		Standard RT							
1		408270		4.856							
2		402821		4.859							
3		401938		4.859							
4		402785		4.859							
5		404232		4.854							
Average		404009		4.857							
SD		2520.14		0.00							
RSD		0.62		0.05							
Assay (mg)		5.0795									

Assay (%)	101.59
-----------	--------

Sr. No.	Sample Area/Abs
1	415547
2	419135
3	
4	
5	
6	
Average	417341

Analysed By	B. Rat
Date	04/11/2020

Checked By	CH 23/11/2020
Date	



EXCEL SHEET FOR UNIFORMITY OF CONTENT

Name of Product		RAMITHIAZIDE 5 mg/12.5 mg (HYDROCHLOROTHIAZIDE)																																																																																																																						
Date of Analysis		03/11/2020																																																																																																																						
Mfg. Date		OCT-2020																																																																																																																						
WS No.		NA																																																																																																																						
WS Weight (WS)		24.88																																																																																																																						
Sample Weight (SW)		1																																																																																																																						
Batch No.		GF201004																																																																																																																						
Exp. Date		SEP-2023																																																																																																																						
% Purity		100.1																																																																																																																						
WS Validity		NA																																																																																																																						
Label Claim (LC)		12.5																																																																																																																						
Conversion Factor1		1																																																																																																																						
Conversion Factor2		1																																																																																																																						
Conversion Factor3		1																																																																																																																						
Conversion Factor4		1																																																																																																																						
Std. Dilution		<table border="1"> <tr> <td>24.88</td> <td>5</td> <td>1</td> <td>1</td> <td>1</td> <td>1</td> </tr> <tr> <td>25</td> <td>100</td> <td>1</td> <td>1</td> <td>1</td> <td>1</td> </tr> </table>										24.88	5	1	1	1	1	25	100	1	1	1	1																																																																																																	
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Sample Dilution		<table border="1"> <tr> <td>1</td> <td>1</td> <td>1</td> <td>1</td> <td>1</td> <td>1</td> </tr> <tr> <td>250</td> <td>1</td> <td>1</td> <td>1</td> <td>1</td> <td>1</td> </tr> </table>										1	1	1	1	1	1	250	1	1	1	1	1																																																																																																	
1	1	1	1	1	1																																																																																																																			
250	1	1	1	1	1																																																																																																																			
Calculation Formula		<table border="1"> <tr> <td>Smp. Area</td> <td>Std Dilution</td> <td>100.1</td> <td>100</td> <td>Conversion Factor1</td> <td>Conversion Factor3</td> <td rowspan="2">% Assay</td> </tr> <tr> <td>Std. Area</td> <td>Sample Dilution</td> <td>100</td> <td>12.5</td> <td>Conversion Factor2</td> <td>Conversion Factor4</td> </tr> </table>										Smp. Area	Std Dilution	100.1	100	Conversion Factor1	Conversion Factor3	% Assay	Std. Area	Sample Dilution	100	12.5	Conversion Factor2	Conversion Factor4																																																																																																
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Sr. No.		<table border="1"> <thead> <tr> <th>Standard Area</th> <th>Standard RT</th> <th colspan="6">Sample</th> <th></th> </tr> <tr> <th></th> <th></th> <th>UC</th> <th>AREA</th> <th>Smp. Weight</th> <th>%</th> <th>mg</th> <th>Minimum %</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>1639190</td> <td>2.108</td> <td>UC1</td> <td>1602775</td> <td>1</td> <td>98.32</td> <td>12.29</td> <td rowspan="5">98.32</td> </tr> <tr> <td>2</td> <td>1620577</td> <td>2.110</td> <td>UC2</td> <td>1613969</td> <td>1</td> <td>99.01</td> <td>12.38</td> </tr> <tr> <td>3</td> <td>1610230</td> <td>2.109</td> <td>UC3</td> <td>1620402</td> <td>1</td> <td>99.40</td> <td>12.43</td> </tr> <tr> <td>4</td> <td>1622507</td> <td>2.109</td> <td>UC4</td> <td>1618761</td> <td>1</td> <td>99.30</td> <td>12.41</td> </tr> <tr> <td>5</td> <td>1627135</td> <td>2.108</td> <td>UC5</td> <td>1604486</td> <td>1</td> <td>98.43</td> <td>12.30</td> </tr> <tr> <td>6</td> <td></td> <td></td> <td>UC6</td> <td>1630004</td> <td>1</td> <td>99.99</td> <td>12.50</td> <td rowspan="3">Maximum %</td> </tr> <tr> <td>7</td> <td></td> <td></td> <td>UC7</td> <td>1620469</td> <td>1</td> <td>99.41</td> <td>12.43</td> </tr> <tr> <td>8</td> <td></td> <td></td> <td>UC8</td> <td>1619704</td> <td>1</td> <td>99.36</td> <td>12.42</td> </tr> <tr> <td>Average</td> <td>1623928</td> <td>2.109</td> <td>UC9</td> <td>1630526</td> <td>1</td> <td>100.02</td> <td>12.50</td> <td rowspan="2">100.02</td> </tr> <tr> <td>SD</td> <td>10536.80619</td> <td>0.00083666</td> <td>UC10</td> <td>1625981</td> <td>1</td> <td>99.75</td> <td>12.47</td> </tr> <tr> <td>RSD</td> <td>0.7</td> <td>0.0</td> <td colspan="5">AVG</td> <td>99.30</td> </tr> </tbody> </table>										Standard Area	Standard RT	Sample									UC	AREA	Smp. Weight	%	mg	Minimum %	1	1639190	2.108	UC1	1602775	1	98.32	12.29	98.32	2	1620577	2.110	UC2	1613969	1	99.01	12.38	3	1610230	2.109	UC3	1620402	1	99.40	12.43	4	1622507	2.109	UC4	1618761	1	99.30	12.41	5	1627135	2.108	UC5	1604486	1	98.43	12.30	6			UC6	1630004	1	99.99	12.50	Maximum %	7			UC7	1620469	1	99.41	12.43	8			UC8	1619704	1	99.36	12.42	Average	1623928	2.109	UC9	1630526	1	100.02	12.50	100.02	SD	10536.80619	0.00083666	UC10	1625981	1	99.75	12.47	RSD	0.7	0.0	AVG					99.30
Standard Area	Standard RT	Sample																																																																																																																						
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1	1639190	2.108	UC1	1602775	1	98.32	12.29	98.32																																																																																																																
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5	1627135	2.108	UC5	1604486	1	98.43	12.30																																																																																																																	
6			UC6	1630004	1	99.99	12.50	Maximum %																																																																																																																
7			UC7	1620469	1	99.41	12.43																																																																																																																	
8			UC8	1619704	1	99.36	12.42																																																																																																																	
Average	1623928	2.109	UC9	1630526	1	100.02	12.50	100.02																																																																																																																
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Analysed By		D. Sathish								Checked By																																																																																																														
Date		04/11/2020								Date																																																																																																														

23/11/2020

D. J. J.
03/11/2020

03/11/2020



INSTRUMENT METHOD



14

Instrument Method: RAMITHIAZIDE_ASSAY_DISSO_FP_IM

Stored: 31/10/2020 19:24:01 IST

Method Information

Method Comments IM
Method Modified User SRIRAM
Method Locked No
Method Id 1004
Old Id
Method Version 3
Method Edit User
Source S/W Info Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615

W2489 Instrument Setup

Wavelength Mode Single Wavelength
Lamp On On

Channel A

Comment
Wavelength 210(nm)
Sampling Rate 10(points/sec)
Data Mode Absorbance
Time Constant 0.1(sec)
Autozero On Wavelength Change Maintain Baseline
Autozero On Inject Start Yes

Analog 1

Sensitivity 2.0000(AUFS)
Chart Polarity Positive (+)
Voltage Offset 0(mV)
Enable Chart Mark Yes

Run Events Yes

Pulse Width 1.0(sec)
Rect Wave Period 0.2(sec)

W2690/5 Instrument Setup

Type W2690/5
Instrument Status On
Channel Name 2690/5
Description PRESSURE ENABLE
Use Channel Monitor On
Monitor Parameter System Pressure

Analysed by: *[Signature]*
Date : 03/11/2020

Checked by: *[Signature]*
Date : 03/11/2020

Reported by User: RAJARAJESHWARI (RAJI)
Report Method: INSTRUMENT METHOD
Report Method ID: 1380
Page: 1 of 3

Project Name: 2020\QC_HPL_003\NOV-2020
Printed Date: 03/11/2020
Printed Time: 11:48:19 Asia/Calcutta

157

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	1.000
%A	100.0
%B	0.0
%C	0.0
%D	0.0
High Limit	5000.0
Low Limit	0.0
Enable Sample Temp	True
Enable Column Temp	True
Bubble Detect	True
Pre Column Volume	0.0
Sample Temp Target	25.0
Sample Temp Range	5.0
Spurge A	0.0
Spurge B	0.0
Spurge C	0.0
Spurge D	0.0
Column Temp Target	25.0
Column Temp Range	5.0
Flow Ramp	2.00
Column choice	No Change
Column Equil Minutes	0.00
Needle Wash	Extended
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 3 31/10/2020 19:24:01 IST User Vallarasan Method (\\Hplc\\2020\\QC_HPL_003\\OCT-2020 : 6044)
copied into project. (from Full Audit Trail project)
Version 3 29/10/2020 07:42:53 IST User SRIRAM PUPM CHANGED
Version 2 27/10/2020 20:55:48 IST User RAJI SAVE
Version 1 27/10/2020 08:56:15 IST User SRIRAM Created method 'RAMITHIAZIDE_ASSAY_DISO_FP_IM'. IM

Analysed by: *DBJ*
Date : 03/11/2020

Checked by: *JT*
Date : 03/11/2020

Reported by User: RAJARAJESHWARI (RAJI)
Report Method: INSTRUMENT METHOD
Report Method ID: 1380
Page: 2 of 3

Project Name: 2020\\QC_HPL_003\\NOV-2020
Printed Date: 03/11/2020
Printed Time: 11:48:19 Asia/Calcutta

Method Version Summaries

	Method Name	Method Type	Method Comments	Method Date	Method Modified User
1	RAMITHIAZIDE_ASSAY_DISO_FP_IM	Instrument	IM	31/10/2020 19:24:01 IST	SRIRAM
2	RAMITHIAZIDE_ASSAY_DISO_FP_IM	Instrument	IM	31/10/2020 19:24:01 IST	RAJI
3	RAMITHIAZIDE_ASSAY_DISO_FP_IM	Instrument	IM	31/10/2020 19:24:01 IST	SRIRAM

Method Version Summaries

	Method Locked	Method Id	Old Id	Method Version	Source S/W Info
1	No	1004		3	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615
2	No	1003		2	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615
3	No	1002		1	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615

Analysed by: *D. Raj*
Date: 03/11/2020

Checked by: *J. H.*
Date: 03/11/2020

Reported by User: RAJARAJESHWARI (RAJI)
Report Method: INSTRUMENT METHOD
Report Method ID: 1380
Page: 3 of 3

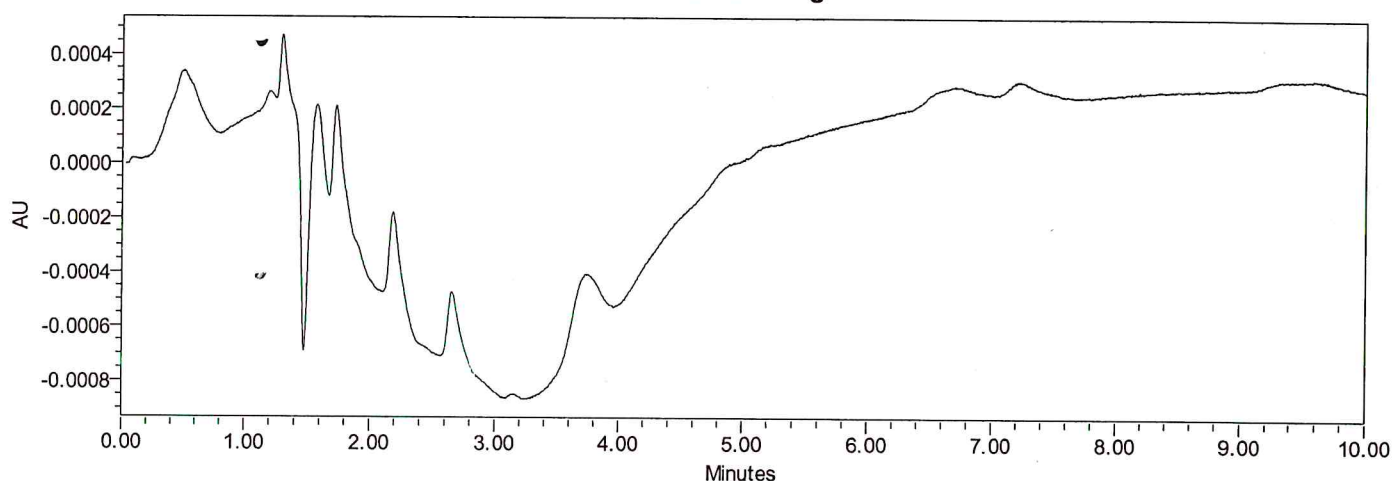
Project Name: 2020\QC_HPL_003\NOV-2020
Printed Date: 03/11/2020
Printed Time: 11:48:19 Asia/Calcutta

SAMPLE INFORMATION

Sample Name: BLANK
Sample Type: Control
Vial: 97
Injection #: 1
Injection Volume: 10.00 ul
Run Time: 10.0 Minutes
Date Acquired: 03/11/2020 12:40:04 IST
Date Processed: 04/11/2020 08:59:43 IST

Acquired By: RAJI
Sample Set Name: 03112020_RAMITHIA_AS_CU_FP_SS
Acq. Method Set: RAMITHIAZIDE_ASSAY_DISSO_FP_IM
Processing Method: RAMITHIAZIDE_ASSAY_PM
Channel Name: W2489 ChA
Proc. Chnl. Descr.: W2489 ChA 210nm

Auto-Scaled Chromatogram



Peak Results

	Name	Injection	RT	Area
1	HYDROCHLOROTHIAZIDE	1	2.127	
2	RAMIPRIL	1	4.965	

Analysed by: D. Raji
Date: 04/11/2020

Checked by: J. H. S. S.
Date: 04/11/2020

Reported by User: RAJARAJESHWARI (RAJI)
Report Method: CHROMATOGRAPHIC DATA
Report Method ID: 1423
Page: 1 of 1

Project Name: 2020\QC_HPL_003\NOV-2020
Printed Date: 04/11/2020
Printed Time: 10:23:34 Asia/Calcutta



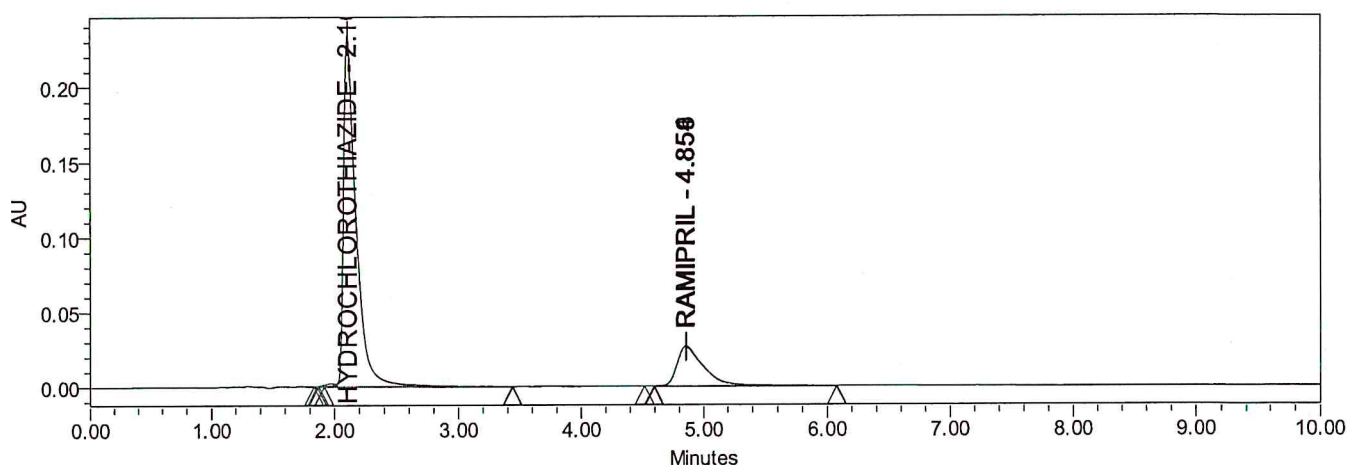
RSD REPORT



SAMPLE INFORMATION

Sample Name: STD SOLUTION
 Sample Type: Standard
 Vial: 98
 Injection #: 1, 2, 4, 5, 3
 Injection Volume: 10.00 ul
 Run Time: 10.0 Minutes
 Acquired By: RAJI
 Sample Set Name: 03112020_RAMITHIA_AS_CU_FP_SS
 Acq. Method Set: RAMITHIAZIDE_ASSAY_DISSO_FP_IM
 Processing Method: RAMITHIAZIDE_ASSAY_PM
 Channel Name: W2489 ChA
 Proc. Chnl. Descr.: W2489 ChA 210nm
 Date Acquired: 03/11/2020 12:51:18 IST, 03/11/2020 13:02:45 IST, 03/11/2020 13:13:58 IST, 03/11/2020 13:24:48 IST, 03/11/2020 13:36:03 IST
 Date Processed: 04/11/2020 08:59:44 IST

Auto-Scaled Chromatogram



Peak Name: HYDROCHLOROTHIAZIDE

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count
1	HYDROCHLOROTHIAZIDE	1	2.108	1639190	1.4	2271
2	HYDROCHLOROTHIAZIDE	2	2.110	1620577	1.4	2236
3	HYDROCHLOROTHIAZIDE	3	2.109	1610230	1.5	2281
4	HYDROCHLOROTHIAZIDE	4	2.109	1622507	1.4	2318
5	HYDROCHLOROTHIAZIDE	5	2.108	1627135	1.5	2200
Mean			2.109	1623928	1.4	2261
Std. Dev.			0.001	10536.723		
% RSD			0.0	0.6		

Analysed by: *D. Raji*
 Date: 04/11/2020

Checked by: *J. J.*
 Date: 23/11/2020

Reported by User: RAJARAJESHWARI (RAJI)
 Report Method: RSD REPORT SYSTEM SUITABILITY
 Report Method ID: 3473
 Page: 1 of 2

Project Name: 2020\QC_HPL_003\NOV-2020
 Printed Date: 04/11/2020
 Printed Time: 10:24:10 Asia/Calcutta

Peak Name: RAMIPRIL

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count	USP Resolution
1	RAMIPRIL	1	4.856	408270	1.2	2276	9.1
2	RAMIPRIL	2	4.859	402821	1.3	2254	9.1
3	RAMIPRIL	3	4.859	401938	1.4	2293	9.1
4	RAMIPRIL	4	4.859	402785	1.3	2281	9.1
5	RAMIPRIL	5	4.854	404232	1.4	2203	9.0
Mean			4.858	404009	1.3	2261	9.1
Std. Dev.			0.002	2520.003			
% RSD			0.0	0.6			

Analysed by: *D.D.*
Date : 04/11/2020

Checked by: *Jy*
Date : 23/11/2020

Reported by User: RAJARAJESHWARI (RAJI)
Report Method: RSD REPORT SYSTEM SUITABILITY
Report Method ID: 3473
Page: 2 of 2

Project Name: 2020\QC_HPL_003\NOV-2020
Printed Date: 04/11/2020
Printed Time: 10:24:10 Asia/Calcutta

SAMPLE INFORMATION

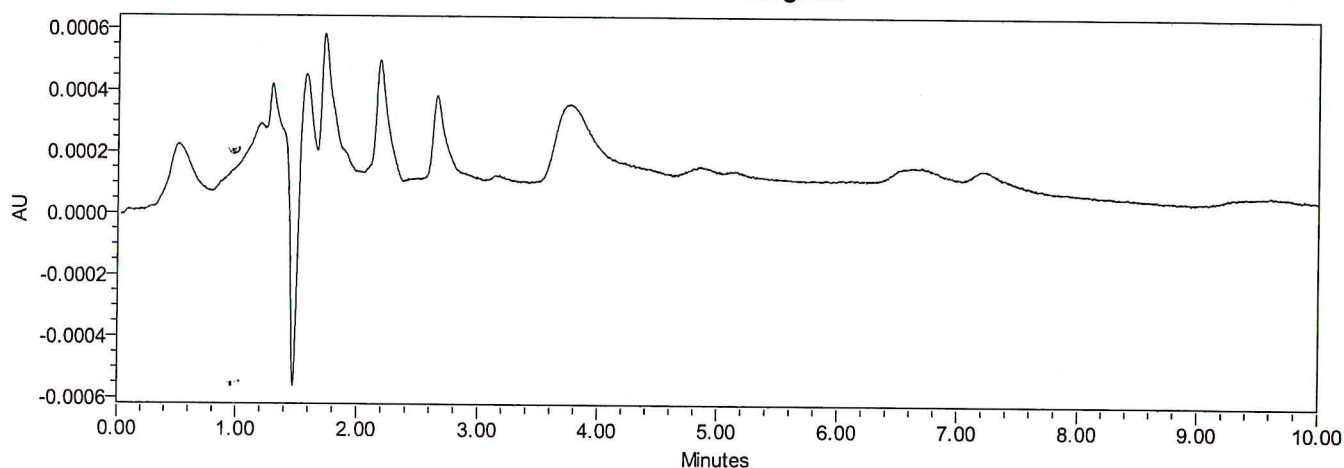
Sample Name: BLANK
Sample Type: Control
Vial: 97
Injection #: 1
Injection Volume: 10.00 ul
Run Time: 10.0 Minutes

Acquired By: RAJI
Sample Set Name: 03112020_RAMITHIA_AS_CU_FP_SS
Acq. Method Set: RAMITHIAZIDE_ASSAY_DISSO_FP_IM
Processing Method: RAMITHIAZIDE_ASSAY_PM
Channel Name: W2489 ChA
Proc. Chnl. Descr.: W2489 ChA 210nm

Date Acquired: 03/11/2020 13:47:21 IST

Date Processed: 04/11/2020 08:59:44 IST

Auto-Scaled Chromatogram



Peak Results

	Name	Injection	RT	Area
1	HYDROCHLOROTHIAZIDE	1	2.127	
2	RAMIPRIL	1	4.965	

Analysed by: D. Raj
Date: 04/11/2020

Checked by: RAJI
Date: 23/11/2020

Reported by User: RAJARAJESHWARI (RAJI)
Report Method: CHROMATOGRAPHIC DATA
Report Method ID: 1423
Page: 1 of 1

Project Name: 2020\QC_HPL_003\NOV-2020
Printed Date: 04/11/2020
Printed Time: 10:24:30 Asia/Calcutta



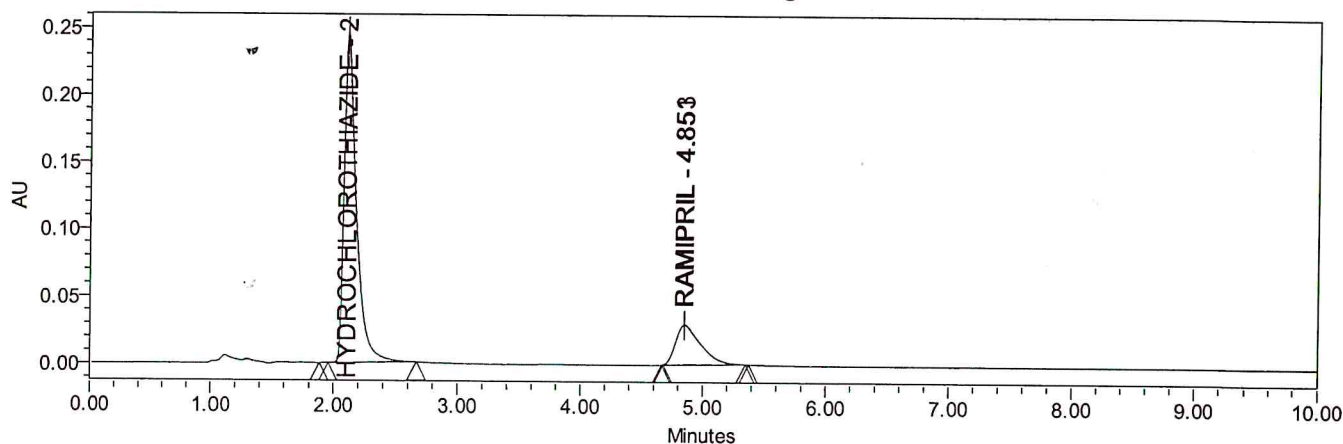
RSD REPORT



SAMPLE INFORMATION

Sample Name: RAMITHIA 5/12.5 GF201004 SPL_2, RAMITHIA 5/12.5 Acquired By: RAJI
 Sample Type: Unknown Sample Set Name: 03112020_RAMITHIA_AS_CU_FP_SS
 Vial: 99, 100 Acq. Method Set: RAMITHIAZIDE_ASSAY_DISSO_FP_IM
 Injection #: 1 Processing Method: RAMITHIAZIDE_ASSAY_PM
 Injection Volume: 10.00 ul Channel Name: W2489 ChA
 Run Time: 10.0 Minutes Proc. Chnl. Descr.: W2489 ChA 210nm
 Date Acquired: 03/11/2020 13:58:34 IST, 03/11/2020 14:09:48 IST
 Date Processed: 04/11/2020 09:00:01 IST, 04/11/2020 09:00:27 IST

Auto-Scaled Chromatogram



Peak Name: HYDROCHLOROTHIAZIDE

	Peak Name	Injection	RT	Area
1	HYDROCHLOROTHIAZIDE	1	2.107	1648372
2	HYDROCHLOROTHIAZIDE	1	2.108	1685099
Mean			2.107	1666736
Std. Dev.			0.000	25969.878
% RSD			0.0	1.6

Peak Name: RAMIPRIL

	Peak Name	Injection	RT	Area
1	RAMIPRIL	1	4.851	415547
2	RAMIPRIL	1	4.853	419135

Analysed by: D. Raj
 Date: 04/11/2020

Checked by: J. Raj
 Date: 23/11/2020

Reported by User: RAJARAJESHWARI (RAJI)
 Report Method: RSD REPORT
 Report Method ID: 3838
 Page: 1 of 2

Project Name: 2020\QC_HPL_003\NOV-2020
 Printed Date: 04/11/2020
 Printed Time: 10:24:57 Asia/Calcutta

Peak Name: RAMIPRIL

	Peak Name	Injection	RT	Area
Mean			4.852	417341
Std. Dev.			0.001	2537.274
% RSD			0.0	0.6

Analysed by: *D. Dey*
Date : 04/11/2020

Checked by: *J. Dey*
Date : 04/11/2020

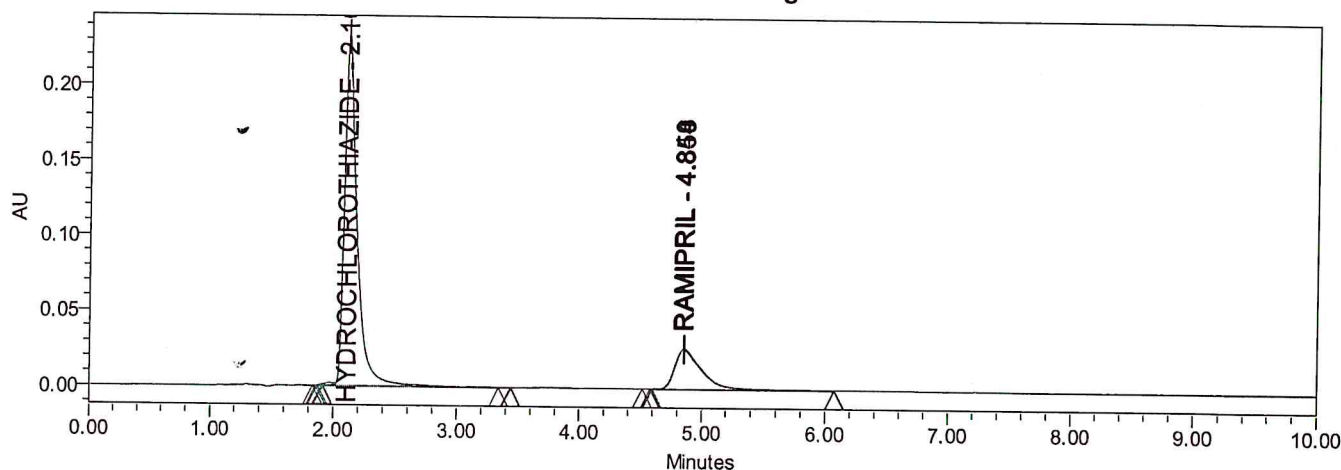
Reported by User: RAJARAJESHWARI (RAJI)
Report Method: RSD REPORT
Report Method ID: 3838
Page: 2 of 2

Project Name: 2020\QC_HPL_003\NOV-2020
Printed Date: 04/11/2020
Printed Time: 10:24:57 Asia/Calcutta

SAMPLE INFORMATION

Sample Name: STD SOLUTION, STD SOLUTION (B) Acquired By: RAJI
Sample Type: Standard Sample Set Name: 03112020_RAMITHIA_AS_CU_FP_SS
Vial: 98 Acq. Method Set: RAMITHIAZIDE_ASSAY_DISSO_FP_IM
Injection #: 1, 2, 4, 5, 3 Processing Method: RAMITHIAZIDE_ASSAY_PM
Injection Volume: 10.00 ul Channel Name: W2489 ChA
Run Time: 10.0 Minutes Proc. Chnl. Descr.: W2489 ChA210nm
Date Acquired: 03/11/2020 12:51:18 IST, 03/11/2020 13:02:45 IST, 03/11/2020 13:13:58 IST, 03/11/2020 13:24:48 IST, 03/11/2020 13:36:03 IST, 03/11/2020 14:21:16 IST
Date Processed: 04/11/2020 08:59:44 IST

Auto-Scaled Chromatogram



Peak Name: HYDROCHLOROTHIAZIDE

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count
1	HYDROCHLOROTHIAZIDE	1	2.108	1639190	1.4	2271
2	HYDROCHLOROTHIAZIDE	1	2.106	1610012	1.4	2226
3	HYDROCHLOROTHIAZIDE	2	2.110	1620577	1.5	2236
4	HYDROCHLOROTHIAZIDE	3	2.109	1610230	1.5	2281
5	HYDROCHLOROTHIAZIDE	4	2.109	1622507	1.4	2318
6	HYDROCHLOROTHIAZIDE	5	2.108	1627135	1.5	2200
Mean			2.108	1621609	1.5	2255
Std. Dev.			0.001	11004.3322		
% RSD			0.1	0.7		

Analysed by: D. J. J.
Date: 04/11/2020

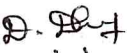
Checked by: J. J. J.
Date: 23/11/2020

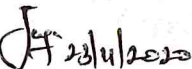
Reported by User: RAJARAJESHWARI (RAJI)
Report Method: RSD REPORT SYSTEM SUITABILITY
Report Method ID: 3473
Page: 1 of 2

Project Name: 2020\QC_HPL_003\NOV-2020
Printed Date: 04/11/2020
Printed Time: 10:28:08 Asia/Calcutta

Peak Name: RAMIPRIL

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count	USP Resolution
1	RAMIPRIL	1	4.848	401734	1.3	2237	8.9
2	RAMIPRIL	1	4.856	408270	1.4	2276	9.1
3	RAMIPRIL	2	4.859	402821	1.4	2254	9.1
4	RAMIPRIL	3	4.859	401938	1.3	2293	9.1
5	RAMIPRIL	4	4.859	402785	1.4	2281	9.1
6	RAMIPRIL	5	4.854	404232	1.4	2203	9.0
Mean			4.856	403630	1.4	2257	9.1
Std. Dev.			0.004	2437.785			
% RSD			0.11	0.6			

Analysed by: 
Date : 04/11/2020

Checked by: 
Date : 04/11/2020

Reported by User: RAJARAJESHWARI (RAJI)
Report Method: RSD REPORT SYSTEM SUITABILITY
Report Method ID: 3473
Page: 2 of 2

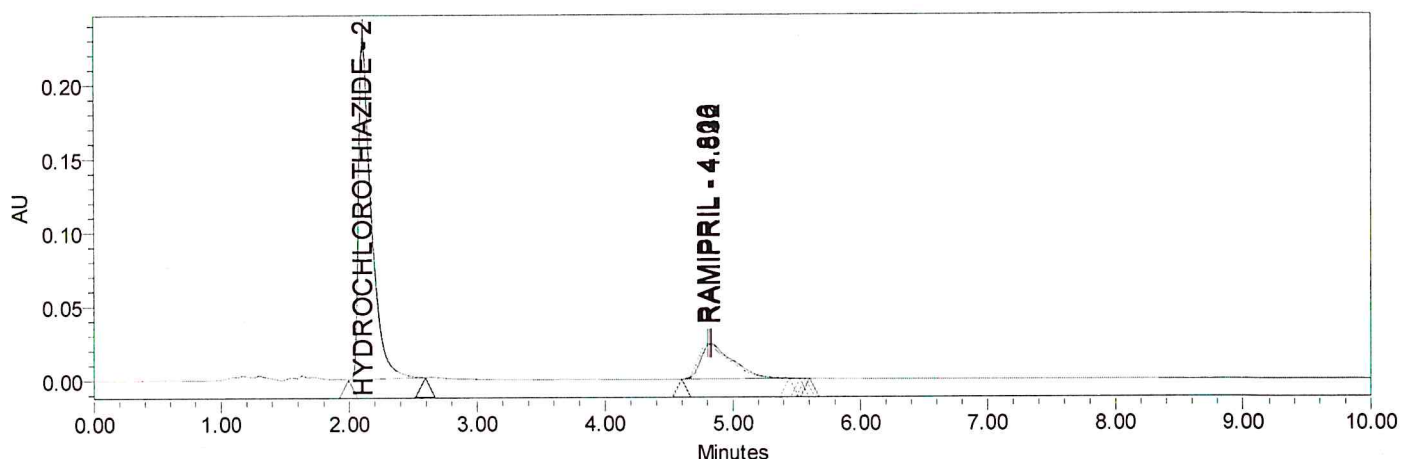
Project Name: 2020\QC_HPL_003\NOV-2020
Printed Date: 04/11/2020
Printed Time: 10:28:08 Asia/Calcutta

SAMPLE INFORMATION

Sample Name: RAMITHIA 5/12.5 GF201004 CU_2, RAMITHIA 5/12.5 Acquired By: RAJI
 Sample Type: Unknown Sample Set Name: 03112020_RAMITHIA_AS_CU_FP_SS
 Vial: 105, 103, 106, 104, 107 Acq. Method Set: RAMITHIAZIDE_ASSAY_DISSO_FP_IM
 Injection #: 1 Processing Method: RAMITHIAZIDE_ASSAY_PM
 Injection Volume: 10.00 ul Channel Name: W2489 ChA
 Run Time: 10.0 Minutes Proc. Chnl. Descr.: W2489 ChA 210nm

Date Acquired: 03/11/2020 15:10:13 IST, 03/11/2020 15:21:27 IST, 03/11/2020 15:32:39 IST, 03/11/2020 15:43:54 IST, 03/11/2020 15:55:05 IST
 Date Processed: 04/11/2020 09:02:39 IST, 04/11/2020 09:02:40 IST, 04/11/2020 09:03:42 IST

Auto-Scaled Chromatogram



Peak Name: HYDROCHLOROTHIAZIDE

	Peak Name	Injection	RT	Area
1	HYDROCHLOROTHIAZIDE	1	2.108	1602775
2	HYDROCHLOROTHIAZIDE	1	2.112	1613969
3	HYDROCHLOROTHIAZIDE	1	2.114	1620402
4	HYDROCHLOROTHIAZIDE	1	2.115	1618761
5	HYDROCHLOROTHIAZIDE	1	2.109	1604486
Mean			2.112	1612079
Std. Dev.			0.003	8088.703
% RSD			0.1	0.5

Analysed by: D. Raj
 Date: 04/11/2020

Checked by: S. Raj
 Date: 04/11/2020

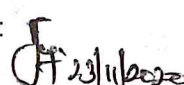
Reported by User: RAJARAJESHWARI (RAJI)
 Report Method: RSD REPORT
 Report Method ID: 3838
 Page: 1 of 2

Project Name: 2020\QC_HPL_003\NOV-2020
 Printed Date: 04/11/2020
 Printed Time: 10:29:30 Asia/Calcutta

Peak Name: RAMIPRIL

	Peak Name	Injection	RT	Area
1	RAMIPRIL	1	4.826	413992
2	RAMIPRIL	1	4.832	405074
3	RAMIPRIL	1	4.816	411343
4	RAMIPRIL	1	4.830	413643
5	RAMIPRIL	1	4.803	406342
Mean			4.821	410079
Std. Dev.			0.012	4142.162
% RSD			0.2	1.0

Analysed by: 
Date : 04/11/2020

Checked by: 
Date : 04/11/2020

Reported by User: RAJARAJESHWARI (RAJI)
Report Method: RSD REPORT
Report Method ID: 3838
Page: 2 of 2

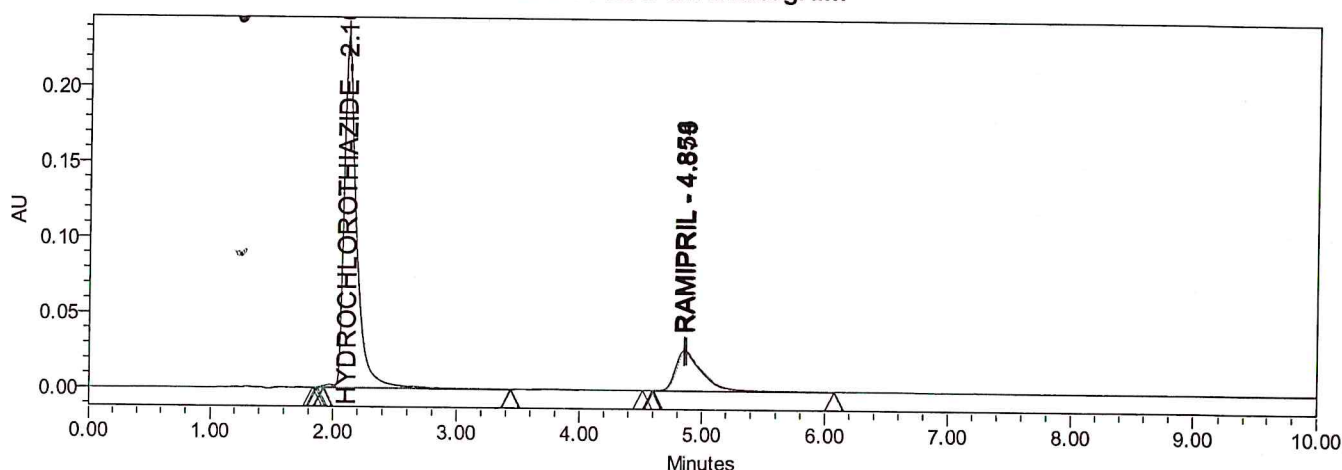
Project Name: 2020\QC_HPL_003\NOV-2020
Printed Date: 04/11/2020
Printed Time: 10:29:30 Asia/Calcutta

SAMPLE INFORMATION

Sample Name: STD SOLUTION, STD SOLUTION (B) Acquired By: RAJI
Sample Type: Standard Sample Set Name: 03112020_RAMITHIA_AS_CU_FP_SS
Vial: 98 Acq. Method Set: RAMITHIAZIDE_ASSAY_DISSO_FP_IM
Injection #: 1, 2, 4, 5, 3 Processing Method: RAMITHIAZIDE_ASSAY_PM
Injection Volume: 10.00 µl Channel Name: W2489 ChA
Run Time: 10.0 Minutes Proc. Chnl. Descr.: W2489 ChA 210nm

Date Acquired: 03/11/2020 12:51:18 IST, 03/11/2020 13:02:45 IST, 03/11/2020 13:13:58 IST, 03/11/2020 13:24:48 IST, 03/11/2020 13:36:03 IST, 03/11/2020 16:06:22 IST
Date Processed: 04/11/2020 08:59:44 IST

Auto-Scaled Chromatogram



Peak Name: HYDROCHLOROTHIAZIDE

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count
1	HYDROCHLOROTHIAZIDE	1	2.108	1639190	1.5	2271
2	HYDROCHLOROTHIAZIDE	1	2.113	1629153	1.4	2316
3	HYDROCHLOROTHIAZIDE	2	2.110	1620577	1.4	2236
4	HYDROCHLOROTHIAZIDE	3	2.109	1610230	1.5	2281
5	HYDROCHLOROTHIAZIDE	4	2.109	1622507	1.5	2318
6	HYDROCHLOROTHIAZIDE	5	2.108	1627135	1.4	2200
Mean			2.109	1624799	1.5	2270
Std. Dev.			0.002	9662.712		
% RSD			0.1	0.6		

Analysed by: D. Raji
Date: 04/11/2020

Checked by: J. Raji
Date: 04/11/2020

Reported by User: RAJARAJESHWARI (RAJI)
Report Method: RSD REPORT SYSTEM SUITABILITY
Report Method ID: 3473
Page: 1 of 2

Project Name: 2020\QC_HPL_003\NOV-2020
Printed Date: 04/11/2020
Printed Time: 10:29:04 Asia/Calcutta

Peak Name : RAMIPRIL

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count	USP Resolution
1	RAMIPRIL	1	4.873	405558	1.4	2290	9.0
2	RAMIPRIL	1	4.856	408270	1.3	2276	9.1
3	RAMIPRIL	2	4.859	402821	1.4	2254	9.1
4	RAMIPRIL	3	4.859	401938	1.4	2293	9.1
5	RAMIPRIL	4	4.859	402785	1.3	2281	9.1
6	RAMIPRIL	5	4.854	404232	1.4	2203	9.0
Mean			4.860	404267	1.4	2266	9.1
Std. Dev.			0.007	2340.981			
% RSD			0.1	0.6			

Analysed by: 
Date : 04/11/2020

Checked by: 
Date : 04/11/2020

Reported by User: RAJARAJESHWARI (RAJI)
Report Method: RSD REPORT SYSTEM SUITABILITY
Report Method ID: 3473
Page: 2 of 2

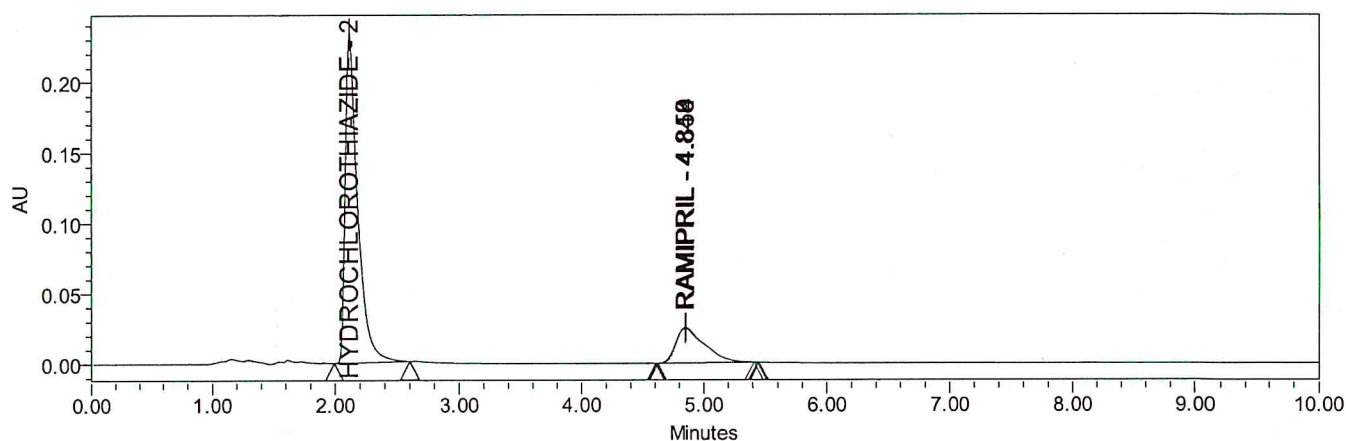
Project Name: 2020\QC_HPL_003\NOV-2020
Printed Date: 04/11/2020
Printed Time: 10:29:04 Asia/Calcutta

SAMPLE INFORMATION

Sample Name: RAMITHIA 5/12.5 GF201004 CU_9, RAMITHIA 5/12.5 Acquired By: RAJI
 Sample Type: Unknown Sample Set Name: 03112020_RAMITHIA_AS_CU_FP_SS
 Vial: 109, 108, 110, 112, 111 Acq. Method Set: RAMITHIAZIDE_ASSAY_DISSO_FP_IM
 Injection #: 1 Processing Method: RAMITHIAZIDE_ASSAY_PM
 Injection Volume: 10.00 ul Channel Name: W2489 ChA
 Run Time: 10.0 Minutes Proc. Chnl. Descr.: W2489 ChA 210nm

Date Acquired: 03/11/2020 16:17:38 IST, 03/11/2020 16:28:36 IST, 03/11/2020 16:40:06 IST, 03/11/2020 16:51:34 IST, 03/11/2020 17:03:00 IST
 Date Processed: 04/11/2020 09:04:28 IST, 04/11/2020 09:04:44 IST, 04/11/2020 09:05:35 IST, 04/11/2020

Auto-Scaled Chromatogram



Peak Name: HYDROCHLOROTHIAZIDE

	Peak Name	Injection	RT	Area
1	HYDROCHLOROTHIAZIDE	1	2.113	1630004
2	HYDROCHLOROTHIAZIDE	1	2.114	1620469
3	HYDROCHLOROTHIAZIDE	1	2.113	1619704
4	HYDROCHLOROTHIAZIDE	1	2.113	1630526
5	HYDROCHLOROTHIAZIDE	1	2.114	1625981
Mean			2.113	1625337
Std. Dev.			0.001	5112.771
% RSD			0.0	0.3

Analysed by: D. Raj
 Date: 02/11/2020

Checked by: J. Raj
 Date: 02/11/2020

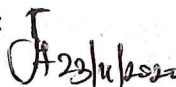
Reported by User: RAJARAJESHWARI (RAJI)
 Report Method: RSD REPORT
 Report Method ID: 3838
 Page: 1 of 2

Project Name: 2020\QC_HPL_003\NOV-2020
 Printed Date: 04/11/2020
 Printed Time: 10:32:03 Asia/Calcutta

Peak Name: RAMIPRIL

	Peak Name	Injection	RT	Area
1	RAMIPRIL	1	4.849	422540
2	RAMIPRIL	1	4.849	408210
3	RAMIPRIL	1	4.848	422160
4	RAMIPRIL	1	4.854	420749
5	RAMIPRIL	1	4.850	406902
Mean			4.850	416112
Std. Dev.			0.002	7852.786
% RSD			0.1	0.3

Analysed by: 
Date : 04/11/2020

Checked by: 
Date : 23/11/2020

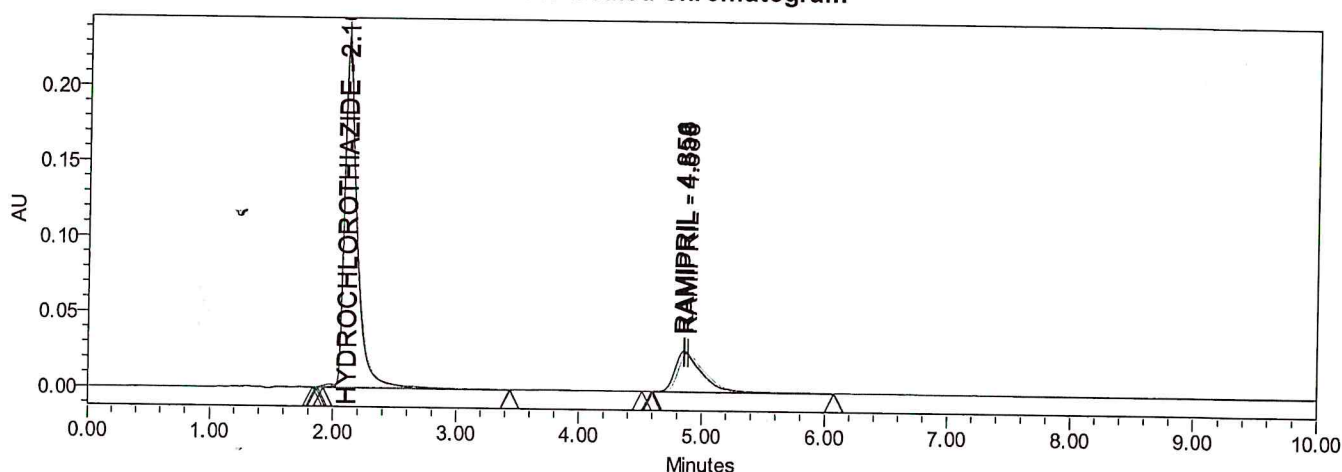
Reported by User: RAJARAJESHWARI (RAJI)
Report Method: RSD REPORT
Report Method ID: 3838
Page: 2 of 2

Project Name: 2020\QC_HPL_003\NOV-2020
Printed Date: 04/11/2020
Printed Time: 10:32:03 Asia/Calcutta

SAMPLE INFORMATION

Sample Name: STD SOLUTION, STD SOLUTION (B) Acquired By: RAJI
Sample Type: Standard Sample Set Name: 03112020_RAMITHIA_AS_CU_FP_SS
Vial: 98 Acq. Method Set: RAMITHIAZIDE_ASSAY_DISSO_FP_IM
Injection #: 1, 2, 4, 5, 3 Processing Method: RAMITHIAZIDE_ASSAY_PM
Injection Volume: 10.00 ul Channel Name: W2489 ChA
Run Time: 10.0 Minutes Proc. Chnl. Descr.: W2489 ChA 210nm
Date Acquired: 03/11/2020 12:51:18 IST, 03/11/2020 13:02:45 IST, 03/11/2020 13:13:58 IST, 03/11/2020 13:24:48 IST, 03/11/2020 13:36:03 IST, 03/11/2020 17:14:16 IST
Date Processed: 04/11/2020 08:59:44 IST

Auto-Scaled Chromatogram



Peak Name: HYDROCHLOROTHIAZIDE

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count
1	HYDROCHLOROTHIAZIDE	1	2.108	1639190	1.4	2271
2	HYDROCHLOROTHIAZIDE	1	2.114	1630614	1.5	2230
3	HYDROCHLOROTHIAZIDE	2	2.110	1620577	1.4	2236
4	HYDROCHLOROTHIAZIDE	3	2.109	1610230	1.4	2281
5	HYDROCHLOROTHIAZIDE	4	2.109	1622507	1.5	2318
6	HYDROCHLOROTHIAZIDE	5	2.108	1627135	1.5	2200
Mean			2.110	1625042	1.5	2256
Std. Dev.			0.002	9811.636		
% RSD			0.1	0.6		

Analysed by: D. D. D.
Date: 04/11/2020

Checked by: J. J. J.
Date: 23/11/2020

Reported by User: RAJARAJESHWARI (RAJI)
Report Method: RSD REPORT SYSTEM SUITABILITY
Report Method ID: 3473
Page: 1 of 2

Project Name: 2020\QC_HPL_003\NOV-2020
Printed Date: 04/11/2020
Printed Time: 10:29:39 Asia/Calcutta

Peak Name: RAMIPRIL

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count	USP Resolution
1	RAMIPRIL	1	4.886	404913	1.3	2222	8.8
2	RAMIPRIL	1	4.856	408270	1.4	2276	9.1
3	RAMIPRIL	2	4.859	402821	1.3	2254	9.1
4	RAMIPRIL	3	4.859	401938	1.4	2293	9.1
5	RAMIPRIL	4	4.859	402785	1.4	2281	9.1
6	RAMIPRIL	5	4.854	404232	1.3	2203	9.0
Mean			4.862	404160	1.4	2255	9.0
Std. Dev.			0.012	2283.942			
% RSD			0.2	0.6			

Analysed by: *P. D. D. 4*
Date : 04/11/2020

Checked by: *J. A. 23/11/2020*
Date : 23/11/2020

Reported by User: RAJARAJESHWARI (RAJI)
Report Method: RSD REPORT SYSTEM SUITABILITY
Report Method ID: 3473
Page: 2 of 2

Project Name: 2020\QC_HPL_003\NOV-2020
Printed Date: 04/11/2020
Printed Time: 10:29:39 Asia/Calcutta

Processing Method: RAMITHIAZIDE_ASSAY_PM

Type: LC

Stored: 01/11/2020 13:45:10 IST

Method Information

Method Comments
Method Modified User
Method Locked
Method Id
Old Id
Method Version
Method Edit User
Source S/W Info

PROCESSING METHOD

RAJI

No

1873

1209

2

Empower 3 Software Build 3471
SPs Installed: Service Release 3
DB ID: 2530846615

Traditional

10.0

No

3

(m/z)

(m/z)

Pure

No

SET1

50.000(%)

(min)

1.0000(Da)

1.000

5

0.000(%)

Average

1.00(Da)

None

No

100.00(Da)

80.0(%)

Centroid Top(%)

80.00

Heights

0.500(Da)

None

None

5.00

Never

Integration Algorithm
MS Ret Time Window
MS Ret Time Presearch
MS Search Depth
Start Mass Limit
End Mass Limit
PBM Search Mode
Duplicate Spectra
PBM Reference Sets
Search Threshold
Noise Baseline
Peak Separation
Baseline Multiplier
Spectra To Average
Noise Threshold
Combine Type
Expected Mass Peak Separation
Expected Mass Calculation Type
Include the uncorrected Target or Base Mass in the list of expected masses
Expected Mass Base Value
Expected Mass Base Intensity
Centroid Center Type
Centroid Top (%)
Centroid Intensity
Min. Peak Width at Half-Height
Smoothing Type
Average By
RT Window %
Update RT

Analysed by: D. Jay
Date: 04/11/2020

Checked by: J
Date: 04/23/11/2020

Reported by User: RAJARAJESHWARI (RAJI)
Report Method: PROCESSING METHOD
Report Method ID: 1381
Page: 1 of 5

Project Name: 2020\QC_HPL_003\NOV-2020
Printed Date: 04/11/2020
Printed Time: 10:30:57 Asia/Calcutta

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	0.010(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)
Calculate Peak Statistical Moments	No

Integration Parameters

Minimum Area	50000($\mu V \cdot sec$)
Minimum Height	0(μV)
Threshold	5.000($\mu V/sec$)
Peak Width	50.00(sec)

Integration Events

	Time (min)	Type	Value	Stop (min)
1	0.000	Valley to Valley		
2	0.000	Inhibit Integration		1.889
3	3.446	Inhibit Integration		4.600
4	6.081	Inhibit Integration		

Component Table

	Name	Component Type	Peak Label	Retention Time (min)	RT Window (min)	Peak Match	Calculate Suit Results
1	HYDROCHLOROTHIAZIDE			2.127	1.000	Closest	Yes
2	RAMIPRIL			4.965	1.000	Closest	Yes

Analysed by: *D. Singh*
Date: 04/11/2020

Checked by: *J. Rajarajeshwari*
Date: 04/11/2020

Reported by User: RAJARAJESHWARI (RAJI)
Report Method: PROCESSING METHOD
Report Method ID: 1381
Page: 2 of 5

Project Name: 2020\QC_HPL_003\NOV-2020
Printed Date: 04/11/2020
Printed Time: 10:30:57 Asia/Calcutta

35

Component Table

	Flag Outside Limits	3D Channel Name (Description)	Channel	Y Value	X Value	Fit	Weighting	Internal Std	RT Reference
1	Yes		W2489 ChA	Area	Amount	Linear	None		
2	Yes		W2489 ChA	Area	Amount	Linear	None		

Component Table

	Rel RT Reference	RRT	Rel Resol Reference	Curve Reference	Relative Response	Impurity RRF	Must	Default Pk	Default Pk Start (min)	Default Pk End (min)	Default Units	Type
1					1.000000	1.0000	No	No				Single
2					1.000000	1.0000	No	No				Single

Component Table

	Impurity Type	CCompRef1	CCompRef2	CCompRef3	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-'HYDROCHLOROTHIAZIDE" table contains no data.

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

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

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

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

Processing Method Group 'Def Amts-'RAMIPRIL" 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

Impurity Parameters

Calculate Total Impurities No
 Impurity Response
 w Value
 Main Component

Analysed by: D. Dey
 Date : 04/11/2020

Checked by: J
 Date : 04/23/11/2020

Reported by User: RAJARAJESHWARI (RAJI)
 Report Method: PROCESSING METHOD
 Report Method ID: 1381
 Page: 3 of 5

Project Name: 2020\QC_HPL_003\NOV-2020
 Printed Date: 04/11/2020
 Printed Time: 10:30:57 Asia/Calcutta

Reporting Threshold 0.05
Identification Threshold

Qualification Threshold
Total Impurities Threshold
Maximum Impurity Threshold

Excluded Component Types
Internal Standard Peaks

Revision History

Version 2 01/11/2020 13:45:10 IST User RAJI PEAK WIDTH CHANGE
Version 1 31/10/2020 19:24:03 IST User Vallarasan Method (Hplc\2020\QC_HPL_003\OCT-2020 : 5409)
copied into project. (from Full Audit Trail project)
Version 1 28/10/2020 07:37:13 IST User RAJI Created method 'RAMITHIAZIDE_ASSAY_PM'. PROCESSING
METHOD

Method Version Summaries

	Method Name	Method Type	Method Comments	Method Date	Method Modified User
1	RAMITHIAZIDE_ASSAY_PM	Processing	PROCESSING METHOD	05/11/2020 09:32:21 IST	RAJI
2	RAMITHIAZIDE_ASSAY_PM	Processing	PROCESSING METHOD	05/11/2020 09:25:26 IST	RAJI
3	RAMITHIAZIDE_ASSAY_PM	Processing	PROCESSING METHOD	04/11/2020 16:46:21 IST	RAJI
4	RAMITHIAZIDE_ASSAY_PM	Processing	PROCESSING METHOD	04/11/2020 16:43:21 IST	RAJI
5	RAMITHIAZIDE_ASSAY_PM	Processing	PROCESSING METHOD	04/11/2020 16:41:17 IST	RAJI
6	RAMITHIAZIDE_ASSAY_PM	Processing	PROCESSING METHOD	04/11/2020 16:27:44 IST	RAJI
7	RAMITHIAZIDE_ASSAY_PM	Processing	PROCESSING METHOD	04/11/2020 16:23:12 IST	RAJI
8	RAMITHIAZIDE_ASSAY_PM	Processing	PROCESSING METHOD	04/11/2020 13:34:57 IST	RAJI
9	RAMITHIAZIDE_ASSAY_PM	Processing	PROCESSING METHOD	04/11/2020 09:07:04 IST	RAJI
10	RAMITHIAZIDE_ASSAY_PM	Processing	PROCESSING METHOD	01/11/2020 13:45:10 IST	RAJI
11	RAMITHIAZIDE_ASSAY_PM	Processing	PROCESSING METHOD	31/10/2020 19:24:03 IST	RAJI

Method Version Summaries

	Method Locked	Method Id	Old Id	Method Version
1	No	3778	3744	11
2	No	3744	3449	10
3	No	3449	3439	9
4	No	3439	3419	8
5	No	3419	3375	7
6	No	3375	3362	6
7	No	3362	3260	5
8	No	3260	3139	4
9	No	3139	1873	3
10	No	1873	1209	2
11	No	1209		1

Method Version Summaries

	Source S/W Info
1	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615

Analysed by: D. Dey
Date : 02/11/2020

Checked by: J. J. J.
Date : 02/11/2020

Reported by User: RAJARAJESHWARI (RAJI)
Report Method: PROCESSING METHOD
Report Method ID: 1381
Page: 4 of 5

Project Name: 2020\QC_HPL_003\NOV-2020
Printed Date: 04/11/2020
Printed Time: 10:30:57 Asia/Calcutta

Method Version Summaries

Source S/W Info	
2	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615
3	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615
4	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615
5	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615
6	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615
7	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615
8	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615
9	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615
10	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615
11	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615

Analysed by: *D. Raj*
 Date : 04/11/2020

Checked by: *J. 22/11/2020*
 Date : 04/22/11/2020

Reported by User: RAJARAJESHWARI (RAJI)
 Report Method: PROCESSING METHOD
 Report Method ID: 1381
 Page: 5 of 5

Project Name: 2020\QC_HPL_003\NOV-2020
 Printed Date: 04/11/2020
 Printed Time: 10:30:57 Asia/Calcutta

		EXCEL SHEET FOR DISSOLUTION CALCULATION																																																																									
Name of Product		RAMITHIAZIDE 5mg-12.5mg TABLETS(RAMPRIIL)																																																																									
Date of Analysis	02.11.2020	Batch No.	GF201004																																																																								
Mfg. Date	OCT-2020	Exp. Date	SEP-2023																																																																								
WS No.	NA	% Purity	99.3																																																																								
WS Weight (WS)	15.35	WS Validity	NA																																																																								
Sample Weight (SW)	1	Label Claim (LC)	5																																																																								
<table border="1"> <tr> <td rowspan="2">Std. Dilution</td> <td>15.35</td> <td>5</td> <td>1</td> <td>1</td> <td>1</td> <td>1</td> <td>CF1</td> <td>1</td> </tr> <tr> <td>250</td> <td>50</td> <td>1</td> <td>1</td> <td>1</td> <td>1</td> <td>CF2</td> <td>1</td> </tr> <tr> <td rowspan="2">Sample Dilution</td> <td>1</td> <td>1</td> <td>1</td> <td>1</td> <td>1</td> <td>1</td> <td>CF3</td> <td>1</td> </tr> <tr> <td>750</td> <td>1</td> <td>1</td> <td>1</td> <td>1</td> <td>1</td> <td>CF4</td> <td>1</td> </tr> </table>						Std. Dilution	15.35	5	1	1	1	1	CF1	1	250	50	1	1	1	1	CF2	1	Sample Dilution	1	1	1	1	1	1	CF3	1	750	1	1	1	1	1	CF4	1																																				
Std. Dilution	15.35	5	1	1	1		1	CF1	1																																																																		
	250	50	1	1	1	1	CF2	1																																																																			
Sample Dilution	1	1	1	1	1	1	CF3	1																																																																			
	750	1	1	1	1	1	CF4	1																																																																			
<table border="1"> <tr> <td rowspan="2">Calculation Formula</td> <td>Smp. Area/Abs</td> <td>Std Dilution</td> <td>99.3</td> <td>100</td> <td>CF1</td> <td>CF3</td> </tr> <tr> <td>Std. Area/Abs</td> <td>Sample Dilution</td> <td>100</td> <td>5</td> <td>CF2</td> <td>CF4</td> </tr> </table>						Calculation Formula	Smp. Area/Abs	Std Dilution	99.3	100	CF1	CF3	Std. Area/Abs	Sample Dilution	100	5	CF2	CF4																																																									
Calculation Formula	Smp. Area/Abs	Std Dilution	99.3	100	CF1		CF3																																																																				
	Std. Area/Abs	Sample Dilution	100	5	CF2	CF4																																																																					
<table border="1"> <tr> <th>Sr. No.</th> <th>Standard Area/Abs</th> <th>Standard RT</th> <th>Tablet</th> <th>Area/Abs.</th> <th>Result %</th> <th>Result mg</th> </tr> <tr> <td>1</td> <td>130112</td> <td>4.914</td> <td>Tab1</td> <td>138864</td> <td>97.73</td> <td>4.89</td> </tr> <tr> <td>2</td> <td>130116</td> <td>4.915</td> <td>Tab2</td> <td>141543</td> <td>99.62</td> <td>4.98</td> </tr> <tr> <td>3</td> <td>130128</td> <td>4.914</td> <td>Tab3</td> <td>147429</td> <td>103.76</td> <td>5.19</td> </tr> <tr> <td>4</td> <td>129894</td> <td>4.914</td> <td>Tab4</td> <td>143645</td> <td>101.10</td> <td>5.06</td> </tr> <tr> <td>5</td> <td>129470</td> <td>4.913</td> <td>Tab5</td> <td>140612</td> <td>98.96</td> <td>4.95</td> </tr> <tr> <td>6</td> <td></td> <td></td> <td>Tab6</td> <td>144174</td> <td>101.47</td> <td>5.07</td> </tr> <tr> <td>Average</td> <td>129944</td> <td>4.914</td> <td>Average</td> <td></td> <td>100.44</td> <td>5.02</td> </tr> <tr> <td>SD</td> <td>282.3295946</td> <td>0.000707107</td> <td>Minimum</td> <td></td> <td>97.73</td> <td>4.89</td> </tr> <tr> <td>%RSD</td> <td>0.2</td> <td>0.0</td> <td>Maximum</td> <td></td> <td>103.76</td> <td>5.19</td> </tr> </table>						Sr. No.	Standard Area/Abs	Standard RT	Tablet	Area/Abs.	Result %	Result mg	1	130112	4.914	Tab1	138864	97.73	4.89	2	130116	4.915	Tab2	141543	99.62	4.98	3	130128	4.914	Tab3	147429	103.76	5.19	4	129894	4.914	Tab4	143645	101.10	5.06	5	129470	4.913	Tab5	140612	98.96	4.95	6			Tab6	144174	101.47	5.07	Average	129944	4.914	Average		100.44	5.02	SD	282.3295946	0.000707107	Minimum		97.73	4.89	%RSD	0.2	0.0	Maximum		103.76	5.19
Sr. No.	Standard Area/Abs	Standard RT	Tablet	Area/Abs.	Result %	Result mg																																																																					
1	130112	4.914	Tab1	138864	97.73	4.89																																																																					
2	130116	4.915	Tab2	141543	99.62	4.98																																																																					
3	130128	4.914	Tab3	147429	103.76	5.19																																																																					
4	129894	4.914	Tab4	143645	101.10	5.06																																																																					
5	129470	4.913	Tab5	140612	98.96	4.95																																																																					
6			Tab6	144174	101.47	5.07																																																																					
Average	129944	4.914	Average		100.44	5.02																																																																					
SD	282.3295946	0.000707107	Minimum		97.73	4.89																																																																					
%RSD	0.2	0.0	Maximum		103.76	5.19																																																																					
Analysed By 		Checked By 																																																																									
Date 03/11/2020		Date 23/11/2020																																																																									



EXCEL SHEET FOR DISSOLUTION CALCULATION

Name of Product	RAMITHIAZIDE 5mg-12.5mg TABLETS(HYDROCHLOROTHIAZIDE)			
Date of Analysis	02.11.2020	Batch No.	GF201004	
Mfg. Date	OCT-2020	Exp. Date	SEP-2023	
WS No.	NA	% Purity	100.1	
WS Weight (WS)	40.59	WS Validity	NA	
Sample Weight (SW)	1	Label Claim (LC)	12.5	

Std. Dilution	40.59	5	1	1	1	1	CF1	1
	250	50	1	1	1	1	CF2	1
Sample Dilution	1	1	1	1	1	1	CF3	1
	750	1	1	1	1	1	CF4	1

Calculation Formula	Smp. Area/Abs	Std Dilution	100.1	100	CF1	CF3
	Std. Area/Abs	Sample Dilution	100	12.5	CF2	CF4

Sr. No.	Standard Area/Abs	Standard RT
1	526427	2.115
2	525729	2.116
3	526293	2.115
4	525944	2.115
5	524099	2.115
6		
Average	525698	2.115
SD	935.9144192	0.000447214
%RSD	0.2	0.0

Tablet	Area/Abs.
Tab1	542703
Tab2	549943
Tab3	538541
Tab4	505267
Tab5	542219
Tab6	542583
Average	
Minimum	
Maximum	

Result %	Result mg
100.67	12.58
102.01	12.75
99.90	12.49
93.72	11.72
100.58	12.57
100.65	12.58
99.59	12.45
93.72	11.72
102.01	12.75

Analysed By 
Date 03/11/2020

Checked By 
Date 23/11/2020

	Vial	Inj Vol (uL)	# of Injs	SampleName	Function	Method Set / Report or Export Method	Run Time (Minutes)
1	27	10.0	1	DISSO_BLANK	Inject Samples	RAMITHIAZIDE_ASSAY_DISSO_FP_IM	10.00
2	28	10.0	5	DISSO_STANDARD_5mg/12.5mg	Inject Samples	RAMITHIAZIDE_ASSAY_DISSO_FP_IM	10.00
3	27	10.0	1	DISSO_BLANK	Inject Samples	RAMITHIAZIDE_ASSAY_DISSO_FP_IM	10.00
4	29	10.0	1	GF201004_5mg/12.5mg_JAR_01	Inject Samples	RAMITHIAZIDE_ASSAY_DISSO_FP_IM	10.00
5	30	10.0	1	GF201004_5mg/12.5mg_JAR_02	Inject Samples	RAMITHIAZIDE_ASSAY_DISSO_FP_IM	10.00
6	31	10.0	1	GF201004_5mg/12.5mg_JAR_03	Inject Samples	RAMITHIAZIDE_ASSAY_DISSO_FP_IM	10.00
7	32	10.0	1	GF201004_5mg/12.5mg_JAR_04	Inject Samples	RAMITHIAZIDE_ASSAY_DISSO_FP_IM	10.00
8	33	10.0	1	GF201004_5mg/12.5mg_JAR_05	Inject Samples	RAMITHIAZIDE_ASSAY_DISSO_FP_IM	10.00
9	34	10.0	1	GF201004_5mg/12.5mg_JAR_06	Inject Samples	RAMITHIAZIDE_ASSAY_DISSO_FP_IM	10.00
0	28	10.0	1	DISSO_5mg/12.5mg_BKT_STD	Inject Samples	RAMITHIAZIDE_ASSAY_DISSO_FP_IM	10.00
1	27	10.0	1	DISSO_BLANK	Inject Samples	RAMITHIAZIDE_ASSAY_DISSO_FP_IM	10.00
2	35	10.0	5	DISSO_STANDARD_10mg/25mg	Inject Samples	RAMITHIAZIDE_ASSAY_DISSO_FP_IM	10.00
3	27	10.0	1	DISSO_BLANK	Inject Samples	RAMITHIAZIDE_ASSAY_DISSO_FP_IM	10.00
4	36	10.0	1	GF201009_10mg/25mg_JAR_01	Inject Samples	RAMITHIAZIDE_ASSAY_DISSO_FP_IM	10.00
5	37	10.0	1	GF201009_10mg/25mg_JAR_02	Inject Samples	RAMITHIAZIDE_ASSAY_DISSO_FP_IM	10.00
6	38	10.0	1	GF201009_10mg/25mg_JAR_03	Inject Samples	RAMITHIAZIDE_ASSAY_DISSO_FP_IM	10.00
7	39	10.0	1	GF201009_10mg/25mg_JAR_04	Inject Samples	RAMITHIAZIDE_ASSAY_DISSO_FP_IM	10.00
8	40	10.0	1	GF201009_10mg/25mg_JAR_05	Inject Samples	RAMITHIAZIDE_ASSAY_DISSO_FP_IM	10.00
9	41	10.0	1	GF201009_10mg/25mg_JAR_06	Inject Samples	RAMITHIAZIDE_ASSAY_DISSO_FP_IM	10.00
0	35	10.0	1	DISSO_10mg/25mg_BKT_STD	Inject Samples	RAMITHIAZIDE_ASSAY_DISSO_FP_IM	10.00
1					Equilibrate	WASHING SOLUTION_B_MSET	60.00
2					Equilibrate	WASHING SOLUTION_C_MSET	120.00
3					Equilibrate	SHUTDOWN_MSET	0.01

MP
02/11/2020

02/11/2020

Instrument Method: RAMITHIAZIDE_ASSAY_DISO_FP_IM

Stored: 31/10/2020 19:24:01 IST

Method Information

Method Comments IM
 Method Modified User SRIRAM
 Method Locked No
 Method Id 1004
 Old Id
 Method Version 3
 Method Edit User
 Source SW Info Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615

W2489 Instrument Setup

Wavelength Mode Single Wavelength
 Lamp On On

Channel A

Comment
 Wavelength 210(nm)
 Sampling Rate 10(points/sec)
 Data Mode Absorbance
 Time Constant 0.1(sec)
 Autozero On Wavelength Change Maintain Baseline
 Autozero On Inject Start Yes

Analog 1

Sensitivity 2.0000(AUFS)
 Chart Polarity Positive (+)
 Voltage Offset 0(mV)
 Enable Chart Mark Yes

Run Events Yes

Pulse Width 1.0(sec)
 Rect Wave Period 0.2(sec)

W2690/5 Instrument Setup

Type W2690/5
 Instrument Status On
 Channel Name 2690/5
 Description PRESSURE ENABLE
 Use Channel Monitor On
 Monitor Parameter System Pressure

Analysed by : 
 Date : 02/11/2020

Checked by : 
 Date : 02/11/2020

Reported by User: RAJARAJESHWARI (RAJI)
 Report Method: INSTRUMENT METHOD
 Report Method ID: 1380
 Page: 1 of 3

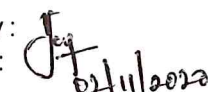
Project Name: 2020\QC_HPL_003\NOV-2020
 Printed Date: 02/11/2020
 Printed Time: 23:07:49 Asia/Calcutta

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 1.000
%A 100.0
%B 0.0
%C 0.0
%D 0.0
High Limit 5000.0
Low Limit 0.0
Enable Sample Temp True
Enable Column Temp True
Bubble Detect True
Pre Column Volume 0.0
Sample Temp Target 25.0
Sample Temp Range 5.0
Spurge A 0.0
Spurge B 0.0
Spurge C 0.0
Spurge D 0.0
Column Temp Target 25.0
Column Temp Range 5.0
Flow Ramp 2.00
Column choice No Change
Column Equil Minutes 0.00
Needle Wash Extended
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 3 31/10/2020 19:24:01 IST User Vallarasan Method (\\Hplc\\2020\\QC_HPL_003\\OCT-2020 : 6044)
copied into project. (from Full Audit Trail project)
Version 3 29/10/2020 07:42:53 IST User SRIRAM PUPM CHANGED
Version 2 27/10/2020 20:55:48 IST User RAJI SAVE
Version 1 27/10/2020 08:56:15 IST User SRIRAM Created method 'RAMITHIAZIDE_ASSAY_DISO_FP_IM'. IM

Analysed by: 
Date : 02/11/2020

Checked by: 
Date : 02/11/2020

Reported by User: RAJARAJESHWARI (RAJI)
Report Method: INSTRUMENT METHOD
Report Method ID: 1380
Page: 2 of 3

Project Name: 2020\\QC_HPL_003\\NOV-2020
Printed Date: 02/11/2020
Printed Time: 23:07:49 Asia/Calcutta

Method Version Summaries

	Method Name	Method Type	Method Comments	Method Date	Method Modified User
1	RAMITHIAZIDE_ASSAY_DISO_FP_IM	Instrument	IM	31/10/2020 19:24:01 IST	SRIRAM
2	RAMITHIAZIDE_ASSAY_DISO_FP_IM	Instrument	IM	31/10/2020 19:24:01 IST	RAJI
3	RAMITHIAZIDE_ASSAY_DISO_FP_IM	Instrument	IM	31/10/2020 19:24:01 IST	SRIRAM

Method Version Summaries

	Method Locked	Method Id	Old Id	Method Version	Source S/W Info
1	No	1004		3	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615
2	No	1003		2	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615
3	No	1002		1	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615

Analysed by: 
Date: 02/11/2020

Checked by: 
Date: 02/11/2020

Reported by User: RAJARAJESHWARI (RAJI)
Report Method: INSTRUMENT METHOD
Report Method ID: 1380
Page: 3 of 3

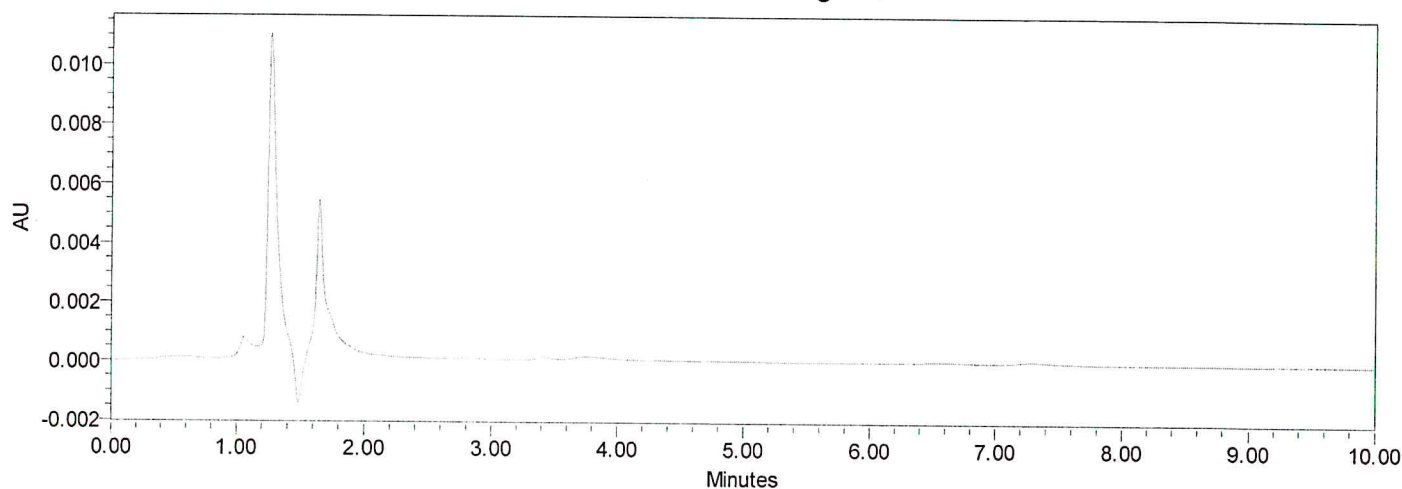
Project Name: 2020\QC_HPL_003\NOV-2020
Printed Date: 02/11/2020
Printed Time: 23:07:49 Asia/Calcutta

SAMPLE INFORMATION

Sample Name: DISSO_BLANK
Sample Type: Unknown
Vial: 27
Injection #: 1
Injection Volume: 10.00 ul
Run Time: 10.0 Minutes
Date Acquired: 03/11/2020 05:55:20 IST
Date Processed: 03/11/2020 13:03:26 IST

Acquired By: SRIRAM
Sample Set Name: 02112020_RAMITHIAZIDE_ASSAY_UC
Acq. Method Set: RAMITHIAZIDE_ASSAY_DISSO_FP_IM
Processing Method: RAMITHIAZIDE_ASSAY_STD_PM
Channel Name: W2489 ChA
Proc. Chnl. Descr.: W2489 ChA 210nm

Auto-Scaled Chromatogram



Peak Results

	Name	Injection	RT	Area
1	HCT	1	2.070	
2	RAMIPRIL	1	4.586	

Analysed by: *[Signature]*
Date: 03/11/2020

Checked by: *[Signature]*
Date: 03/11/2020

Reported by User: RAJARAJESHWARI (RAJI)
Report Method: CHROMATOGRAPHIC DATA
Report Method ID: 1423
Page: 1 of 1

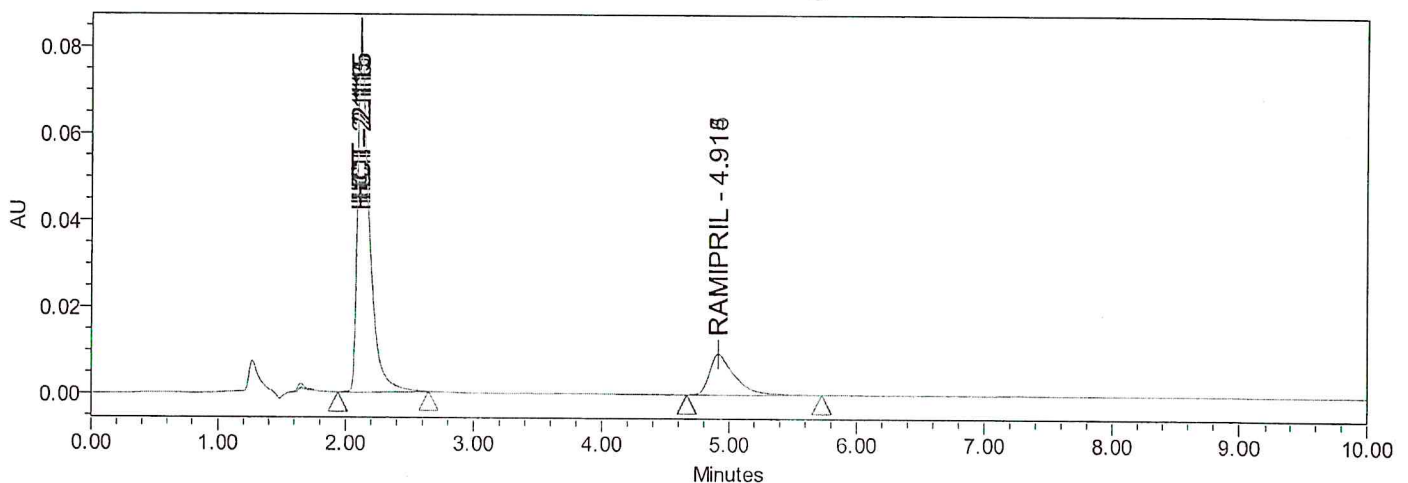
Project Name: 2020\QC_HPL_003\NOV-2020
Printed Date: 03/11/2020
Printed Time: 19:11:15 Asia/Calcutta

SAMPLE INFORMATION

Sample Name: DISSO_STANDARD_5mg/12.5mg Acquired By: SRIRAM
Sample Type: Unknown Sample Set Name: 02112020_RAMITHIAZIDE_ASSAY_UC
Vial: 28 Acq. Method Set: RAMITHIAZIDE_ASSAY DISSO_FP_IM
Injection #: 1, 2, 4, 5, 3 Processing Method: RAMITHIAZIDE_ASSAY_STD_PM
Injection Volume: 10.00 ul Channel Name: W2489 ChA
Run Time: 10.0 Minutes Proc. Chnl. Descr.: W2489 ChA 210nm

Date Acquired: 03/11/2020 06:06:33 IST, 03/11/2020 06:17:48 IST, 03/11/2020 06:29:03 IST, 03/11/2020 06:40:17 IST, 03/11/2020 06:51:28 IST
Date Processed: 03/11/2020 13:03:26 IST

Auto-Scaled Chromatogram



Peak Name: HCT

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count
1	HCT	1	2.115	526427	1.2	2595
2	HCT	2	2.116	525729	1.2	2341
3	HCT	3	2.115	526293	1.0	2551
4	HCT	4	2.115	525944	1.2	2556
5	HCT	5	2.115	524099	1.1	2545
Mean			2.115	525698	1.1	2518
Std. Dev.			0.000	936.035		
% RSD			0.0	0.2		

Analysed by: *[Signature]*
Date: 03/11/2020

Checked by: *[Signature]*
Date: 23/11/2020

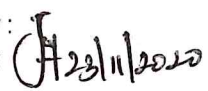
Reported by User: SRIRAM (SRIRAM)
Report Method: RSD REPORT SYSTEM SUITABILITY
Report Method ID: 3473
Page: 1 of 2

Project Name: 2020\QC_HPL_003\NOV-2020
Printed Date: 03/11/2020
Printed Time: 19:11:37 Asia/Calcutta

Peak Name: RAMIPRIL

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count	USP Resolution
1	RAMIPRIL	1	4.914	130112	1.4	2806	9.9
2	RAMIPRIL	2	4.915	130116	1.2	2721	9.7
3	RAMIPRIL	3	4.914	130128	1.3	2816	9.8
4	RAMIPRIL	4	4.914	129894	1.2	2816	9.8
5	RAMIPRIL	5	4.913	129470	1.3	2810	9.8
Mean			4.914	129944	1.3	2794	9.8
Std. Dev.			0.001	282.430			
% RSD			0.0	0.2			

Analysed by: 
Date: 03/11/2020

Checked by: 
Date: 03/11/2020

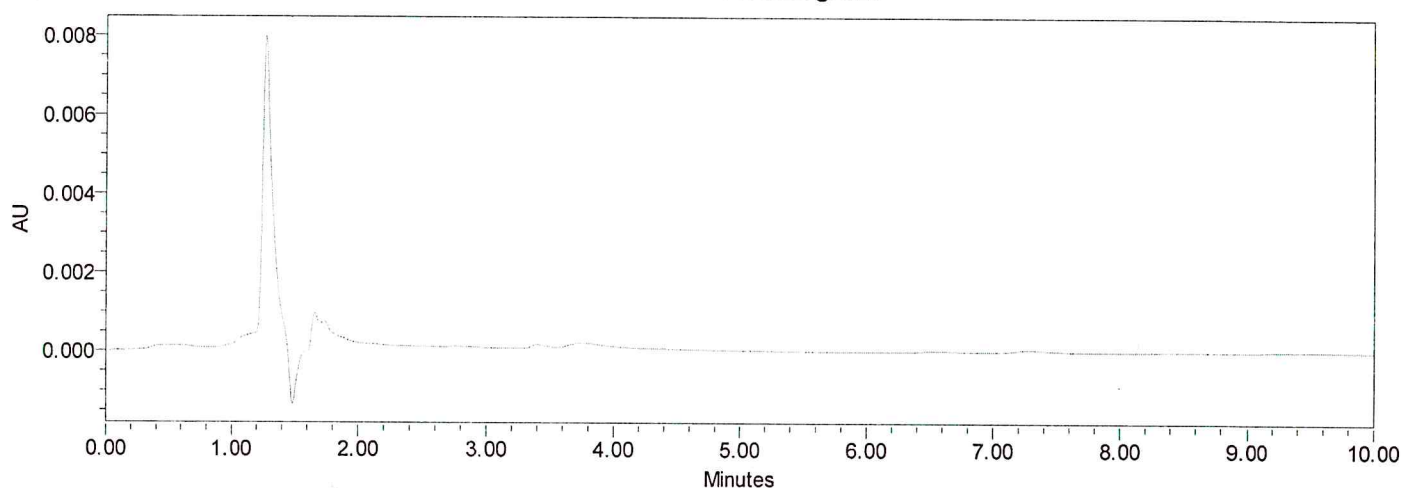
Reported by User: SRIRAM (SRIRAM)
Report Method: RSD REPORT SYSTEM SUITABILITY
Report Method ID: 3473
Page: 2 of 2

Project Name: 2020\QC_HPL_003\NOV-2020
Printed Date: 03/11/2020
Printed Time: 19:11:37 Asia/Calcutta

SAMPLE INFORMATION

Sample Name:	DISSO_BLANK	Acquired By:	SRIRAM
Sample Type:	Unknown	Sample Set Name:	02112020_RAMITHIAZIDE_ASSAY_UC
Vial:	27	Acq. Method Set:	RAMITHIAZIDE_ASSAY_DISSO_FP_IM
Injection #:	1	Processing Method:	RAMITHIAZIDE_ASSAY_STD_PM
Injection Volume:	10.00 ul	Channel Name:	W2489 ChA
Run Time:	10.0 Minutes	Proc. Chnl. Descr.:	W2489 ChA 210nm
Date Acquired: 03/11/2020 07:02:45 IST			
Date Processed: 03/11/2020 13:03:26 IST			

Auto-Scaled Chromatogram



Peak Results

	Name	Injection	RT	Area
1	HCT	1	2.070	
2	RAMIPRIL	1	4.586	

Analysed by: *[Signature]*
Date: 03/11/2020

Checked by: *[Signature]*
Date: 03/11/2020

Reported by User: RAJARAJESHWARI (RAJI)
Report Method: CHROMATOGRAPHIC DATA
Report Method ID: 1423
Page: 1 of 1

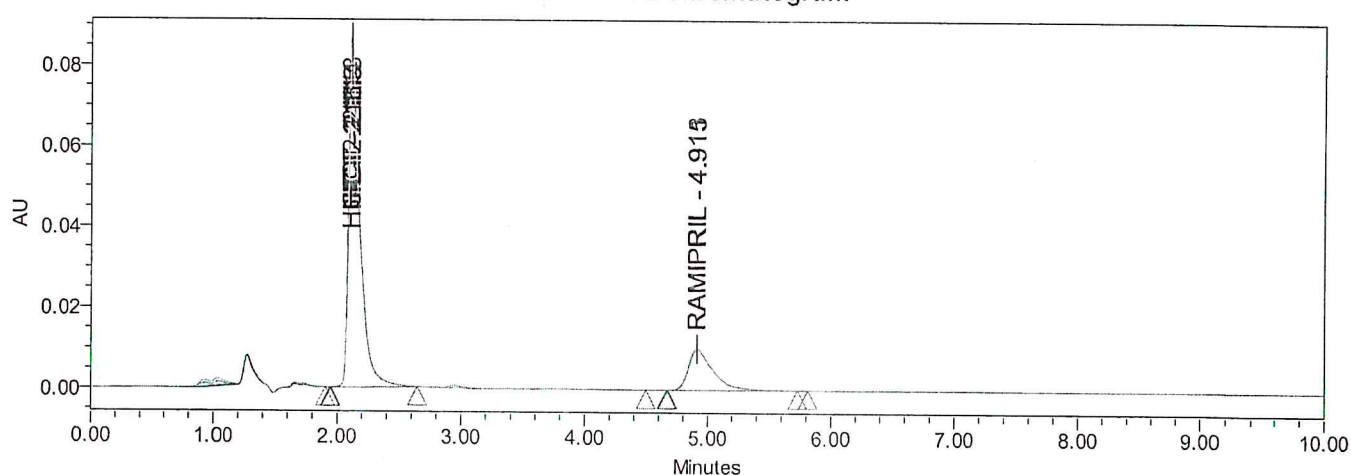
Project Name: 2020\QC_HPL_003\NOV-2020
Printed Date: 03/11/2020
Printed Time: 19:12:09 Asia/Calcutta

SAMPLE INFORMATION

Sample Name: GF201004_5mg/12.5mg_JAR_05, Acquired By: SRIRAM
Sample Type: Unknown Sample Set Name: 02112020_RAMITHIAZIDE_ASSAY_UC
Vial: 29, 31, 33, 32, 30, 34 Acq. Method Set: RAMITHIAZIDE_ASSAY_DISSO_FP_IM
Injection #: 1 Processing Method: RAMITHIAZIDE_ASSAY_STD_PM
Injection Volume: 10.00 ul Channel Name: W2489 ChA
Run Time: 10.0 Minutes Proc. Chnl. Descr.: W2489 ChA 210nm

Date Acquired: 03/11/2020 07:13:59 IST, 03/11/2020 07:25:14 IST, 03/11/2020 07:36:25 IST, 03/11/2020 07:47:39 IST, 03/11/2020 07:58:53 IST, 03/11/2020 08:10:08 IST
Date Processed: 03/11/2020 13:03:27 IST

Auto-Scaled Chromatogram



Peak Name: HCT

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count
1	HCT	1	2.115	542703	1.2	2474
2	HCT	1	2.113	549943	1.2	2544
3	HCT	1	2.116	538541	1.0	2518
4	HCT	1	2.116	505267	1.2	2607
5	HCT	1	2.114	542219	1.0	2568
6	HCT	1	2.114	542583	1.2	2584
Mean			2.115	536876	1.1	2549
Std. Dev.			0.001	15923.040		
% RSD			0.1	3.0		

Analysed by: *[Signature]*
Date: 03/11/2020

Checked by: *[Signature]*
Date: 03/11/2020

Reported by User: SRIRAM (SRIRAM)
Report Method: RSD REPORT SYSTEM SUITABILITY
Report Method ID: 3473
Page: 1 of 2

Project Name: 2020\QC_HPL_003\NOV-2020
Printed Date: 03/11/2020
Printed Time: 19:12:23 Asia/Calcutta

Peak Name: RAMIPRIL

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count	USP Resolution
1	RAMIPRIL	1	4.915	138864	1.4	2829	10.0
2	RAMIPRIL	1	4.911	141543	1.2	2808	9.9
3	RAMIPRIL	1	4.913	147429	1.3	2725	9.8
4	RAMIPRIL	1	4.913	143645	1.2	2814	9.9
5	RAMIPRIL	1	4.915	140612	1.3	2820	9.9
6	RAMIPRIL	1	4.911	144174	1.3	2788	9.8
Mean			4.913	142711	1.3	2797	9.9
Std. Dev.			0.002	3027.980			
% RSD			0.0	2.1			

Analysed by: 
Date: 03/11/2020

Checked by: 
Date: 23/11/2020

Reported by User: SRIRAM (SRIRAM)
Report Method: RSD REPORT SYSTEM SUITABILITY
Report Method ID: 3473
Page: 2 of 2

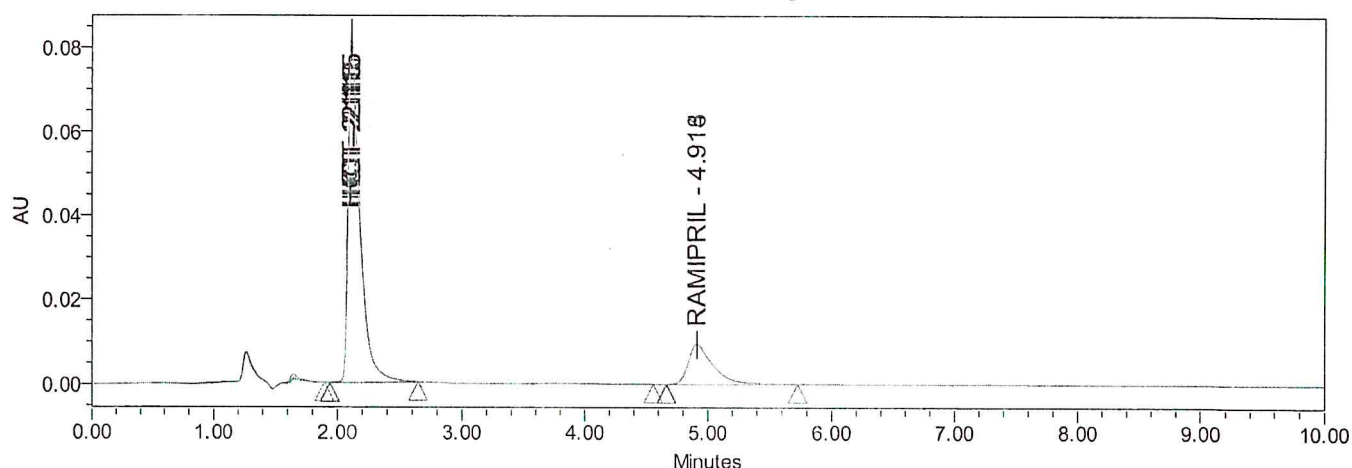
Project Name: 2020\QC_HPL_003\NOV-2020
Printed Date: 03/11/2020
Printed Time: 19:12:23 Asia/Calcutta

SAMPLE INFORMATION

Sample Name: DISSO_STANDARD_5mg/12.5mg, Acquired By: SRIRAM
Sample Type: Unknown Sample Set Name: 02112020_RAMITHIAZIDE_ASSAY_UC
Vial: 28 Acq. Method Set: RAMITHIAZIDE_ASSAY DISSO_FP_IM
Injection #: 1, 2, 4, 5, 3 Processing Method: RAMITHIAZIDE_ASSAY_STD_PM
Injection Volume: 10.00 ul Channel Name: W2489 ChA
Run Time: 10.0 Minutes Proc. Chnl. Descr.: W2489 ChA 210nm

Date Acquired: 03/11/2020 06:06:33 IST, 03/11/2020 06:17:48 IST, 03/11/2020 06:29:03 IST, 03/11/2020 06:40:17 IST, 03/11/2020 06:51:28 IST, 03/11/2020 08:21:25 IST
Date Processed: 03/11/2020 13:03:26 IST, 03/11/2020 13:03:27 IST

Auto-Scaled Chromatogram



Peak Name: HCT

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count
1	HCT	1	2.115	526427	1.2	2595
2	HCT	1	2.115	532766	1.2	2218
3	HCT	2	2.116	525729	1.0	2341
4	HCT	3	2.115	526293	1.2	2551
5	HCT	4	2.115	525944	1.1	2556
6	HCT	5	2.115	524099	1.2	2545
Mean			2.115	526876	1.2	2468
Std. Dev.			0.000	3004.367		
% RSD			0.0	0.6		

Analysed by: *[Signature]*
Date: 03/11/2020

Checked by: *[Signature]*
Date: 03/11/2020

Reported by User: SRIRAM (SRIRAM)
Report Method: RSD REPORT SYSTEM SUTABILITY
Report Method ID: 3473
Page: 1 of 2

Project Name: 2020\QC_HPL_003\NOV-2020
Printed Date: 03/11/2020
Printed Time: 19:12:55 Asia/Calcutta

Peak Name: RAMIPRIL

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count	USP Resolution
1	RAMIPRIL	1	4.913	132800	1.2	2643	9.6
2	RAMIPRIL	1	4.914	130112	1.4	2806	9.9
3	RAMIPRIL	2	4.915	130116	1.2	2721	9.7
4	RAMIPRIL	3	4.914	130128	1.3	2816	9.8
5	RAMIPRIL	4	4.914	129894	1.2	2816	9.8
6	RAMIPRIL	5	4.913	129470	1.3	2810	9.8
Mean			4.914	130420	1.3	2769	9.8
Std. Dev.			0.001	1193.005			
% RSD			0.0	0.9			

Analysed by: 
Date: 03/11/2020

Checked by: 
Date: 03/11/2020

Reported by User: SRIRAM (SRIRAM)
Report Method: RSD REPORT SYSTEM SUITABILITY
Report Method ID: 3473
Page: 2 of 2

Project Name: 2020\QC_HPL_003\NOV-2020
Printed Date: 03/11/2020
Printed Time: 19:12:55 Asia/Calcutta

	Vial	Inj Vol (uL)	# of Injs	SampleName	Function	Method Set / Report Method	Run Time (Minutes)
1	1	30.0	1	RS_BLANK	Inject Samples	RAMITHIAZIDE_RS_FP_MSET	30.00
2	2	30.0	6	STANDARD_RS	Inject Samples	RAMITHIAZIDE_RS_FP_MSET	30.00
3	1	30.0	1	RS_BLANK	Inject Samples	RAMITHIAZIDE_RS_FP_MSET	30.00
4	3	30.0	1	PLACEBO_10mg/12.5mg	Inject Samples	RAMITHIAZIDE_RS_FP_MSET	30.00
5	4	30.0	1	PLACEBO_10mg/25mg	Inject Samples	RAMITHIAZIDE_RS_FP_MSET	30.00
6	5	30.0	1	PLACEBO_5mg/12.5mg	Inject Samples	RAMITHIAZIDE_RS_FP_MSET	30.00
7	1	30.0	1	RS_BLANK	Inject Samples	RAMITHIAZIDE_RS_FP_MSET	30.00
8	6	30.0	1	RAMI_GF201006_10mg/12.5mg	Inject Samples	RAMITHIAZIDE_RS_FP_MSET	30.00
9	7	30.0	1	RAMI_GF201007_10mg/12.5mg	Inject Samples	RAMITHIAZIDE_RS_FP_MSET	30.00
10	8	30.0	1	RAMI_GF201008_10mg/12.5mg	Inject Samples	RAMITHIAZIDE_RS_FP_MSET	30.00
11	9	30.0	1	RAMI_GF201010_10mg/12.5mg	Inject Samples	RAMITHIAZIDE_RS_FP_MSET	30.00
12	10	30.0	1	RAMI_GF201009_10mg/25mg	Inject Samples	RAMITHIAZIDE_RS_FP_MSET	30.00
13	11	30.0	1	RAMI_GF201004_5mg/12.5mg	Inject Samples	RAMITHIAZIDE_RS_FP_MSET	30.00
14	2	30.0	1	RS_BKT_STD	Inject Samples	RAMITHIAZIDE_RS_FP_MSET	30.00
15					Equilibrate	WASHING SOLUTION_C_MSET	120.00
16					Equilibrate	WASHING SOLUTION_B_MSET	30.00
17					Equilibrate	SHUTDOWN_MSET	0.01

[Signature]
05/11/2020

[Signature]
05/11/2020

Instrument Method: RAMITHIAZIDE_RS_FP_IM

Stored: 11/5/2020 5:06:35 PM IST

Method Information

Method Comments	INSTRUMENT METHOD CREATED
Method Modified User	SRIRAM
Method Locked	No
Method Id	2470
Old Id	
Method Version	1
Method Edit User	
Source S/W Info	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2404097152

W2690/5 Instrument Setup

Type	W2690/5
Instrument Status	On
Channel Name	2690/5
Description	PRESSURE ENABLE
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	Gradient
Flow	1.000
%A	70.0
%B	30.0
%C	0.0
%D	0.0
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

Analysed by: 
Date : 05/11/2020Checked by: 
Date : 05/11/2020Reported by User: SRIRAM (SRIRAM)
Report Method: INSTRUMENT METHOD
Report Method ID 1044
Page: 1 of 3Project Name: 2020\QC_HPL_001\NOV-2020
Printed Date 11/5/2020
Printed Time 8:04:18 PM A:

Spurge B 0.0
 Spurge C 0.0
 Spurge D 0.0
 Column Temp Target 25.0
 Column Temp Range 5.0
 Flow Ramp 2.00
 Column choice No Change
 Column Equil Minutes 0.00
 Needle Wash Extended
 Switch 1 No Change
 Switch 2 No Change
 Switch 3 No Change
 Switch 4 No Change
 Use Events False
 Solvent A MOBILE PHASE A
 Solvent B MOBILE PHASE B
 Solvent C
 Solvent D

W2690/5 Gradient Table

	Time	Flow	%A	%B	%C	%D	Curve
1		1.00	70.0	30.0	0.0	0.0	
2	7.00	1.00	70.0	30.0	0.0	0.0	6
3	9.00	1.00	50.0	50.0	0.0	0.0	6
4	25.00	1.00	50.0	50.0	0.0	0.0	6
5	30.00	1.00	70.0	30.0	0.0	0.0	6

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
 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

Analysed by: 
 Date : 05/11/2020

Checked by: 
 Date : 05/11/2020

Revision History

Version 1 11/5/2020 5:06:35 PM IST User SRIRAM Created method 'RAMITHIAZIDE_RS_FP_IM'.
INSTRUMENT METHOD CREATED

Method Version Summaries

	Method Name	Method Type	Method Comments	Method Date
1	RAMITHIAZIDE_RS_FP_IM	Instrument	INSTRUMENT METHOD CREATED	11/5/2020 5:06:35 PM IST

Method Version Summaries

	Method Modified User	Method Locked	Method Id	Old Id	Method Version
1	SRIRAM	No	2470		1

Method Version Summaries

	Source S/W Info
1	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2404097152

Analysed by: 
Date : 05/11/2020

Checked by: 
Date : 05/11/2020

Reported by User: SRIRAM (SRIRAM)
Report Method: INSTRUMENT METHOD
Report Method ID 1044
Page: 3 of 3

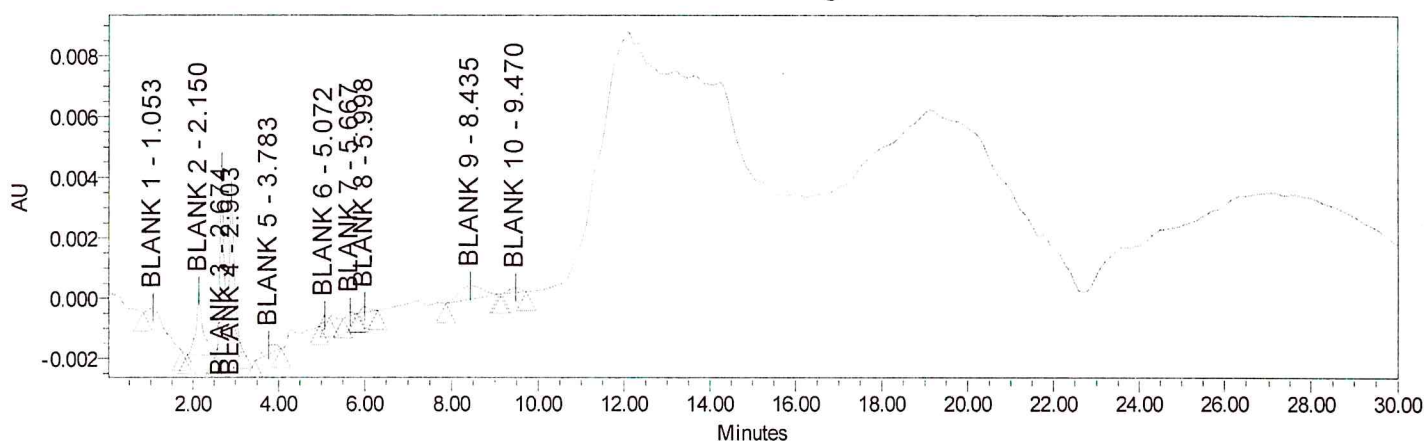
Project Name: 2020\QC_HPL_001\NOV-2020
Printed Date 11/5/2020
Printed Time 8:04:18 PM A:

SAMPLE INFORMATION

Sample Name: RS_BLANK
Sample Type: Unknown
Vial: 1
Injection #: 1
Injection Volume: 30.00 ul
Run Time: 30.0 Minutes
Date Acquired: 11/5/2020 7:04:40 PM IST
Date Processed: 11/6/2020 1:13:00 PM IST

Acquired By: SRIRAM
Sample Set Name: 05112020_RAMITHIAZIDE_RS_FP
Acq. Method Set: RAMITHIAZIDE_RS_FP_MSET
Processing Method: RAMITHIAZIDE_RS_BLANK 1_PM
Channel Name: 2487Channel 1
Proc. Chnl. Descr.: 2487Channel 1

Auto-Scaled Chromatogram



Peak Results

	Name	RT	Area
1	BLANK 1	1.053	11073
2	BLANK 2	2.150	25888
3	BLANK 3	2.674	30918
4	BLANK 4	2.903	29754
5	BLANK 5	3.783	6340
6	BLANK 6	5.072	1443
7	BLANK 7	5.667	1331
8	BLANK 8	5.998	2215
9	BLANK 9	8.435	16522
10	BLANK 10	9.470	3100

Analysed by: 
Date: 06/11/2020

Checked by: 
Date: 06/11/2020

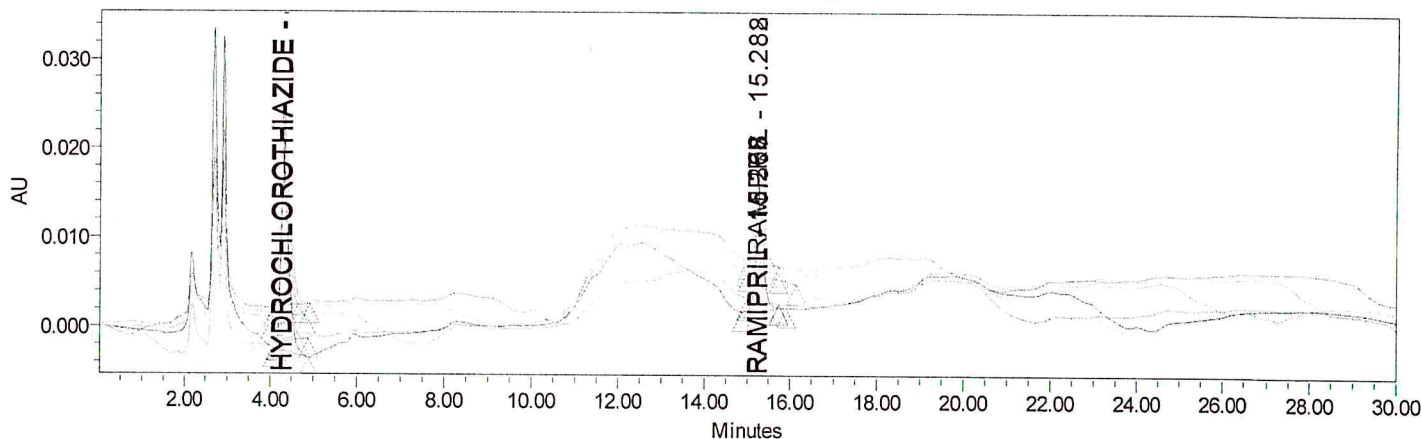
SAMPLE INFORMATION

Sample Name: STANDARD_RS
Sample Type: Unknown
Vial: 2
Injection #: 1, 6, 2, 4, 5, 3
Injection Volume: 30.00 ul
Run Time: 30.0 Minutes

Acquired By: SRIRAM
Sample Set Name: 05112020_RAMITHIAZIDE_RS_FP
Acq. Method Set: RAMITHIAZIDE_RS_FP_MSET
Processing Method: RAMITHIAZIDE_RS_STD_PM
Channel Name: 2487Channel 1
Proc. Chnl. Descr.: 2487Channel 1

Date Acquired: 11/5/2020 7:36:39 PM IST, 11/5/2020 8:08:36 PM IST, 11/5/2020 8:40:19 PM IST,
11/5/2020 9:12:14 PM IST, 11/5/2020 9:43:58 PM IST, 11/5/2020 10:15:41 PM IST
Date Processed: 11/6/2020 1:03:15 PM IST, 11/6/2020 1:03:22 PM IST, 11/6/2020 1:03:28 PM IST,

Auto-Scaled Chromatogram



Peak Name: HYDROCHLOROTHIAZIDE

	Injection	Peak Name	RT	Area	USP Plate Count
1	1	HYDROCHLOROTHIAZIDE	4.336	261767	2489
2	2	HYDROCHLOROTHIAZIDE	4.329	250060	2756
3	3	HYDROCHLOROTHIAZIDE	4.307	253624	2506
4	4	HYDROCHLOROTHIAZIDE	4.327	250659	2533
5	5	HYDROCHLOROTHIAZIDE	4.303	255081	2511
6	6	HYDROCHLOROTHIAZIDE	4.287	256005	2472
Mean			4.315	254533	2545
Std. Dev.			0.019	4257.602	
% RSD			0.4	1.7	

Analysed by: *[Signature]*
Date: 12/11/2020

Checked by: *[Signature]*
Date: 23/11/2020

Reported by User: SRIRAM (SRIRAM)
Report Method: RSD REPORT SYSTEM :
Report Method II 1245
Page: 1 of 2

Project Name: 2020\QC_HPL_001\NOV-2020
Printed Date: 11/6/2020
Printed Time: 2:36:15 PM A:

Peak Name: RAMIPRIL

	Injection	Peak Name	RT	Area	USP Plate Count	USP Resolution
1	1	RAMIPRIL	15.307	144679	42145	32.7
2	2	RAMIPRIL	15.288	142425	41425	33.7
3	3	RAMIPRIL	15.288	153877	36514	31.9
4	4	RAMIPRIL	15.282	144148	34080	31.4
5	5	RAMIPRIL	15.273	147818	35065	32.1
6	6	RAMIPRIL	15.268	151849	36669	32.4
Mean			15.284	147466	37650	32.4
Std. Dev.			0.014	4574.269		
% RSD			0.1	3.1		

Analysed by: 
Date: 02/11/2020

Checked by: 
Date: 23/11/2020

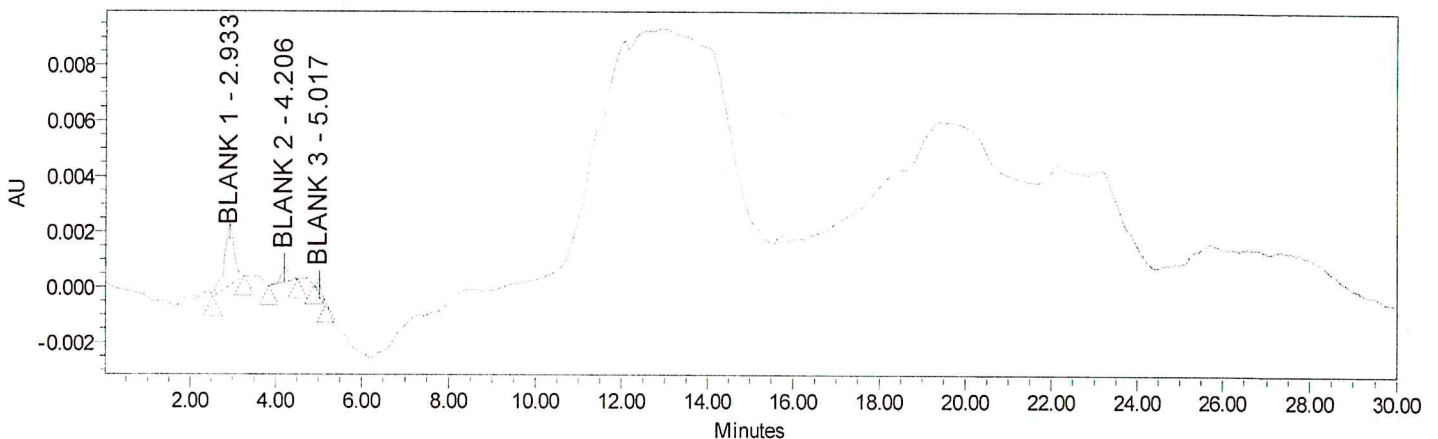
Reported by User: SRIRAM (SRIRAM)
Report Method: RSD REPORT SYSTEM :
Report Method ID 1245
Page: 2 of 2

Project Name: 2020\QC_HPL_001\NOV-2020
Printed Date 11/6/2020
Printed Time 2:36:15 PM A:

SAMPLE INFORMATION

Sample Name: RS_BLANK
Sample Type: Unknown
Vial: 1
Injection #: 1
Injection Volume: 30.00 ul
Run Time: 30.0 Minutes
Acquired By: SRIRAM
Sample Set Name: 05112020_RAMITHIAZIDE_RS_FP
Acq. Method Set: RAMITHIAZIDE_RS_FP_MSET
Processing Method: RAMITHIAZIDE_RS_BLANK 2_PM
Channel Name: 2487Channel 1
Proc. Chnl. Descr.: 2487Channel 1
Date Acquired: 11/5/2020 10:47:32 PM IST
Date Processed: 11/6/2020 1:15:47 PM IST

Auto-Scaled Chromatogram



Peak Results

	Name	RT	Area
1	BLANK 1	2.933	37353
2	BLANK 2	4.206	6979
3	BLANK 3	5.017	2360

Analysed by: 
Date: 02/11/2020

Checked by: 
Date: 23/11/2020

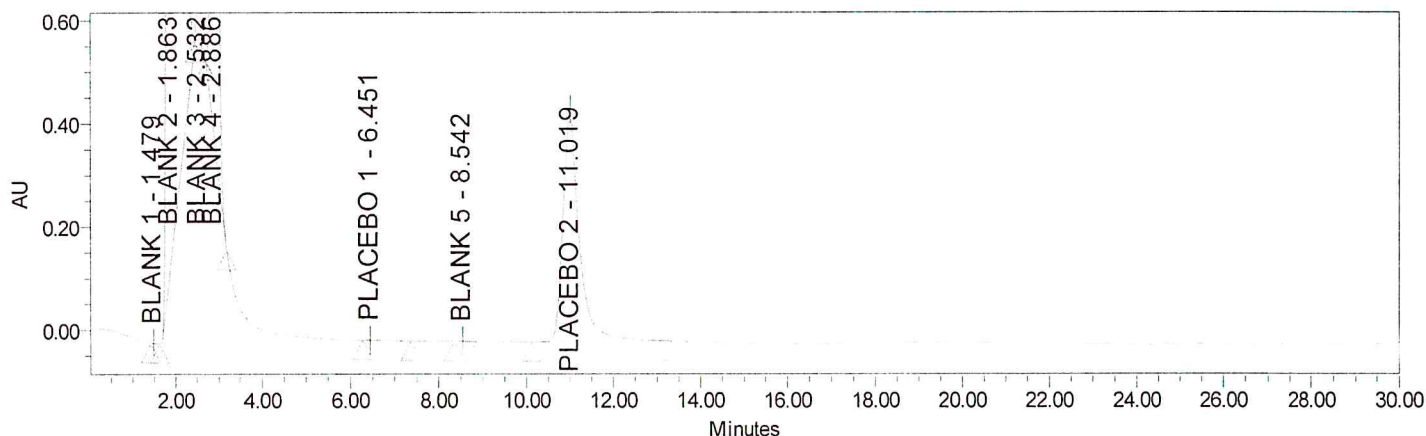
Reported by User: SRIRAM (SRIRAM)
Report Method: CHROMATOGRAPHIC DATA
Report Method ID: 2634
Page: 1 of 1

Project Name: 2020\QC_HPL_001\NOV-2020
Printed Date: 11/6/2020
Printed Time: 2:36:01 PM A:

SAMPLE INFORMATION

Sample Name: PLACEBO_5mg/12.5mg
Sample Type: Unknown
Vial: 5
Injection #: 1
Injection Volume: 30.00 ul
Run Time: 30.0 Minutes
Acquired By: SRIRAM
Sample Set Name: 05112020_RAMITHIAZIDE_RS_FP
Acq. Method Set: RAMITHIAZIDE_RS_FP_MSET
Processing Method: RAMITHIAZIDE_RS_PLACE5_12_PM
Channel Name: 2487Channel 1
Proc. Chnl. Descr.: 2487Channel 1
Date Acquired: 11/6/2020 12:22:59 AM IST
Date Processed: 11/6/2020 1:33:38 PM IST

Auto-Scaled Chromatogram



Peak Results

	Name	RT	Area
1	BLANK 1	1.479	6417
2	BLANK 2	1.863	23821271
3	BLANK 3	2.532	1508395
4	BLANK 4	2.886	14726398
5	PLACEBO 1	6.451	25210
6	BLANK 5	8.542	11007
7	PLACEBO 2	11.019	11688456

Analysed by: *[Signature]*
Date: 06/11/2020

Checked by: *[Signature]*
Date: 23/11/2020

Reported by User: SRIRAM (SRIRAM)
Report Method: CHROMATOGRAPHIC DATA
Report Method ID: 2602
Page: 1 of 1

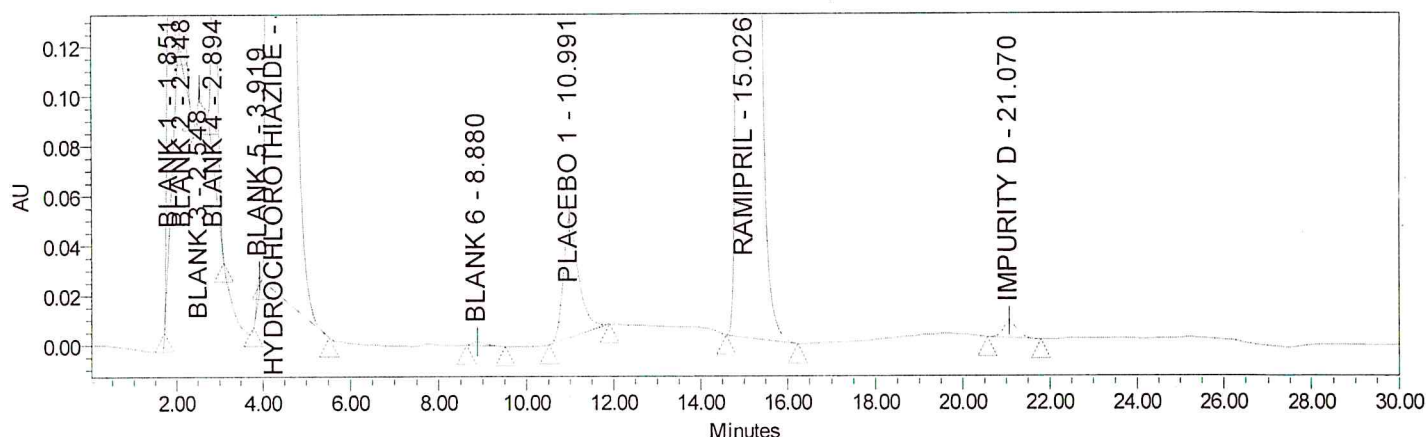
Project Name: 2020\QC_HPL_001\NOV-2020
Printed Date: 11/6/2020
Printed Time: 1:37:41 PM A

SAMPLE INFORMATION

Sample Name: RAMI_GF201004_5mg/12.5mg
Sample Type: Unknown
Vial: 11
Injection #: 1
Injection Volume: 30.00 ul
Run Time: 30.0 Minutes
Date Acquired: 11/6/2020 4:05:46 AM IST
Date Processed: 11/6/2020 2:47:19 PM IST

Acquired By: SRIRAM
Sample Set Name: 05112020_RAMITHIAZIDE_RS_FP
Acq. Method Set: RAMITHIAZIDE_RS_FP_MSET
Processing Method: RAMITHIAZIDE_RS_GF201004_PM
Channel Name: 2487Channel 1
Proc. Chnl. Descr.: 2487Channel 1

Auto-Scaled Chromatogram



Peak Results

	Name	RT	Area
1	BLANK 1	1.851	1063854
2	BLANK 2	2.148	383962
3	BLANK 3	2.548	114802
4	BLANK 4	2.894	1674351
5	BLANK 5	3.919	46240
6	HYDROCHLOROTHIAZIDE	4.283	90887853
7	BLANK 6	8.880	31535
8	PLACEBO 1	10.991	1186764
9	IMPURITY E	13.370	
10	IMPURITY A	13.670	
11	RAMIPRIL	15.026	48860067

Analysed by: *[Signature]*
Date: 01/11/2020

Checked by: *[Signature]*
Date: 23/11/2020

Peak Results

	Name	RT	Area
12	IMPURITY D	21.070	146087

Analysed by
Date


06/11/2020

Checked by:
Date


06/11/2020

Reported by User: SRIRAM (SRIRAM)
Report Method: CHROMATOGRAPHIC DATA
Report Method ID: 2690
Page: 2 of 2

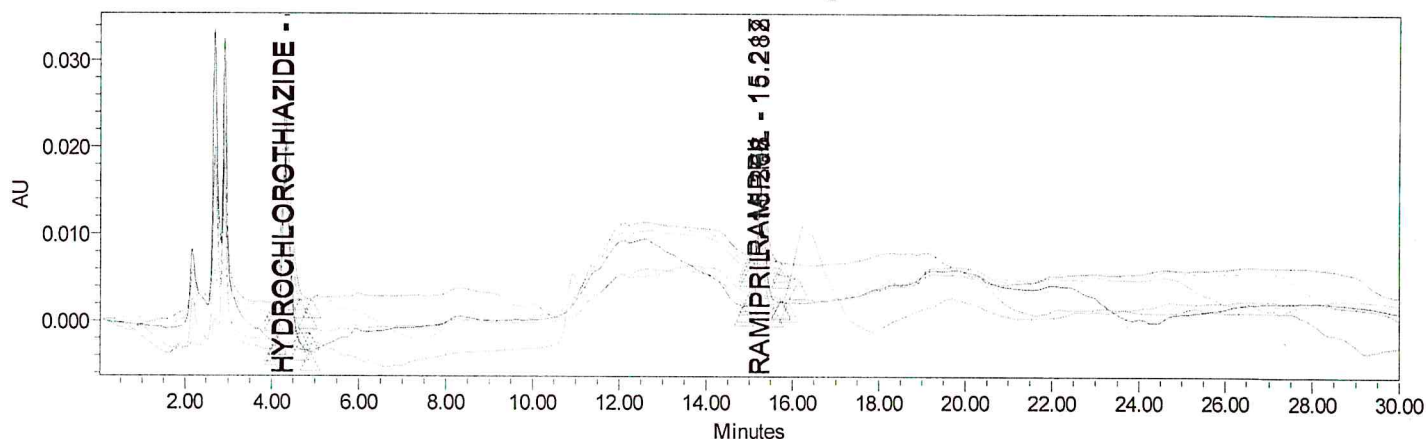
Project Name: 2020\QC_HPL_001\NOV-2020
Printed Date 11/6/2020
Printed Time 2:52:05 PM A:

SAMPLE INFORMATION

Sample Name: STANDARD_RS, RS_BKT_STD Acquired By: SRIRAM
Sample Type: Unknown Sample Set Name 05112020_RAMITHIAZIDE_RS_FP
Vial: 2 Acq. Method Set: RAMITHIAZIDE_RS_FP_MSET
Injection #: 1, 6, 2, 4, 5, 3 Processing Method: RAMITHIAZIDE_RS_STD_PM
Injection Volume: 30.00 ul Channel Name: 2487Channel 1
Run Time: 30.0 Minutes Proc. Chnl. Descr.: 2487Channel 1

Date Acquired: 11/5/2020 7:36:39 PM IST, 11/5/2020 8:08:36 PM IST, 11/5/2020 8:40:19 PM IST,
11/5/2020 9:12:14 PM IST, 11/5/2020 9:43:58 PM IST, 11/5/2020 10:15:41 PM IST,
Date Processed: 11/6/2020 1:03:15 PM IST, 11/6/2020 1:03:22 PM IST, 11/6/2020 1:03:28 PM IST,

Auto-Scaled Chromatogram



Peak Name: HYDROCHLOROTHIAZIDE

	Injection	Peak Name	RT	Area	USP Plate Count
1	1	HYDROCHLOROTHIAZIDE	4.336	261767	2489
2	1	HYDROCHLOROTHIAZIDE	4.273	257648	2192
3	2	HYDROCHLOROTHIAZIDE	4.329	250060	2756
4	3	HYDROCHLOROTHIAZIDE	4.307	253624	2506
5	4	HYDROCHLOROTHIAZIDE	4.327	250659	2533
6	5	HYDROCHLOROTHIAZIDE	4.303	255081	2511
7	6	HYDROCHLOROTHIAZIDE	4.287	256005	2472
Mean			4.309	254978	2494
Std. Dev.			0.023	4061.114	

Analysed by:
Date: 05/11/2020

Checked by:
Date: 23/11/2020

Reported by User: SRIRAM (SRIRAM)
Report Method: RSD REPORT SYSTEM :
Report Method II 1245
Page: 1 of 2

Project Name: 2020\QC_HPL_001\NOV-2020
Printed Date 11/6/2020
Printed Time 2:40:48 PM A:

Peak Name: HYDROCHLOROTHIAZIDE

	Injection	Peak Name	RT	Area	USP Plate Count
% RSD			0.5	1.6	

Peak Name: RAMIPRIL

	Injection	Peak Name	RT	Area	USP Plate Count	USP Resolution
1	1	RAMIPRIL	15.217	146072	31989	30.2
2	1	RAMIPRIL	15.307	144679	42145	32.7
3	2	RAMIPRIL	15.288	142425	41425	33.7
4	3	RAMIPRIL	15.288	153877	36514	31.9
5	4	RAMIPRIL	15.282	144148	34080	31.4
6	5	RAMIPRIL	15.273	147818	35065	32.1
7	6	RAMIPRIL	15.268	151849	36669	32.4
Mean			15.275	147267	36841	32.1
Std. Dev.			0.028	4208.805		
% RSD			0.2	2.9		

Analysed by: 
Date : 02/11/2020

Checked by: 
Date : 02/11/2020

Reported by User: SRIRAM (SRIRAM)
Report Method: RSD REPORT SYSTEM :
Report Method II 1245
Page: 2 of 2

Project Name: 2020\QC_HPL_001\NOV-2020
Printed Date 11/6/2020
Printed Time 2:40:48 PM A:

Processing Method: RAMITHIAZIDE_RS_STD_PM

Type: LC

Stored: 11/6/2020 1:05:18 PM IST

Method Information

Method Comments	PROCESSING METHOD
Method Modified User	SRIRAM
Method Locked	No
Method Id	2584
Old Id	
Method Version	1
Method Edit User	
Source S/W Info	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2404097152 Traditional
Integration Algorithm	3
Search Depth	No
Retention Time Presearch	10.0
RT Presearch Window	(m/z)
Start Mass Limit	(m/z)
End Mass Limit	Pure
PBM Search Mode	No
Duplicate Spectra	SET1
PBM Reference Sets	50.000(%)
Search Threshold	(min)
Noise Baseline	1.0000(Da)
Peak Separation	1.000
Baseline Multiplier	5
Spectra To Average	0.000(%)
Noise Threshold	Average
Combine Type	1.00(Da)
Expected Mass Peak Separation	None
Expected Mass Calculation Type	No
Include the uncorrected Target or Base Mass in the list of expected masses	100.00(Da)
Expected Mass Base Value	80.0(%)
Expected Mass Base Intensity	Centroid Top(%)
Centroid Center Type	

Analysed by: *SRM*
Date: 02/11/2020

Checked by: *SRM*
Date: 02/11/2020

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

System Suitability Information

Void Volume Time	0.010(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)

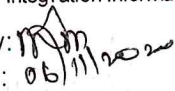
Integration Parameters

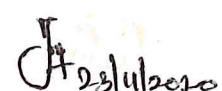
Minimum Area	0(μ V*sec)
Minimum Height	0(μ V)
Threshold	10.000(μ V/sec)
Peak Width	80.00(sec)

Integration Events

	Time (min)	Type	Value	Stop (min)
1	0.000	Valley to Valley		
2	0.000	Inhibit Integration		3.834
3	4.976	Inhibit Integration		14.600
4	16.163	Inhibit Integration		

Integration Information 'Relative Limits-HYDROCHLOROTHIAZIDE' table contains no data.

Analysed by: 
Date : 06/11/2020

Checked by: 
Date : 06/11/2020

Reported by User: SRIRAM (SRIRAM)
Report Method: PROCESSING METHOD
Report Method IL1045
Page: 2 of 3

Project Name: 2020\QC_HPL_001\NOV-2020
Printed Date 11/6/2020
Printed Time 3:35:30 PM A:

Integration Information 'Relative Limits-'RAMIPRIL" table contains no data.

Integration Information '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

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 1 11/6/2020 1:05:18 PM IST User SRIRAM Created method
'RAMITHIAZIDE_RS_STD_PM'. PROCESSING METHOD

Method Version Summaries

	Method Name	Method Type	Method Comments	Method Date
1	RAMITHIAZIDE_RS_STD_PM	Processing	PROCESSING METHOD	11/6/2020 1:05:18 PM IST

Method Version Summaries

	Method Modified User	Method Locked	Method Id	Old Id	Method Version
1	SRIRAM	No	2584		1

Method Version Summaries

	Source S/W Info
1	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2404097152

Analysed by: 
Date : 06/11/2020

Checked by: 
Date : 23/11/2020

Reported by User: SRIRAM (SRIRAM)
Report Method: PROCESSING METHOD
Report Method ID 1045
Page: 3 of 3

Project Name: 2020\QC_HPL_001\NOV-2020
Printed Date 11/6/2020
Printed Time 3:35:30 PM A:

 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: <u>22/10/2020</u>
	MICROBIAL LIMIT TEST	No.: F/QCMB/006/02 Revision No.: 00 Review Period: 02 years Effective Date: <u>24/04/19</u>
TITLE:	MICROBIAL LIMIT TEST REPORT	

MICROBIOLOGICAL TEST REPORT

Name of Product:	Ramithiazide 5mg / 12.5 mg		
Type of Product	Finished product		
Batch No./ Lot No.	GF201004	A.R. No.	FP/16/12/01
Mfg. Date	Oct-2020	Exp. Date	Sep-2023
Date of Analysis	16/11/2020	Date of Completion	23/11/2020

S.No:	Test Required	Result	Specification
1.	Total aerobic microbial count	10 cfu	Not more than <u>1000</u> cfu g or ml
2.	Total yeast and mould count	10 cfu	Not more than <u>100</u> 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: <u>D. Dharg</u> 16/11/2020	Reported by: <u>D. Dharg</u> 23/11/2020	Checked by: <u>CH</u> 23/11/2020
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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009	Page 2 of 6	Issued by QA/Date: <u>8/22/10/2020</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>	

Name of Product:	Batch No./ Lot No.	A.R. No.	Ref. Specification No.
Ramithiargide 5/12-5mg	GIF201004		
Type of Product	Sample Received on	Date of Analysis	Date of Completion
Finished product	16/11/2020	16/11/2020	23/11/2020

Media and Accessories used:

Autoclave Id. No: MB/BE/001

Micropipette Id. No:

MB/MOP/003
MB/MOP/005
MB/MOP/006

S. No.	Name of the Media	Media Preparation Details		Media Batch No.
		Date	Sterilization cycle No.	
1	SCDM	12/11/2020	MS-20-0542	MP/20/1493
2	SCDA	16/11/2020	MS-20-0545	MP/20/1502
3	SDA	16/11/2020	MS-20-0545	MP/20/1503
4	MCB	12/11/2020	MS-20-0542	MP/20/1497
5	MCA	18/11/2020	MS-20-0551	MP/20/1520
6	RVSE	NA	NA	NA
7	XLDA	12/11/2020	NA	MP/20/1498
8	MSA	11/11/2020	MS-20-0540	MP/20/1490
9	CA	11/11/2020	MS-20-0540	MP/20/1489
10	EE	NA		
11	VRBGA			
12	GN			
13	XLDA			

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

Media Mfg.: Himedia Media Lot No: LQ2068 Expiry at: 07/2021

D. S. Rao
16/11/2020

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009	Page 3 of 6	Issued by QA/Date: <u>28/10/2020</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>	

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

Procedure:

LAF Id. No: MB/LBF/001

BSC Id. No: MB/BSC/001

a) Sample preparation:

Take 10.00224 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 :

Take 10.00364 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		Done by	Observed by
	Temp. (°C)	Duration (days)	Date	Time	Date	Time		
TAMC	30-35	3-5	16/11/2020	18:00	21/11/2020	14:05	D. S. S. S.	D. S. S. S.
TYMC	20-25	5-7	16/11/2020	18:05	23/11/2020	14:11	D. S. S. S.	D. S. S. S.

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009	Page 4 of 6	Issued by QA/Date:  28/10/20
	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	

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	16/11/2020	18:00	17/11/2020	14:00	D. Singh 16/11/2020	D. Singh 17/11/2020
Pre enrichment for <i>Salmonella abony</i>	30-35	18-24	16/11/2020	18:00	17/11/2020	14:00	D. Singh 16/11/2020	D. Singh 17/11/2020
Pre enrichment for Bile tolerant gram negative bacteria	20-25	2-5					NA	

Test for Specified Microorganisms

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009	Page 5 of 6 Issued by QA/Date: <u>22/10/2020</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>

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	17/11/2020	15:50	19/11/2020	14:10	D. Shetty	D. Shetty
	MCA	30 -35	18 - 72	19/11/2020	15:58	23/11/2020	14:00	D. Shetty	D. Shetty
<i>Salmonella</i> Species.	RVSE	30 -35	18 -24	17/11/2020	15:45	18/11/2020	13:54	D. Shetty	D. Shetty
	XLDA	30 -35	24 - 48	18/11/2020	15:52	20/11/2020	13:55	D. Shetty	D. Shetty
<i>S. aureus</i>	MSA	30 -35	18 -72	17/11/2020	15:45	20/11/2020	13:55	D. Shetty	D. Shetty
<i>P. aeruginosa</i>	CA	30 -35	18 -72	17/11/2020	15:45	20/11/2020	13:55	D. Shetty	D. Shetty
<i>Bile tolerant gram negative bacteria</i>	EE	30-35	24-48						
	VRBGA	30-35	18-24						
<i>Shigella</i> Species.	GN	30-35	24-48						
	XLDA	30-35	24-48						

D. Shetty
17/11/2020

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009	Page 6 of 6 Issued by QA/Date: <u>28/10/2020</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	<1	<1	<1
Average	01		<1	

Calculation:

TAMC: Average Count X Dilution factor= 01 Countx10= 10 cfu/gm/ml.

TYMC: Average Count X Dilution factor= <1 Countx10= <10 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>D. Dhargy</u> <u>16/11/2020.</u>	Reported by: <u>D. Dhargy</u> <u>23/11/2020</u>	Checked by: <u>J. J. J. J.</u>
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