

ASSAY METHOD VALIDATION

Product name :	Ramithiazide Tablet
Strength :	Ramipril and Hydrochlorothiazide
B. No. :	GP170403
Parameter :	Accuracy of Ramipril
LNB No./Pg. No.:	419/038
Lable claim (mg) :	10

Analysis Date:	8-Jun-17
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Name of standard	Standard purity(%)
Ramipril	99.8

Standard solution:	25.90	mg of Std diluted to	25	ml. with diluent
	2.0	ml. diluted to	100	ml. with diluent

Replicates	RT of HCTZ	Area of HCTZ	RT of Ramipril	Area of Ramipril
1	2.178	14022.153	4.001	9381.447
2	2.180	14027.302	4.000	9400.843
3	2.178	14026.195	4.001	9409.596
4	2.178	14034.324	4.001	9379.922
5	2.180	14039.880	4.003	9388.428
6	2.179	14037.851	4.005	9367.595
Average	2.179	14031.284	4.002	9387.972
SD	0.001	7.091	0.002	15.206
%RSD	0.05	0.05	0.05	0.16

System suitability results of Ramipril		
% RSD of Ramipril	0.16	NMT 2.0%
Theretical plates of Ramipril	5585	NLT 2000
Tailing factor of Ramipril	1.12	NMT 2.0

Level	Level (%)	Standard wt in mg	Diluted to volume (mL)	Taken Solution From	Diluted to volume	Actual Concentration
1	50	13.34	250	5.0	25	10.7
2	50	13.13	250	5.0	25	10.5
3	50	13.39	250	5.0	25	10.7
1	100	24.77	250	5.0	25	19.8
2	100	24.82	250	5.0	25	19.9
3	100	24.79	250	5.0	25	19.8
1	150	37.77	250	5.0	25	30.2
2	150	37.60	250	5.0	25	30.1
3	150	37.68	250	5.0	25	30.1

Accuracy level (%)	Sample	Placebo weight (mg)	Amount added(ppm)	Area	Amount recovered (ppm)	% Recovery	Mean % Recovery	% RSD
50	Sample 1	468.98	10.67	4897.906	10.79	101.1	101.1	0.51
	Sample 2	464.81	10.50	4799.095	10.57	100.6		
	Sample 3	464.26	10.71	4944.512	10.89	101.7		
100	Sample 1	465.19	19.82	8820.949	19.43	98.1	98.5	0.50
	Sample 2	465.46	19.86	8925.371	19.66	99.0		
	Sample 3	463.59	19.83	8855.191	19.51	98.4		
150	Sample 1	463.84	30.22	13783.487	30.36	100.5	100.7	0.22
	Sample 2	465.65	30.08	13782.042	30.36	100.9		
	Sample 3	463.80	30.14	13787.558	30.37	100.7		

Done by:
Date:

Baner
09-Jun-17

Checked by:
Date:

Opam
09-Jun-17

ASSAY METHOD VALIDATION

Product name :	Ramithiazide Tablet
Strength :	Ramipril and Hydrochlorothiazide
B. No. :	GP170403
Parameter :	Accuracy of Hydrochlorothiazide
LNB No./Pg. No.:	419/038
Label claim (mg) :	25

Analysis Date:	8-Jun-17
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Name of standard	Standard purity(%)
Hydrochlorothiazide	99.9

Standard solution:	25.45	mg of Std diluted to	25	mL with diluent
	5.0	mL diluted to	100	mL with diluent

Replicates	RT of HCTZ	Area of HCTZ	RT of Ramipril	Area of Ramipril
1	2.178	14022.153	4.001	9381.447
2	2.180	14027.302	4.000	9400.843
3	2.178	14026.195	4.001	9409.596
4	2.178	14034.324	4.001	9379.922
5	2.180	14039.880	4.003	9388.428
6	2.179	14037.851	4.005	9367.595
Average	2.179	14031.284	4.002	9387.972
SD	0.001	7.091	0.002	15.206
%RSD	0.05	0.05	0.05	0.16

System suitability results of Hydrochlorothiazide		
% RSD of HCTZ	0.05	NMT 2.0%
Theoretical plates of HCTZ	3904	NLT 2000
Tailing factor of HCTZ	1.30	NMT 2.0

Preparation of Accuracy level

Level	Level (%)	Standard wt in mg	Diluted to volume (mL)	Taken Solution From Stock Solution in ml	Diluted to volume (mL)	Actual Concentration (ppm)
1	50	32.86	250	5.0	25	26.3
2	50	31.70	250	5.0	25	25.4
3	50	33.30	250	5.0	25	26.6
1	100	62.59	250	5.0	25	50.1
2	100	63.20	250	5.0	25	50.6
3	100	62.65	250	5.0	25	50.1
1	150	93.83	250	5.0	25	75.1
2	150	93.69	250	5.0	25	75.0
3	150	93.82	250	5.0	25	75.1

Accuracy level (%)	Sample	Placebo weight (mg)	Amount added(ppm)	Area	Amount recovered (ppm)	% Recovery	Mean % Recovery	% RSD
50	Sample 1	468.98	26.29	7354.546	26.65	101.4	101.2	0.41
	Sample 2	464.81	25.36	7050.771	25.55	100.8		
	Sample 3	464.26	26.64	7464.556	27.05	101.5		
100	Sample 1	465.19	50.07	14024.138	50.82	101.5	101.6	0.17
	Sample 2	465.46	50.56	14206.420	51.48	101.8		
	Sample 3	463.59	50.12	14046.120	50.90	101.6		
150	Sample 1	463.84	75.06	20957.790	75.95	101.2	101.3	0.18
	Sample 2	465.65	74.95	20998.029	76.10	101.5		
	Sample 3	463.80	75.06	20970.367	76.00	101.3		

Done by:
Date:

P. Kumar
09-Jun-17

Checked by:
Date:

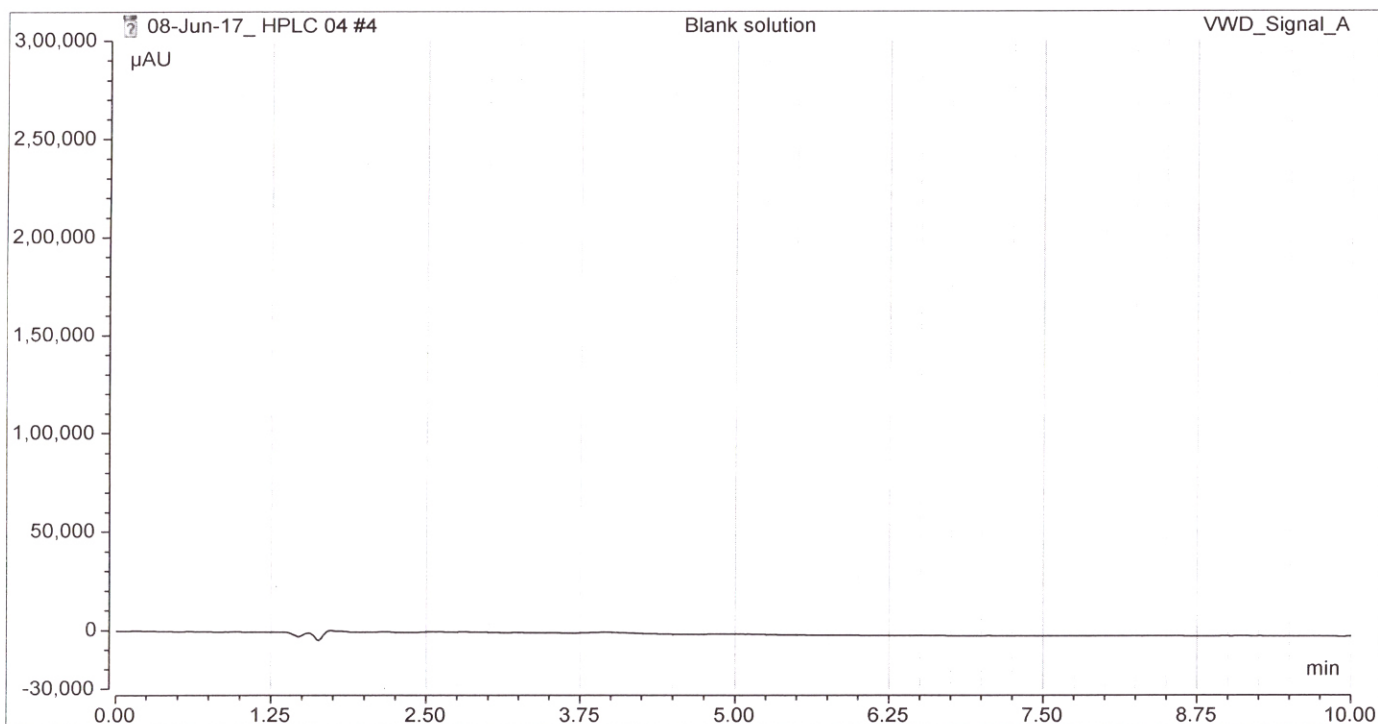
Dr. M. S. Kumar
09-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Blank solution	Run Time (min):	10.00
Vial Number:	Vial:1	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	VWD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 04	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	08-Jun-17 22:38	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 %
Total:							

Default/Integration

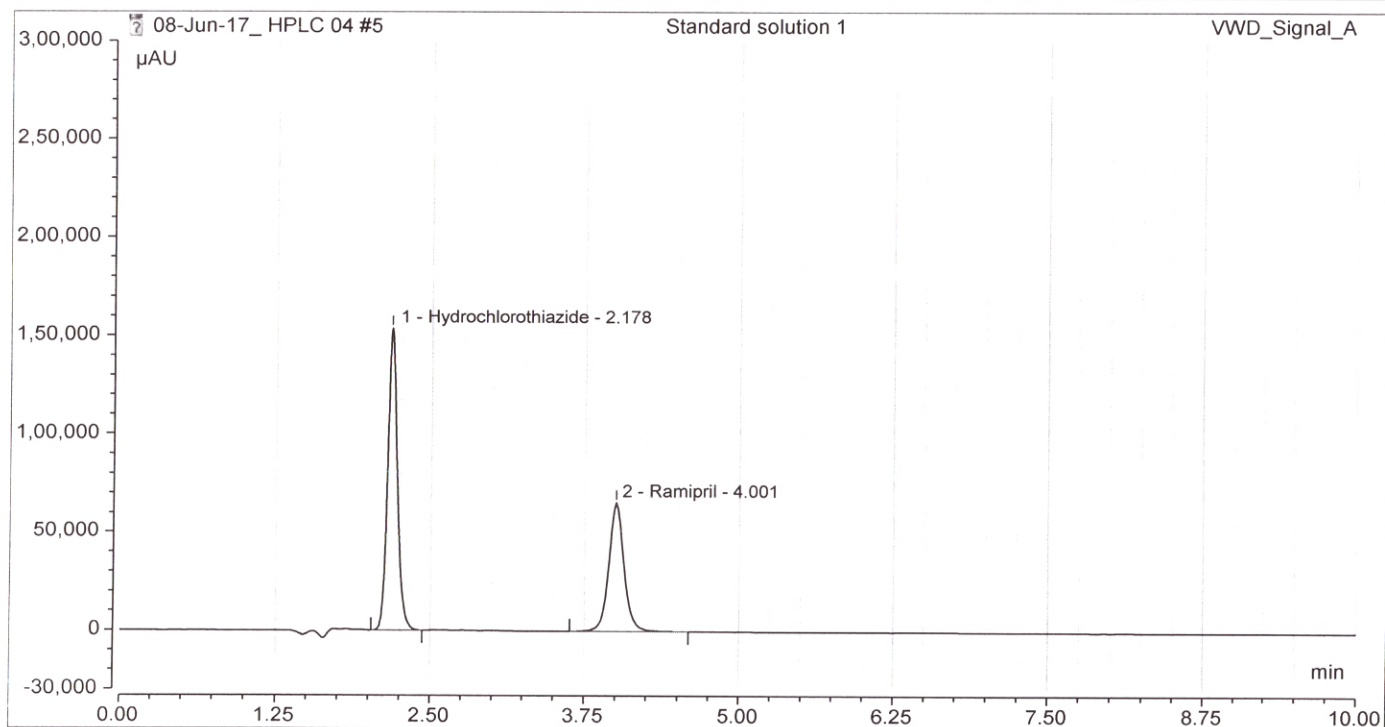
Chromeleon (c) Dionex
Version 7.2.4.8525

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Standard solution 1	Run Time (min):	10.00
Vial Number:	Vial:2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	VWD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 04	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	08-Jun-17 22:50	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 %
1	Hydrochlorothiazide	2.178	14022.153	3904	1.30	10.31	59.91
2	Ramipril	4.001	9381.447	5585	1.12	n.a.	40.09
Total:							

Pankaj Gurav
09-Jun-17

Default/Integration

Pankaj Gurav
12-Jun-17

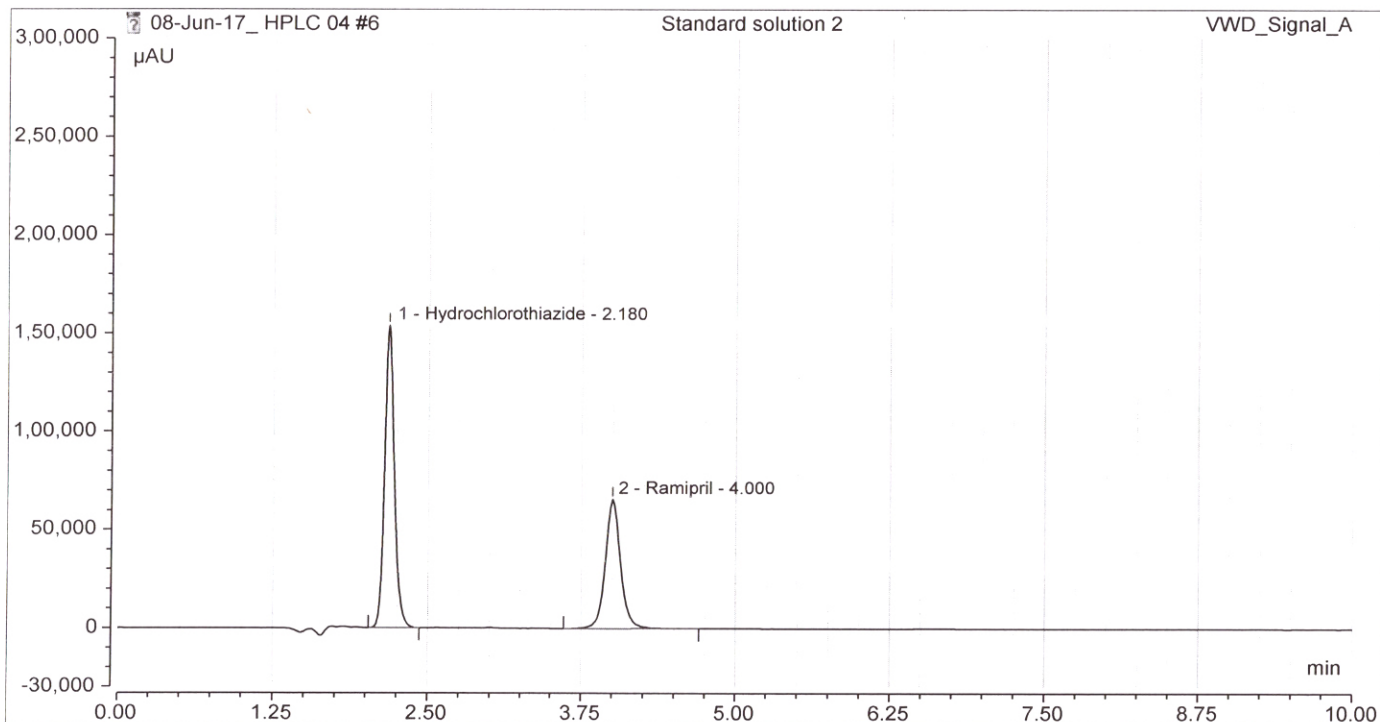
Chromeleon (c) Dionex
Version 7.2.4.8525

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Standard solution 2	Run Time (min):	10.00
Vial Number:	Vial:2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	VWD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_04	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	08-Jun-17 23:01	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	2.180	14027.302	3911	1.26	10.30	59.87
2	Ramipril	4.000	9400.843	5594	1.12	n.a.	40.13
Total:							

09-Jun-17

Default/Integration

09-Jun-17

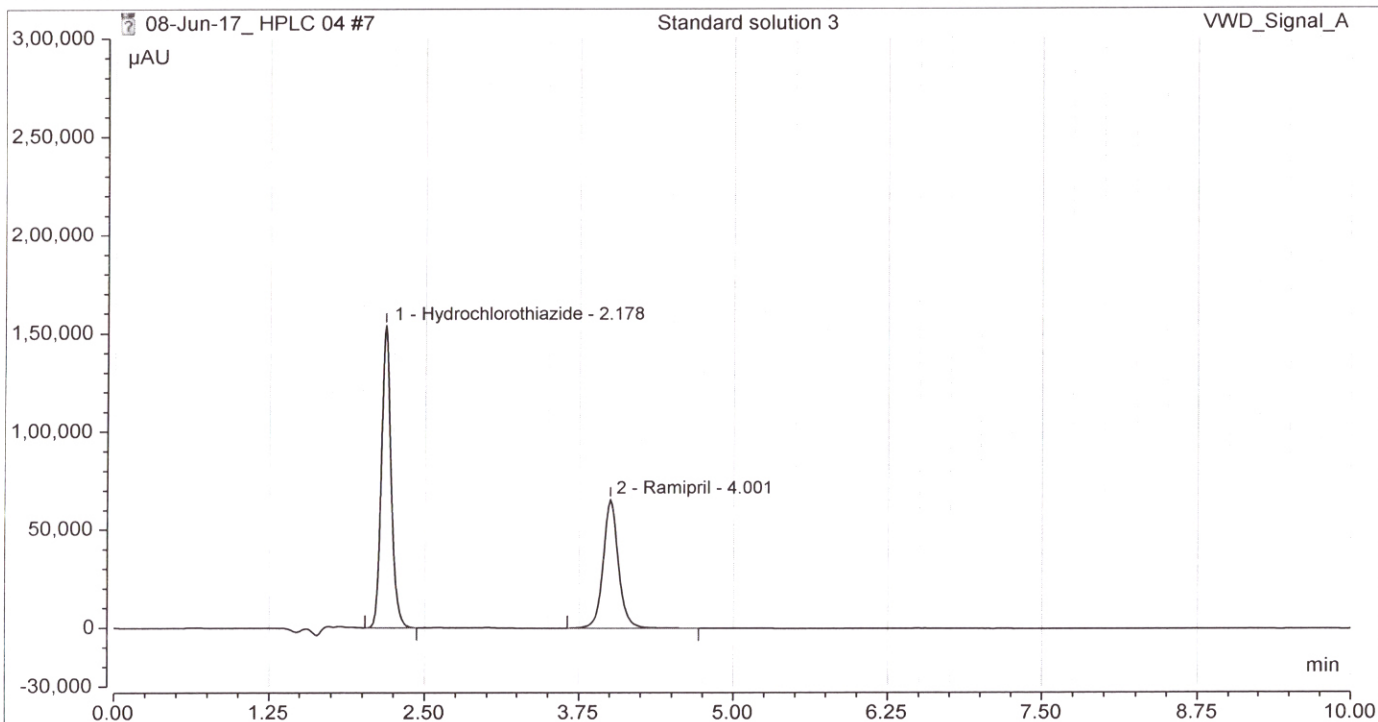
Chromeleon (c) Dionex
Version 7.2.4.8525

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Standard solution 3	Run Time (min):	10.00
Vial Number:	Vial:2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	VWD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_04	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	08-Jun-17 23:13	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

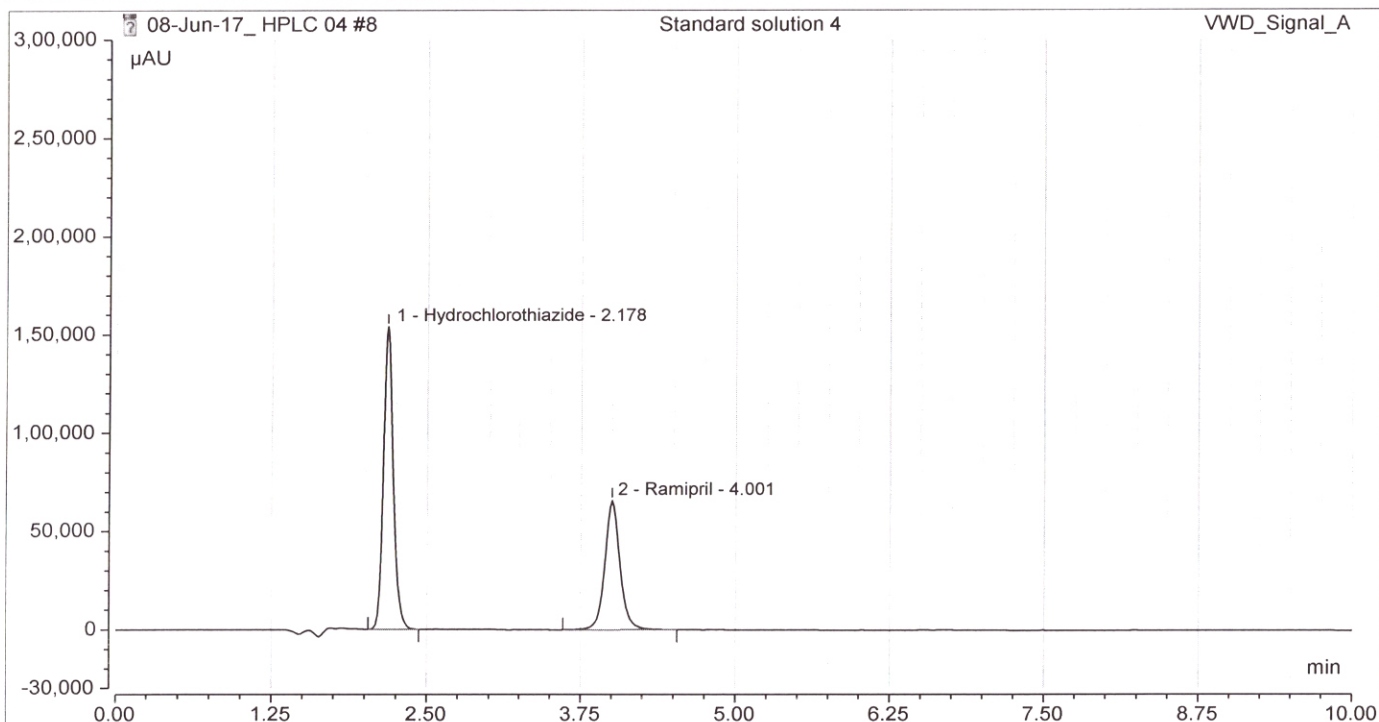
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.178	14026.195	3905	1.29	10.32	59.85
2	Ramipril	4.001	9409.596	5602	1.12	n.a.	40.15
Total:							

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Standard solution 4	Run Time (min):	10.00
Vial Number:	Vial:2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	VWD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 04	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	08-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	2.178	14034.324	3901	1.29	10.32	59.94
2	Ramipril	4.001	9379.922	5593	1.11	n.a.	40.06
Total:							

Pankaj Gurav
08-Jun-17

Default/Integration

Pankaj Gurav
12-Jun-17

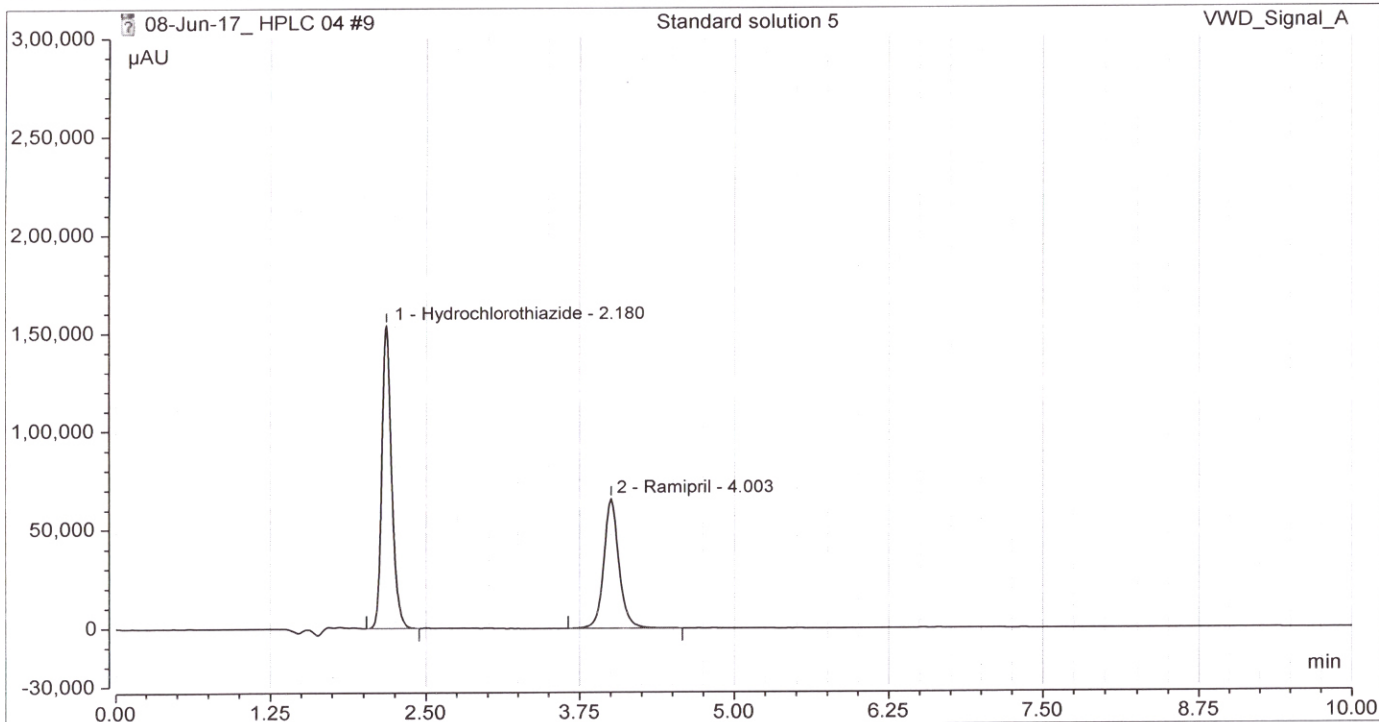
Chromeleon (c) Dionex
Version 7.2.4.8525

QbD Research & Developement Pvt.Ltd.

Injection Details

Injection Name:	Standard solution 5	Run Time (min):	10.00
Vial Number:	Vial:2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	VWD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 04	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	08-Jun-17 23:36	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	2.180	14039.880	3902	1.26	10.32	59.93
2	Ramipril	4.003	9388.428	5604	1.10	n.a.	40.07
Total:							

Pankaj Gurav
09-Jun-17

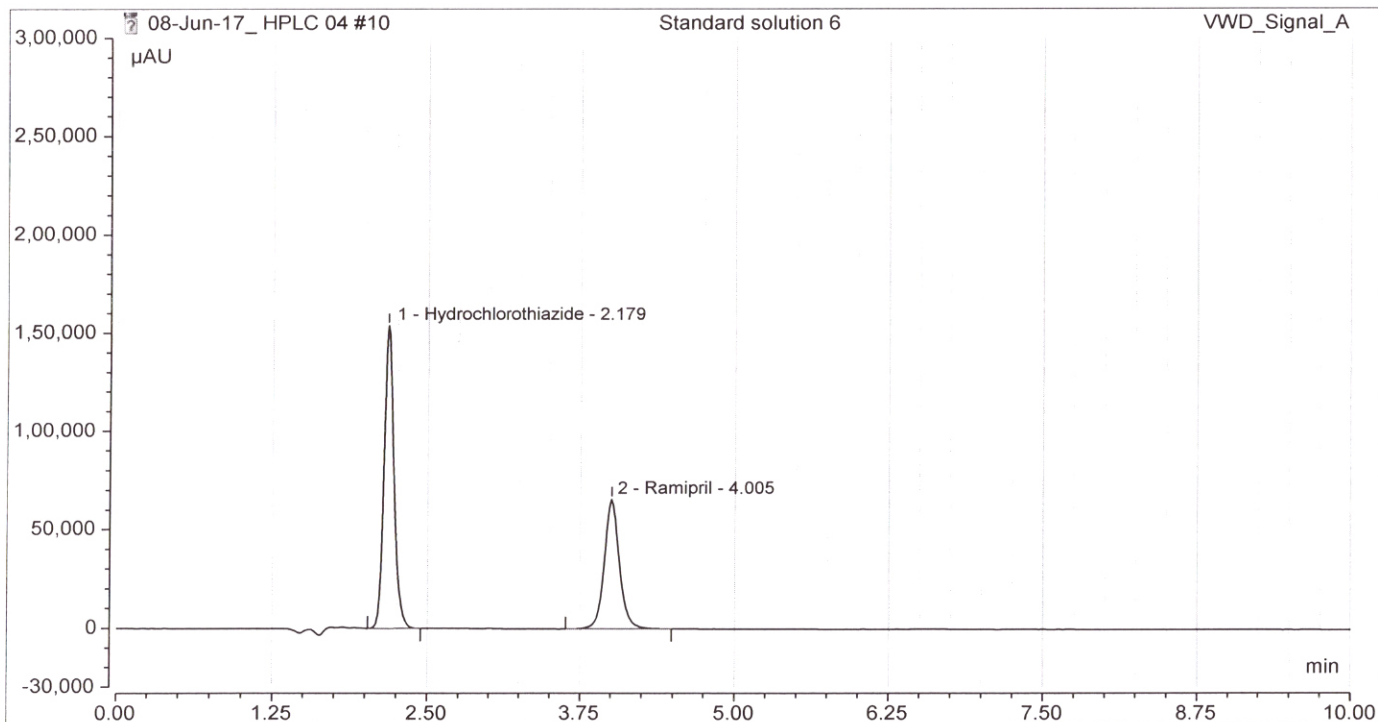
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12-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Standard solution 6	Run Time (min):	10.00
Vial Number:	Vial:2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	VWD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_04	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	08-Jun-17 23:47	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

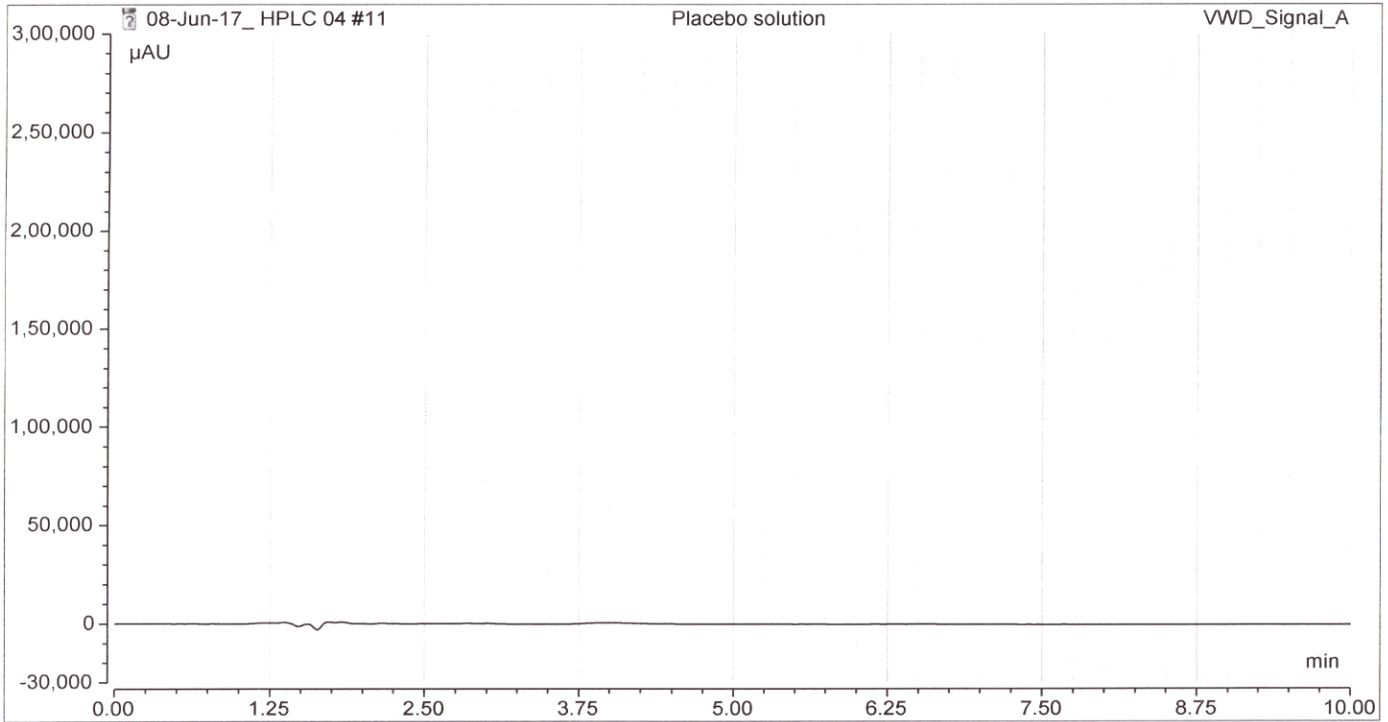
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.179	14037.851	3902	1.30	10.33	59.98
2	Ramipril	4.005	9367.595	5604	1.10	n.a.	40.02
Total:							

Pankaj
09-Jun-17

Pankaj
12-Jun-17

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

Injection Name:	Placebo solution	Run Time (min):	10.00
Vial Number:	Vial:3	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	VWD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 04	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	08-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 μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
Total:							

Pankaj
09-Jun-17

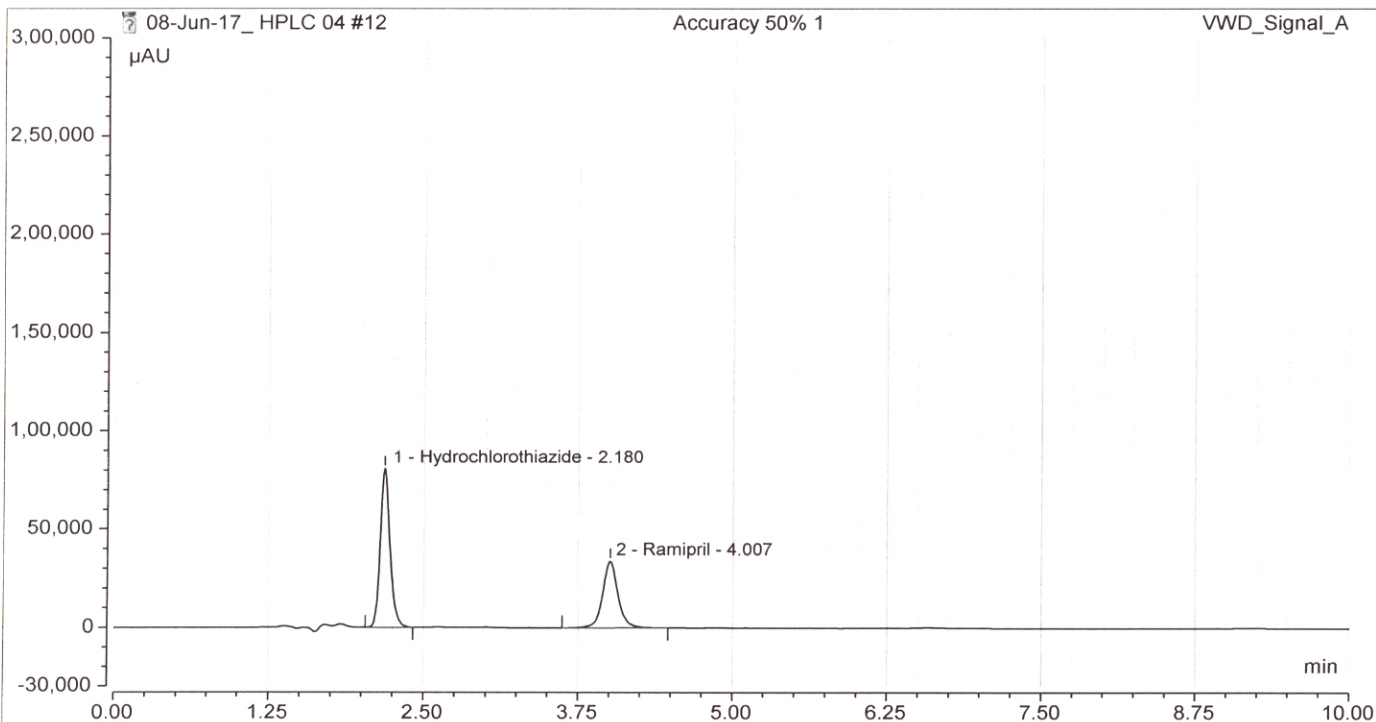
Pankaj
12-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Accuracy 50% 1	Run Time (min):	10.00
Vial Number:	Vial:4	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	VWD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_04	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	09-Jun-17 00:10	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	2.180	7354.546	3914	1.27	10.33	60.03
2	Ramipril	4.007	4897.906	5591	1.09	n.a.	39.97
Total:							

Pankaj Gurav
09-Jun-17

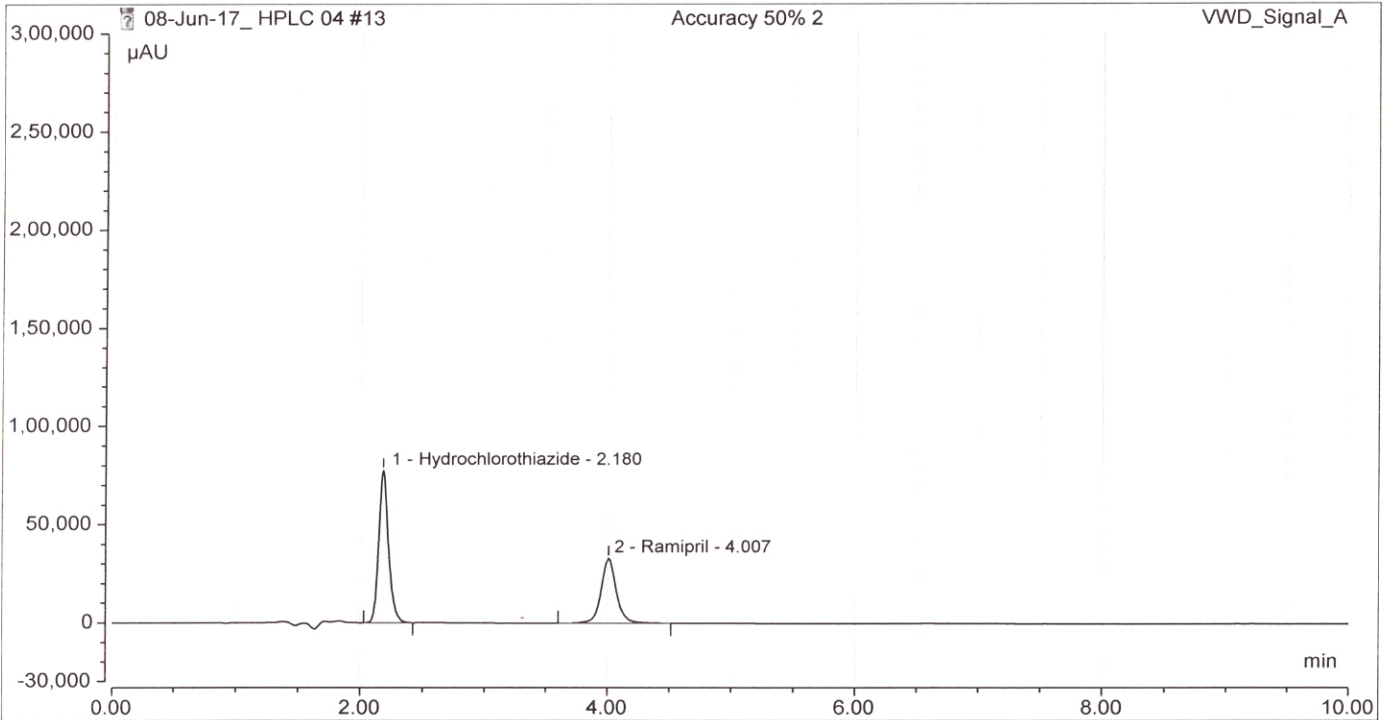
Default/Integration

Pankaj Gurav
12-Jun-17

Chromeleon (c) Dionex
Version 7.2.4.8525

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

Injection Name:	Accuracy 50% 2	Run Time (min):	10.00
Vial Number:	Vial:5	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	VWD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 04	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	09-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 μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.180	7050.771	3908	1.27	10.31	59.50
2	Ramipril	4.007	4799.095	5555	1.09	n.a.	40.50
Total:							

Pankaj Gurav
09-Jun-17

Default/Integration

Pankaj Gurav
12-Jun-17

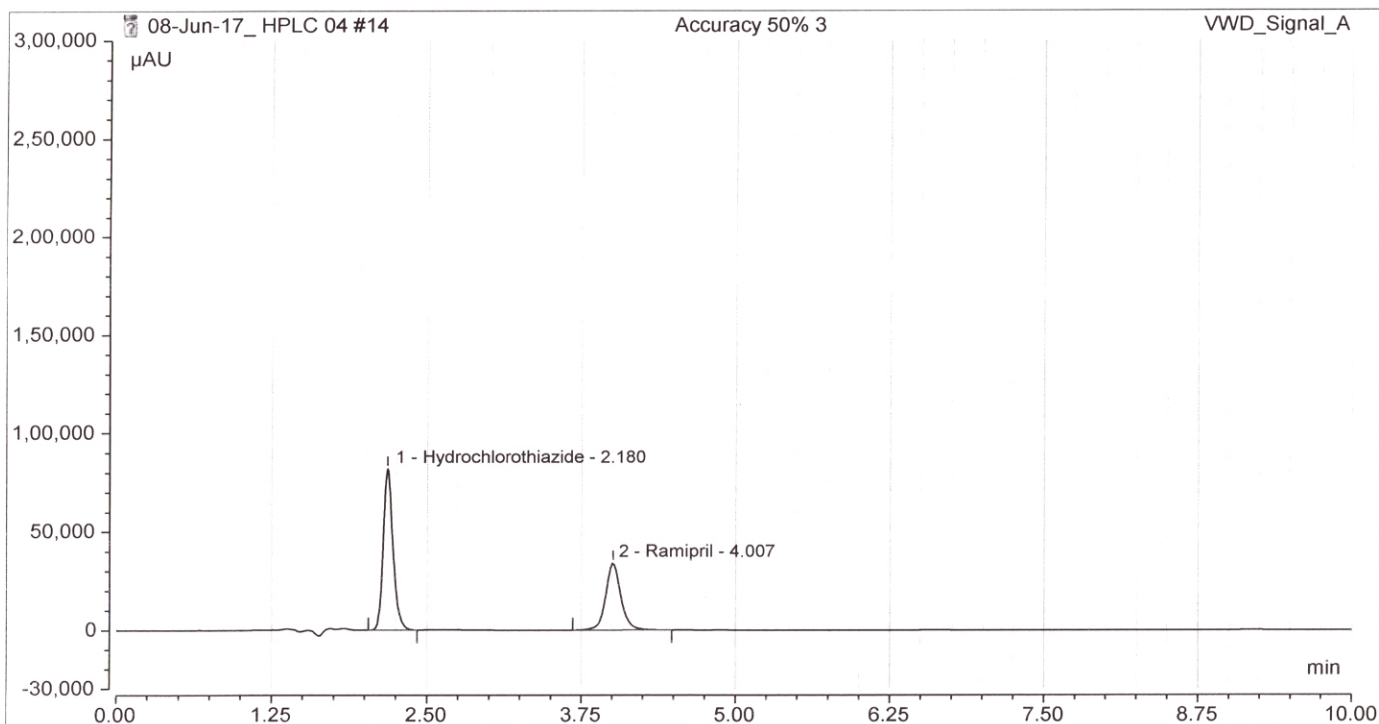
Chromeleon (c) Dionex
Version 7.2.4.8525

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Accuracy 50% 3	Run Time (min):	10.00
Vial Number:	Vial:6	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	VWD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 04	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	09-Jun-17 00:33	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	2.180	7464.556	3906	1.28	10.29	60.15
2	Ramipril	4.007	4944.512	5529	1.10	n.a.	39.85
Total:							

Pankaj
09-Jun-17

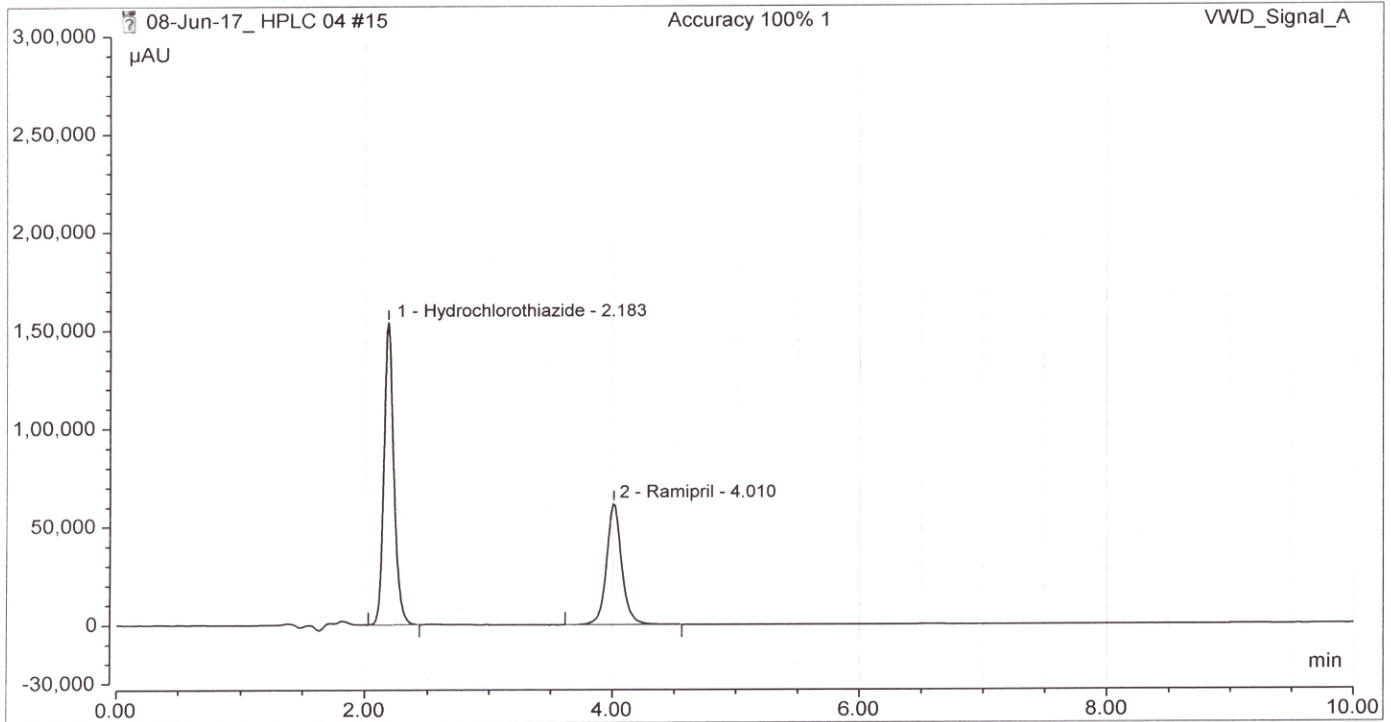
Default/Integration

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12-Jun-17

Chromeleon (c) Dionex
Version 7.2.4.8525

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

Injection Name:	Accuracy 100% 1	Run Time (min):	10.00
Vial Number:	Vial:7	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	VWD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_04	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	09-Jun-17 00:45	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	2.183	14024.138	3918	1.25	10.33	61.39
2	Ramipril	4.010	8820.949	5611	1.10	n.a.	38.61
Total:							

Pankaj Gurav
09-Jun-17

Default/Integration

Pankaj Gurav
12-Jun-17

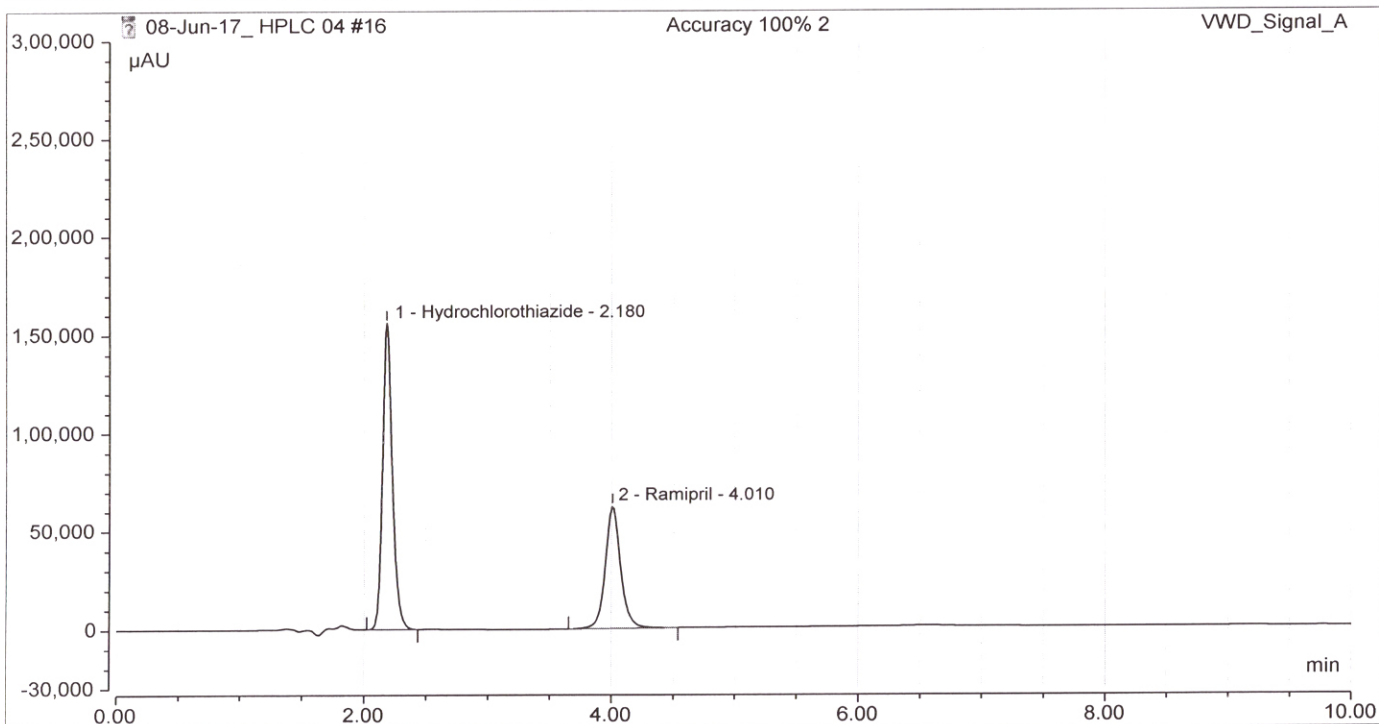
Chromeleon (c) Dionex
Version 7.2.4.8525

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Accuracy 100% 2	Run Time (min):	10.00
Vial Number:	Vial:8	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	VWD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 04	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	09-Jun-17 00:56	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	2.180	14206.420	3912	1.30	10.35	61.42
2	Ramipril	4.010	8925.371	5598	1.10	n.a.	38.58
Total:							

Pankaj Gurav
09-Jun-17

Default/Integration

Pankaj Gurav
12-Jun-17

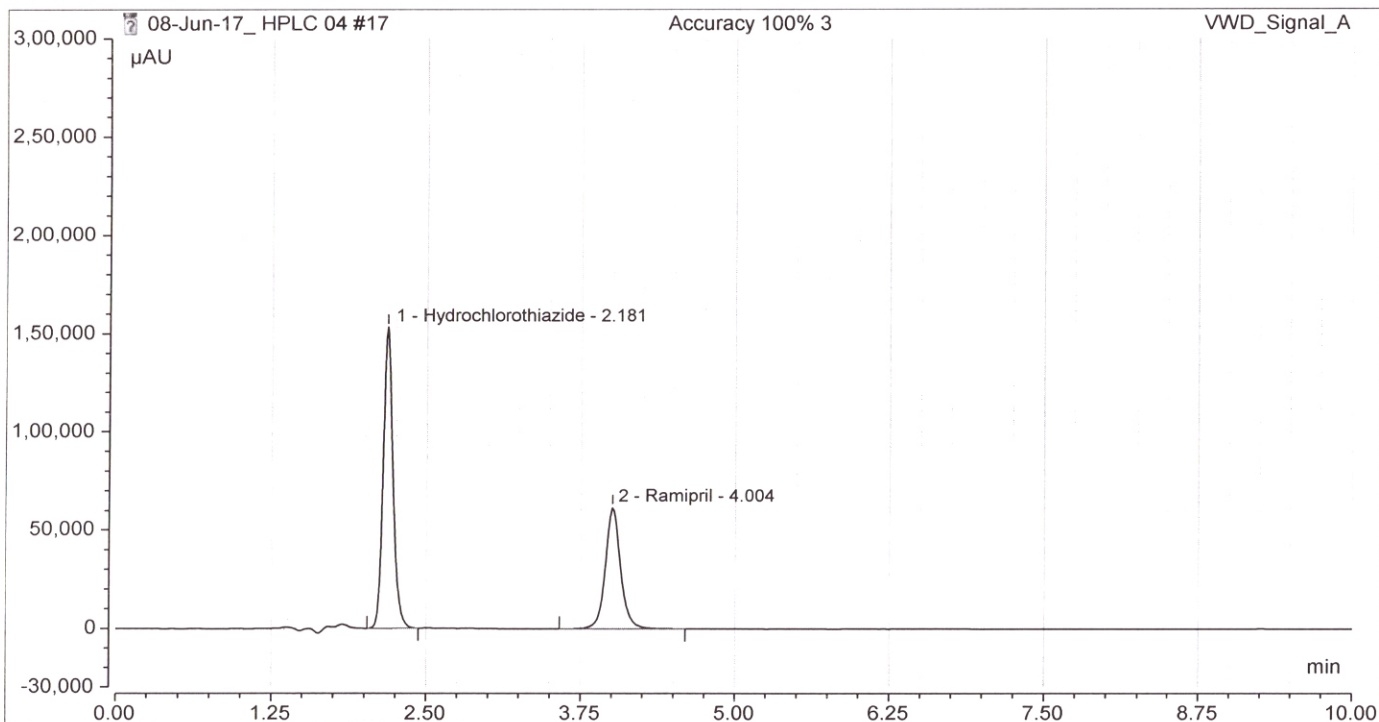
Chromeleon (c) Dionex
Version 7.2.4.8525

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Accuracy 100% 3	Run Time (min):	10.00
Vial Number:	Vial:9	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	VWD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 04	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	09-Jun-17 01:08	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

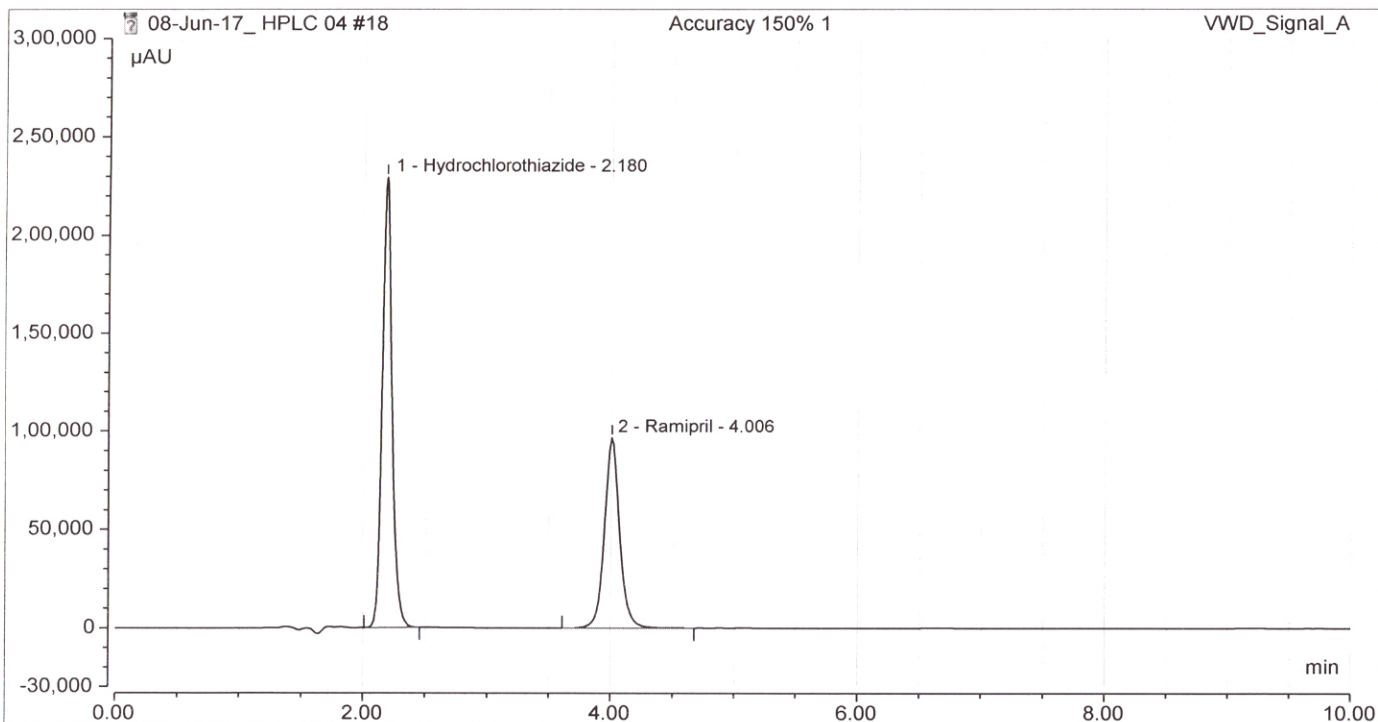
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.181	14046.120	3870	1.27	10.28	61.33
2	Ramipril	4.004	8855.191	5570	1.12	n.a.	38.67
Total:							

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Accuracy 150% 1	Run Time (min):	10.00
Vial Number:	Vial:10	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	VWD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 04	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	09-Jun-17 01:19	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	2.180	20957.790	3895	1.29	10.32	60.33
2	Ramipril	4.006	13783.487	5596	1.12	n.a.	39.67
Total:							

Pankaj Gurav
09-Jun-17

Default/Integration

Pankaj Gurav
12-Jun-17

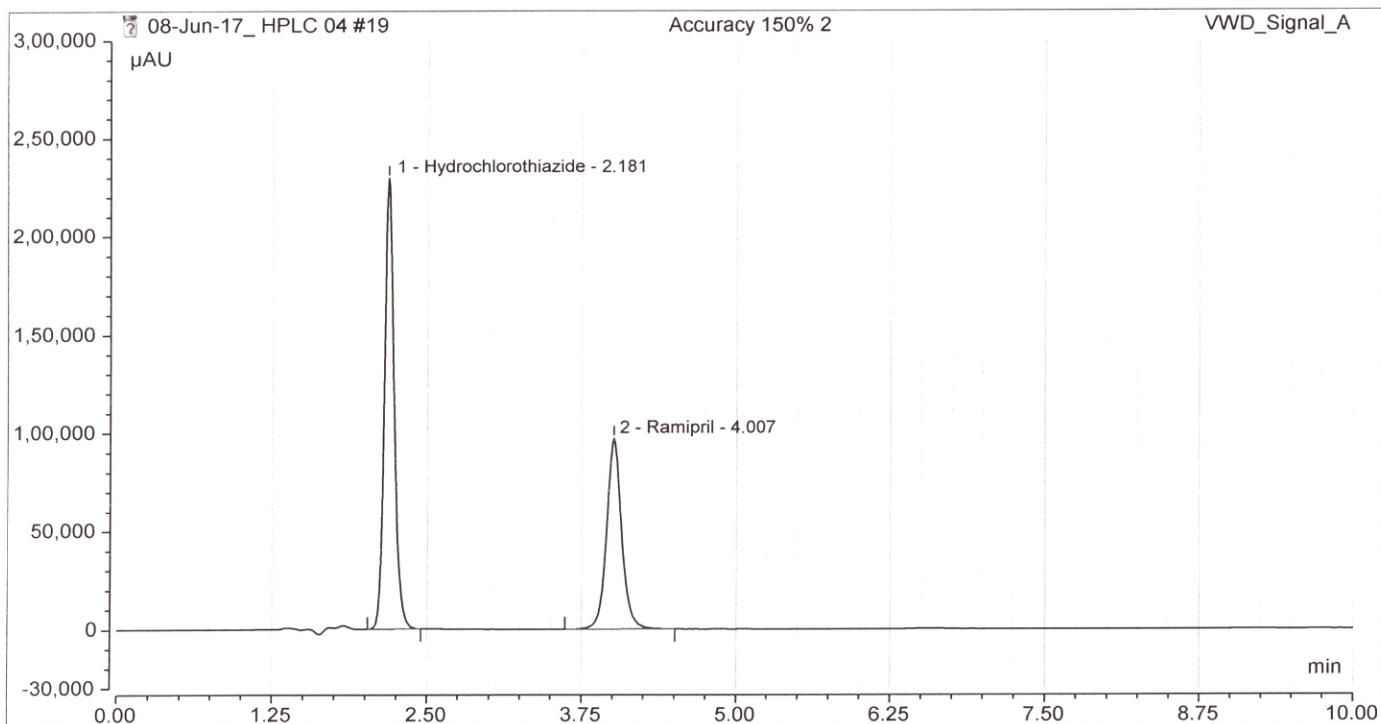
Chromeleon (c) Dionex
Version 7.2.4.8525

QbD Research & Developement Pvt.Ltd.

Injection Details

Injection Name:	Accuracy 150% 2	Run Time (min):	10.00
Vial Number:	Vial:11	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	VWD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_04	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	09-Jun-17 01:31	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	2.181	20998.029	3878	1.28	10.30	60.37
2	Ramipril	4.007	13782.042	5582	1.12	n.a.	39.63
Total:							

Pankaj Gurav
09-Jun-17

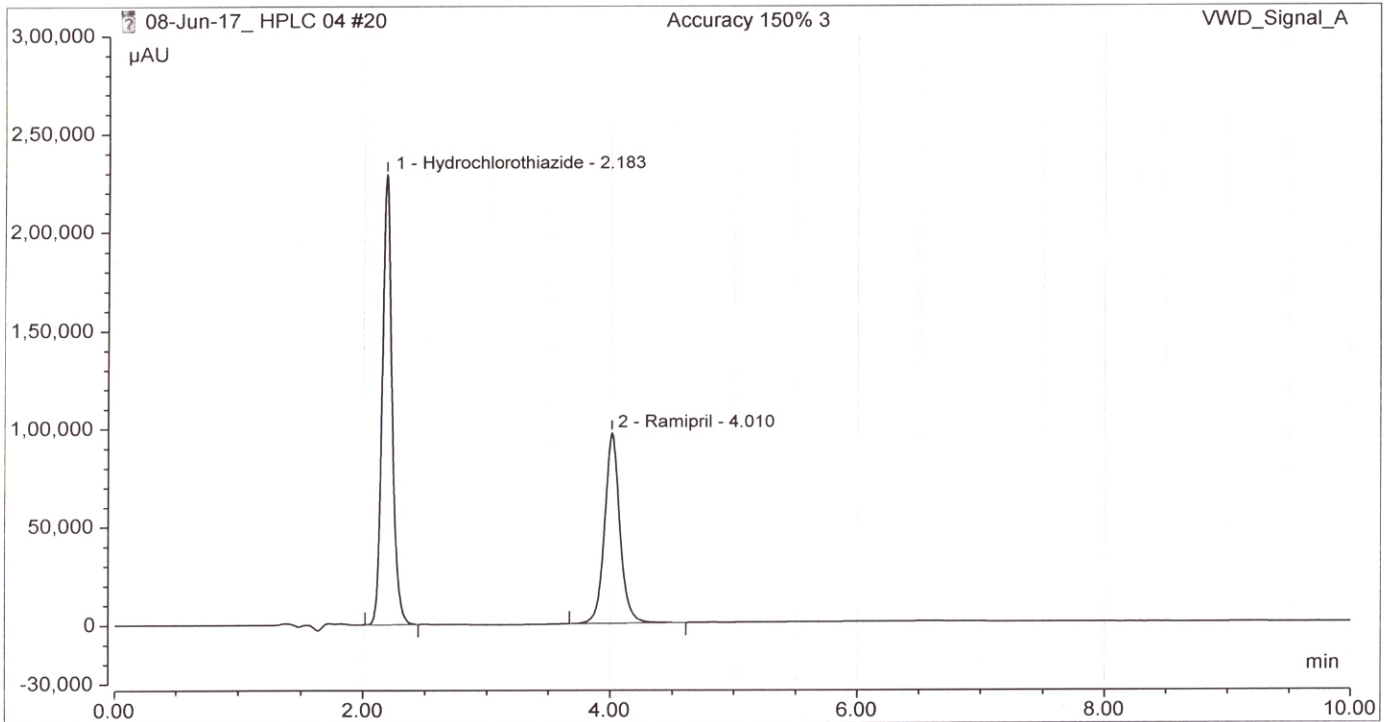
Default/Integration

Pankaj Gurav
12-Jun-17

Chromeleon (c) Dionex
Version 7.2.4.8525

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

Injection Name:	Accuracy 150% 3	Run Time (min):	10.00
Vial Number:	Vial:12	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	VWD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 04	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	09-Jun-17 01:42	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	2.183	20970.367	3897	1.25	10.31	60.33
2	Ramipril	4.010	13787.558	5597	1.11	n.a.	39.67
Total:							

Pankaj Gurav
09-Jun-17

Default/Integration

Pankaj Gurav
12-Jun-17

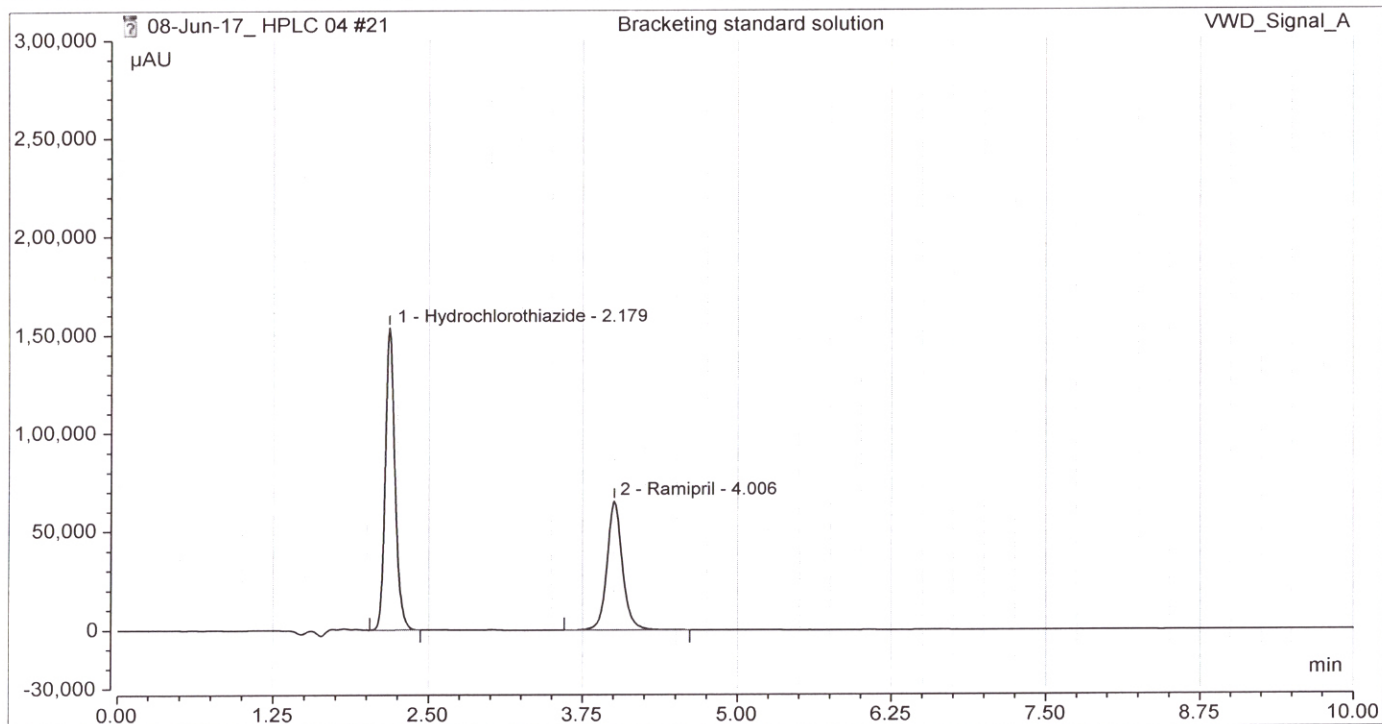
Chromeleon (c) Dionex
Version 7.2.4.8525

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Bracketing standard solution	Run Time (min):	10.00
Vial Number:	Vial:2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	VWD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_04	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	09-Jun-17 01:54	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	2.179	14036.843	3886	1.29	10.32	59.95
2	Ramipril	4.006	9376.114	5591	1.11	n.a.	40.05
Total:							

09-Jun-17

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Sequence: 08-Jun-17_HPLC 04
Last Update Operator: Pankaj Gurav

D_Sign	Name	Position	Volume [µL]	Instrument Method	Processing Method	Status	Comment	Inject Time
1	Pre SST 1	Vial:2	10.00	Ramithiazide Assay- HPLC_ 04	PR Method 1	Finished		08-Jun-17 17:49 +05:30
1	Pre SST 2	Vial:3	10.00	Ramithiazide Assay- HPLC_ 04	PR Method 1	Finished		08-Jun-17 18:19 +05:30
1	Pre SST 1	Vial:2	10.00	Ramithiazide Assay- HPLC_ 04	PR Method 1	Running		08-Jun-17 22:27 +05:30
	Blank solution	Vial:1	10.00	Ramithiazide Assay- HPLC_ 04	PR Method 1	Idle	Accuracy 10/25 mg	
	Standard solution 1	Vial:2	10.00	Ramithiazide Assay- HPLC_ 04	PR Method 1	Idle	Accuracy 10/25 mg	
	Standard solution 2	Vial:2	10.00	Ramithiazide Assay- HPLC_ 04	PR Method 1	Idle	Accuracy 10/25 mg	
	Standard solution 3	Vial:2	10.00	Ramithiazide Assay- HPLC_ 04	PR Method 1	Idle	Accuracy 10/25 mg	
	Standard solution 4	Vial:2	10.00	Ramithiazide Assay- HPLC_ 04	PR Method 1	Idle	Accuracy 10/25 mg	
	Standard solution 5	Vial:2	10.00	Ramithiazide Assay- HPLC_ 04	PR Method 1	Idle	Accuracy 10/25 mg	
	Standard solution 6	Vial:2	10.00	Ramithiazide Assay- HPLC_ 04	PR Method 1	Idle	Accuracy 10/25 mg	
	Placebo solution	Vial:3	10.00	Ramithiazide Assay- HPLC_ 04	PR Method 1	Idle	Accuracy 10/25 mg	
	Accuracy 50% 1	Vial:4	10.00	Ramithiazide Assay- HPLC_ 04	PR Method 1	Idle	Accuracy 10/25 mg	
	Accuracy 50% 2	Vial:5	10.00	Ramithiazide Assay- HPLC_ 04	PR Method 1	Idle	Accuracy 10/25 mg	
	Accuracy 50% 3	Vial:6	10.00	Ramithiazide Assay- HPLC_ 04	PR Method 1	Idle	Accuracy 10/25 mg	
	Accuracy 100% 1	Vial:7	10.00	Ramithiazide Assay- HPLC_ 04	PR Method 1	Idle	Accuracy 10/25 mg	
	Accuracy 100% 2	Vial:8	10.00	Ramithiazide Assay- HPLC_ 04	PR Method 1	Idle	Accuracy 10/25 mg	
	Accuracy 100% 3	Vial:9	10.00	Ramithiazide Assay- HPLC_ 04	PR Method 1	Idle	Accuracy 10/25 mg	
	Accuracy 150% 1	Vial:10	10.00	Ramithiazide Assay- HPLC_ 04	PR Method 1	Idle	Accuracy 10/25 mg	
	Accuracy 150% 2	Vial:11	10.00	Ramithiazide Assay- HPLC_ 04	PR Method 1	Idle	Accuracy 10/25 mg	
	Accuracy 150% 3	Vial:12	10.00	Ramithiazide Assay- HPLC_ 04	PR Method 1	Idle	Accuracy 10/25 mg	
	Bracketing standard solution	Vial:2	10.00	Ramithiazide Assay- HPLC_ 04	PR Method 1	Idle	Accuracy 10/25 mg	
	Wash	Vial:1	10.00	Wash method D_H 04 NEW	PR Method 1	Idle	Accuracy 10/25 mg	
	Shut	Vial:1	10.00	Shut method _HPLC 04 NEW	PR Method 1	Idle	Accuracy 10/25 mg	

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Name	Ramithiazide Assay- HPLC_ 04
Data Vault	XVault
Path	chrom://qbd-pc-15/XVault/QbD-INST-HPLC-04/515/08-Jun-17_ HPLC 04.seq/Ramithiazide Assay- HPLC_ 04.instmeth
Comment	Ramithiazide Assay
Description	New instrument method created
Run time	10.000 [min]
Instrument	QbD-INST-HPLC-04 on qbd-pc-15
Created	08-Jun-17 17:36 +05:30 Santosh Padmere
Last Update	08-Jun-17 17:36 +05:30 Santosh Padmere

Santosh Padmere
08-Jun-17

Pankaj Gurav
08-Jun-17

Stage	Time min	Command	Value	Comment
Instrument Setup	initial			
Inject Preparation	0.000	Wait	LCSystem.Read y	
Inject	0.000	LCSystem.ALS.Inject	Blank=Inject	
Start Run	0.000	LCSystem.ALS_Temperature.AcqOn LCSystem.QuatPump_Dir_PistonA.AcqOn LCSystem.QuatPump_Flow.AcqOn LCSystem.QuatPump_Pressure.AcqOn LCSystem.QuatPump_SolventRatioA.AcqO n LCSystem.QuatPump_SolventRatioB.AcqO n LCSystem.QuatPump_SolventRatioC.AcqO n LCSystem.QuatPump_SolventRatioD.AcqO n LCSystem.TCC_Left_Temperature.AcqOn LCSystem.TCC_Right_Temperature.AcqOn LCSystem.VWD_Board_Temperature.Acq On LCSystem.VWD_OpticalUnit_Temp.AcqOn LCSystem.VWD_Reference_Intensity.AcqO n LCSystem.VWD_Sample_Intensity.AcqOn LCSystem.VWD_UVLamp_AnodeVoltage.A cqOn LCSystem.VWD_Signal_A.AcqOn		
Run			Duration = 10.000 [min]	
Stop Run	0.000			
	10.000	LCSystem.ALS_Temperature.AcqOff LCSystem.QuatPump_Dir_PistonA.AcqOff LCSystem.QuatPump_Flow.AcqOff LCSystem.QuatPump_Pressure.AcqOff LCSystem.QuatPump_SolventRatioA.AcqO ff LCSystem.QuatPump_SolventRatioB.AcqO ff LCSystem.QuatPump_SolventRatioC.AcqO ff		

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LCSystem.QuatPump_SolventRatioD.AcqOff
LCSystem.TCC_Left_Temperature.AcqOff
LCSystem.TCC_Right_Temperature.AcqOff

LCSystem.VWD_Board_Temperature.AcqOff
LCSystem.VWD_OpticalUnit_Temp.AcqOff

LCSystem.VWD_Reference_Intensity.AcqOff
LCSystem.VWD_Sample_Intensity.AcqOff
LCSystem.VWD_UVLamp_AnodeVoltage.AcqOff
LCSystem.VWD_Signal_A.AcqOff

End

Property	Value
Settings for module Quat. Pump (G1311C - Pump: PUMP.0)	
Flow	1.000 [mL/min]
Low Pressure Limit	0.00 [bar]
High Pressure Limit	400.00 [bar]
Maximum Flow Gradient	100.000 [mL/min ²]
Primary Channel	Automatic
Section Stroke (StrokeA)	
Automatic Stroke Calculation	Yes
Section Compress (CompressA)	
Compressibility Mode	Compressibility Value Set
Compressibility	100 [10e-6/bar]
Section Stop Time (StopTime)	
Stoptime Mode	Time set
Stoptime	10.00 [min]
Section Post Time (PostTime)	
Posttime Mode	Off
Solvent Composition (SolventComposition)	
0	
Channel	A
Name 1	Mobile Phase
Used	Yes
Percent	100.0 [%]
1	
Channel	B
Name 1	
Used	No
2	
Channel	C
Name 1	
Used	No
3	
Channel	D
Name 1	
Used	No
Timetable (Timetable)	
Settings for module Sampler (G1329B - Sampler: SAMPLER.0)	
Section Auxiliary (Auxiliary)	
Draw Speed	200 [µL/min]
Eject Speed	200 [µL/min]
Draw Position Offset	0.0 [mm]
Section Injection (Injection)	
Injection Mode	Injection with needle wash
Injection Volume	10.00 [µL]
Section Needle Wash (Injection_NeedleWash)	
Needle Wash Location	Wash Vial
Wash Location	Vial 100

Prakash
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Section High throughput (HighThroughput)	
Section Overlapped Injection (HighThroughput_OverlappedInjection)	
Enable Overlapped Injection	No
Section Thermostat (Thermostat)	
Not Ready Temperature Mode	Enable Analysis With Any Temperature
Thermostat Control	Thermostat Control Set Value
Thermostat Temperature	25 [°C]
Section Stop Time (StopTime)	
Stoptime Mode	As pump/No limit
Section Post Time (PostTime)	
Posttime Mode	Off
Section Timetable (Timetable)	
Timetable (Timetable_TimetableEntry)	
Settings for module Column Comp. (G1316A - Column Comp.: COLCOMP.0)	
Section Left Temperature Control (LeftTemperatureControl)	
Temperature Control Mode	Temperature Set
Temperature	25.00 [°C]
Section Enable Analysis Left Temperature (LeftTemperatureControl_NotReadyLimit)	
Enable Analysis Left Temperature On	Yes
Enable Analysis Left Temperature Value	0.80 [°C]
Section Right Temperature Control (RightTemperatureControl)	
Right temperature Control Mode	Combined
Section Enable Analysis Right Temperature (RightTemperatureControl_NotReadyLimit)	
Enable Analysis Right Temperature On	Yes
Enable Analysis Right Temperature Value	0.80 [°C]
Section Stop Time (StopTime)	
Stoptime Mode	As pump/injector
Section Post Time (PostTime)	
Posttime Mode	Off
Section Timetable (Timetable)	
Timetable (Timetable_TimetableEntry)	
Settings for module VWD (G1314F - VWD: VWD.0)	
Signal Peakwidth	> 0.1 min (2 s resp. time) (5 Hz)
Analog Output Source Channel	1
Signal Polarity	Positive (+)
Lamp on required for aquisition	Yes

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Acquire Signal without Reference	No
Acquire Reference only	No
Section Analog Output (AnalogOutput)	
Analog Zero Offset	5 [%]
Analog Attenuation	1000 [mAU]
Section Signals (Signals)	
Section Signal (Signals_Signal)	
Use Signal	Yes
Signal ID	Signal A
Signal Wavelength	210 [nm]
Section Autobalance (PrepareAutomation)	
Autobalance Prerun	Yes
Autobalance Postrun	No
Section Scan Variables (ScanVariables)	
Scan Range From	190 [nm]
Scan Range To	400 [nm]
Scan Range Step	2 [nm]
Section Stoptime (StopTime)	
Stoptime Mode	As pump/injector
Section Posttime (PostTime)	
Posttime Mode	Off
Section Timetable (Timetable)	
Timetable (Timetable_TimetableEntry)	

Property	Value
Settings for module Sampler (G1329B - Pretreatment (PretreatmentInstruction)	

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08 Jun 17

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