

ASSAY METHOD VALIDATION

Product name :	Ramithiazide Tablets
Label claim (mg) :	10
Content :	Ramipril
B. No. :	GP170403
Parameter :	Linearity
LNB No./Pg. No.:	419/034

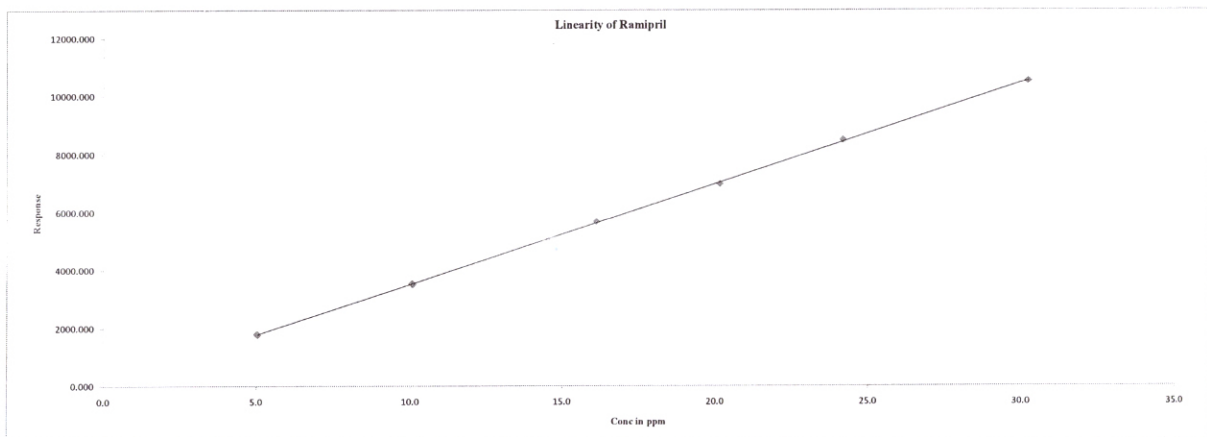
Analysis Date: 6-Jun-17

Name of standard	Standard purity(%)	Standard wt (mg)	Dilution details	Conc (ppm)
Ramipril	99.80	50.34	50	20.1

Injection No.	Retention Time	Area of Standard
1	3.753	7007.386
2	3.753	7018.219
3	3.753	7031.934
4	3.757	7008.798
5	3.757	6989.347
6	3.753	6992.041
Average	3.754	7007.954
SD	0.00	16.01
%RSD	0.06	0.23
System suitability results		
% RSD of Area	0.23	NMT 1.5%
Tailing factor	1.00	NMT 2.0
Theoretical plates	9677	NLT 2000

Accuracy Stock :	
Standard wt (mg)	Dilution details
50.34	50 mL with diluent

Level	Linearity level (%)	ml of Standard Stock Solution added	Diluted to volume (mL)	Actual Concentration (ppm)	Area of sample	Average area
1	25	0.5	100	5.0	1793.527	1789.150
					1792.789	
					1785.713	
					1780.852	
					1795.589	
					1786.431	
2	50	1.0	100	10.1	3531.387	3531.410
					3535.378	
					3527.465	
					5672.921	
3	75	1.6	100	16.1	5674.689	5674.802
					5676.795	
					6998.638	
4	100	2.0	100	20.1	6976.426	6984.227
					6977.616	
					8484.320	
5	125	2.4	100	24.2	8476.854	8483.543
					8489.456	
					10516.722	
6	150	3.0	100	30.2	10531.706	10517.807
					10542.009	
					10499.757	
					10505.742	
					10510.904	



Slope	347.37
y-intercept	43.12
Correlation coefficient	0.9999

Done by: *Banerjee*
08-Jun-17

Checked by: *Sharma*
10-Jun-17

ASSAY METHOD VALIDATION

Product name :	Ramithiazide Tablets
Label claim (mg):	25
Content:	Hydrochlorothiazide
B. No.:	GP170403
Parameter:	Linearity
LNB No./Pg. No.:	419/034

Analysis Date: 6-Jun-17

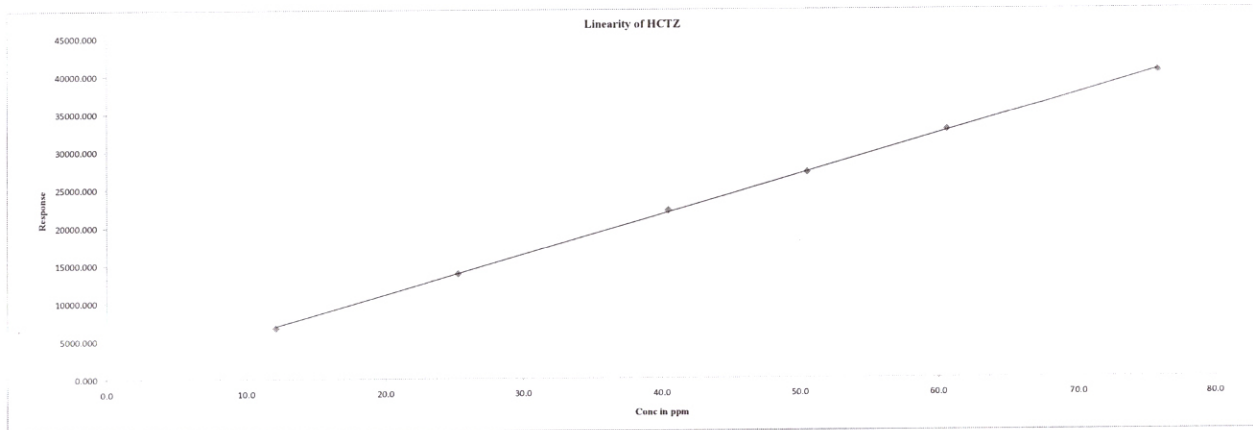
Name of standard	Standard B. No.	Standard purity(%)	Standard wt (mg)	Dilution details	Conc (ppm)
Hydrochlorothiazide	20140403	99.9	50.50	50	50.5

Injection No.	Retention Time	Area of Standard
1	2.113	27192.801
2	2.113	27239.583
3	2.117	27322.059
4	2.117	27238.009
5	2.117	27175.641
6	2.113	27184.405
Average	2.115	27225.416
SD	0.00	54.63
%RSD	0.10	0.20
System suitability results		
% RSD of Area	0.20	NMT 1.5%
Tailing factor	1.09	NMT 2.0
Theoretical plates	10362	NLT 2000

Accuracy Stock :

Standard wt (mg)	Dilution details
50.50	50 mL with diluent

Level	Linearity level (%)	ml of Standard Stock Solution added	Diluted to volume (mL)	Actual Concentration (ppm)	Area of sample	Average area
1	25	1.2	100	12.1	6759.543	6761.625
					6742.148	
					6761.846	
					6740.715	
					6798.745	
					6766.757	
2	50	2.5	100	25.3	13907.523	13905.135
					13902.865	
					13905.017	
3	75	4.0	100	40.4	22197.151	22179.585
					22158.106	
					22183.498	
4	100	5.0	100	50.5	27155.943	27122.050
					27084.756	
					27125.449	
5	125	6.0	100	60.6	32725.509	32723.721
					32723.357	
					32722.296	
6	150	7.5	100	75.8	40376.322	40390.549
					40480.045	
					40458.462	
					40360.603	
					40379.248	
					40288.613	



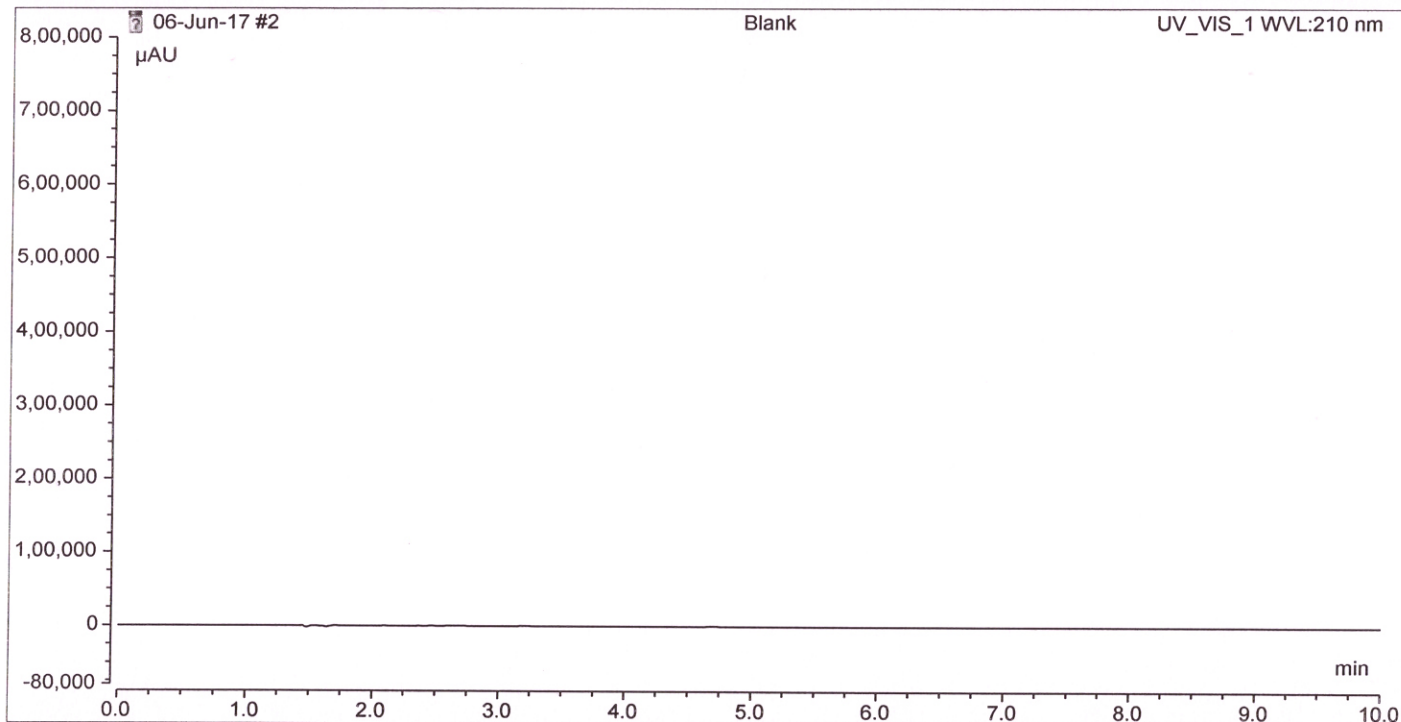
Slope	528.69
y-intercept	530.01
Correlation coefficient	0.9999

Done by: *[Signature]*
Date: 08-Jun-17

Checked by: *[Signature]*
Date: 08-Jun-17

QbD Research & Development Pvt.Ltd.**Injection Details**

Injection Name:	Blank	Run Time (min):	10.00
Vial Number:	GA1	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	06-Jun-17 20:50	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram**Integration Results**

No.	Peak Name	Retention Time min	Area µAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
Total:							

Default/Integration

Chromeleon (c) Dionex
Version 7.2.4.8525

Pankaj
08-Jun-17

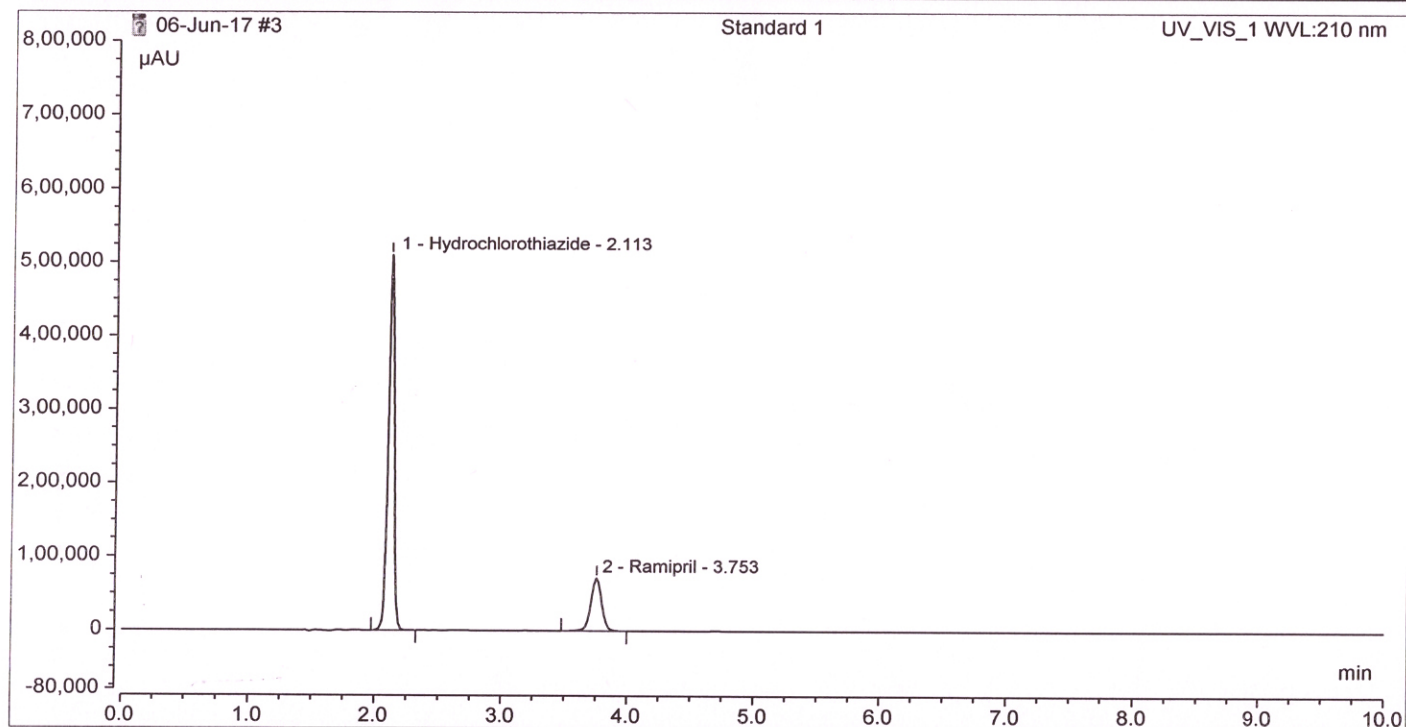
Pankaj
10-Jun-17

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Injection Details

Injection Name:	Standard 1	Run Time (min):	10.00
Vial Number:	GA2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	06-Jun-17 21:02	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area $\mu\text{AU} \cdot \text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.113	27192.801	10362	1.09	13.92	79.51
2	Ramipril	3.753	7007.386	9677	1.00	n.a.	20.49
Total:							

Default/Integration

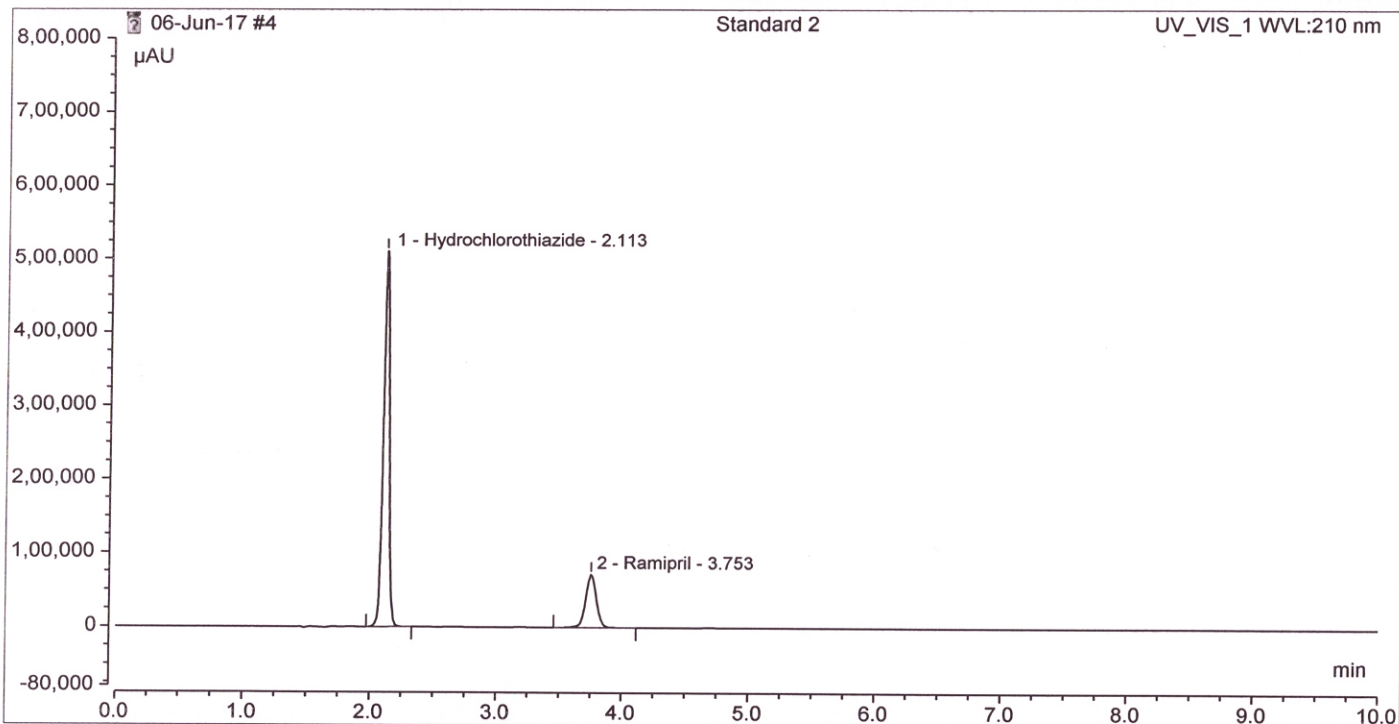
Chromeleon (c) Dionex
Version 7.2.4.8525Pankaj
08-Jun-17Pankaj
10-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Standard 2	Run Time (min):	10.00
Vial Number:	GA2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	06-Jun-17 21:14	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.113	27239.583	10357	1.10	13.92	79.51
2	Ramipril	3.753	7018.219	9685	1.01	n.a.	20.49
Total:							

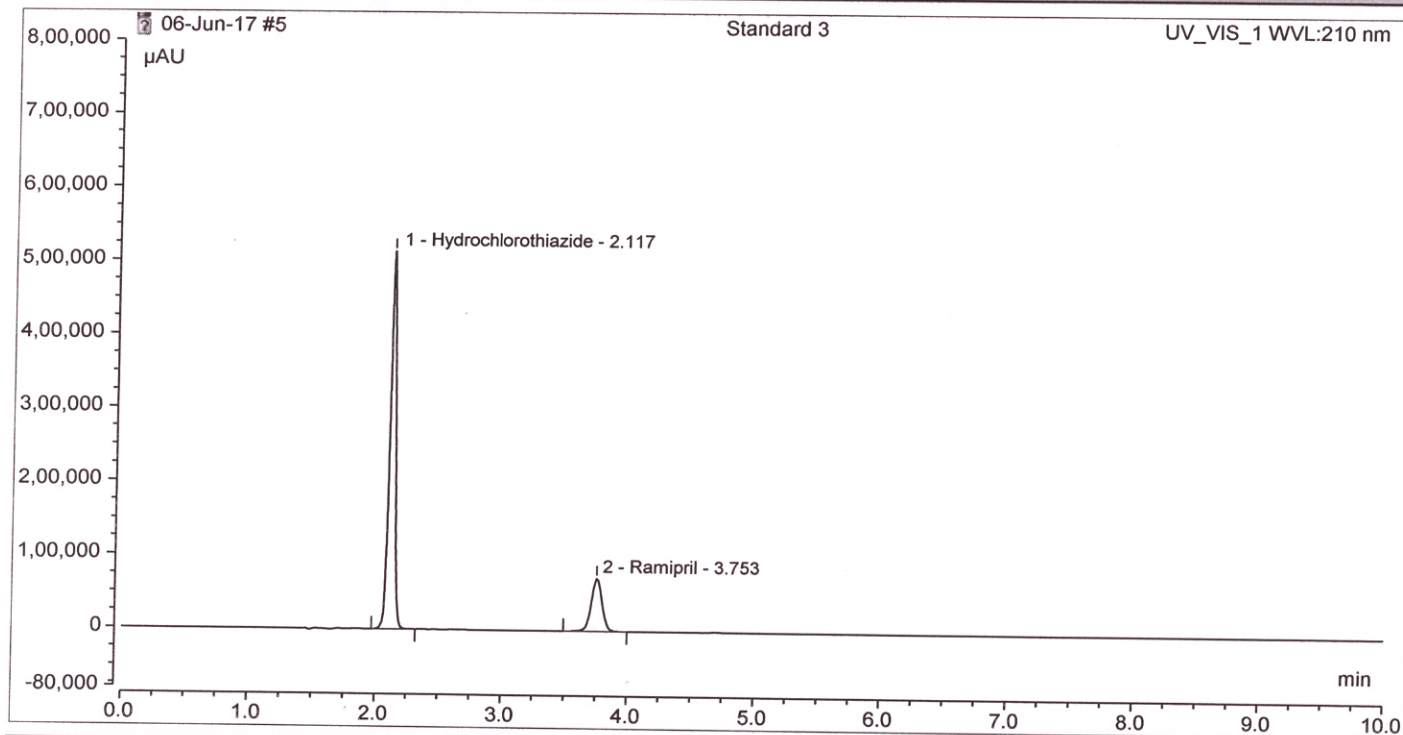
Pankaj
08-Jun-17Pankaj
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Injection Details

Injection Name:	Standard 3	Run Time (min):	10.00
Vial Number:	GA2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	06-Jun-17 21:26	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area $\mu\text{AU} \cdot \text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.117	27322.059	10464	1.03	13.92	79.53
2	Ramipril	3.753	7031.934	9714	1.02	n.a.	20.47
Total:							

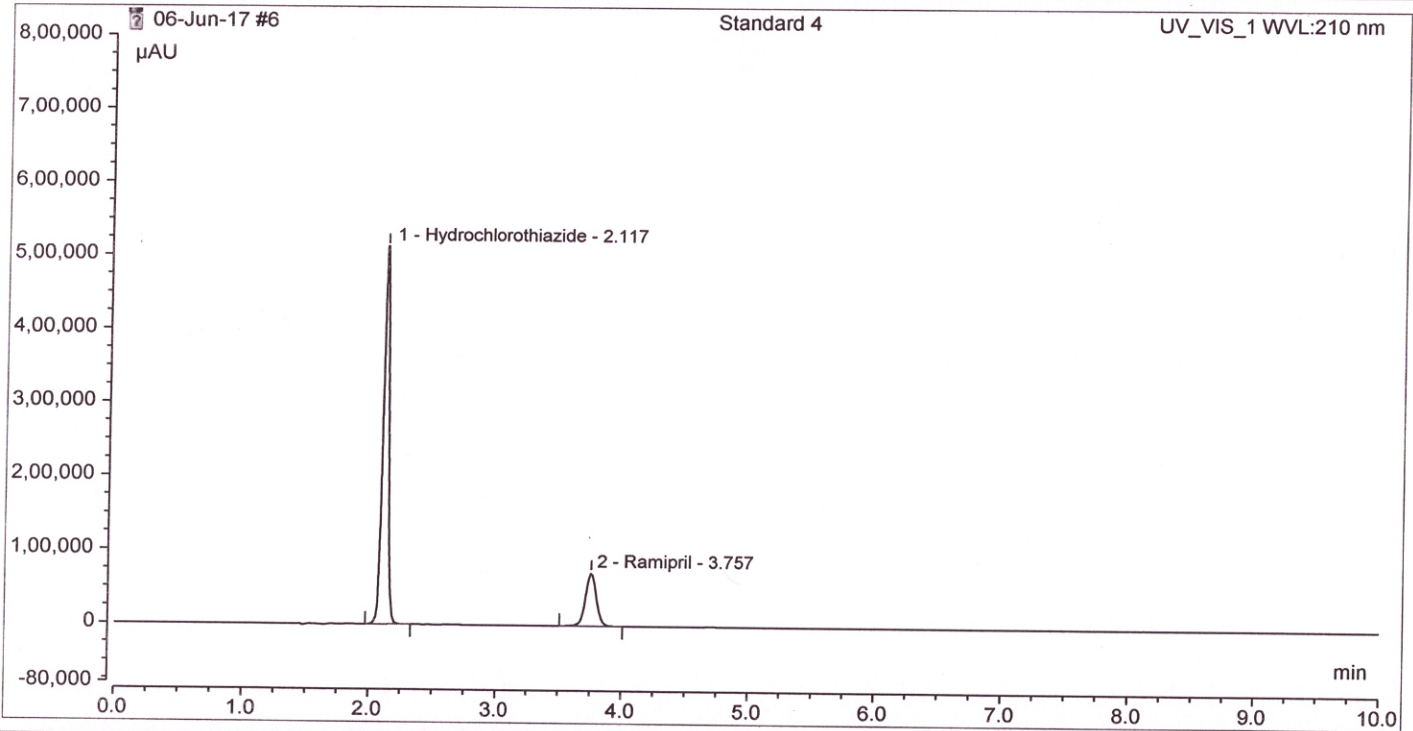
Pankaj Gurav
08-Jun-17Pankaj Gurav
10-Jun-17

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Injection Details

Injection Name:	Standard 4	Run Time (min):	10.00
Vial Number:	GA2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	06-Jun-17 21:38	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.117	27238.009	10501	1.03	13.97	79.53
2	Ramipril	3.757	7008.798	9756	1.00	n.a.	20.47
Total:							

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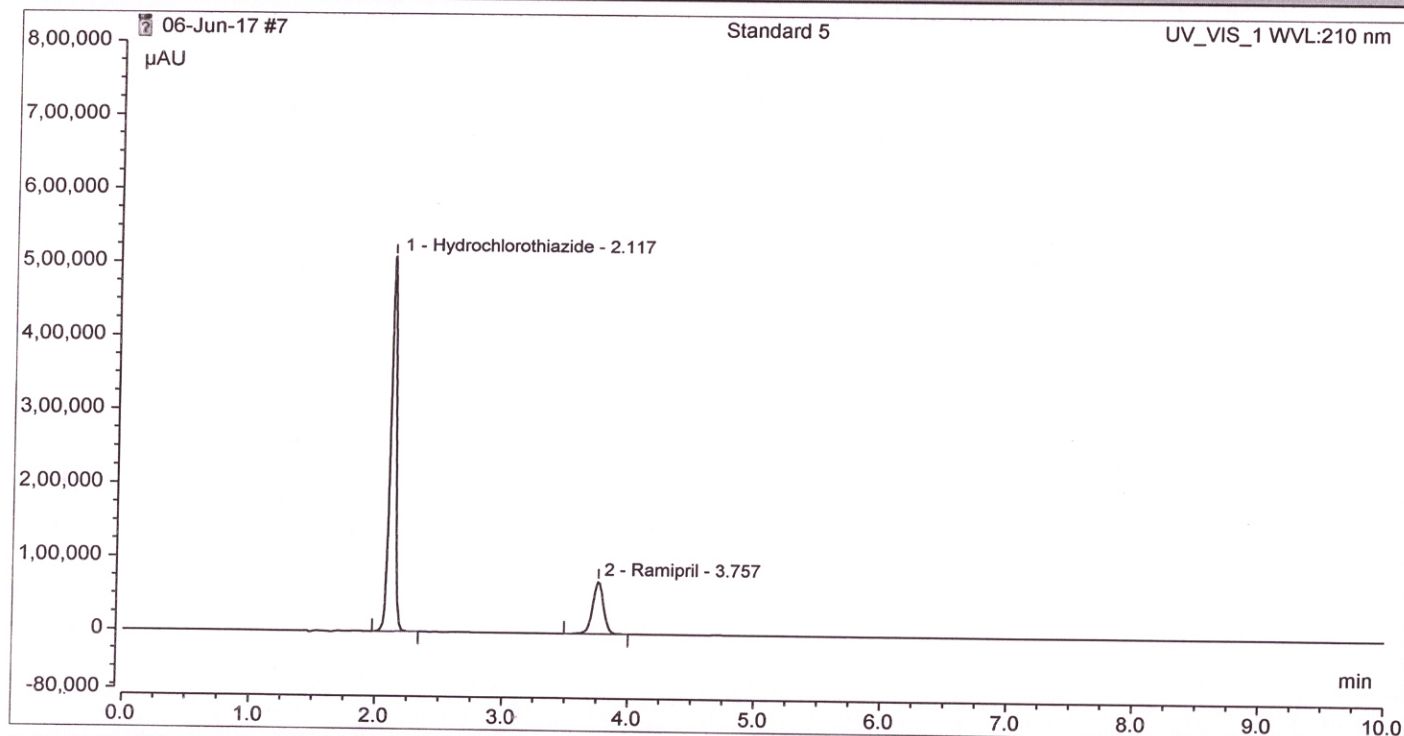
Pankaj Gurav

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Injection Details

Injection Name:	Standard 5	Run Time (min):	10.00
Vial Number:	GA2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	06-Jun-17 21:49	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.117	27175.641	10405	1.04	13.94	79.54
2	Ramipril	3.757	6989.347	9742	1.00	n.a.	20.46
Total:							

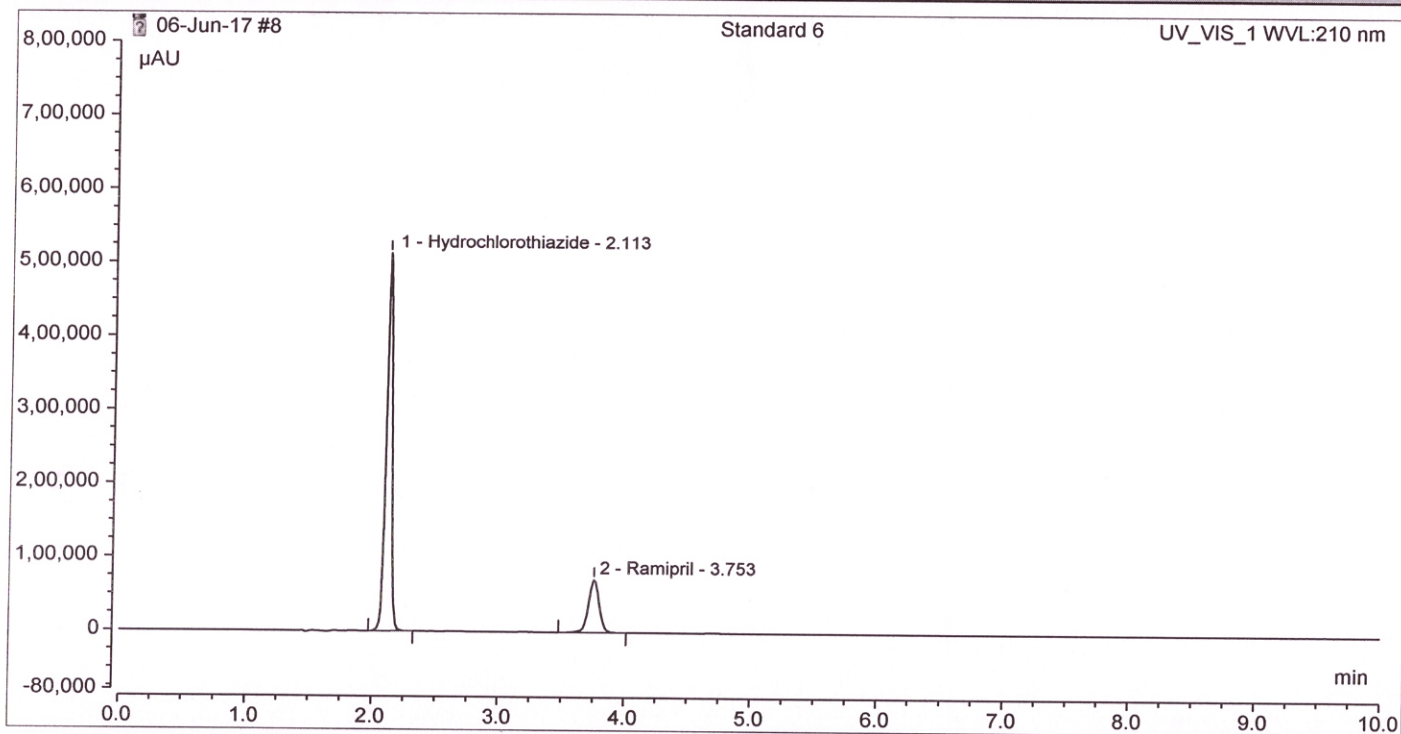
Pankaj
08-Jun-17Pankaj
10-Jun-17

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Injection Details

Injection Name:	Standard 6	Run Time (min):	10.00
Vial Number:	GA2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	06-Jun-17 22:01	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area $\mu\text{AU} \cdot \text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.113	27184.405	10513	1.08	13.99	79.54
2	Ramipril	3.753	6992.041	9763	1.02	n.a.	20.46
Total:							

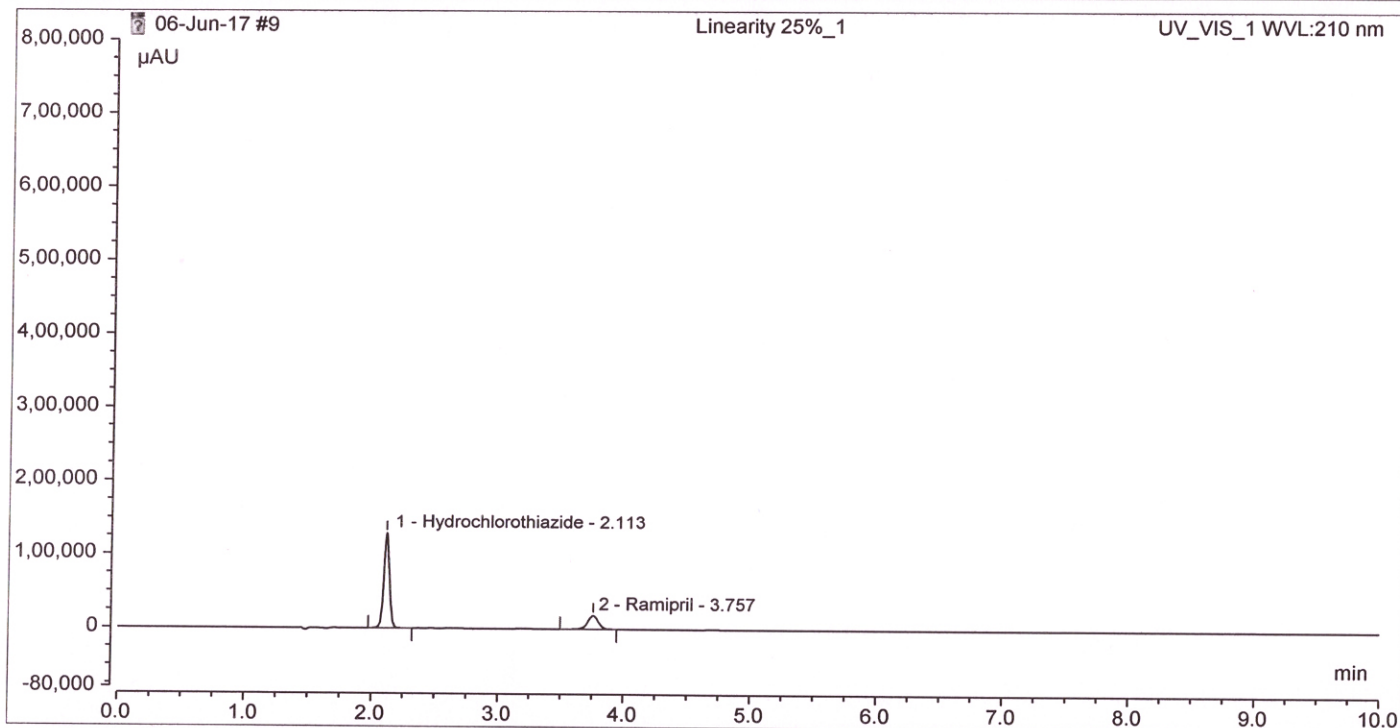
Pankaj
08-Jun-17Pankaj
10-Jun-17

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Injection Details

Injection Name:	Linearity 25%_1	Run Time (min):	10.00
Vial Number:	GA3	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	06-Jun-17 22:13	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.113	6759.543	10704	1.08	14.07	79.03
2	Ramipril	3.757	1793.527	9796	0.99	n.a.	20.97
Total:							

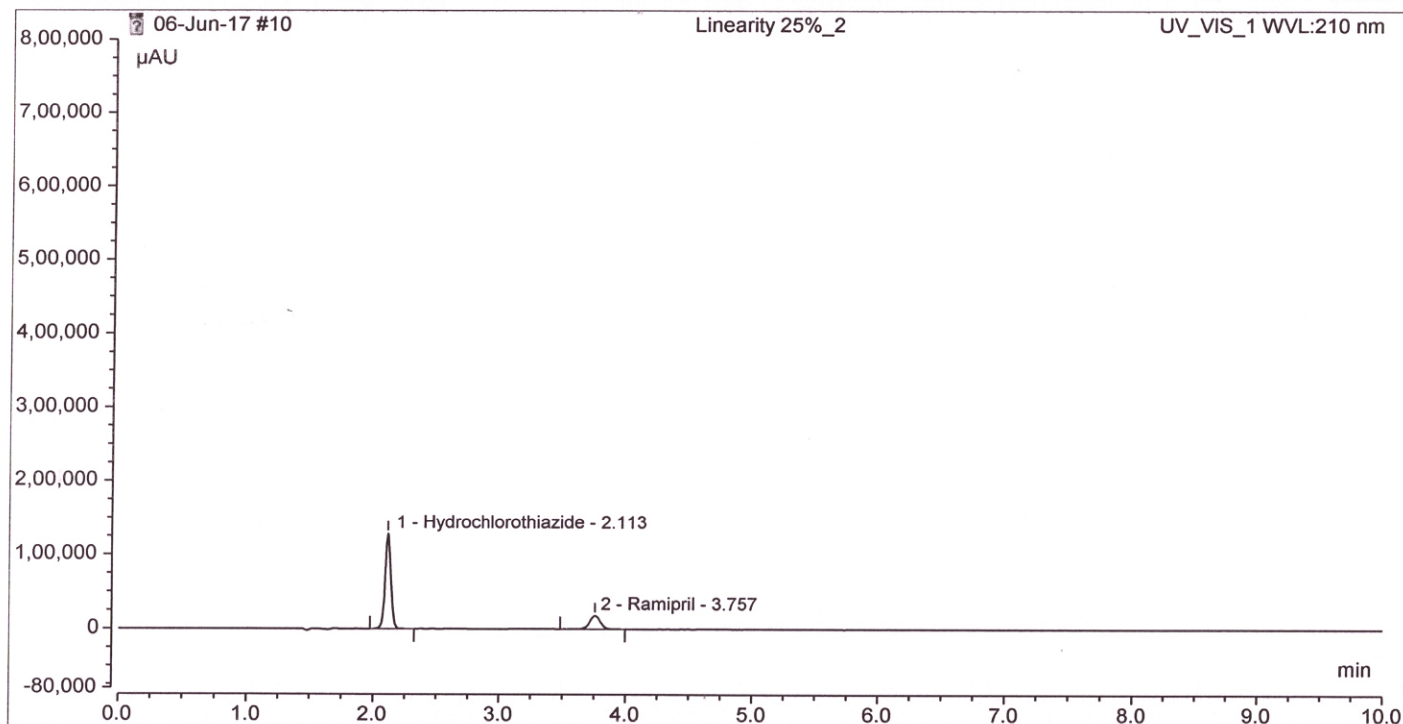
Pankaj
08-Jun-17Pankaj
10-Jun-17

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Injection Details

Injection Name:	Linearity 25%_2	Run Time (min):	10.00
Vial Number:	GA3	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	06-Jun-17 22:25	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.113	6742.148	10700	1.08	14.08	78.99
2	Ramipril	3.757	1792.789	9814	0.99	n.a.	21.01
Total:							

Default/Integration

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Version 7.2.4.8525

Pankaj
08-Jun-17

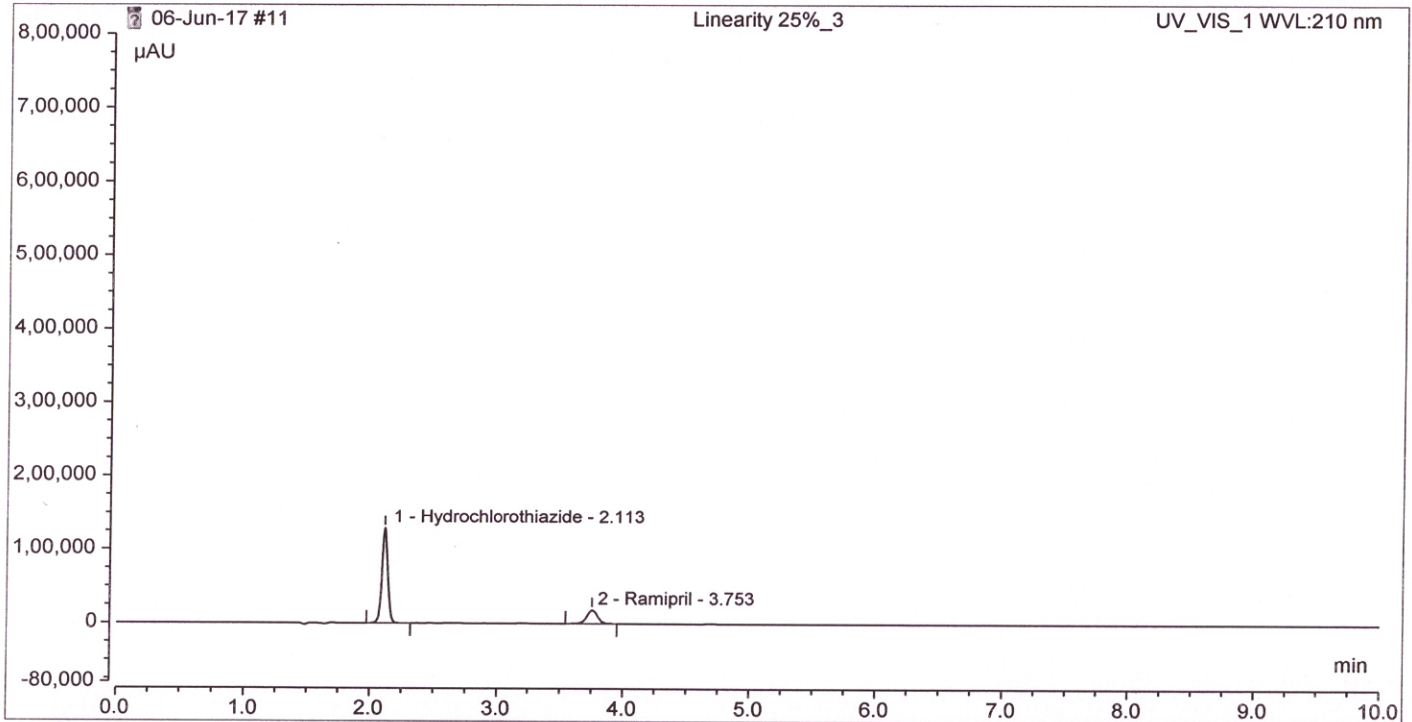
Rajin
10-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Linearity 25%_3	Run Time (min):	10.00
Vial Number:	GA3	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	06-Jun-17 22:36	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.113	6761.846	10688	1.06	14.04	79.11
2	Ramipril	3.753	1785.713	9781	1.02	n.a.	20.89
Total:							

Pankaj
08-Jun-17

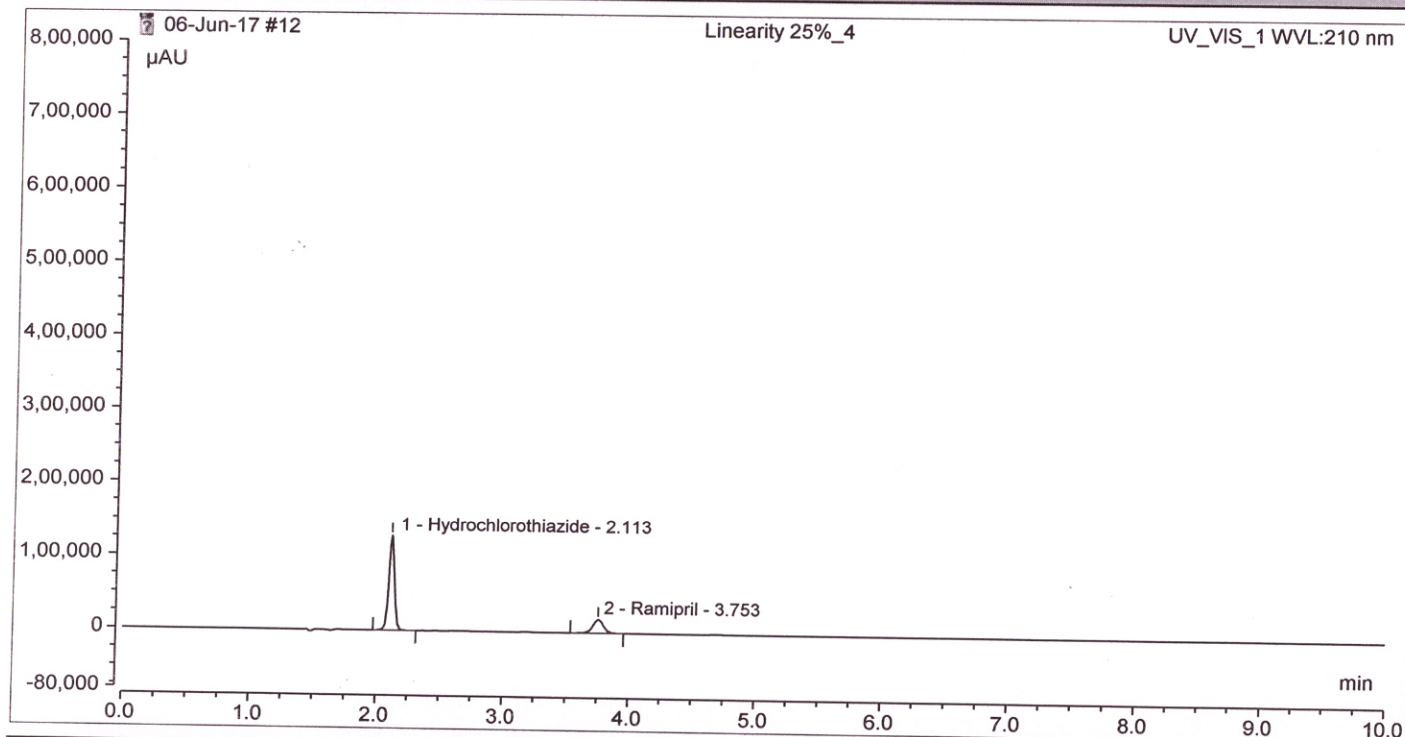
Pankaj
10-Jun-17

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Injection Details

Injection Name:	Linearity 25%_4	Run Time (min):	10.00
Vial Number:	GA3	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	06-Jun-17 22:48	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area µAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.113	6740.715	10652	1.07	14.05	79.10
2	Ramipril	3.753	1780.852	9813	1.02	n.a.	20.90
Total:							

Pankaj Gurav
08-Jun-17

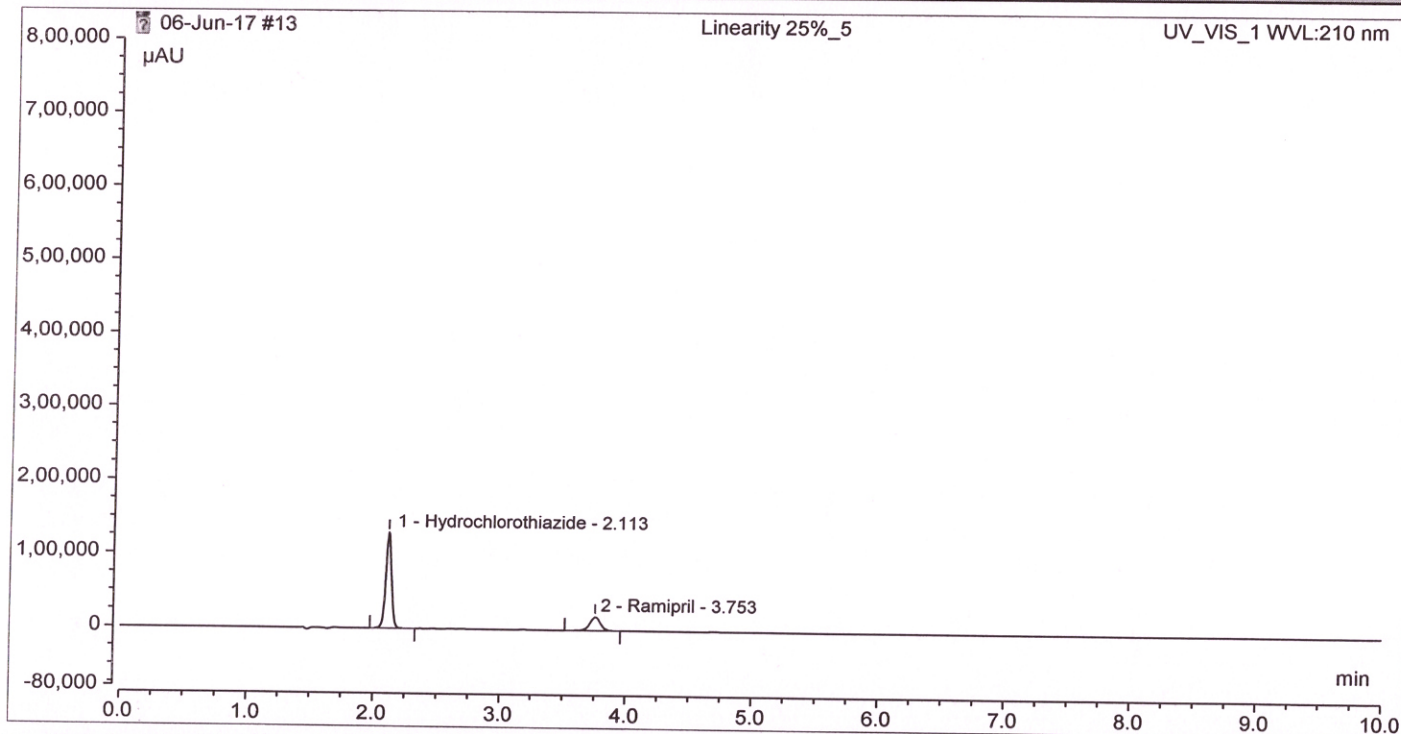
Pankaj Gurav
10-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Linearity 25%_5	Run Time (min):	10.00
Vial Number:	GA3	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	06-Jun-17 23:00	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.113	6798.745	10683	1.06	14.05	79.11
2	Ramipril	3.753	1795.589	9810	1.01	n.a.	20.89
Total:							

Pankaj
08-Jun-17

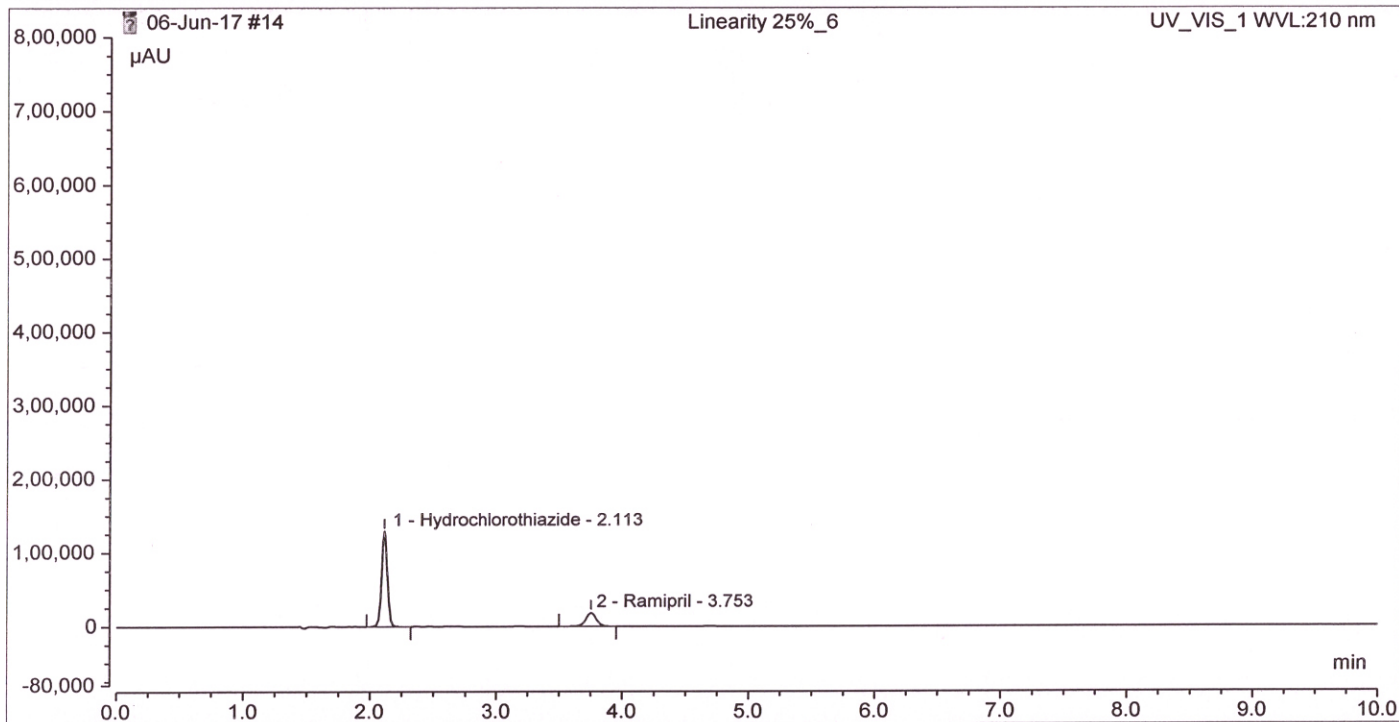
Ryan
10-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Linearity 25%_6	Run Time (min):	10.00
Vial Number:	GA3	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	06-Jun-17 23:12	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.113	6766.757	10657	1.05	14.02	79.11
2	Ramipril	3.753	1786.431	9742	1.00	n.a.	20.89
Total:							

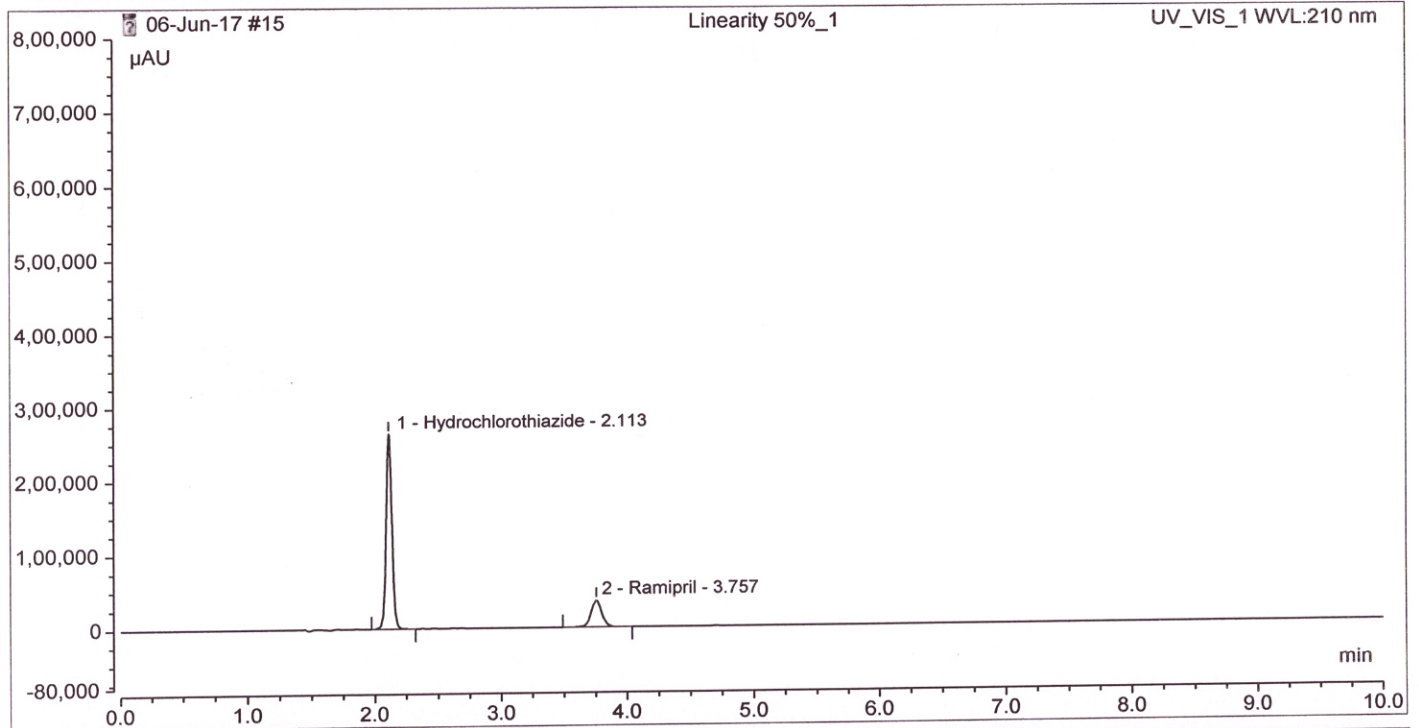
Pankaj
08-Jun-17Pankaj
10-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Linearity 50%_1	Run Time (min):	10.00
Vial Number:	GA4	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	06-Jun-17 23:24	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.113	13907.523	10597	1.09	14.06	79.75
2	Ramipril	3.757	3531.387	9817	1.00	n.a.	20.25
Total:							

Default/Integration

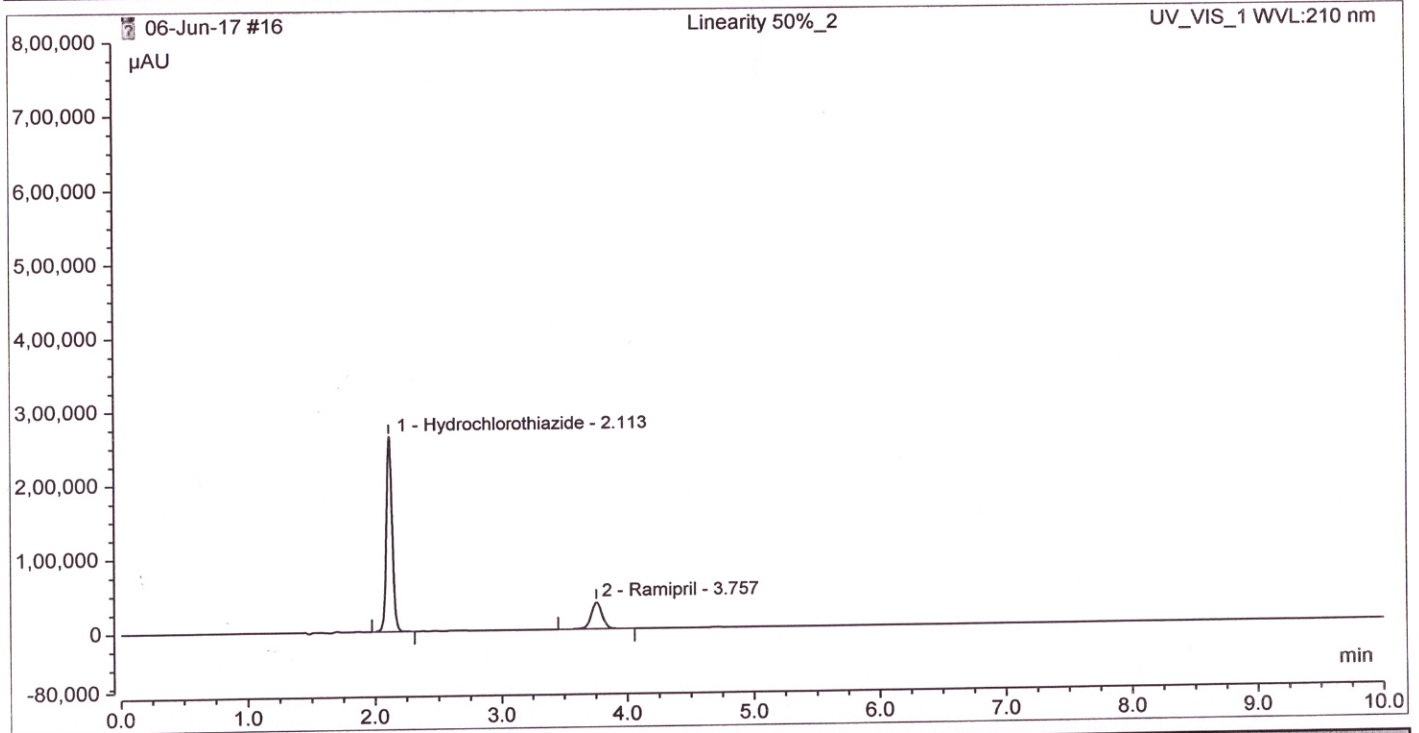
Chromeleon (c) Dionex
Version 7.2.4.8525Pankaj
08-Jun-17Pankaj
10-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Linearity 50%_2	Run Time (min):	10.00
Vial Number:	GA4	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	06-Jun-17 23:35	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.113	13902.865	10608	1.09	14.04	79.73
2	Ramipril	3.757	3535.378	9765	1.01	n.a.	20.27
Total:							

Default/Integration

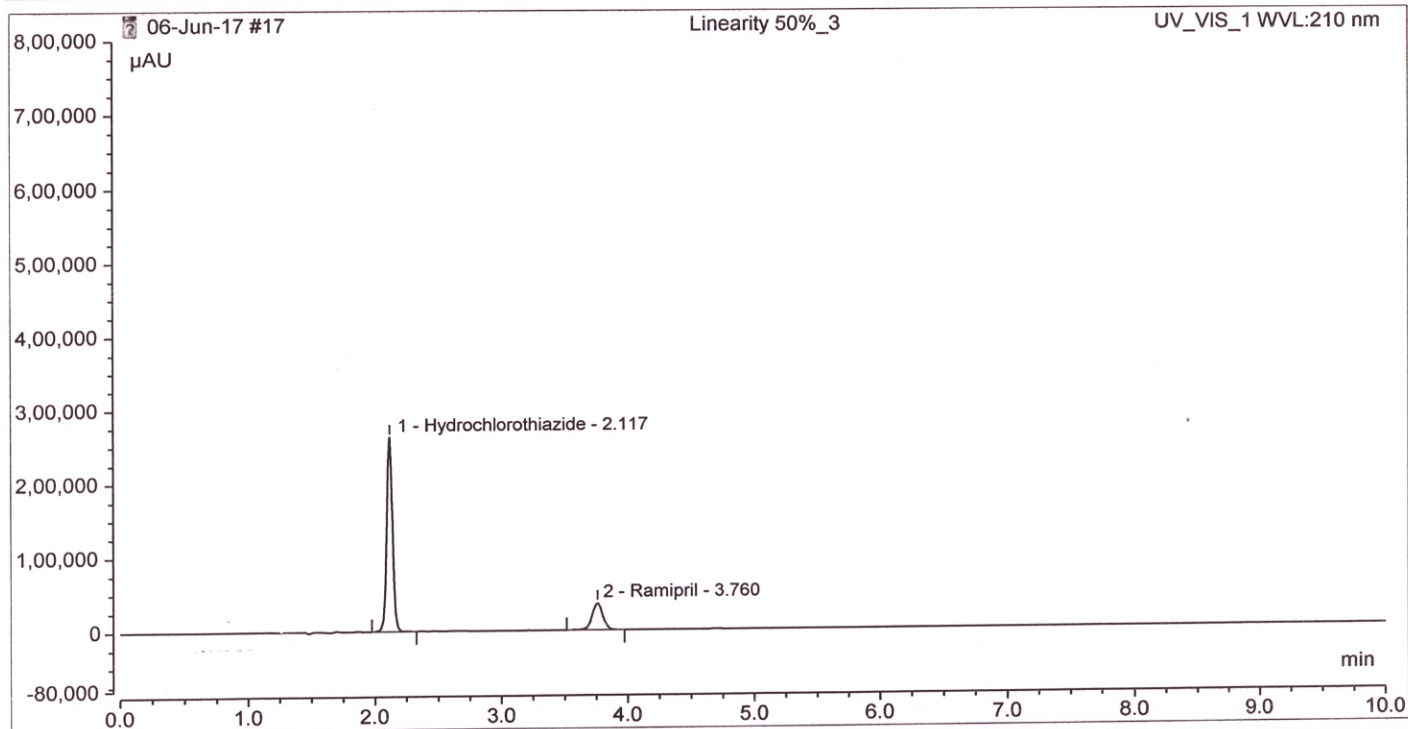
Chromeleon (c) Dionex
Version 7.2.4.8525Pankaj
08-Jun-17Pankaj
10-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Linearity 50%_3	Run Time (min):	10.00
Vial Number:	GA4	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	06-Jun-17 23:47	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.117	13905.017	10557	1.04	14.04	79.76
2	Ramipril	3.760	3527.465	9831	0.99	n.a.	20.24
Total:							

Default/Integration

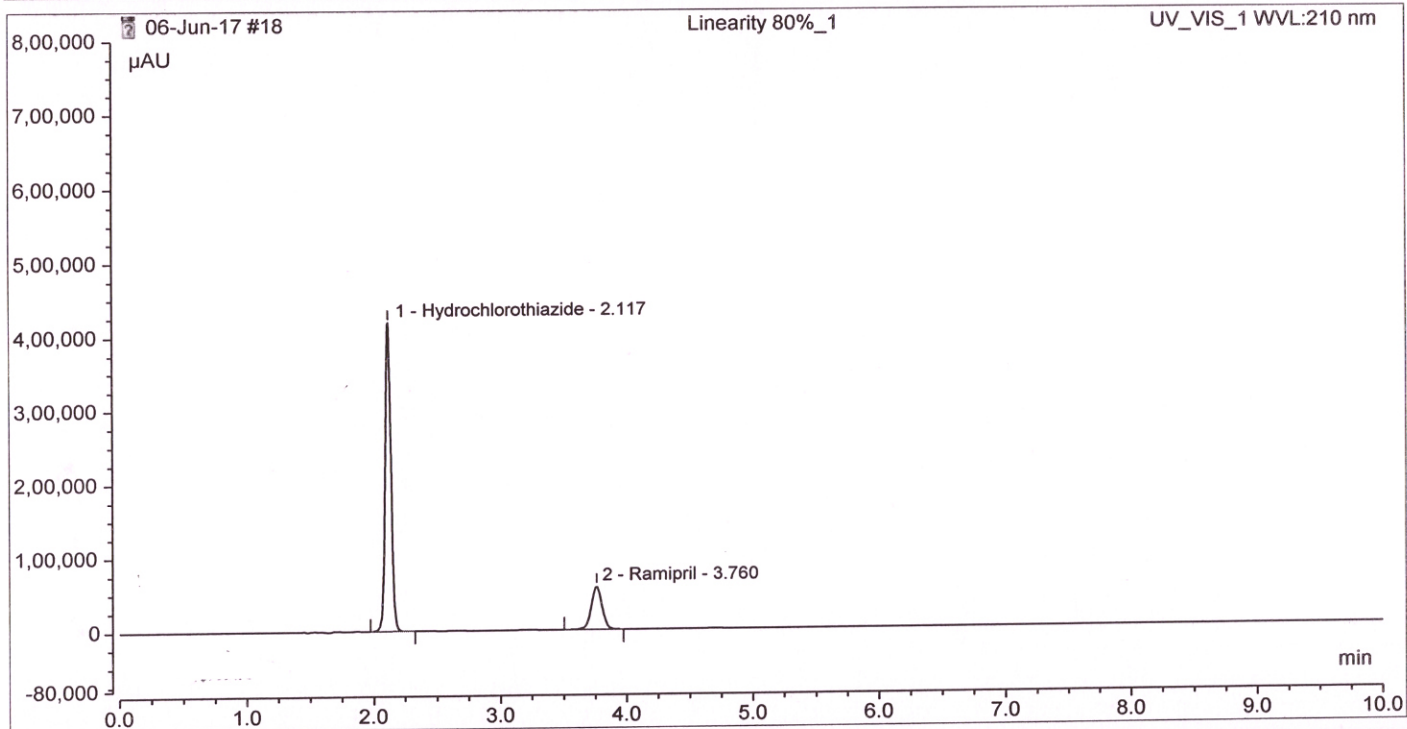
Chromeleon (c) Dionex
Version 7.2.4.8525Pankaj
08-Jun-17Pankaj
10-Jun-17

QbD Research & Developement Pvt.Ltd.

Injection Details

Injection Name:	Linearity 80%_1	Run Time (min):	10.00
Vial Number:	GA5	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	06-Jun-17 23:59	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area $\mu\text{AU} \cdot \text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.117	22197.151	10537	1.04	14.03	79.65
2	Ramipril	3.760	5672.921	9810	0.99	n.a.	20.35
Total:							

Default/Integration

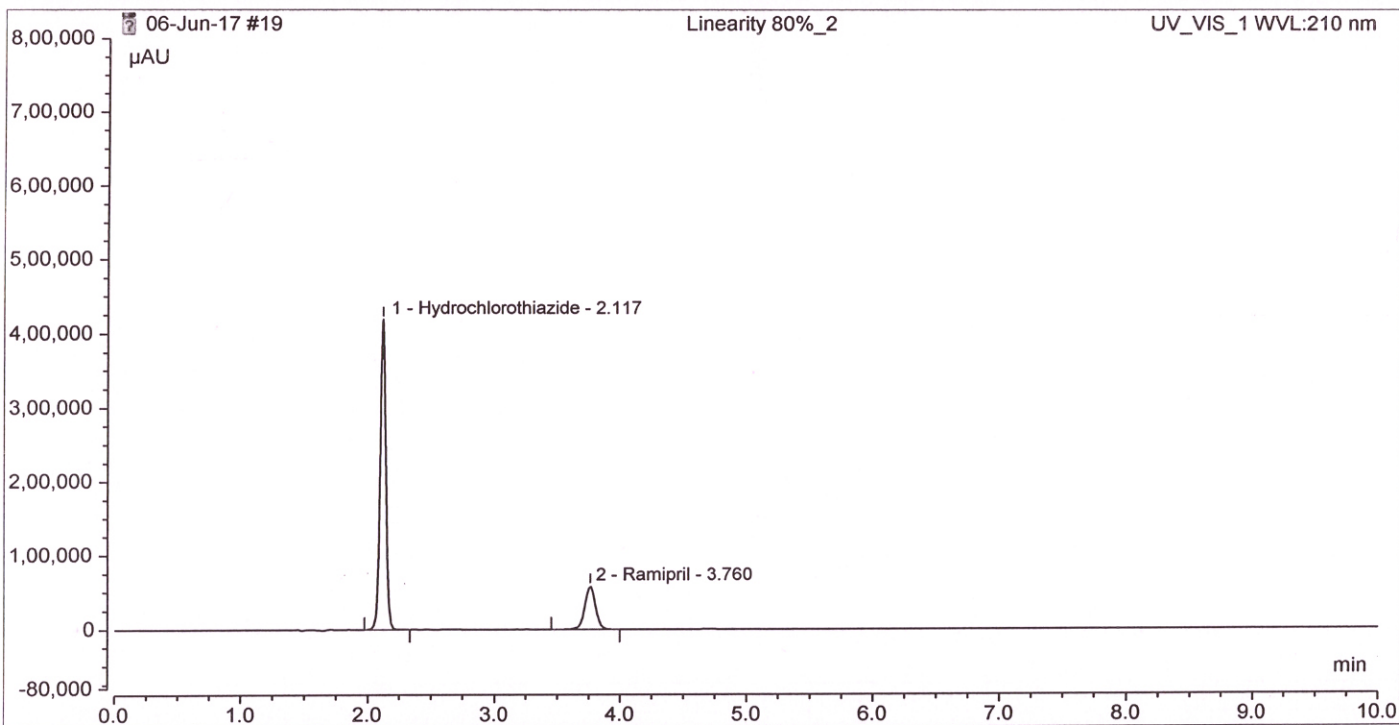
Chromeleon (c) Dionex
Version 7.2.4.8525Pankaj
08-Jun-17Pankaj
10-June-17

QbD Research & Developement Pvt.Ltd.

Injection Details

Injection Name:	Linearity 80%_2	Run Time (min):	10.00
Vial Number:	GA5	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	07-Jun-17 00:11	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area $\mu\text{AU} \cdot \text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.117	22158.106	10564	1.05	14.04	79.61
2	Ramipril	3.760	5674.689	9837	1.00	n.a.	20.39
Total:							

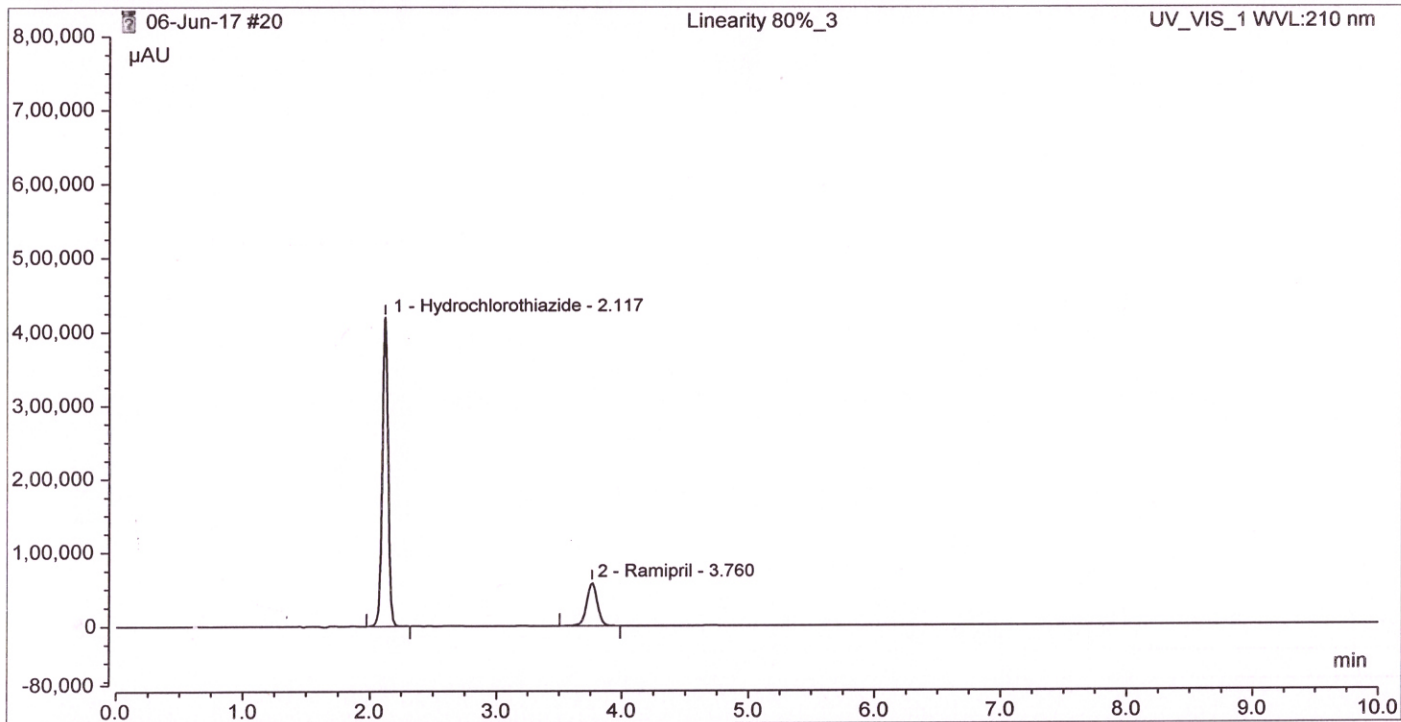
Pankaj
08-Jun-17Pankaj
10-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Linearity 80%_3	Run Time (min):	10.00
Vial Number:	GA5	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	07-Jun-17 00:22	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area $\mu\text{AU} \cdot \text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.117	22183.498	10556	1.05	14.04	79.62
2	Ramipril	3.760	5676.795	9832	1.01	n.a.	20.38
Total:							

Default/Integration

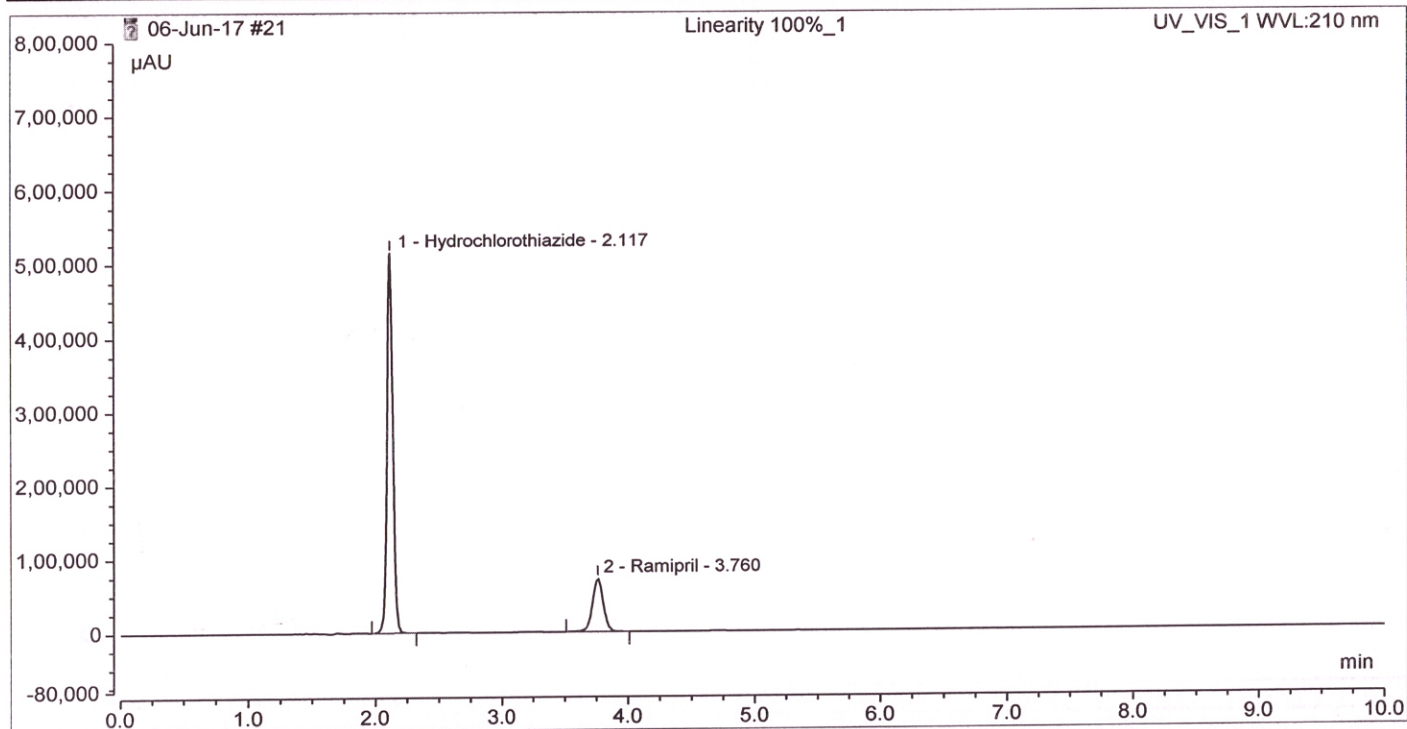
Chromeleon (c) Dionex
Version 7.2.4.8525Pankaj
08-Jun-17Pankaj
10-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Linearity 100%_1	Run Time (min):	10.00
Vial Number:	GA6	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	07-Jun-17 00:34	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.117	27155.943	10612	1.04	14.06	79.51
2	Ramipril	3.760	6998.638	9853	1.01	n.a.	20.49
Total:							

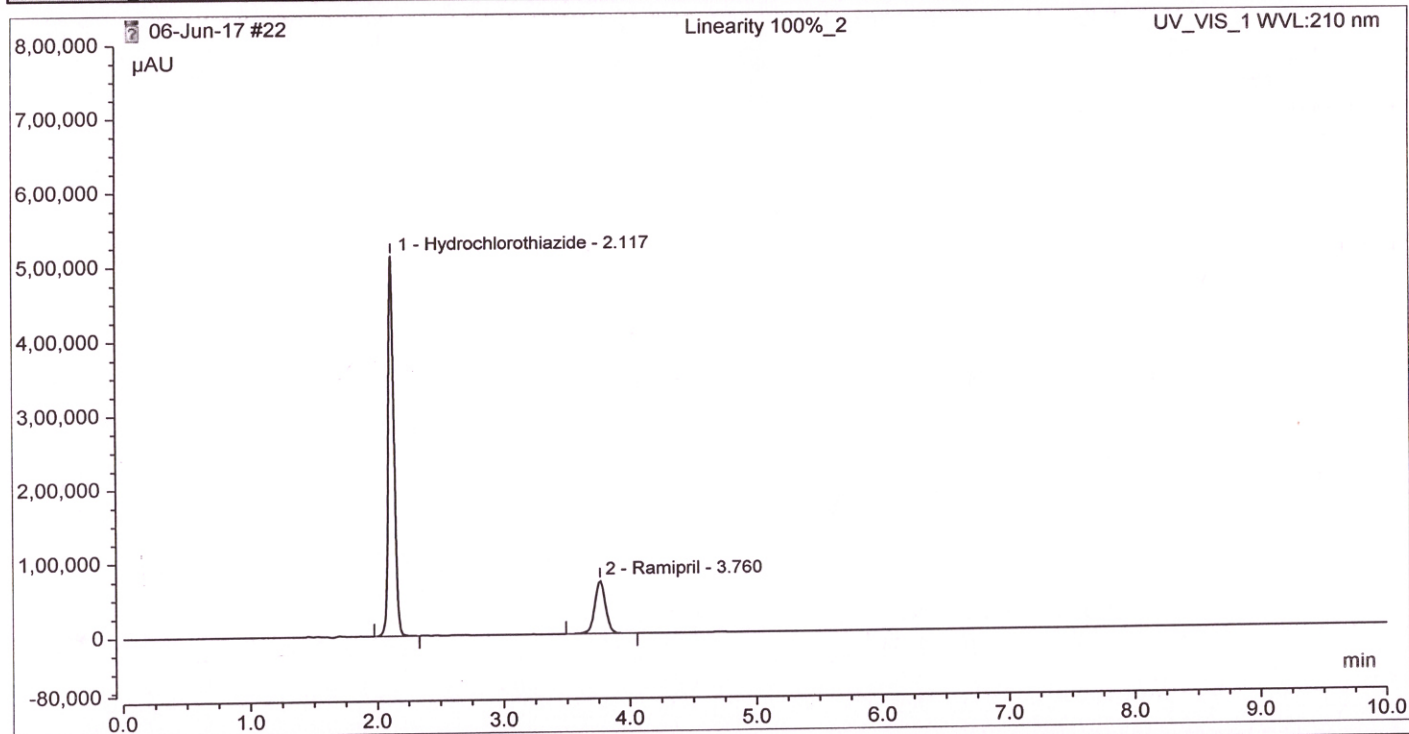
Pankaj
08-Jun-17Pankaj
10-June-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Linearity 100%_2	Run Time (min):	10.00
Vial Number:	GA6	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	07-Jun-17 00:46	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.117	27084.756	10617	1.03	14.08	79.52
2	Ramipril	3.760	6976.426	9877	1.01	n.a.	20.48
Total:							

Default/Integration

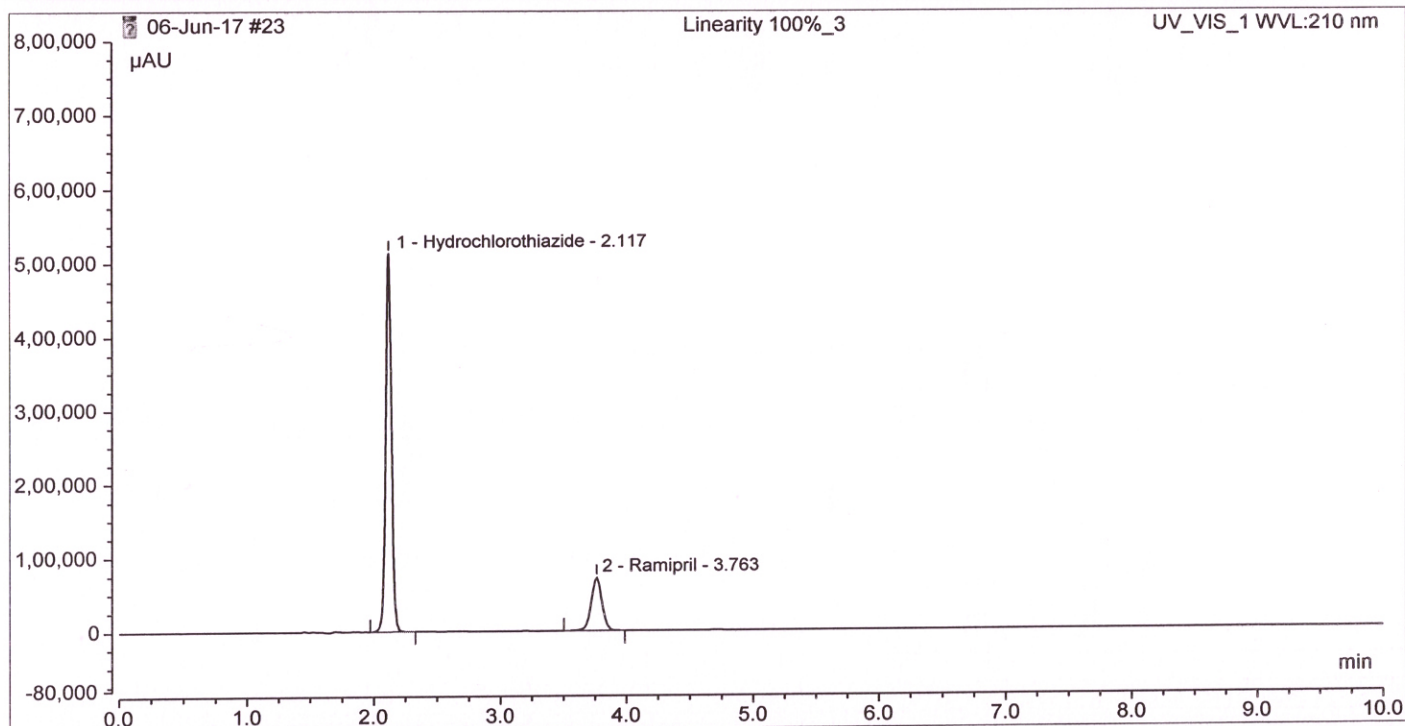
Chromeleon (c) Dionex
Version 7.2.4.8525Pankaj
08-Jun-17Pankaj
10-Jun-17

QbD Research & Developement Pvt.Ltd.

Injection Details

Injection Name:	Linearity 100%_3	Run Time (min):	10.00
Vial Number:	GA6	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	07-Jun-17 00:58	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.117	27125.449	10554	1.05	14.08	79.54
2	Ramipril	3.763	6977.616	9872	0.99	n.a.	20.46
Total:							

Default/Integration

Chromeleon (c) Dionex
Version 7.2.4.8525

Pankaj
08-Jun-17

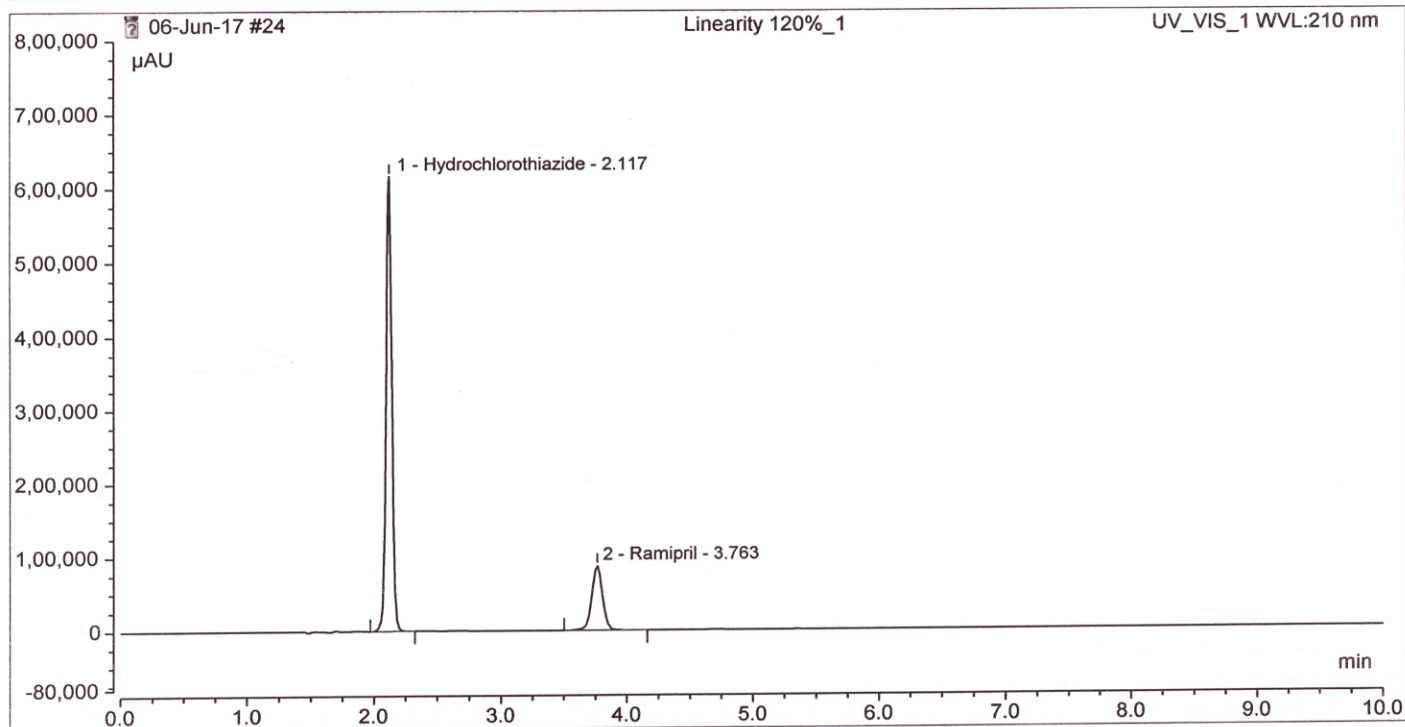
Pankaj
10-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Linearity 120%_1	Run Time (min):	10.00
Vial Number:	GA7	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	07-Jun-17 01:09	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area $\mu\text{AU} \cdot \text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.117	32725.509	10458	1.05	14.06	79.41
2	Ramipril	3.763	8484.320	9885	0.99	n.a.	20.59
Total:							

Default/Integration

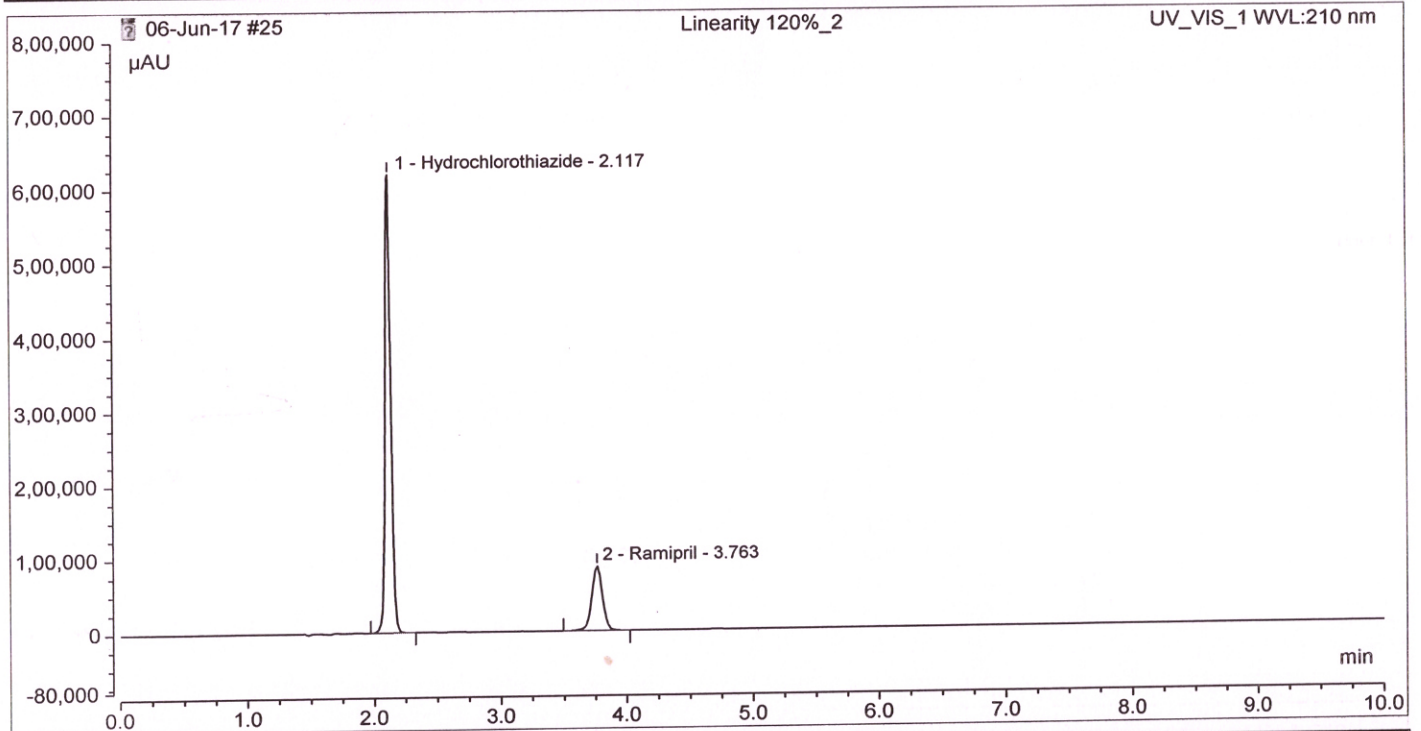
Chromeleon (c) Dionex
Version 7.2.4.8525Pankaj
08-Jun-17Rajni
10-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Linearity 120%_2	Run Time (min):	10.00
Vial Number:	GA7	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	07-Jun-17 01:21	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.117	32723.357	10593	1.04	14.11	79.43
2	Ramipril	3.763	8476.854	9928	0.99	n.a.	20.57
Total:							

Default/Integration

Chromeleon (c) Dionex
Version 7.2.4.8525Pankaj
08-Jun-17Pankaj
10-Jun-17

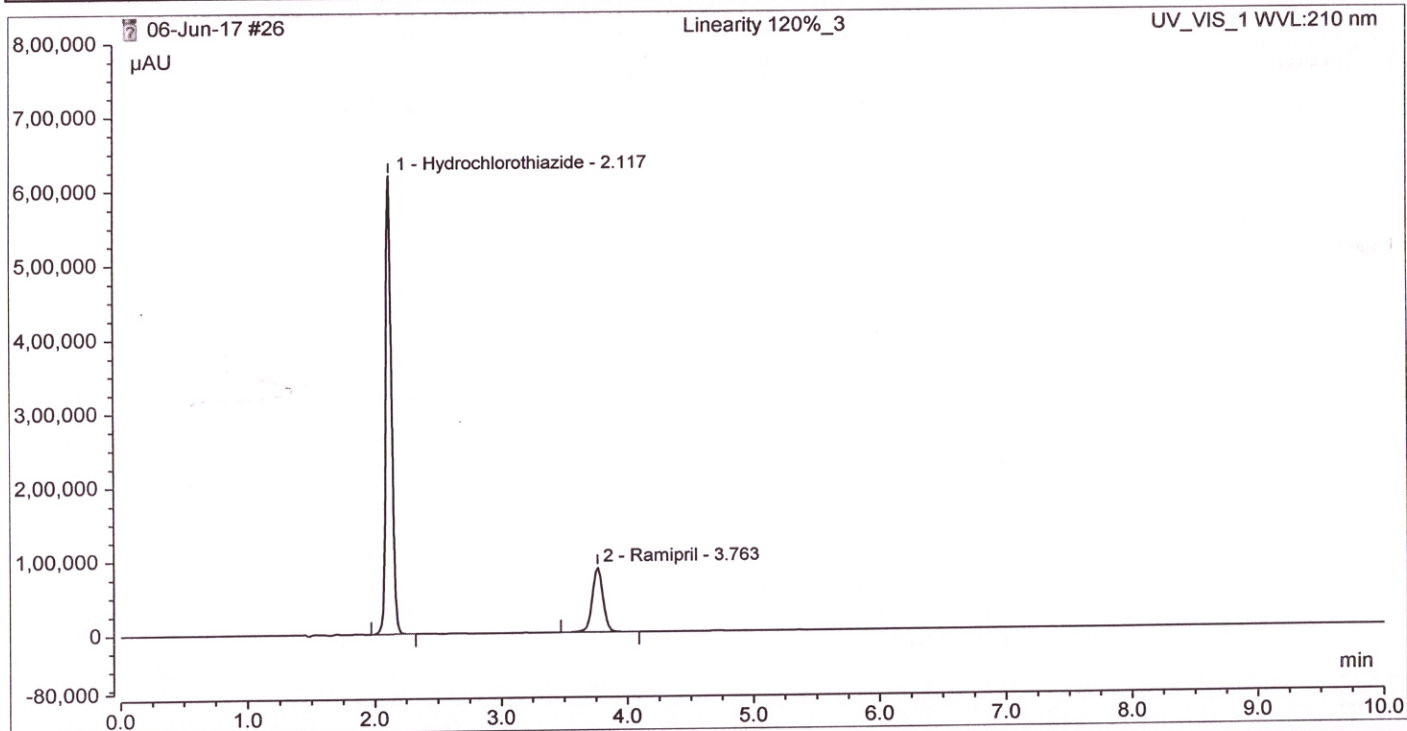
QbD Research & Developement Pvt.Ltd.

Injection Details

Injection Name: Linearity 120%_3
Vial Number: GA7
Injection Type: Unknown
Calibration Level:
Instrument Method: Ramithiazide Assay- HPLC_ 67
Processing Method: PR Method 1
Injection Date/Time: 07-Jun-17 01:33
User Name: Pankaj Gurav

Run Time (min): 10.00
Injection Volume: 10.00
Channel: UV_VIS_1
Wavelength: 210
Bandwidth: 1
Dilution Factor: 1.0000
Sample Weight: 1.0000
Sample Weight: 1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.117	32722.296	10606	1.04	14.11	79.40
2	Ramipril	3.763	8489.456	9918	0.99	n.a.	20.60
Total:							

Default/Integration

Chromeleon (c) Dionex
Version 7.2.4.8525

08-Jun-17

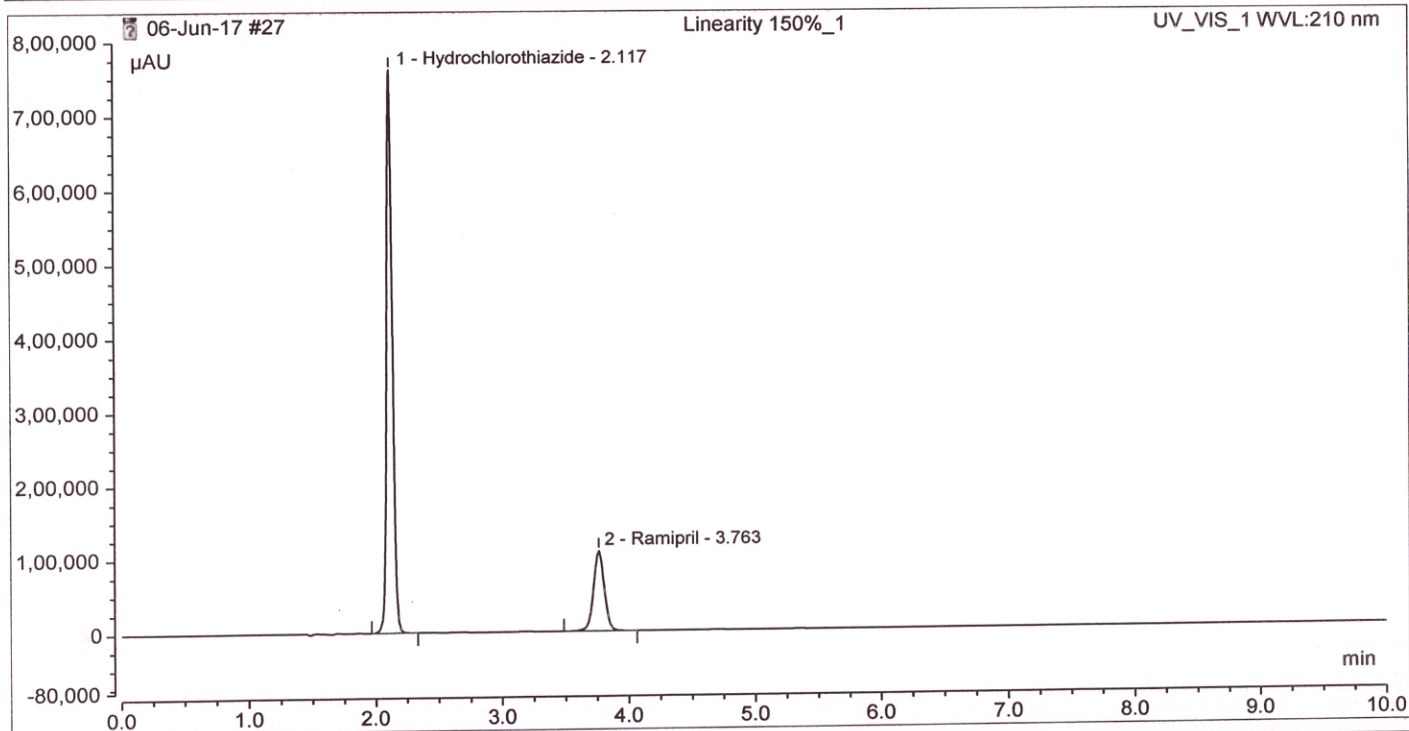
08-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Linearity 150%_1	Run Time (min):	10.00
Vial Number:	GA8	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	07-Jun-17 01:45	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.117	40376.322	10502	1.04	14.09	79.34
2	Ramipril	3.763	10516.722	9925	1.00	n.a.	20.66
Total:							

Default/Integration

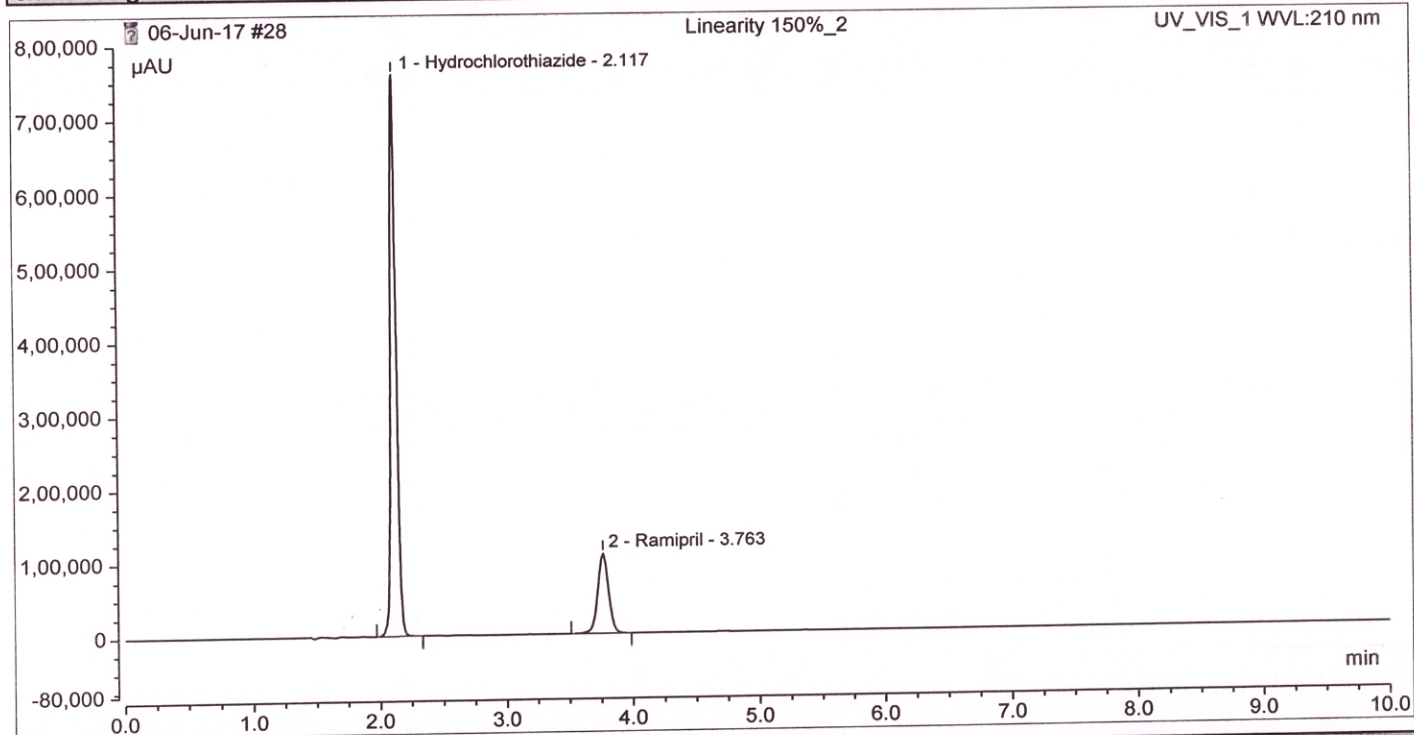
Chromleon (c) Dionex
Version 7.2.4.8525Pankaj
08-Jun-17Pankaj
10-Jun-17

QbD Research & Developement Pvt.Ltd.

Injection Details

Injection Name:	Linearity 150%_2	Run Time (min):	10.00
Vial Number:	GA8	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	07-Jun-17 01:57	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area % -
1	Hydrochlorothiazide	2.117	40480.045	10404	1.05	14.06	79.35
2	Ramipril	3.763	10531.706	9899	1.00	n.a.	20.65
Total:							

Default/Integration

 Chromeleon (c) Dionex
 Version 7.2.4.8525

 Pankaj
 08-Jun-17

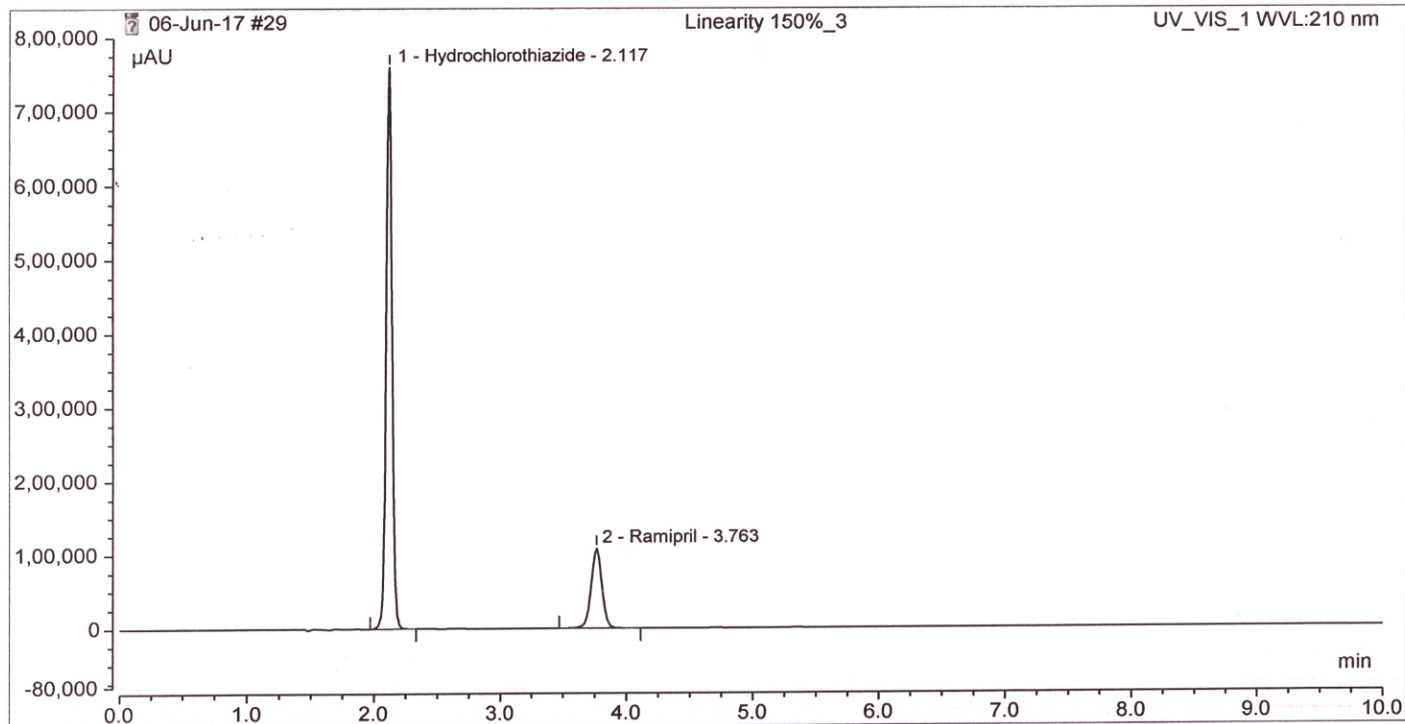
 Pankaj
 10-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Linearity 150%_3	Run Time (min):	10.00
Vial Number:	GA8	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	07-Jun-17 02:08	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.117	40458.462	10413	1.05	14.06	79.33
2	Ramipril	3.763	10542.009	9912	1.00	n.a.	20.67
Total:							

Default/Integration

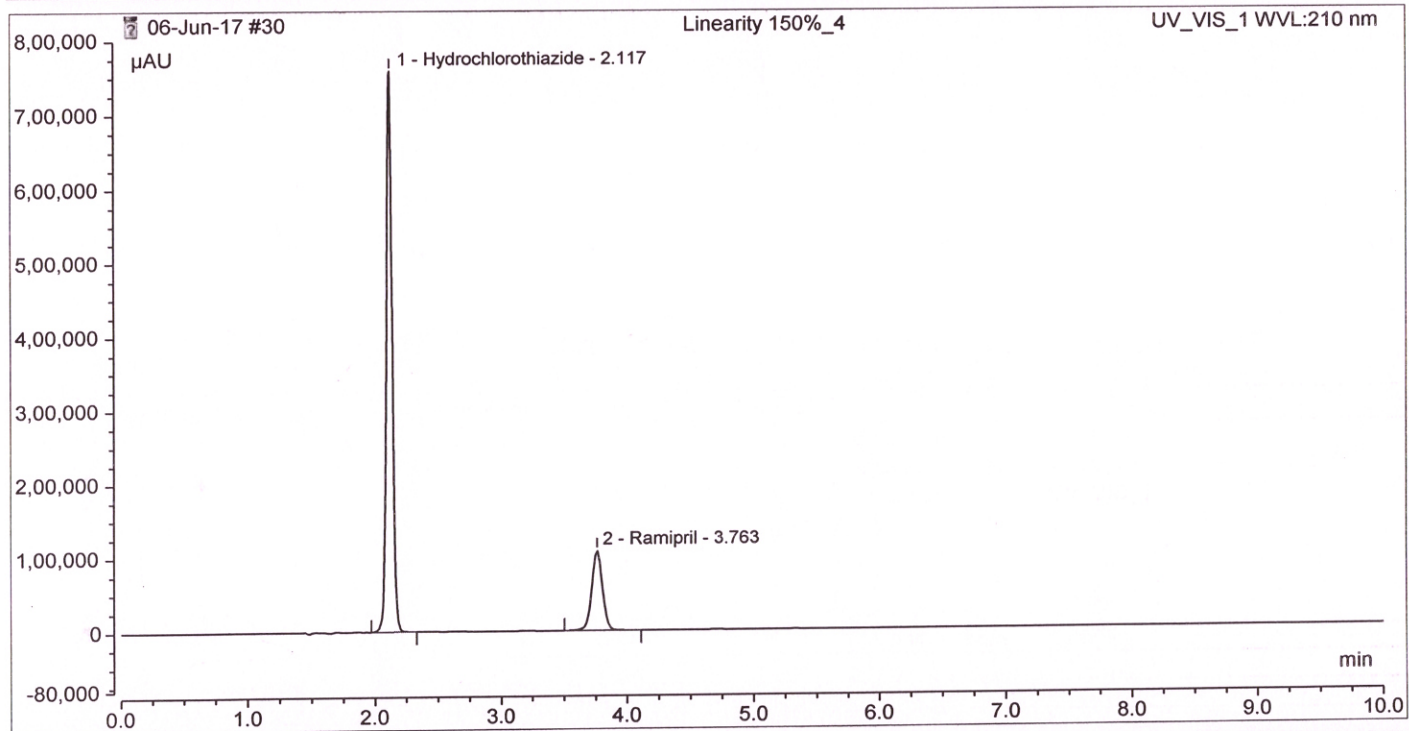
Chromeleon (c) Dionex
Version 7.2.4.8525Pankaj
08-Jun-17Pankaj
10-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Linearity 150%_4	Run Time (min):	10.00
Vial Number:	GA8	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	07-Jun-17 02:20	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.117	40360.603	10467	1.04	14.08	79.36
2	Ramipril	3.763	10499.757	9921	0.99	n.a.	20.64
Total:							

Default/Integration

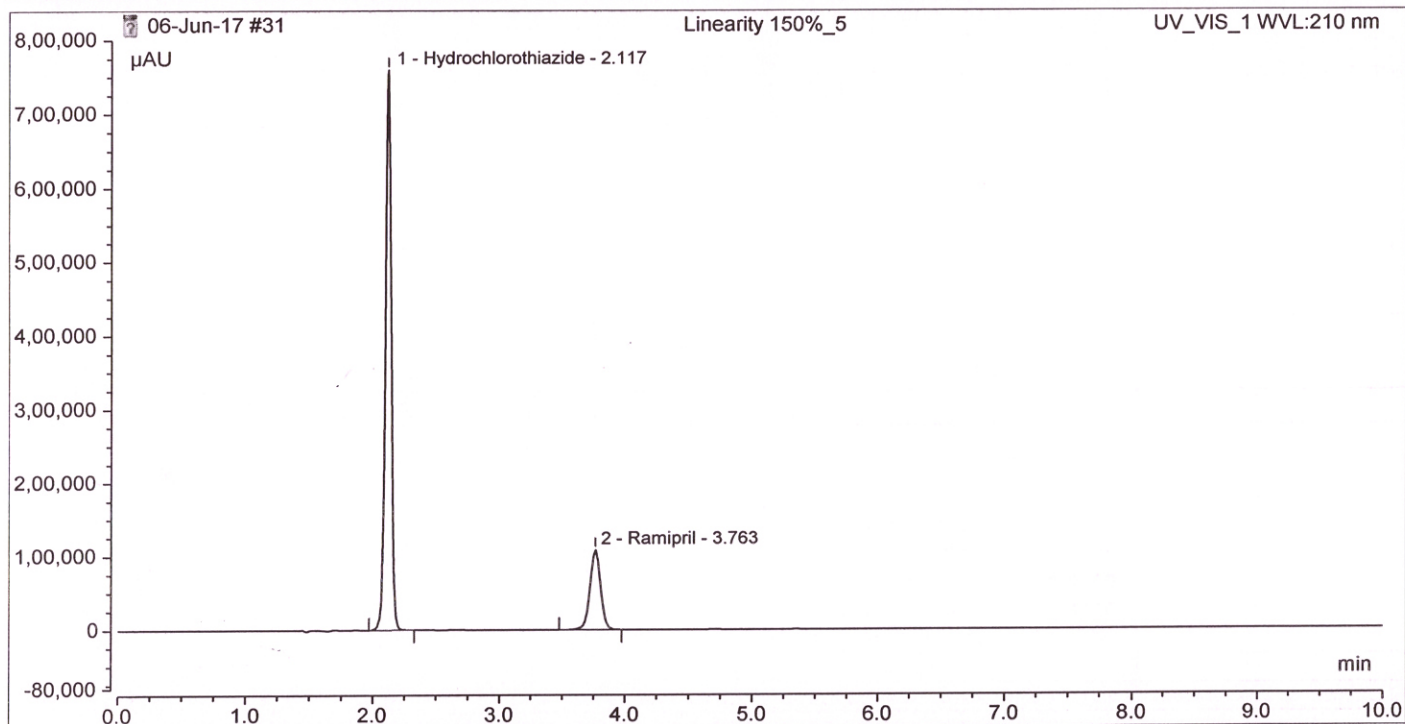
Chromeleon (c) Dionex
Version 7.2.4.8525Pankaj
08-Jun-17Pankaj
10-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Linearity 150%_5	Run Time (min):	10.00
Vial Number:	GA8	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	07-Jun-17 02:32	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.117	40379.248	10456	1.05	14.08	79.35
2	Ramipril	3.763	10505.742	9916	1.00	n.a.	20.65
Total:							

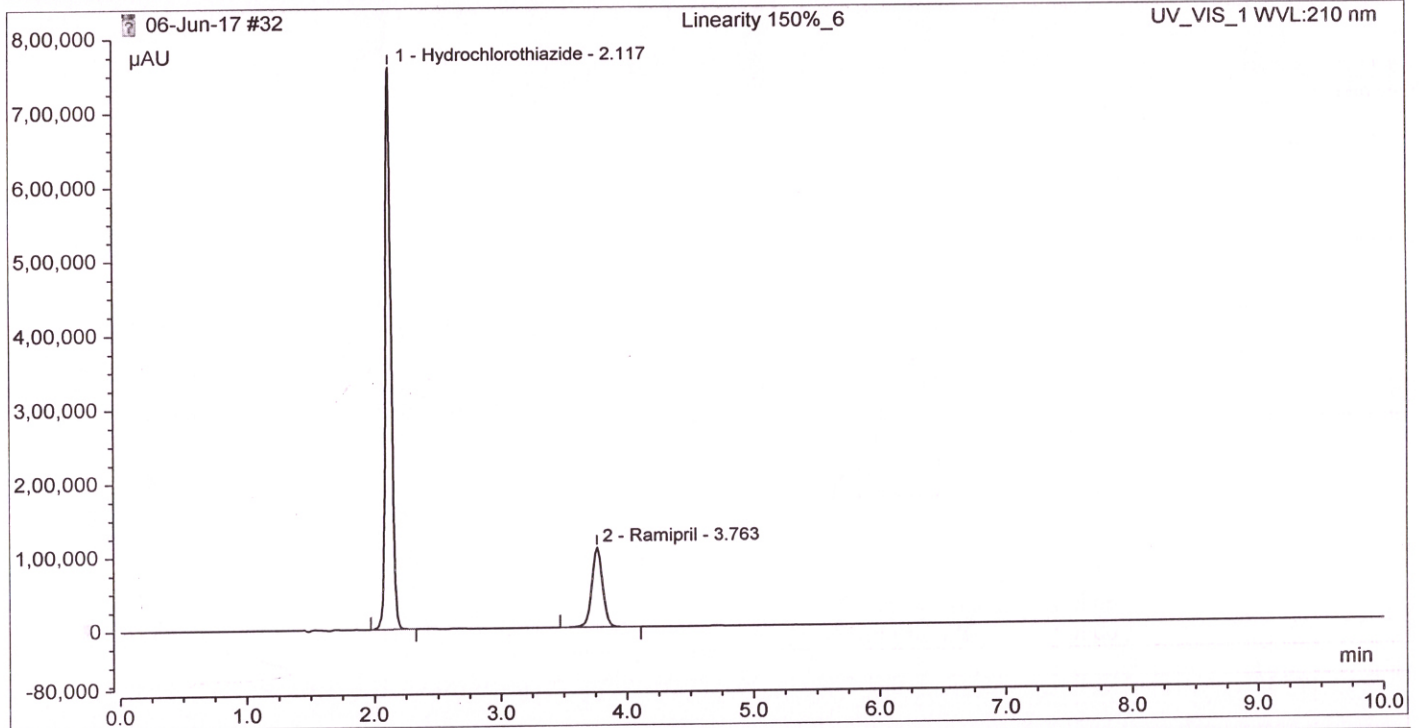
Pankaj Gurav
08-Jun-17Pankaj Gurav
10-Jun-17

QbD Research & Developement Pvt.Ltd.

Injection Details

Injection Name:	Linearity 150%_6	Run Time (min):	10.00
Vial Number:	GA8	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	07-Jun-17 02:44	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.117	40288.613	10533	1.04	14.10	79.31
2	Ramipril	3.763	10510.904	9932	1.01	n.a.	20.69
Total:							

Default/Integration

Pankaj Gurav
08-Jun-17

Chromeleon (c) Dionex
Version 7.2.4.8525

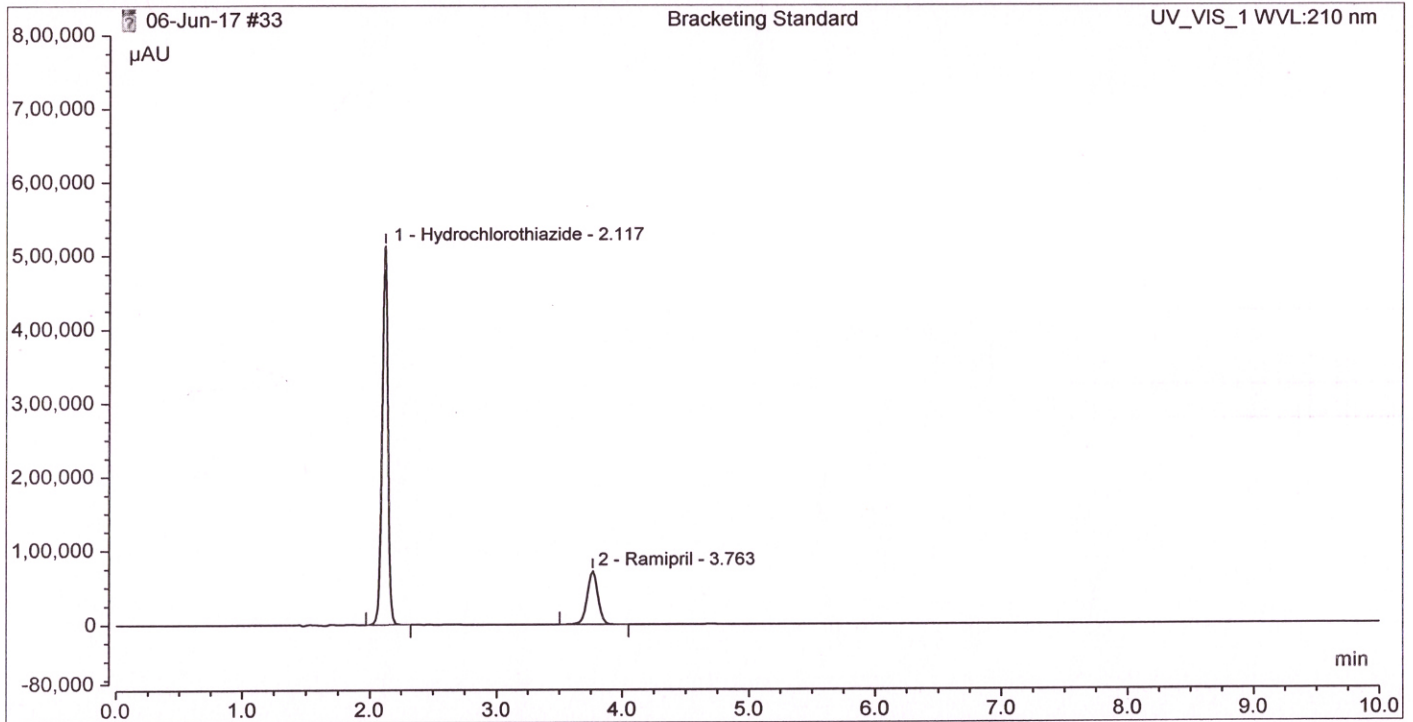
Aliyari
10-Jun-17

QbD Research & Developement Pvt.Ltd.

Injection Details

Injection Name:	Bracketing Standard	Run Time (min):	10.00
Vial Number:	GA2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 67	Bandwidth:	1
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	07-Jun-17 02:55	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area $\mu\text{AU} \cdot \text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.117	27111.735	10558	1.04	14.08	79.54
2	Ramipril	3.763	6975.678	9882	1.00	n.a.	20.46
Total:							

Pankaj
08-Jun-17Pankaj
10-Jun-17

V_VIS	Name	Position	Volume [µl]	Instrument Method	Processing Method	Status	Comment	Inject Time
None	Pre SST	GA2	10.000	Ramithiazide Assay- HPLC_ 67	PR Method_ 1	Finished		06-Jun-2017 20:07 +05:30
None	Blank	GA1	10.000	Ramithiazide Assay- HPLC_ 67	PR Method 1	Idle	Linearity	
None	Standard 1	GA2	10.000	Ramithiazide Assay- HPLC_ 67	PR Method 1	Idle	Linearity	
None	Standard 2	GA2	10.000	Ramithiazide Assay- HPLC_ 67	PR Method 1	Idle	Linearity	
None	Standard 3	GA2	10.000	Ramithiazide Assay- HPLC_ 67	PR Method 1	Idle	Linearity	
None	Standard 4	GA2	10.000	Ramithiazide Assay- HPLC_ 67	PR Method 1	Idle	Linearity	
None	Standard 5	GA2	10.000	Ramithiazide Assay- HPLC_ 67	PR Method 1	Idle	Linearity	
None	Standard 6	GA2	10.000	Ramithiazide Assay- HPLC_ 67	PR Method 1	Idle	Linearity	
None	Linearity 25%_1	GA3	10.000	Ramithiazide Assay- HPLC_ 67	PR Method 1	Idle	Linearity	
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None	Linearity 80%_2	GA5	10.000	Ramithiazide Assay- HPLC_ 67	PR Method 1	Idle	Linearity	
None	Linearity 80%_3	GA5	10.000	Ramithiazide Assay- HPLC_ 67	PR Method 1	Idle	Linearity	
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None	Linearity 150%_5	GA8	10.000	Ramithiazide Assay- HPLC_ 67	PR Method 1	Idle	Linearity	
None	Linearity 150%_6	GA8	10.000	Ramithiazide Assay- HPLC_ 67	PR Method 1	Idle	Linearity	
None	Bracketing Standard	GA2	10.000	Ramithiazide Assay- HPLC_ 67	PR Method 1	Idle	Linearity	
None	Wash	GA1	10.000	Wash method _HPLC 67 _New	PR Method 1	Idle	Linearity	
None	Shut	GA1	10.000	Shut method _HPLC 67 _New	PR Method 1	Idle	Linearity	

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Name	Ramithiazide Assay- HPLC_ 67
Data Vault	XVault
Path	chrom://qbd-pc-19/XVault/QbD-INST-HPLC-67/101/06-Jun-17.seq/Ramithiazide Assay- HPLC_ 67.instmeth
Comment	Ramithiazide
Description	
Run time	10.000 [min]
Instrument	QbD-INST-HPLC-67 on qbd-pc-19
Created	15-May-2017 18:22 +05:30 Santosh Padmere
Last Update	03-Jun-2017 20:30 +05:30 Sachin Pujari


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Stage	Time min	Command	Value	Comment
Instrument Setup				
	initial	DAD.3DFIELD.MinWavelength	190.0 [nm]	
		DAD.3DFIELD.MaxWavelength	400.0 [nm]	
		DAD.3DFIELD.BunchWidth	1 [nm]	
		DAD.ResponseTime	1.000 [s]	
		DAD.Data_Collection_Rate	5 [Hz]	
		ColumnOven.TempCtrl	On	
		ColumnOven.Temperature.Nominal	25.0 [°C]	
		ColumnOven.Temperature.LowerLimit	5.0 [°C]	
		ColumnOven.Temperature.UpperLimit	80.0 [°C]	
		ColumnOven.EquilibrationTime	0.5 [min]	
		ColumnOven.ReadyTempDelta	1.1 [°C]	
		ColumnOven.Column_A.ActiveColumn	No	
		ColumnOven.Column_A.SystemPressure	"Pump"	
		ColumnOven.Column_B.ActiveColumn	No	
		ColumnOven.Column_B.SystemPressure	"Pump"	
		Sampler.InjectWash	Both	
		Sampler.WashSpeed	20.000 [µl/s]	
		Sampler.WashVolume	200.000 [µl]	
		Sampler.SampleHeight	2.000 [mm]	
		Sampler.WasteSpeed	32.000 [µl/s]	
		Sampler.DispenseDelay	0.000 [s]	
		Sampler.DispSpeed	20.000 [µl/s]	
		Sampler.DrawSpeed	5.000 [µl/s]	
		Sampler.DrawDelay	3.000 [s]	
		Sampler.InjectMode	Normal	
		Sampler.PumpDevice	"Pump"	
		Sampler.SyncWithPump	On	
		Sampler.LoopWashFactor	2.000	
		Sampler.TempCtrl	On	
		Sampler.Temperature.Nominal	25.0 [°C]	
		Sampler.ReadyTempDelta	1.5 [°C]	
		Sampler.Temperature.LowerLimit	4.0 [°C]	
		Sampler.Temperature.UpperLimit	45.0 [°C]	
		PumpModule.Pump.%A.Equate	"%A"	
		PumpModule.Pump.%B.Equate	"%B"	
		PumpModule.Pump.%C.Equate	"%C"	
		PumpModule.Pump.%D.Equate	"%D"	
		PumpModule.Pump.Pressure.LowerLimit	0 [bar]	
		PumpModule.Pump.Pressure.UpperLimit	600 [bar]	
		PumpModule.Pump.MaximumFlowRampUp	6.000 [ml/min²]	
		PumpModule.Pump.MaximumFlowRampDown	5.998 [ml/min²]	
		DAD.UV_VIS_1.Wavelength	210.0 [nm]	

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		DAD.UV_VIS_1.Bandwidth	1 [nm]
		DAD.UV_VIS_1.RefWavelength	Off
		DAD.UV_VIS_1.RefBandwidth	1 [nm]
		DAD.UV_VIS_2.RefWavelength	Off
		DAD.UV_VIS_3.RefWavelength	Off
		DAD.UV_VIS_2.Wavelength	230.0 [nm]
		DAD.UV_VIS_3.Wavelength	234.0 [nm]
		DAD.UV_VIS_2.Bandwidth	1 [nm]
		DAD.UV_VIS_3.Bandwidth	1 [nm]
		DAD.UV_VIS_2.RefBandwidth	1 [nm]
		DAD.UV_VIS_3.RefBandwidth	1 [nm]
		DAD.3DFIELD.RefWavelength	800.0 [nm]
		DAD.3DFIELD.RefBandwidth	1 [nm]
Inject Preparation	0.000		
		DAD.Autozero	
		Wait	DAD.Ready And ColumnOven.Re ady And Sampler.Ready And PumpModule.Pu mp.Ready
Inject	0.000		
		Sampler.Inject	
Start Run	0.000		
		DAD.UV_VIS_1.AcqOn	
		DAD.Temp_Lamphouse.AcqOn	
		ColumnOven.ColumnOven_Temp.AcqOn	
		PumpModule.Pump.Pump_Pressure.AcqOn	
		DAD.UV_VIS_2.AcqOn	
		DAD.UV_VIS_3.AcqOn	
		DAD.3DFIELD.AcqOn	
Run	0.000		Duration = 10.000 [min]
		PumpModule.Pump.Flow.Nominal	1.000 [ml/min]
		PumpModule.Pump.%B.Value	0.0 [%]
		PumpModule.Pump.%C.Value	0.0 [%]
		PumpModule.Pump.%D.Value	0.0 [%]
		PumpModule.Pump.Curve	5
	10.000		
		PumpModule.Pump.Flow.Nominal	1.000 [ml/min]
		PumpModule.Pump.%B.Value	0.0 [%]
		PumpModule.Pump.%C.Value	0.0 [%]
		PumpModule.Pump.%D.Value	0.0 [%]
		PumpModule.Pump.Curve	5
Stop Run			

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```
10.000
DAD.UV_VIS_1.AcqOff
DAD.Temp_Lamphouse.AcqOff
ColumnOven.ColumnOven_Temp.AcqOff
PumpModule.Pump.Pump_Pressure.AcqOff

DAD.UV_VIS_2.AcqOff
DAD.UV_VIS_3.AcqOff
DAD.3DFIELD.AcqOff

End
```


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