

ASSAY METHOD VALIDATION

Product name :	Ramithiazide Tablet
Strength :	Ramipril and Hydrochlorothiazide
B. No. :	GP170402
Parameter :	Accuracy of Ramipril
LNB No./Pg. No.:	419/038
Label claim (mg) :	10

Analysis Date:	9-Jun-17
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Name of standard	Standard purity(%)
Ramipril	99.8

Standard solution:	25.49	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	2.176	7042.617	4.026	9271.924
2	2.176	7025.947	4.022	9284.789
3	2.175	7029.365	4.022	9267.970
4	2.176	7039.472	4.022	9256.825
5	2.176	7034.604	4.019	9277.329
6	2.177	7038.449	4.020	9256.162
Bkt std	2.178	7035.057	4.028	9366.461
Average	2.176	7035.073	4.023	9283.066
SD	0.00	5.83	0.00	38.20
%RSD	0.04	0.08	0.08	0.41

System suitability results of Ramipril		
% RSD	0.41	NMT 2.0 %
Theoretical plates of Ramipril	5629	NLT 2000
Tailing factor of Ramipril	1.10	NMT 2.0

Level	Level (%)	Standard wt in mg	Diluted to volume (mL)	Taken Solution From	Diluted to volume	Actual Concentration
1	50	12.88	250	5.0	25	10.3
2	50	12.74	250	5.0	25	10.2
3	50	12.95	250	5.0	25	10.4
1	100	25.07	250	5.0	25	20.1
2	100	25.14	250	5.0	25	20.1
3	100	25.10	250	5.0	25	20.1
1	150	37.58	250	5.0	25	30.1
2	150	37.56	250	5.0	25	30.0
3	150	37.63	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	467.98	10.30	4774.975	10.47	101.6	101.5	0.31
	Sample 2	465.83	10.19	4701.765	10.31	101.1		
	Sample 3	466.32	10.36	4807.576	10.54	101.7		
100	Sample 1	464.60	20.06	9199.755	20.17	100.6	100.4	0.18
	Sample 2	465.01	20.11	9192.101	20.15	100.2		
	Sample 3	465.13	20.08	9191.341	20.15	100.3		
150	Sample 1	464.49	30.06	13497.348	29.59	98.4	98.5	0.36
	Sample 2	466.10	30.05	13552.427	29.71	98.9		
	Sample 3	464.27	30.10	13483.137	29.56	98.2		

Done by:
Date:

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24-Jun-17

Checked by:
Date:

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22-Jun-17

ASSAY METHOD VALIDATION

Product name :	Ramithiazide Tablet
Strength :	Ramipril and Hydrochlorothiazide
B. No. :	GP170402
Parameter :	Accuracy of Hydrochlorothiazide
Lable claim (mg) :	12.5

Analysis Date:	9-Jun-17
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Name of standard	Standard purity(%)
HCTZ	99.9

Standard solution:	25.23	mg of Std diluted to	25	mL with diluent
	2.5	mL diluted to	100	mL with diluent

Replicates	RT of HCTZ	Area of HCTZ	RT of Ramipril	Area of Ramipril
1	2.176	7042.617	4.026	9271.924
2	2.176	7025.948	4.022	9284.789
3	2.175	7029.365	4.022	9267.970
4	2.176	7039.472	4.022	9256.825
5	2.176	7034.604	4.019	9277.329
6	2.177	7038.449	4.020	9256.162
Bkt std	2.178	7035.057	4.028	9366.461
Average	2.176	7035.073	4.023	9283.066
SD	0.00	5.83	0.00	38.20
%RSD	0.04	0.08	0.08	0.41

System suitability results of Hydrochlorothiazide		
% RSD	0.08	NMT 2.0 %
Theoretical plates of HCTZ	3873	NLT 2000
Tailing factor of HCTZ	1.29	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	15.86	250	5.0	25	12.7
2	50	15.88	250	5.0	25	12.7
3	50	15.83	250	5.0	25	12.7
1	100	31.61	250	5.0	25	25.3
2	100	31.49	250	5.0	25	25.2
3	100	31.55	250	5.0	25	25.2
1	150	46.95	250	5.0	25	37.6
2	150	46.88	250	5.0	25	37.5
3	150	46.82	250	5.0	25	37.5

Accuracy level (%)	Sample	Placebo weight (mg)	Amount added(ppm)	Area	Amount recovered (ppm)	% Recovery	Mean % Recovery	% RSD
50	Sample 1	467.98	12.69	3507.590	12.57	99.0	99.4	0.31
	Sample 2	465.83	12.70	3523.651	12.62	99.4		
	Sample 3	466.32	12.66	3522.441	12.62	99.7		
100	Sample 1	464.60	25.29	7032.703	25.20	99.6	99.7	0.07
	Sample 2	465.01	25.19	7014.152	25.13	99.8		
	Sample 3	465.13	25.24	7029.037	25.18	99.8		
150	Sample 1	464.49	37.56	10364.950	37.13	98.9	99.3	0.36
	Sample 2	466.10	37.50	10418.452	37.33	99.5		
	Sample 3	464.27	37.46	10393.905	37.24	99.4		

Done by:
Date:

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24-Jun-17

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Date:

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24-Jun-17

ID_Signa	Name	Position	Volume [µL]	Instrument Method	Processing Method	Status	Comment	Inject Time
	Pre SST 1	Vial:2	10.00	Ramithiazide Assay- HPLC_04	PR Method 1	Finished		09-Jun-17 17:00 +05:30
	Pre SST 1	Vial:2	10.00	Ramithiazide Assay- HPLC_04	PR Method 1	Finished		09-Jun-17 17:13 +05:30
	Blank solution	Vial:1	10.00	Ramithiazide Assay- HPLC_04	PR Method 1	Finished	Accuracy 10/12.5 mg	09-Jun-17 20:25 +05:30
	Pre SST 1	Vial:2	10.00	Ramithiazide Assay- HPLC_04	PR Method 1	Running		09-Jun-17 20:57 +05:30
	Blank solution	Vial:1	10.00	Ramithiazide Assay- HPLC_04	PR Method 1	Idle	Accuracy 10/12.5 mg	
	Standard solution 1	Vial:2	10.00	Ramithiazide Assay- HPLC_04	PR Method 1	Idle	Accuracy 10/12.5 mg	
	Standard solution 2	Vial:2	10.00	Ramithiazide Assay- HPLC_04	PR Method 1	Idle	Accuracy 10/12.5 mg	
	Standard solution 3	Vial:2	10.00	Ramithiazide Assay- HPLC_04	PR Method 1	Idle	Accuracy 10/12.5 mg	
	Standard solution 4	Vial:2	10.00	Ramithiazide Assay- HPLC_04	PR Method 1	Idle	Accuracy 10/12.5 mg	
	Standard solution 5	Vial:2	10.00	Ramithiazide Assay- HPLC_04	PR Method 1	Idle	Accuracy 10/12.5 mg	
	Standard solution 6	Vial:2	10.00	Ramithiazide Assay- HPLC_04	PR Method 1	Idle	Accuracy 10/12.5 mg	
	Placebo solution	Vial:2	10.00	Ramithiazide Assay- HPLC_04	PR Method 1	Idle	Accuracy 10/12.5 mg	
	Accuracy 50% 1	Vial:3	10.00	Ramithiazide Assay- HPLC_04	PR Method 1	Idle	Accuracy 10/12.5 mg	
	Accuracy 50% 2	Vial:4	10.00	Ramithiazide Assay- HPLC_04	PR Method 1	Idle	Accuracy 10/12.5 mg	
	Accuracy 50% 3	Vial:5	10.00	Ramithiazide Assay- HPLC_04	PR Method 1	Idle	Accuracy 10/12.5 mg	
	Accuracy 100% 1	Vial:6	10.00	Ramithiazide Assay- HPLC_04	PR Method 1	Idle	Accuracy 10/12.5 mg	
	Accuracy 100% 2	Vial:7	10.00	Ramithiazide Assay- HPLC_04	PR Method 1	Idle	Accuracy 10/12.5 mg	
	Accuracy 100% 3	Vial:8	10.00	Ramithiazide Assay- HPLC_04	PR Method 1	Idle	Accuracy 10/12.5 mg	
	Accuracy 150% 1	Vial:9	10.00	Ramithiazide Assay- HPLC_04	PR Method 1	Idle	Accuracy 10/12.5 mg	
	Accuracy 150% 2	Vial:10	10.00	Ramithiazide Assay- HPLC_04	PR Method 1	Idle	Accuracy 10/12.5 mg	
	Accuracy 150% 3	Vial:11	10.00	Ramithiazide Assay- HPLC_04	PR Method 1	Idle	Accuracy 10/12.5 mg	
	Bracketing standard solution	Vial:12	10.00	Ramithiazide Assay- HPLC_04	PR Method 1	Idle	Accuracy 10/12.5 mg	
	Wash	Vial:2	10.00	Wash method D_H 04 NEW	PR Method 1	Idle	Accuracy 10/12.5 mg	
	Shut	Vial:1	10.00	Shut method_HPLC 04 NEW	PR Method 1	Idle	Accuracy 10/12.5 mg	

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Name	Ramithiazide Assay- HPLC_ 04
Data Vault	QbD_2017
Path	chrom://qbdser03/QbD_2017/Method Validation/Generic Health Care/Ramithiazide Tablets/Assay/09-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 Padmure
Last Update	08-Jun-17 17:36 +05:30 Santosh Padmure


09-Jun-17


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Stage	Time min	Command	Value	Comment
Instrument Setup	initial			
Inject Preparation	0.000	Wait	LCSystem.Ready	
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.AcqOn LCSystem.QuatPump_SolventRatioB.AcqOn LCSystem.QuatPump_SolventRatioC.AcqOn LCSystem.QuatPump_SolventRatioD.AcqOn LCSystem.TCC_Left_Temperature.AcqOn LCSystem.TCC_Right_Temperature.AcqOn LCSystem.VWD_Board_Temperature.AcqOn LCSystem.VWD_OpticalUnit_Temp.AcqOn LCSystem.VWD_Reference_Intensity.AcqOn LCSystem.VWD_Sample_Intensity.AcqOn LCSystem.VWD_UVLamp_AnodeVoltage.AcqOn LCSystem.VWD_Signal_A.AcqOn		
Run			Duration = 10.000 [min]	
Stop Run	10.000	LCSystem.ALS_Temperature.AcqOff LCSystem.QuatPump_Dir_PistonA.AcqOff LCSystem.QuatPump_Flow.AcqOff LCSystem.QuatPump_Pressure.AcqOff LCSystem.QuatPump_SolventRatioA.AcqOff LCSystem.QuatPump_SolventRatioB.AcqOff LCSystem.QuatPump_SolventRatioC.AcqOff		

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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

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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

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

Value Enable Analysis Left Temperature 0.80 [°C]

Section Right Temperature Control
(RightTemperatureControl)

Right temperature Control Mode

Combined

Section Enable Analysis Right Temperature
(RightTemperatureControl_NotReadyLimit)

Enable Analysis Right Temperature Yes

On Value Enable Analysis Right Temperature 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

09-Jun-17

Pankaj
09-Jun-17

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)	

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09-Jun-17

Pankaj
22-Jun-17

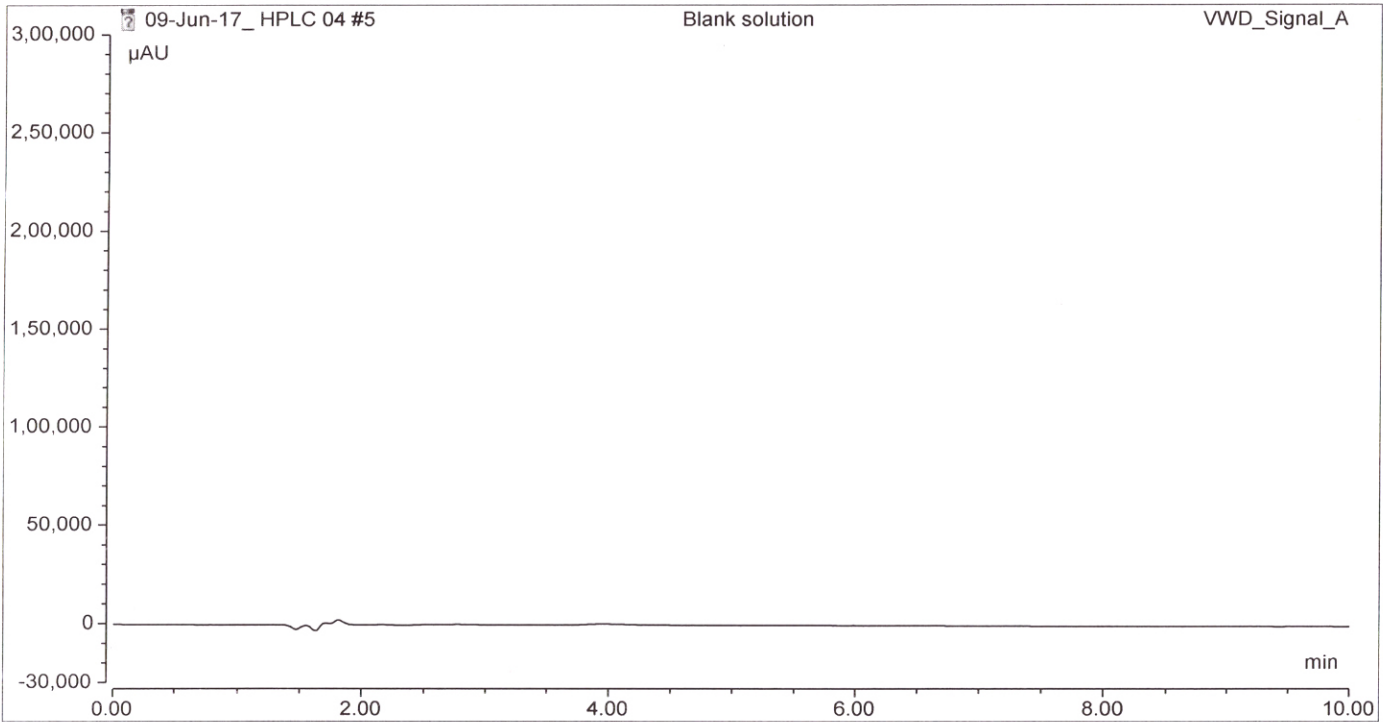
Property	Value
Settings for module Sampler (G1329B - Pretreatment (PretreatmentInstruction)	

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09-Jun-17

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09-Jun-17

QbD Research & Developement 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:	09-Jun-17 21:08	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 %
Total:							

Pankaj Gurav
21-Jun-17

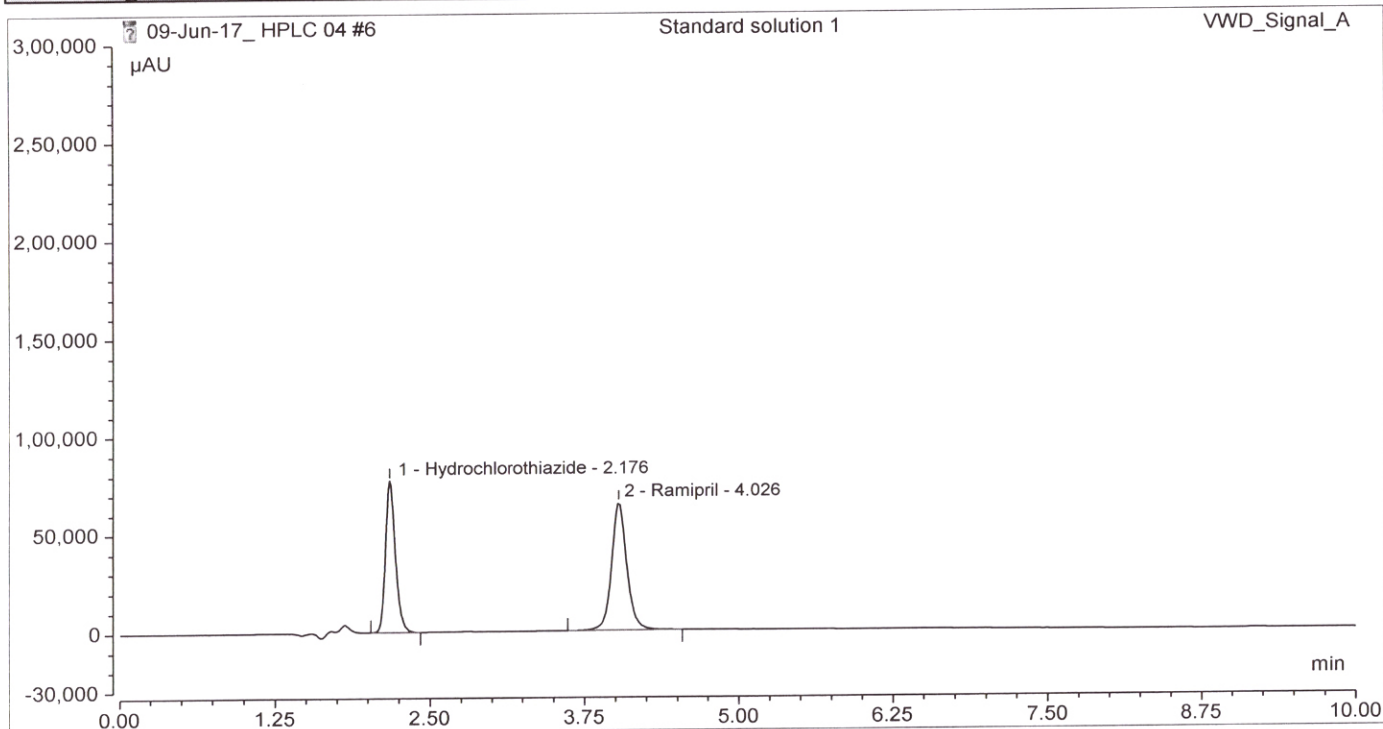
Pankaj Gurav
22-Jun-17

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:	09-Jun-17 21:20	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	2.176	7042.617	3873	1.29	10.44	43.17
2	Ramipril	4.026	9271.924	5629	1.10	n.a.	56.83
Total:							

Pankaj Gurav
21-Jun-17

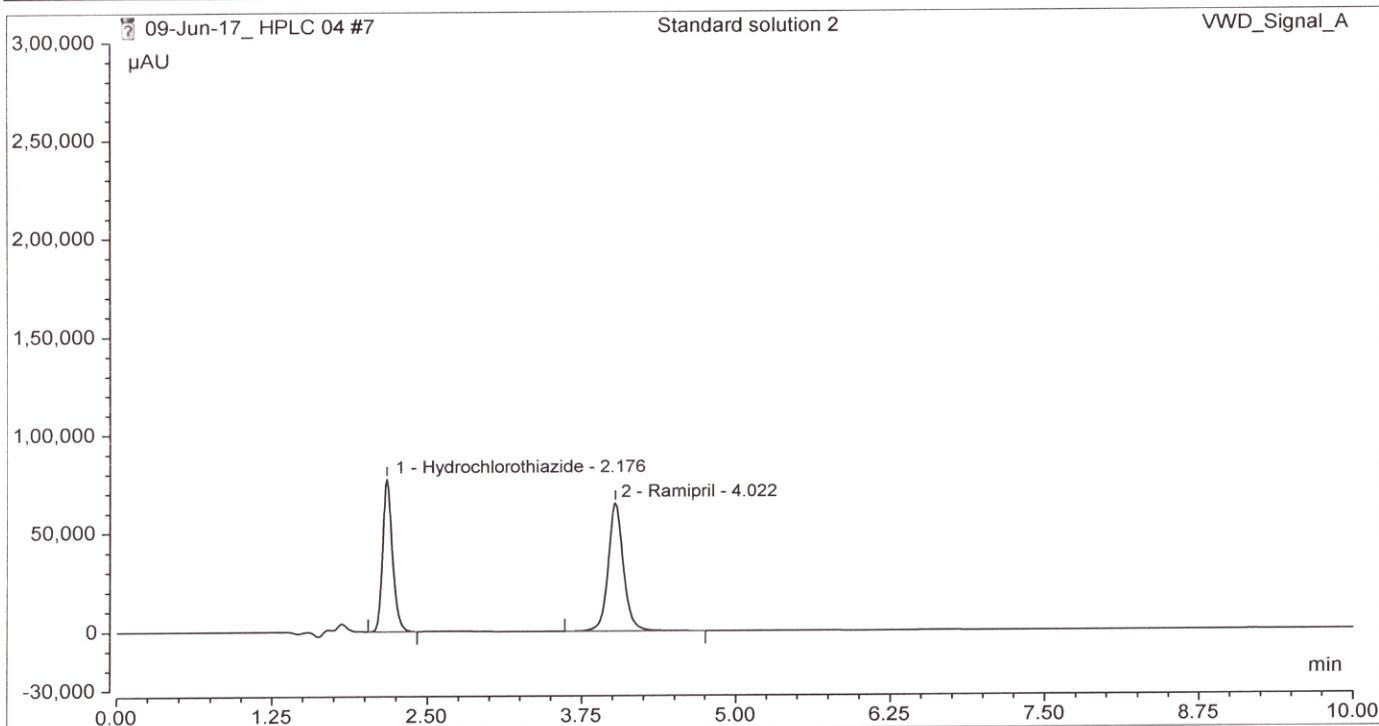
Pankaj Gurav
22-Jun-18

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:	09-Jun-17 21:31	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

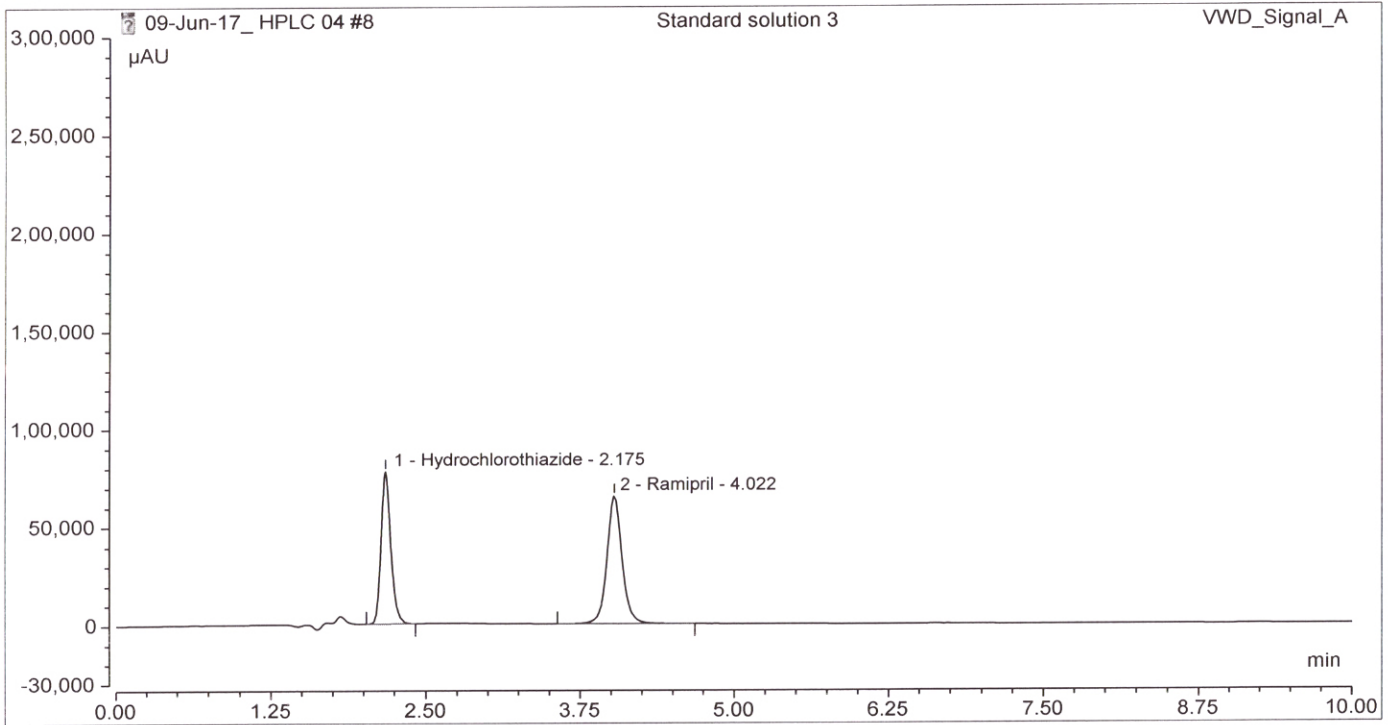
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.176	7025.947	3882	1.26	10.43	43.08
2	Ramipril	4.022	9284.789	5625	1.10	n.a.	56.92
Total:							

Pankaj Gurav
21 Jun 17

Pankaj Gurav
21 Jun 17

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:	09-Jun-17 21:43	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	2.175	7029.365	3888	1.26	10.44	43.13
2	Ramipril	4.022	9267.970	5640	1.09	n.a.	56.87
Total:							

Pankaj Gurav
21-Jun-17

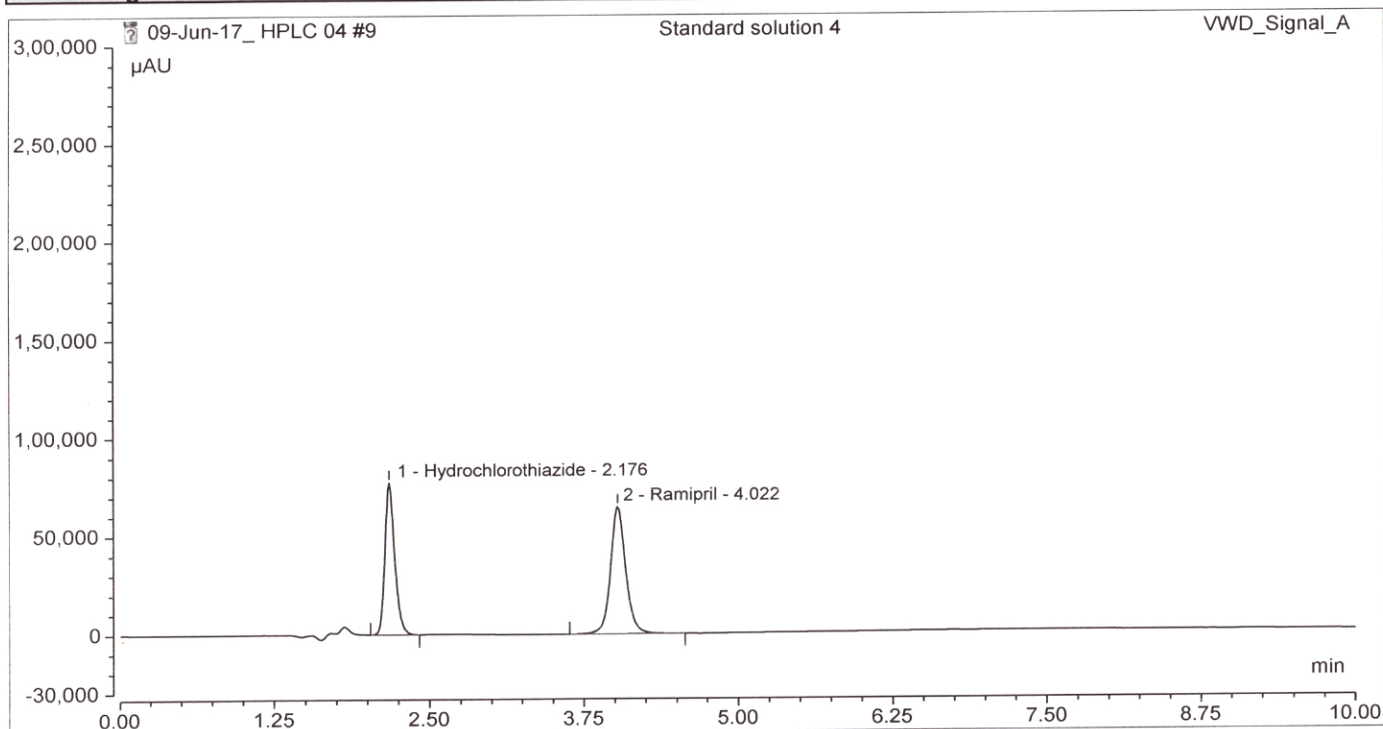
Pankaj Gurav
21-Jun-17

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:	09-Jun-17 21:54	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

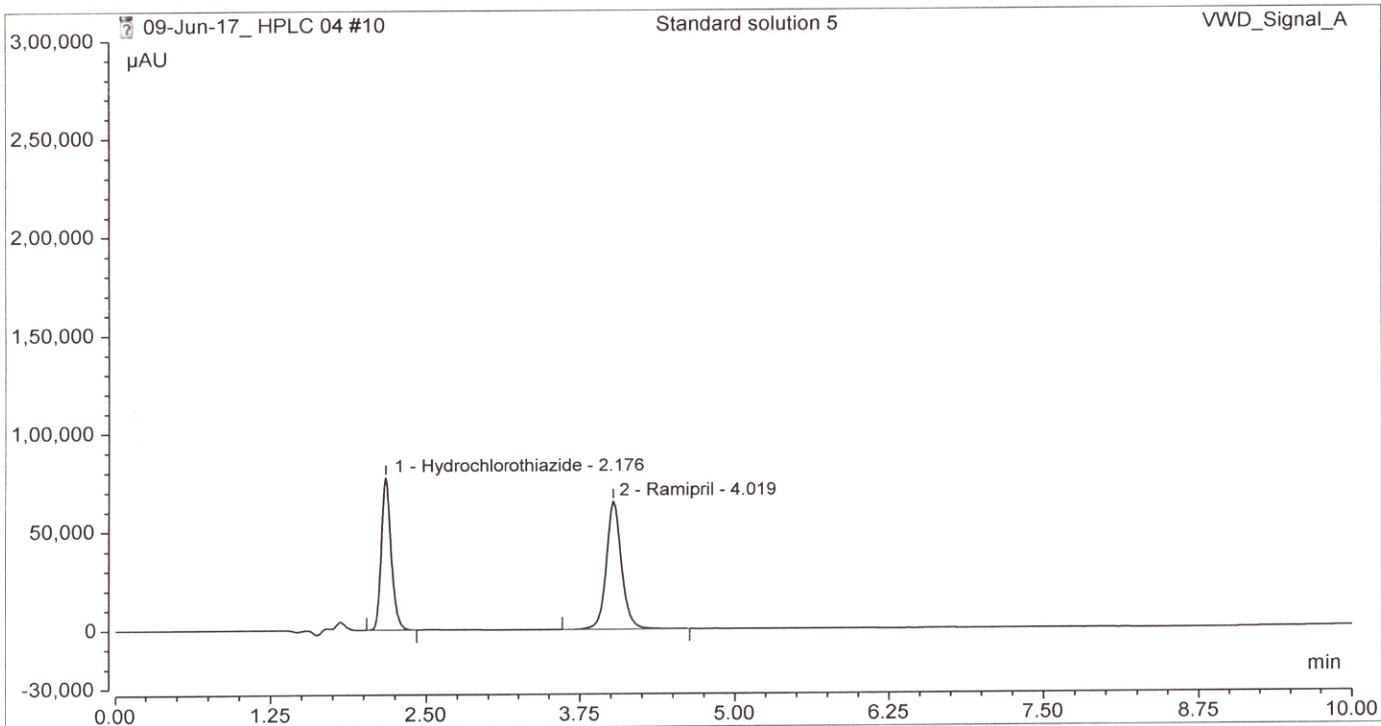
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.176	7039.472	3875	1.27	10.42	43.20
2	Ramipril	4.022	9256.825	5622	1.10	n.a.	56.80
Total:							

Default/Integration

Chromeleon (c) Dionex
Version 7.2.4.8525Pankaj Gurav
21 Jun 17Pankaj Gurav
21 Jun 17

QbD Research & Development 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:	09-Jun-17 22:06	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	2.176	7034.604	3891	1.25	10.42	43.13
2	Ramipril	4.019	9277.329	5624	1.11	n.a.	56.87
Total:							

Pankaj Gurav
22-Jun-17

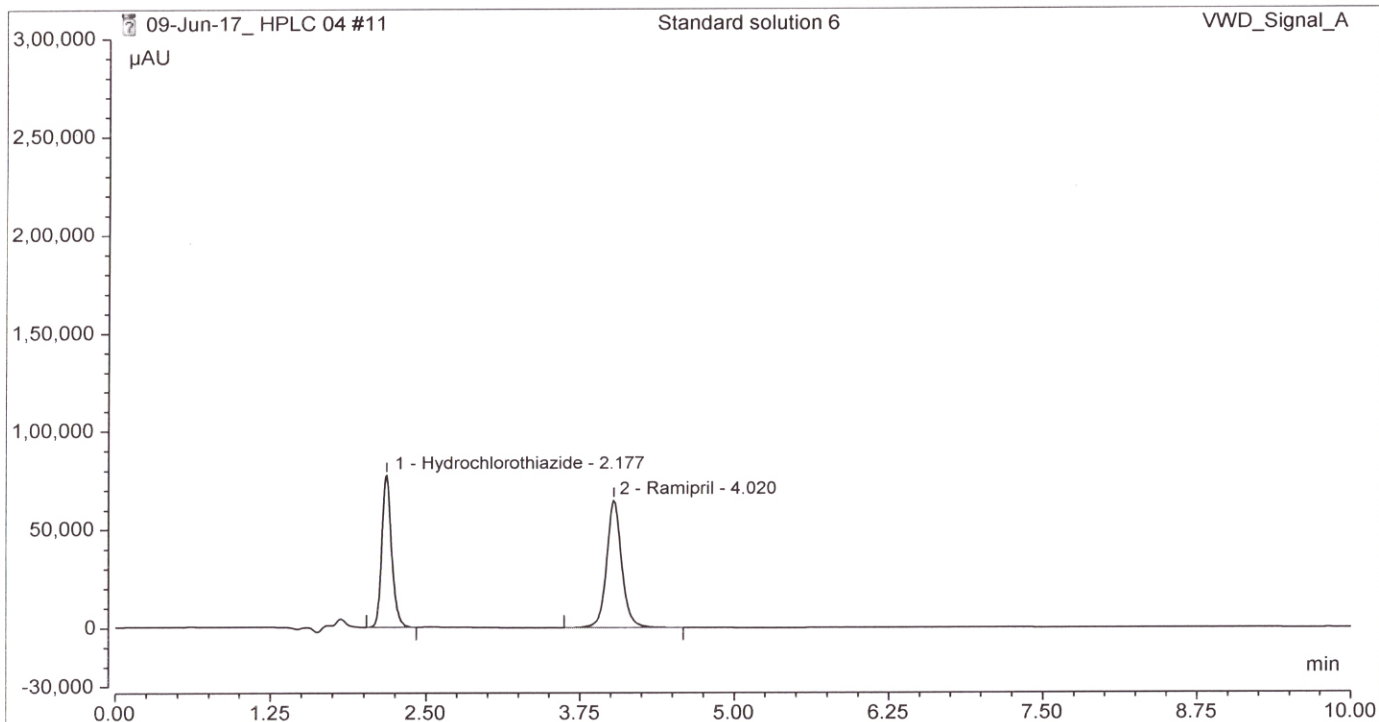
Pankaj Gurav
22-Jun-17

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:	09-Jun-17 22:17	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

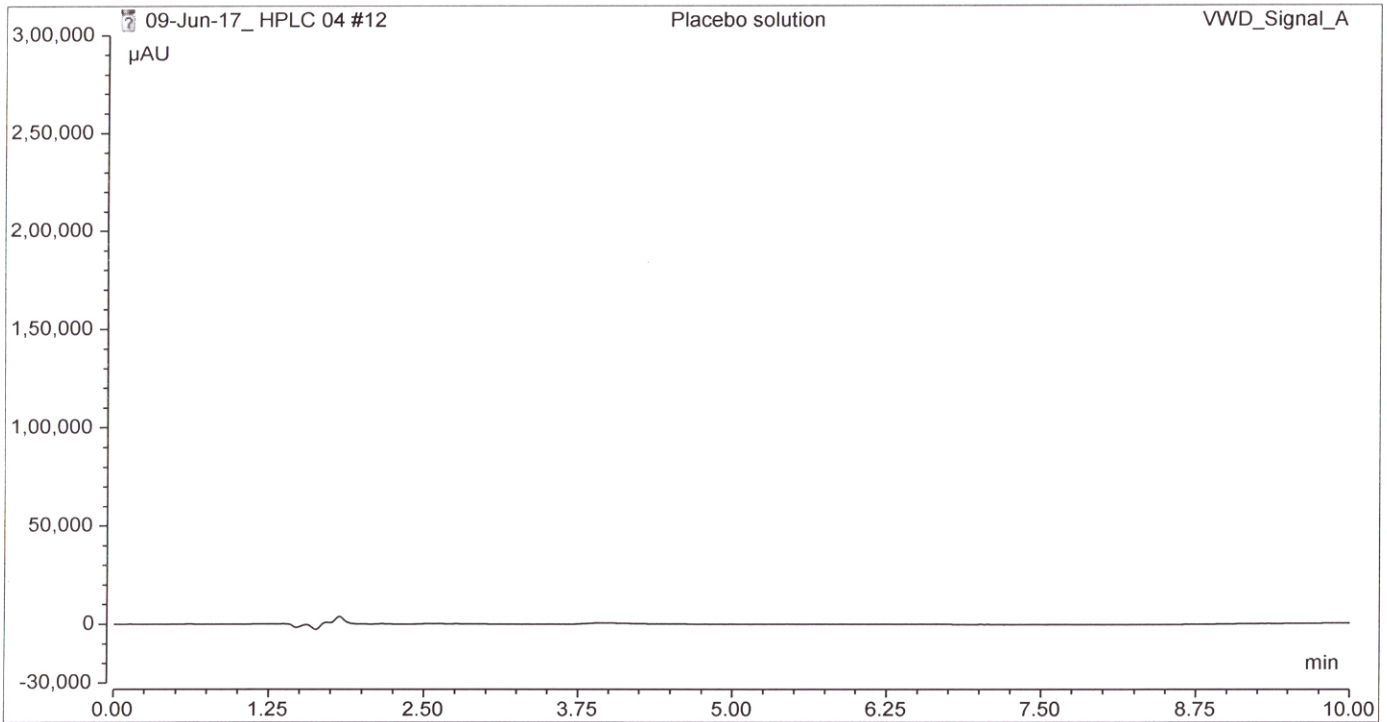
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.177	7038.449	3900	1.24	10.42	43.19
2	Ramipril	4.020	9256.162	5626	1.11	n.a.	56.81
Total:							

Pankaj Gurav
21-Jun-17

Pankaj Gurav
21-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:	09-Jun-17 22:29	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

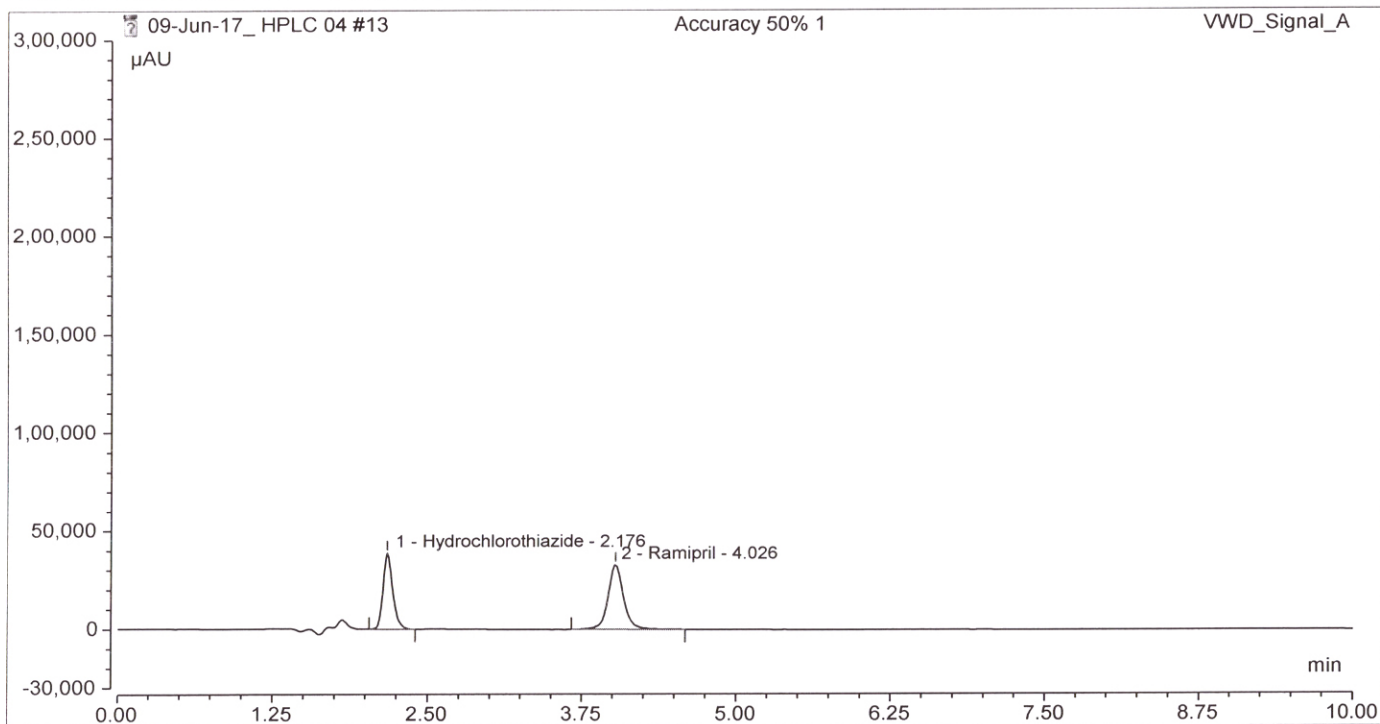
Chromatogram**Integration Results**

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

Pankaj
21-Jun-17Pankaj
22-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 22:40	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	2.176	3507.590	3895	1.27	10.42	42.35
2	Ramipril	4.026	4774.975	5581	1.07	n.a.	57.65
Total:							

Pankaj Gurav
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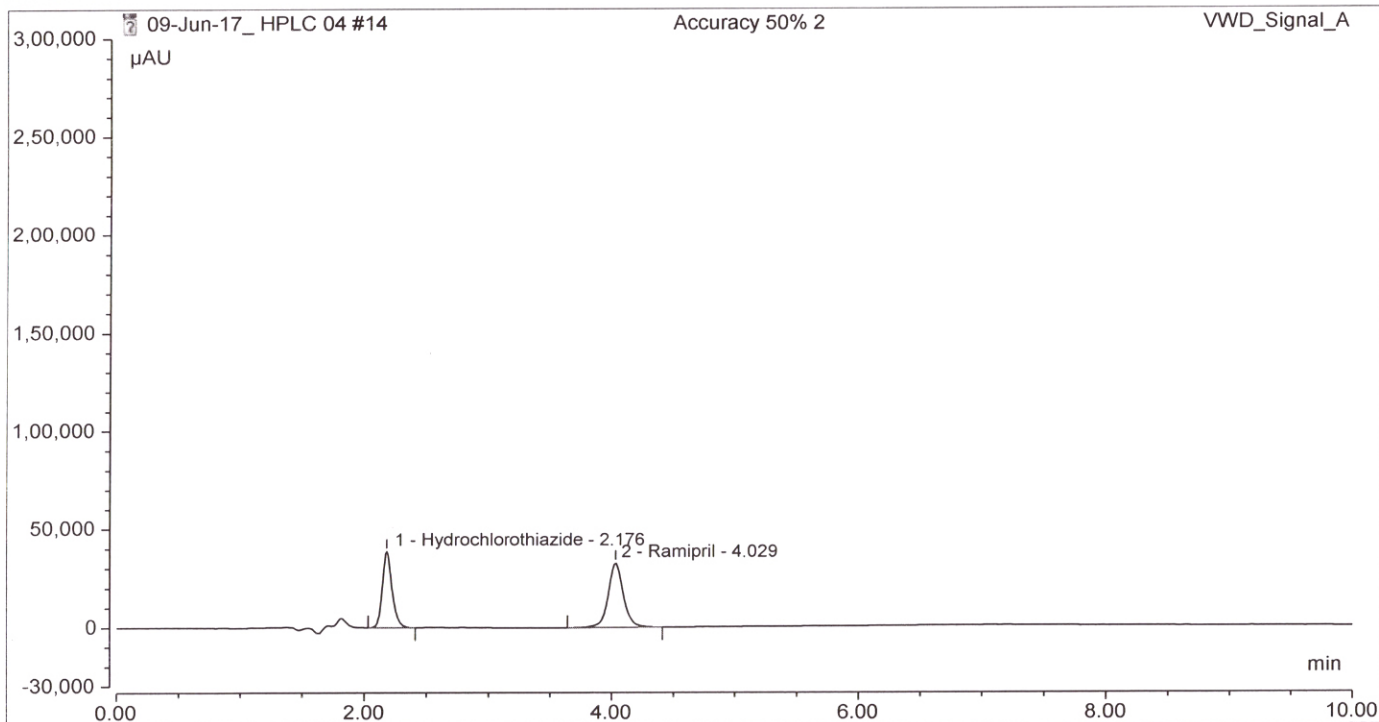
Pankaj Gurav
22-Jun-17

QbD Research & Developement 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 22:52	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	2.176	3523.651	3890	1.28	10.45	42.84
2	Ramipril	4.029	4701.765	5611	1.06	n.a.	57.16
Total:							

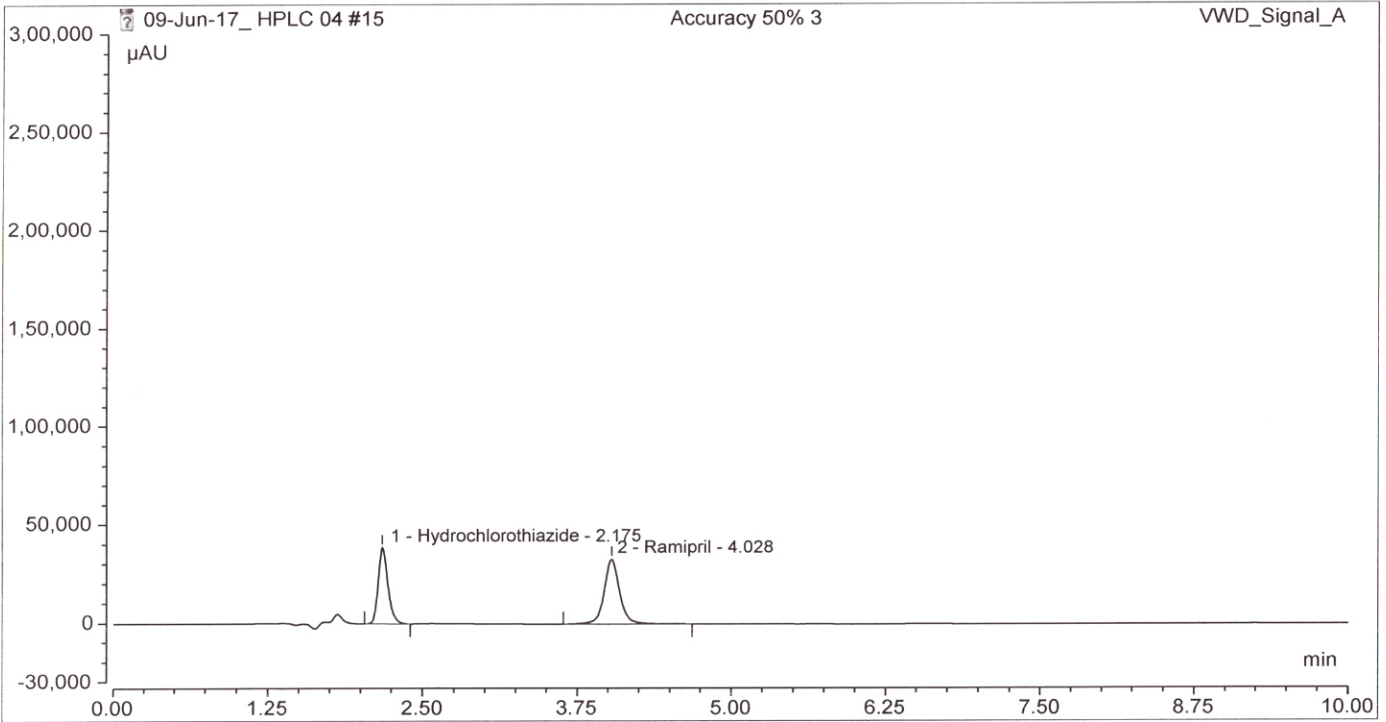
Pankaj Gurav
21-Jun-17Pankaj Gurav
22-Jun-17

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 23:03	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	2.175	3522.441	3884	1.29	10.43	42.29
2	Ramipril	4.028	4807.576	5573	1.08	n.a.	57.71
Total:							

Pankaj
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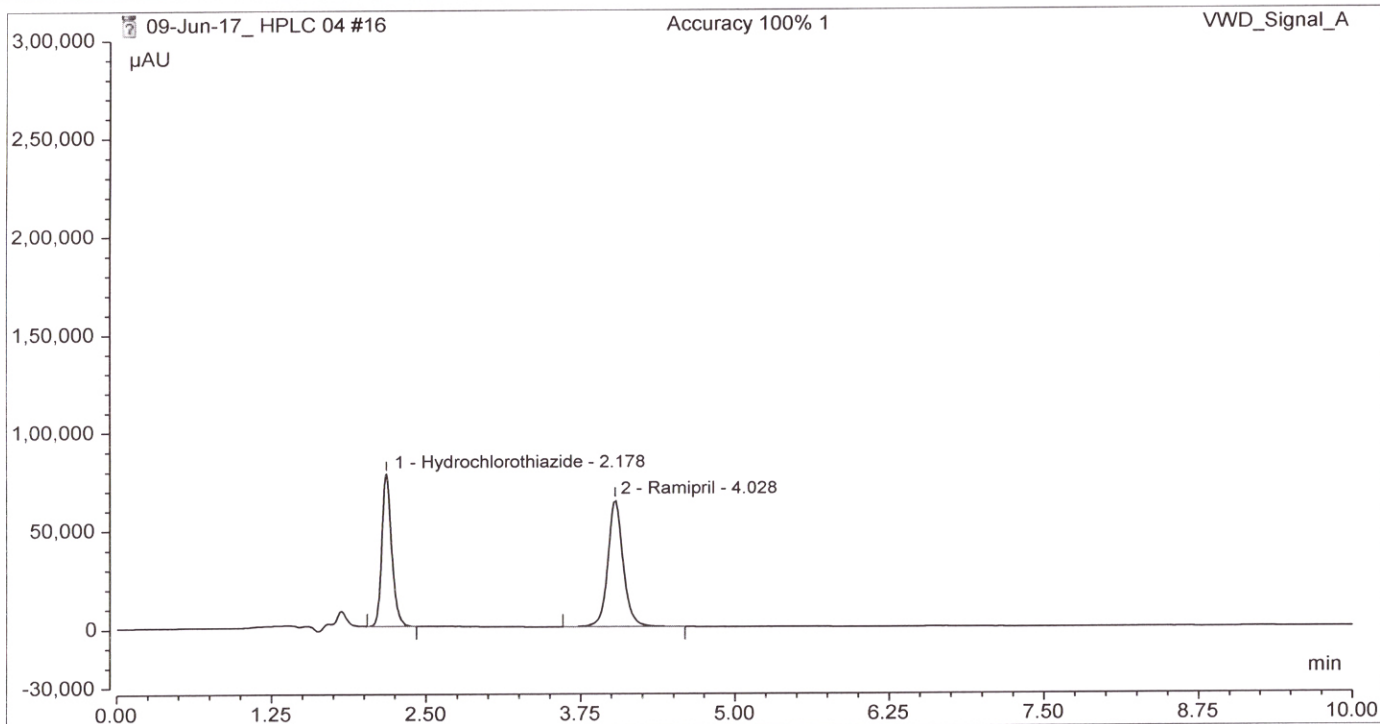
Pankaj
 22-Jun-17

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 23:15	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	7032.703	3903	1.25	10.46	43.32
2	Ramipril	4.028	9199.755	5648	1.10	n.a.	56.68
Total:							

Pankaj
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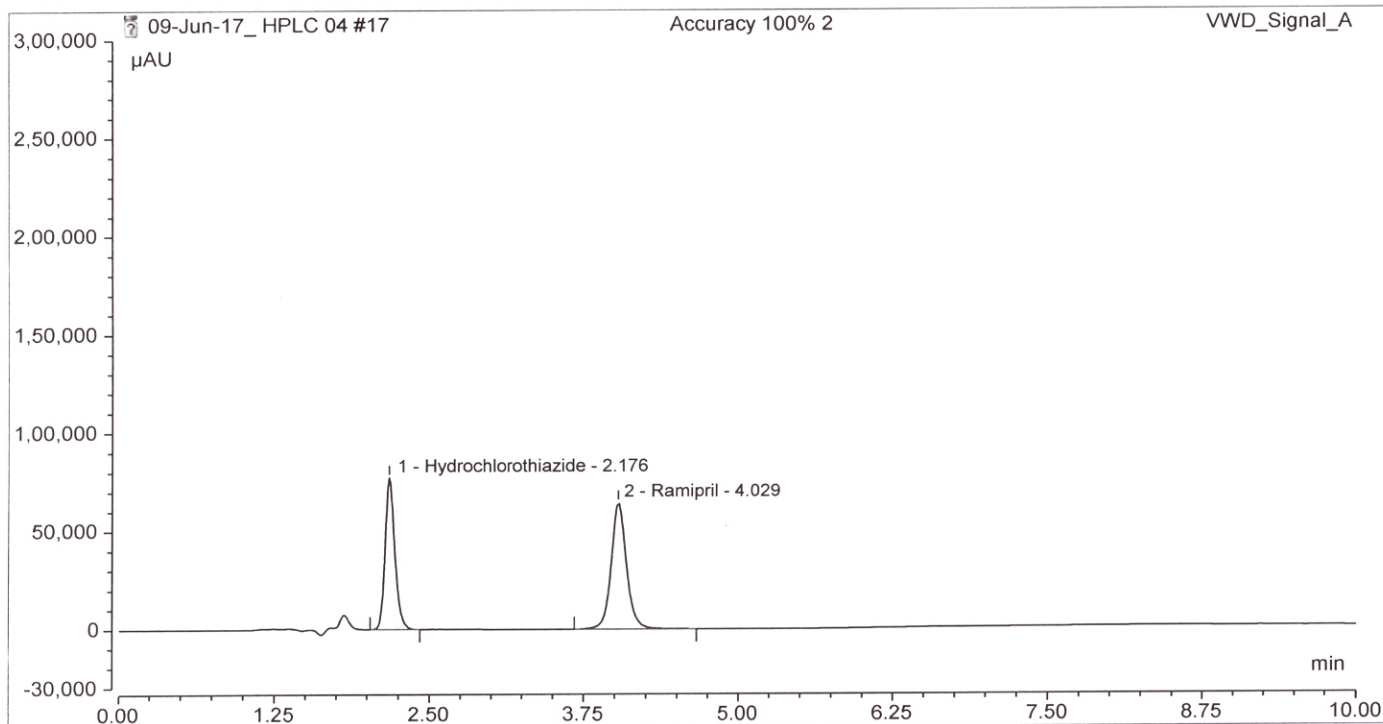
Pankaj
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QbD Research & Development Pvt.Ltd.

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 23:26	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	2.176	7014.152	3903	1.29	10.48	43.28
2	Ramipril	4.029	9192.101	5647	1.10	n.a.	56.72
Total:							

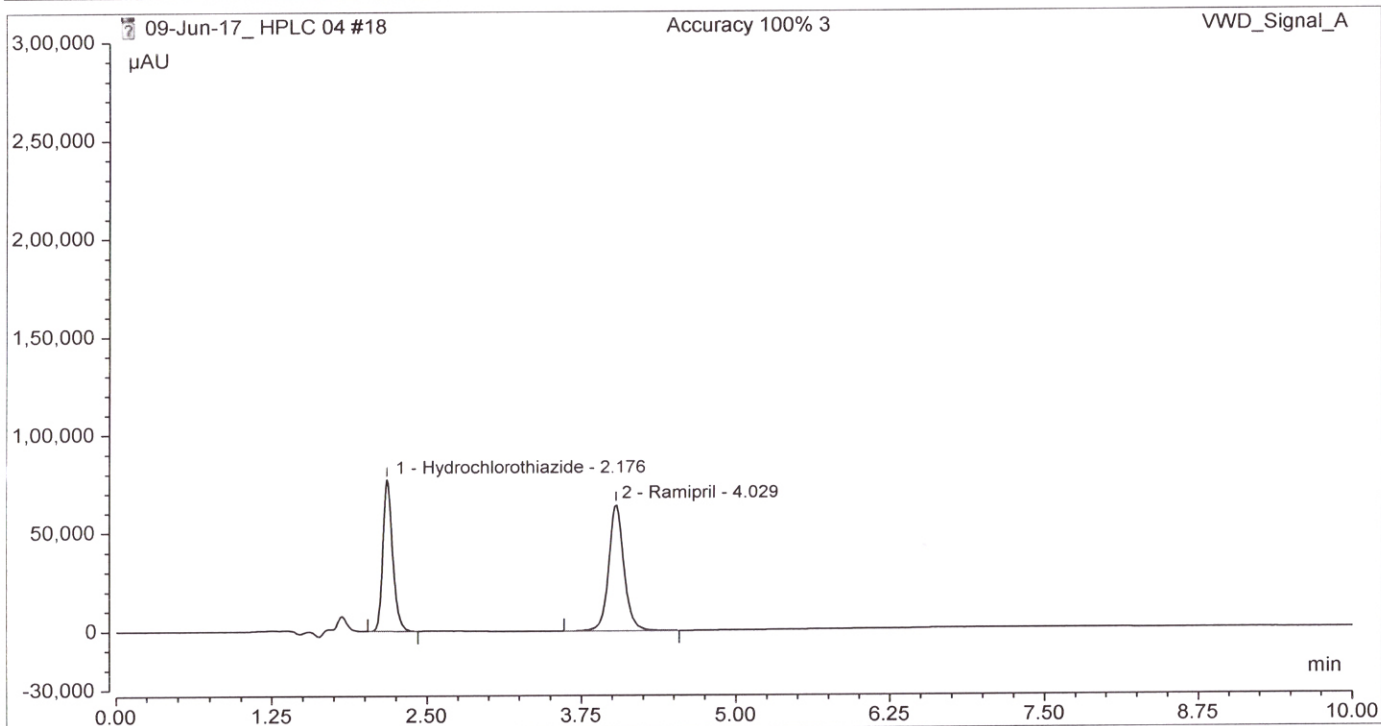
Pankaj Gurav
21-Jun-17Pankaj Gurav
22-Jun-17

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 23:38	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

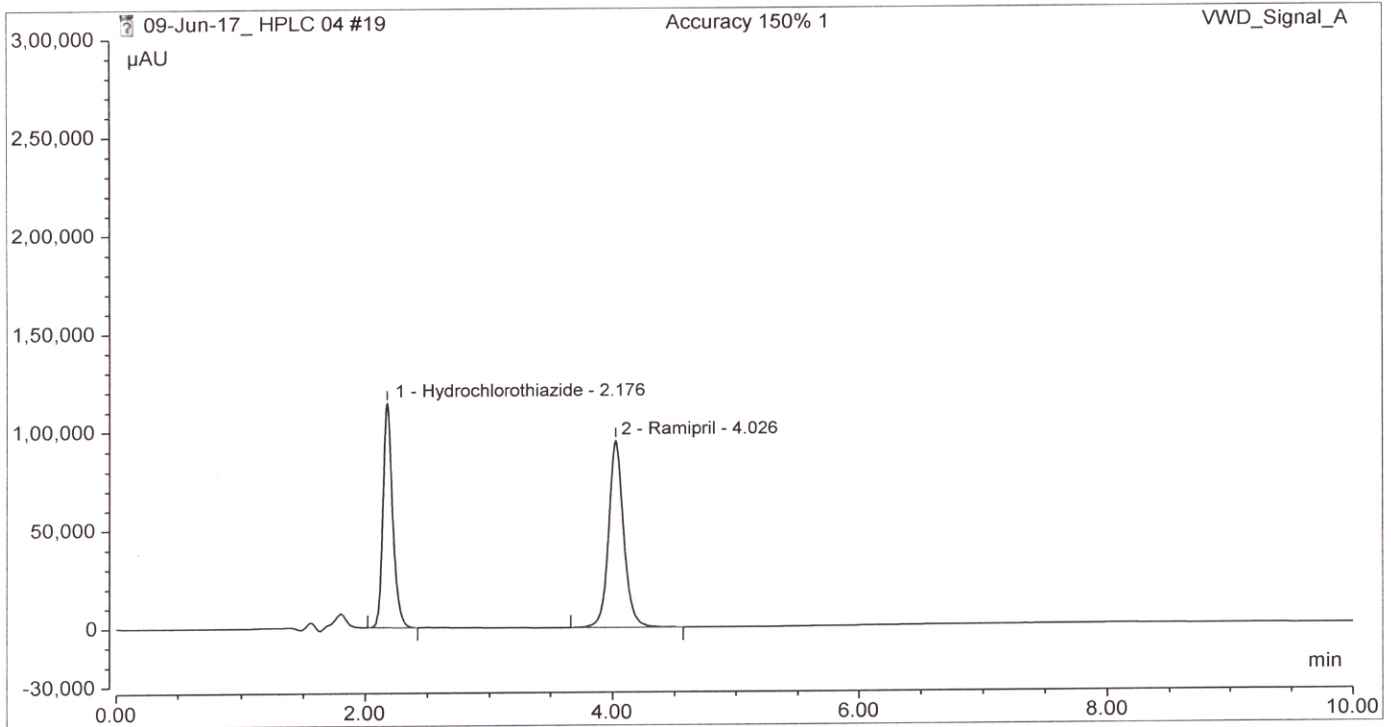
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.176	7029.037	3886	1.30	10.46	43.33
2	Ramipril	4.029	9191.341	5640	1.09	n.a.	56.67
Total:							

Pankaj
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QbD Research & Developement 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 23:49	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	2.176	10364.950	3910	1.28	10.47	43.44
2	Ramipril	4.026	13497.348	5660	1.11	n.a.	56.56
Total:							

Pankaj
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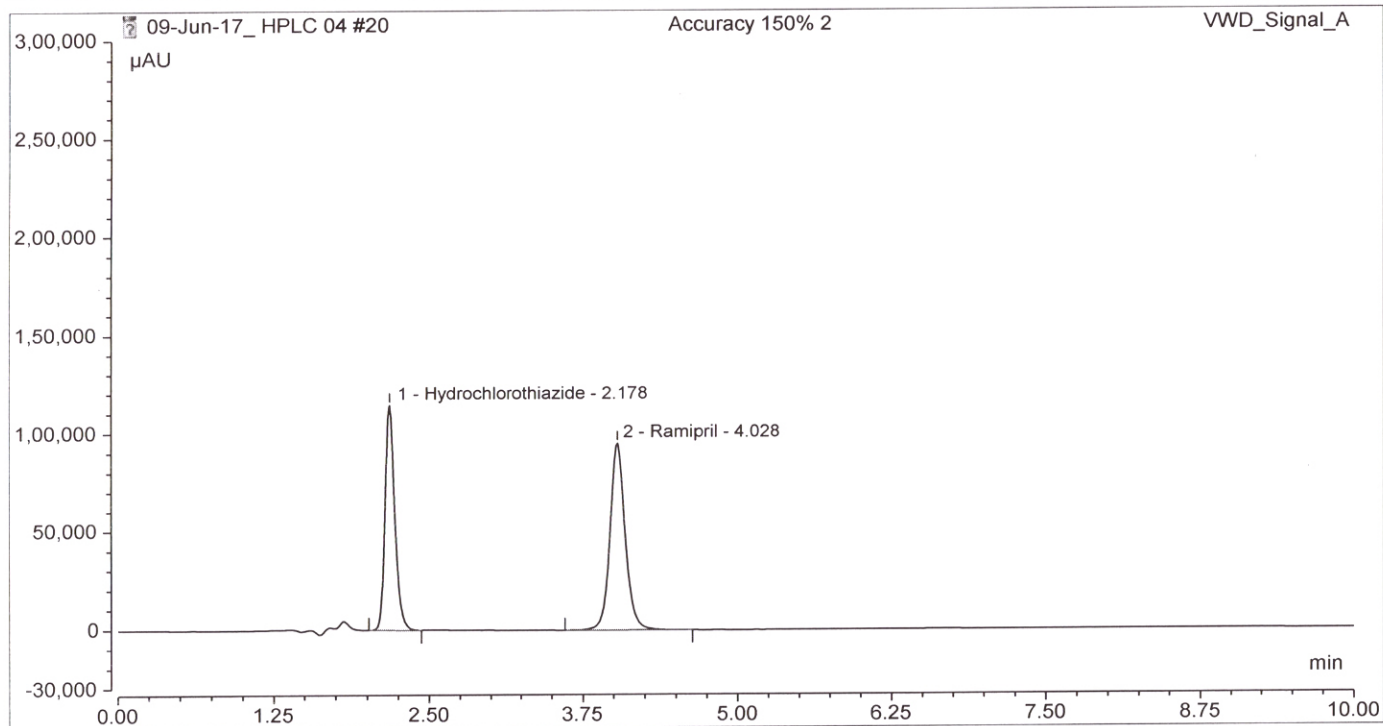
Pankaj
22-Jun-17

QbD Research & Development 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:	10-Jun-17 00:01	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	2.178	10418.452	3907	1.24	10.46	43.46
2	Ramipril	4.028	13552.427	5650	1.09	n.a.	56.54
Total:							

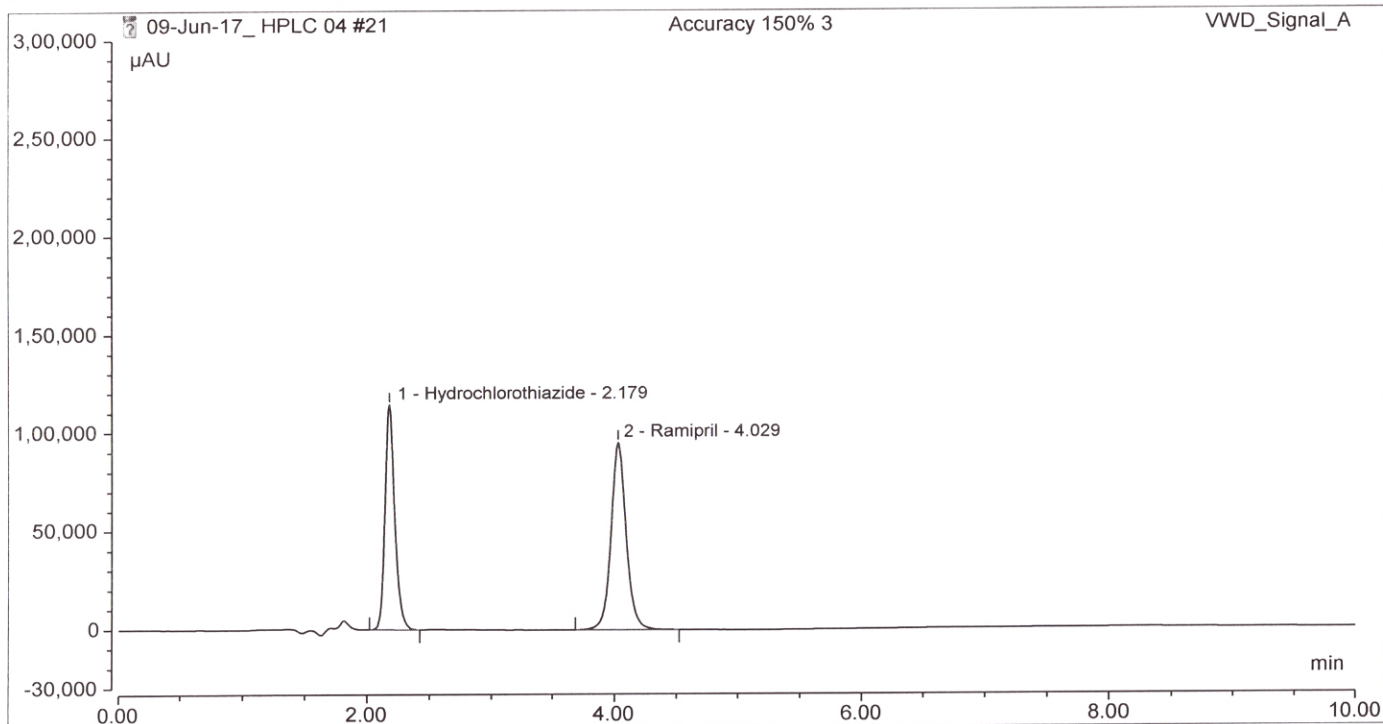
Pankaj Gurav
21-Jun-17Pankaj Gurav
22-Jun-17

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:	10-Jun-17 00:12	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

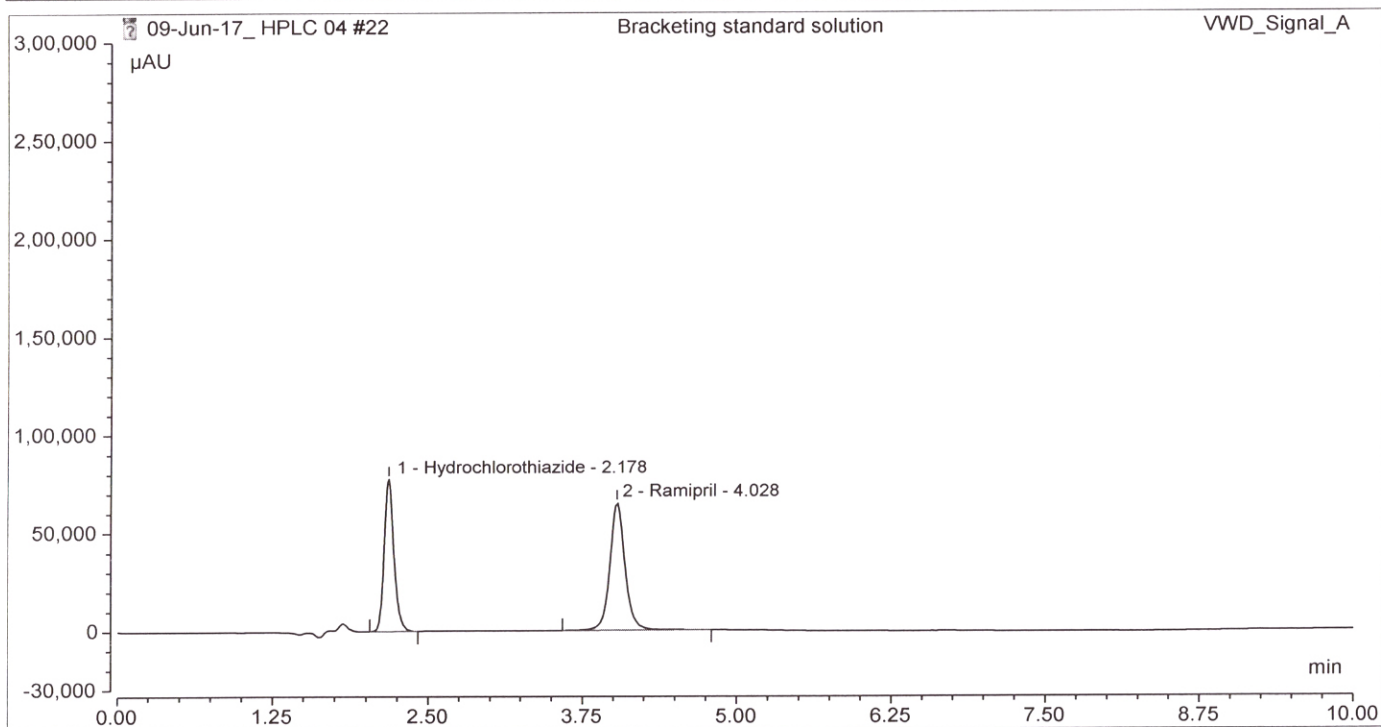
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.179	10393.905	3916	1.25	10.47	43.53
2	Ramipril	4.029	13483.137	5664	1.11	n.a.	56.47
Total:							

Pankaj Gurav
 21-Jun-17

Pankaj Gurav
 22-Jun-17

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:	10-Jun-17 00:24	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	7035.057	3912	1.26	10.47	42.89
2	Ramipril	4.028	9366.461	5654	1.11	n.a.	57.11
Total:							

Pankaj Gurav
21-Jun-17

Pankaj Gurav
21-Jun-17