

RAW DATA OF

(ACCURACY)

RELATED SUBSTANCE METHOD VALIDATION

Product Name:	Ramithiazide Tablets
Label claim (mg):	10 mg And 25 mg
AR No:	D2404181193
Batch No.:	GP180301
Parameter:	Accuracy For Ramipril Impurity D
LNB No./ Page No.	718/001

Analysis Date	19-Nov-18
---------------	-----------

Preparation of standard solution for Ramipril	Weight of standard (mg)	Diluted (mL)	Concentration (ppm)	Purity (As is Basis)
	25.23	25.0		
	2.0	100.0	2.02	99.64
	2.0	20.0		

Ramipril				
Injection No.	Retention Time	Peak Area	Retention Time	Area of Bkt Standard
1	16.127	2099.722	16.053	2132.821
2	16.107	2079.038		
3	16.100	2083.587		
4	16.127	2104.412		
5	16.133	2086.427		
6	16.127	2090.498		
Average	16.120	2090.614	16.111	2096.644
SD	0.0133	9.7393	0.0281	18.2629
%RSD	0.08	0.47	0.17	0.87

System Suitability		
%RSD of Area	0.47	NMT 5.0%

Preparation of standard solution for Hydrochlorothiazide	Weight of standard (mg)	Diluted (mL)	Concentration (ppm)	Purity (As is Basis)
	25.45	25.0		
	2.5	100.0	2.55	99.24
	2.0	20.0		

Hydrochlorothiazide				
Injection No.	Retention Time	Peak Area	Retention Time	Area of Bkt Standard
1	5.147	4385.000	5.180	4405.456
2	5.150	4397.046		
3	5.150	4397.991		
4	5.150	4388.904		
5	5.153	4387.979		
6	5.153	4367.186		
Average	5.151	4387.351	5.155	4389.937
SD	0.0023	11.1549	0.0113	12.2687
%RSD	0.04	0.25	0.22	0.28

System Suitability		
%RSD of Area	0.25	NMT 5.0%

Standard Name	Standard B. No.	Standard purity(%)	Standard wt (mg)	Dilution details	Conc (ppm)	RRF
Ramipril Impurity D	SP-028-152	98.27	14.88	25 mL	595.20	1.22

Injection No.	As Such Sample	
	RT	Peak Area
1	23.930	38262.601
2	23.920	38302.940
3	23.910	38341.274
Average	23.920	38302.272

Preparation of Accuracy level			
Level (%)	mL, diluted to	Diluted (mL)	Actual Concentration (ppm)
LOQ	0.6	20.0	17.55
50	1.0	20.0	29.25
100	2.0	20.0	58.49
150	3.0	20.0	87.74

Accuracy level (%)	Sample	Amount added(ppm)	Area	Corrected Area	Amount recovered (ppm)	% Recovery	Mean % Recovery
LOQ	Sample 1	17.55	56269.142	17966.870	21.10	120.2	120.0
	Sample 2		56204.114	17901.842	21.00	119.7	
	Sample 3		56268.997	17966.725	21.10	120.2	
50	Sample 1	29.25	67111.806	28809.534	33.80	115.6	115.8
	Sample 2		67149.189	28846.917	33.90	115.9	
	Sample 3		67186.512	28884.240	33.90	115.9	
100	Sample 1	58.49	94831.406	56529.134	66.30	113.4	113.6
	Sample 2		94865.375	56563.103	66.40	113.5	
	Sample 3		95030.461	56728.189	66.60	113.9	
150	Sample 1	87.74	122365.078	84062.806	98.70	112.5	112.6
	Sample 2		122440.906	84138.634	98.70	112.5	
	Sample 3		122567.945	84265.673	98.90	112.7	

Done by: *ST*
Date: 27-Nov-18

Checked by: *QbD*
Date: 27-Nov-18

RELATED SUBSTANCE METHOD VALIDATION

Product Name:	Ramithiazide Tablets
Label claim (mg):	10 mg And 25 mg
AR No:	D2404181193
Batch No.:	GP180301
Parameter:	Accuracy For Ramipril Impurity A
LNB No./ Page No.	718/091

Analysis Date 19-Nov-18

Preparation of standard solution for Ramipril	Weight of standard (mg)	Diluted (mL)	Concentration (ppm)	Purity (As is Basis)
	25.23	25.0		
	2.0	100.0	2.02	99.64
	2.0	20.0		

Ramipril				
Injection No.	Retention Time	Peak Area	Retention Time	Area of Bkt Standard
1	16.127	2099.722	16.053	2132.821
2	16.107	2079.038		
3	16.100	2083.587		
4	16.127	2104.412		
5	16.133	2086.427		
6	16.127	2090.498		
Average	16.120	2090.614	16.111	2096.644
SD	0.0133	9.7393	0.0281	18.2629
%RSD	0.08	0.47	0.17	0.87

System Suitability			
%RSD of Area	0.47	0.17	NMT 5.0%

Preparation of standard solution for Hydrochlorothiazide	Weight of standard (mg)	Diluted (mL)	Concentration (ppm)	Purity (As is Basis)
	25.45	25.0		
	2.5	100.0	2.55	99.24
	2.0	20.0		

Hydrochlorothiazide				
Injection No.	Retention Time	Peak Area	Retention Time	Area of Bkt Standard
1	5.147	4385.000	5.180	4405.456
2	5.150	4397.046		
3	5.150	4397.991		
4	5.150	4388.904		
5	5.153	4387.979		
6	5.153	4367.186		
Average	5.151	4387.351	5.155	4389.937
SD	0.0023	11.1549	0.0113	12.2687
%RSD	0.04	0.25	0.22	0.28

System Suitability			
%RSD of Area	0.25	0.22	NMT 5.0%

Sample solution :	Eq to 20 mg	diluted to	20.0	mL with Diluent
-------------------	-------------	------------	------	-----------------

Standard Name	Standard B. No.	Standard purity(%)	Standard wt (mg)	Dilution details	Conc (ppm)	RRF
Ramipril Impurity A	SP-023-164	97.64	6.07	25 mL	242.80	1.15

Preparation of Accuracy level			
Level (%)	mL, diluted to	Diluted (mL)	Actual Concentration (ppm)
LOQ	0.6	20.0	7.11
50	1.0	20.0	11.85
100	2.0	20.0	23.71
150	3.0	20.0	35.56

Accuracy level (%)	Sample	Amount added(ppm)	Area	Amount recovered (ppm)	% Recovery	Mean % Recovery
LOQ	Sample 1	7.11	6182.408	6.80	95.6	95.6
	Sample 2		6172.445	6.80	95.6	
	Sample 3		6178.683	6.80	95.6	
50	Sample 1	11.85	10248.555	11.30	95.3	95.3
	Sample 2		10218.073	11.30	95.3	
	Sample 3		10210.747	11.30	95.3	
100	Sample 1	23.71	20487.535	22.70	95.8	95.6
	Sample 2		20471.264	22.60	95.3	
	Sample 3		20504.030	22.70	95.8	
150	Sample 1	35.56	30939.252	34.20	96.2	96.3
	Sample 2		30962.018	34.30	96.5	
	Sample 3		30950.782	34.20	96.2	

Done by: 
Date: 27-Nov-18

Checked by: 
Date: 27-Nov-18

RELATED SUBSTANCE METHOD VALIDATION

Product Name:	Ramithiazide Tablets
Label claim (mg):	10 mg And 25 mg
AR No:	D2404181193
Batch No.:	GP180301
Parameter:	Accuracy For Ramipril Impurity E
LNB No./ Page No.	718/001

Analysis Date	19-Nov-18
---------------	-----------

Preparation of standard solution for Ramipril	Weight of standard (mg)	Diluted (mL)	Concentration (ppm)	Purity (As is Basis)
	25.23	25.0		
	2.0	100.0	2.02	99.64
	2.0	20.0		

Ramipril				
Injection No.	Retention Time	Peak Area	Retention Time	Area of Bkt Standard
1	16.127	2099.722	16.053	2132.821
2	16.107	2079.038		
3	16.100	2083.587		
4	16.127	2104.412		
5	16.133	2086.427		
6	16.127	2090.498		
Average	16.120	2090.614	16.111	2096.644
SD	0.0133	9.7393	0.0281	18.2629
%RSD	0.08	0.47	0.17	0.87

System Suitability		
%RSD of Area	0.47	NTM 5.0%

Preparation of standard solution for Hydrochlorothiazide	Weight of standard (mg)	Diluted (mL)	Concentration (ppm)	Purity (As is Basis)
	25.45	25.0		
	2.5	100.0	2.55	99.24
	2.0	20.0		

Hydrochlorothiazide				
Injection No.	Retention Time	Peak Area	Retention Time	Area of Bkt Standard
1	5.147	4385.000	5.180	4405.456
2	5.150	4397.046		
3	5.150	4397.991		
4	5.150	4388.904		
5	5.153	4387.979		
6	5.153	4367.186		
Average	5.151	4387.351	5.155	4389.937
SD	0.0023	11.1549	0.0113	12.2687
%RSD	0.04	0.25	0.22	0.28

System Suitability		
%RSD of Area	0.25	NTM 5.0%

Standard Name	Standard B. No.	Standard purity(%)	Standard wt (mg)	Dilution details	Conc (ppm)	RRF
Ramipril Impurity E	SP-027-084	95.39	5.17	25 mL	206.80	22.09

Injection No.	As Such Sample	
	RT	Peak Area
1	14.097	418.297
2	14.087	414.109
3	14.090	425.468
Average	14.091	419.291

Preparation of Accuracy level			
Level (%)	mL, diluted to	Diluted (mL)	Actual Concentration (ppm)
LOQ	0.6	20.0	5.92
50	1.0	20.0	9.86
100	2.0	20.0	19.73
150	3.0	20.0	29.59

Accuracy level (%)	Sample	Amount added(ppm)	Area	Corrected Area	Amount recovered (ppm)	% Recovery	Mean % Recovery
LOQ	Sample 1	5.92	687.928	268.637	5.70	96.3	99.1
	Sample 2		704.799	285.508	6.10	103.1	
	Sample 3		692.966	273.675	5.80	98.0	
50	Sample 1	9.86	903.913	484.622	10.30	104.4	105.4
	Sample 2		914.204	494.913	10.50	106.5	
	Sample 3		908.864	489.573	10.40	105.4	
100	Sample 1	19.73	1447.351	1028.060	21.80	110.5	110.7
	Sample 2		1440.957	1021.666	21.70	110.0	
	Sample 3		1452.617	1033.326	22.00	111.5	
150	Sample 1	29.59	1993.535	1574.244	33.50	113.2	113.9
	Sample 2		2015.388	1596.097	33.90	114.6	
	Sample 3		2005.915	1586.624	33.70	113.9	

Done by: 
Date: 27 Nov 18

Checked by: 
Date: 27 Nov 18



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Instrument ID : QbD-INST-HPLC-67

Sequence Name : HPLC-67_19-Nov-18_A

Data Vault : QbD_2018

Sequence Path : Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq

Seq. Created By : Swaraj A. Jadhav

Seq. Created On : 19-11-2018 14:43:38

Seq. Last Updated By : Swaraj A. Jadhav

Seq. Last Updated On : 19-11-2018 15:14:55

Inj No.	Injection Name	Injection Type	Volume µL	Vial No.	Status	Injection Time	Instrument Method	Processing Method	Level	AR_NO	BATCH_NO	COLUMN_NO
1	Blank Solution	Unknown	30.00	R-1	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
2	Blank Solution	Unknown	30.00	RA1	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
3	Standard Solution 1	Unknown	30.00	RA2	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
4	Standard Solution 2	Unknown	30.00	RA2	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
5	Standard Solution 3	Unknown	30.00	RA2	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
6	Standard Solution 4	Unknown	30.00	RA2	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
7	Standard Solution 5	Unknown	30.00	RA2	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
8	Standard Solution 6	Unknown	30.00	RA2	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
9	Blank Solution	Unknown	30.00	RA1	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
10	Sample Solution 1 (As Such)	Unknown	30.00	RA3	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	Tablets_RS_Pf		D2404181993	GP180301	QbD/LC/COL/128
11	Sample Solution 2 (As Such)	Unknown	30.00	RA4	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	Tablets_RS_Pf		D2404181993	GP180301	QbD/LC/COL/128
12	Sample Solution 3 (As Such)	Unknown	30.00	RA5	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	Tablets_RS_Pf		D2404181993	GP180301	QbD/LC/COL/128
13	LOQ Level 1	Unknown	30.00	RA6	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
14	LOQ Level 2	Unknown	30.00	RA7	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
15	LOQ Level 3	Unknown	30.00	RA8	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
16	50 % Level 1	Unknown	30.00	RB1	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
17	50 % Level 2	Unknown	30.00	RB2	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
18	50 % Level 3	Unknown	30.00	RB3	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
19	100 % Level 1	Unknown	30.00	RB4	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
20	100 % Level 2	Unknown	30.00	RB5	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
21	100 % Level 3	Unknown	30.00	RB6	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
22	150 % Level 1	Unknown	30.00	RB7	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
23	150 % Level 2	Unknown	30.00	RB8	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
24	150 % Level 3	Unknown	30.00	RC1	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
25	Blank Solution	Unknown	30.00	RA1	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
26	Bracketing Standard Solution	Unknown	30.00	RA2	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
27	Wash	Unknown	30.00	RA1	Idle	n.a.	Wash method_HPLC 67_NeRamithiazide Tablets_RS_Pf	Tablets_RS_Pf		N/A	N/A	QbD/LC/COL/128
28	Shut	Unknown	30.00	RA1	Idle	n.a.	Shut method_HPLC 67_NeRamithiazide Tablets_RS_Pf	Tablets_RS_Pf		N/A	N/A	QbD/LC/COL/128

* Refer AR No:- D2404181193 instead of AR No:- D2404181993

19 Nov 18

QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Instrument ID :	QbD-INST-HPLC-67	Seq. Created By :	Swaraj A. Jadhav	Seq. Last Updated By :	Swaraj A. Jadhav
Sequence Name :	HPLC-67_19-Nov-18_A	Seq. Created On :	19-11-2018 14:43:38	Seq. Last Updated On	19-11-2018 15:14:55
Data Vault :	QbD_2018				
Sequence Path :	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq				

<i>Name</i>	HPLC-67_Ramithiazide Tablet_RS_Met
<i>Data Vault</i>	QbD_2018
<i>Path</i>	chrom://qbdser03/QbD_2018/Method Validation/Generic Healthcare/Ramithiazide Tablet/Related Substances/HPLC-67_19- Nov-18_A.seq/HPLC-67_Ramithiazide Tablet_RS_Met.instmeth
<i>Comment</i>	Ramithiazide Tablet
<i>Description</i>	Ramithiazide Tablet instrument method created
<i>Run time</i>	30.000 [min]
<i>Instrument</i>	QbD-INST-HPLC-67 on qbd-pc-19
<i>Created</i>	14-Nov-18 16:46:53 +05:30 Gauri Rane
<i>Last Update</i>	14-Nov-18 16:46:53 +05:30 Gauri Rane

SD
19-Nov-18

SD
19-Nov-18

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	1.0 [°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	75.000 [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	"Mobile Phase A"	
		PumpModule.Pump.%B.Equate	"Mobile Phase 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/min ²]	
		PumpModule.Pump.MaximumFlowRampDown	5.998 [ml/min ²]	

19-Nov-18

19-Nov-18

Inject Preparation	0.000	DAD.UV_VIS_1.Wavelength	210.0 [nm]
		DAD.UV_VIS_1.Bandwidth	4 [nm]
		DAD.UV_VIS_1.RefWavelength	Off
		DAD.UV_VIS_1.RefBandwidth	1 [nm]
		DAD.3DFIELD.RefWavelength	800.0 [nm]
		DAD.3DFIELD.RefBandwidth	1 [nm]
Inject	0.000	DAD.Autozero	
		Wait	DAD.Ready And ColumnOven.Re ady And Sampler.Ready And PumpModule.Pu mp.Ready
Start Run	0.000	Sampler.Inject	
Run	0.000	DAD.UV_VIS_1.AcqOn	
		DAD.3DFIELD.AcqOn	
		DAD.Temp_Lamphouse.AcqOn	
		ColumnOven.ColumnOven_Temp.AcqOn	
		PumpModule.Pump.Pump_Pressure.AcqOn	
			Duration = 30.000 [min]
		PumpModule.Pump.Flow.Nominal	1.000 [ml/min]
		PumpModule.Pump.%B.Value	30.0 [%]
		PumpModule.Pump.%C.Value	0.0 [%]
		PumpModule.Pump.%D.Value	0.0 [%]
		PumpModule.Pump.Curve	5
		PumpModule.Pump.Flow.Nominal	1.000 [ml/min]
		PumpModule.Pump.%B.Value	30.0 [%]
		PumpModule.Pump.%C.Value	0.0 [%]
		PumpModule.Pump.%D.Value	0.0 [%]
		PumpModule.Pump.Curve	5
		PumpModule.Pump.Flow.Nominal	1.000 [ml/min]
		PumpModule.Pump.%B.Value	50.0 [%]
		PumpModule.Pump.%C.Value	0.0 [%]
		PumpModule.Pump.%D.Value	0.0 [%]
		PumpModule.Pump.Curve	5
		PumpModule.Pump.Flow.Nominal	1.000 [ml/min]
		PumpModule.Pump.%B.Value	50.0 [%]
		PumpModule.Pump.%C.Value	0.0 [%]

19 Nov 18

19 Nov 18

Stop Run	30.000	PumpModule.Pump.%D.Value	0.0 [%]
		PumpModule.Pump.Curve	5
		PumpModule.Pump.Flow.Nominal	1.000 [ml/min]
		PumpModule.Pump.%B.Value	30.0 [%]
		PumpModule.Pump.%C.Value	0.0 [%]
		PumpModule.Pump.%D.Value	0.0 [%]
	30.000	PumpModule.Pump.Curve	5
		DAD.UV_VIS_1.AcqOff	
		DAD.3DFIELD.AcqOff	
		DAD.Temp_Lamphouse.AcqOff	
		ColumnOven.ColumnOven_Temp.AcqOff	
		PumpModule.Pump.Pump_Pressure.AcqOff	
End			

88
19-Nov-18

P17
19 Nov 18



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Instrument ID : QbD-INST-HPLC-67
Sequence Name : HPLC-67_19-Nov-18_A
Data Vault : QbD_2018
Sequence Path : Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq

Seq. Created By : Swaraj A. Jadhav
Seq. Created On : 19-11-2018 14:43:38

Inj No.	Injection Name	Injection Type	Volume µL	Vial No.	Status	Injection Time	Instrument Method	Processing Method	Level
1	Blank Solution	Unknown	30.00	RA1	Finished	19-11-2018 15:53:32	67_Ramithiazide Tablet_R	Ramithiazide Tablets_RS_Pf	
2	Blank Solution	Unknown	30.00	RA1	Finished	19-11-2018 16:24:50	67_Ramithiazide Tablet_R	Ramithiazide Tablets_RS_Pf	
3	Standard Solution 1	Unknown	30.00	RA2	Finished	19-11-2018 16:56:07	67_Ramithiazide Tablet_R	Ramithiazide Tablets_RS_Pf	
4	Standard Solution 2	Unknown	30.00	RA2	Finished	19-11-2018 17:27:25	67_Ramithiazide Tablet_R	Ramithiazide Tablets_RS_Pf	
5	Standard Solution 3	Unknown	30.00	RA2	Finished	19-11-2018 17:58:37	67_Ramithiazide Tablet_R	Ramithiazide Tablets_RS_Pf	
6	Standard Solution 4	Unknown	30.00	RA2	Finished	19-11-2018 18:29:55	67_Ramithiazide Tablet_R	Ramithiazide Tablets_RS_Pf	
7	Standard Solution 5	Unknown	30.00	RA2	Finished	19-11-2018 19:01:12	67_Ramithiazide Tablet_R	Ramithiazide Tablets_RS_Pf	
8	Standard Solution 6	Unknown	30.00	RA2	Finished	19-11-2018 19:32:25	67_Ramithiazide Tablet_R	Ramithiazide Tablets_RS_Pf	
9	Blank Solution	Unknown	30.00	RA1	Finished	19-11-2018 20:03:42	67_Ramithiazide Tablet_R	Ramithiazide Tablets_RS_Pf	
10	Sample Solution 1 (As Such)	Unknown	30.00	RA3	Finished	19-11-2018 20:34:55	67_Ramithiazide Tablet_R	Ramithiazide Tablets_RS_Pf	
11	Sample Solution 2 (As Such)	Unknown	30.00	RA4	Finished	19-11-2018 21:06:08	67_Ramithiazide Tablet_R	Ramithiazide Tablets_RS_Pf	
12	Sample Solution 3 (As Such)	Unknown	30.00	RA5	Finished	19-11-2018 21:37:20	67_Ramithiazide Tablet_R	Ramithiazide Tablets_RS_Pf	
13	LOQ Level 1	Unknown	30.00	RA6	Finished	19-11-2018 22:08:33	67_Ramithiazide Tablet_R	Ramithiazide Tablets_RS_Pf	
14	LOQ Level 2	Unknown	30.00	RA7	Finished	19-11-2018 22:39:50	67_Ramithiazide Tablet_R	Ramithiazide Tablets_RS_Pf	
15	LOQ Level 3	Unknown	30.00	RA8	Finished	19-11-2018 23:11:07	67_Ramithiazide Tablet_R	Ramithiazide Tablets_RS_Pf	
16	50 % Level 1	Unknown	30.00	RB1	Finished	19-11-2018 23:42:19	67_Ramithiazide Tablet_R	Ramithiazide Tablets_RS_Pf	
17	50 % Level 2	Unknown	30.00	RB2	Finished	20-11-2018 00:13:36	67_Ramithiazide Tablet_R	Ramithiazide Tablets_RS_Pf	
18	50 % Level 3	Unknown	30.00	RB3	Finished	20-11-2018 00:44:53	67_Ramithiazide Tablet_R	Ramithiazide Tablets_RS_Pf	
19	100 % Level 1	Unknown	30.00	RB4	Finished	20-11-2018 01:16:10	67_Ramithiazide Tablet_R	Ramithiazide Tablets_RS_Pf	
20	100 % Level 2	Unknown	30.00	RB5	Finished	20-11-2018 01:47:22	67_Ramithiazide Tablet_R	Ramithiazide Tablets_RS_Pf	
21	100 % Level 3	Unknown	30.00	RB6	Finished	20-11-2018 02:18:35	67_Ramithiazide Tablet_R	Ramithiazide Tablets_RS_Pf	
22	150 % Level 1	Unknown	30.00	RB7	Finished	20-11-2018 02:49:47	67_Ramithiazide Tablet_R	Ramithiazide Tablets_RS_Pf	
23	150 % Level 2	Unknown	30.00	RB8	Finished	20-11-2018 03:20:59	67_Ramithiazide Tablet_R	Ramithiazide Tablets_RS_Pf	
24	150 % Level 3	Unknown	30.00	RC1	Finished	20-11-2018 03:52:11	67_Ramithiazide Tablet_R	Ramithiazide Tablets_RS_Pf	
25	Blank Solution	Unknown	30.00	RA1	Finished	20-11-2018 04:23:28	67_Ramithiazide Tablet_R	Ramithiazide Tablets_RS_Pf	
26	Bracketing Standard Solution	Unknown	30.00	RA2	Finished	20-11-2018 04:54:46	67_Ramithiazide Tablet_R	Ramithiazide Tablets_RS_Pf	
27	Wash	Unknown	30.00	RA1	Finished	20-11-2018 05:29:58	Wash method _HPLC 67_Ne	Ramithiazide Tablets_RS_Pf	
28	Shut	Unknown	30.00	RA1	Finished	20-11-2018 06:35:14	Shut method _HPLC 67_Ne	Ramithiazide Tablets_RS_Pf	

Seq. Last Updated By : Swaraj A. Jadhav
Seq. Last Updated On : 27-11-2018 19:06:12

AR_NO	BATCH_NO	COLUMN_NO
D2404181993	N/A	QbD/LC/COL/128
D2404181993	N/A	QbD/LC/COL/128
D2404181993	N/A	QbD/LC/COL/128
D2404181993	N/A	QbD/LC/COL/128
D2404181993	N/A	QbD/LC/COL/128
D2404181993	N/A	QbD/LC/COL/128
D2404181993	N/A	QbD/LC/COL/128
D2404181993	N/A	QbD/LC/COL/128
D2404181993	N/A	QbD/LC/COL/128
D2404181993	N/A	QbD/LC/COL/128
D2404181993	GP180301	QbD/LC/COL/128
D2404181993	GP180301	QbD/LC/COL/128
D2404181993	GP180301	QbD/LC/COL/128
D2404181993	N/A	QbD/LC/COL/128
D2404181993	N/A	QbD/LC/COL/128
D2404181993	N/A	QbD/LC/COL/128
D2404181993	N/A	QbD/LC/COL/128
D2404181993	N/A	QbD/LC/COL/128
D2404181993	N/A	QbD/LC/COL/128
D2404181993	N/A	QbD/LC/COL/128
D2404181993	N/A	QbD/LC/COL/128
D2404181993	N/A	QbD/LC/COL/128
D2404181993	N/A	QbD/LC/COL/128
D2404181993	N/A	QbD/LC/COL/128
D2404181993	N/A	QbD/LC/COL/128
D2404181993	N/A	QbD/LC/COL/128
D2404181993	N/A	QbD/LC/COL/128
D2404181993	N/A	QbD/LC/COL/128
N/A	N/A	QbD/LC/COL/128
N/A	N/A	QbD/LC/COL/128

Refer AR NO:- D2404181193 instead of AR NO:- D2404181993

28-Nov-18



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Processing Method

Processing Method Name :	Ramithiazide Tablets_RS_PR		
Processing Method Path :	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq		
Processing Method Created By :	Swaraj A. Jadhav	Processing Method Last Updated By :	Swaraj A. Jadhav
Processing Method Created On :	19-11-2018 14:54:36	Processing Method Last Updated On :	27-11-2018 18:02:43

Detection Alogrithm	Chromeleon 6	Version	4
---------------------	--------------	---------	---

Detection Parameter

Ret. Time min	Param. Name	Param. Value	Inj. Type	Channel
0.000	Minimum Area	20.0000 [Signal*min]	Any	All Channels
0.000	Valley To Valley	On	Any	All Channels
0.446	Inhibit Integration	On	Any	All Channels
4.273	Inhibit Integration	Off	Any	All Channels
4.500	Minimum Width	0.250 [min]	Any	All Channels
5.500	Minimum Width	0.000 [min]	Any	All Channels
7.500	Minimum Height	2000.000 [Signal]	Any	All Channels
9.558	Inhibit Integration	On	Any	All Channels
12.777	Inhibit Integration	Off	Any	All Channels
14.000	Minimum Height	0.000 [Signal]	Any	All Channels
14.000	Tailing Sensitivity Factor	1.200	Any	All Channels
14.500	Tailing Sensitivity Factor	Off	Any	All Channels
15.445	Minimum Area	2000.0000 [Signal*min]	Any	All Channels
22.500	Minimum Area	20.0000 [Signal*min]	Any	All Channels

Peak Table

No.	Peak Name	Ret. Time
1	Placebo	4.617
2	Hydrochlorothiazide	5.140
3	Impurity E	14.063
4	Impurity A	14.640
5	Ramipril	15.900
6	Impurity D	23.887

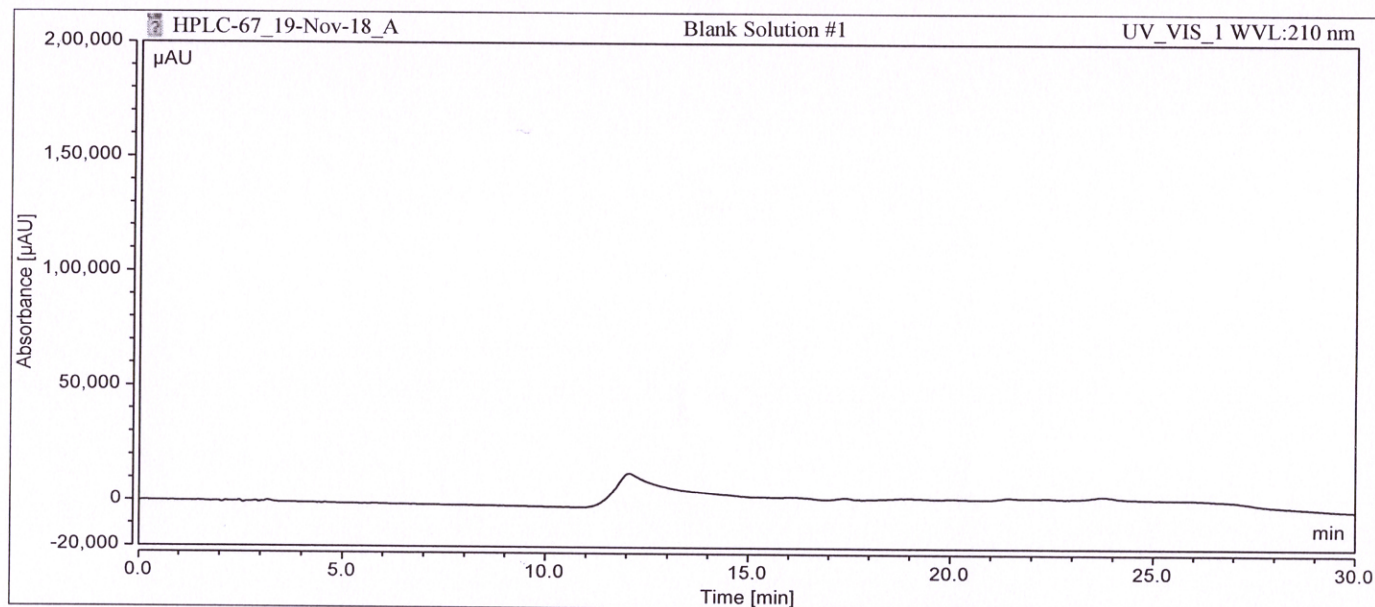
QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Processing Method



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	1	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA1	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	27-11-2018 18:02:43
Injection Date & Time :-	19-11-2018 15:53:32	Experiment Name:-	Accuracy
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq		

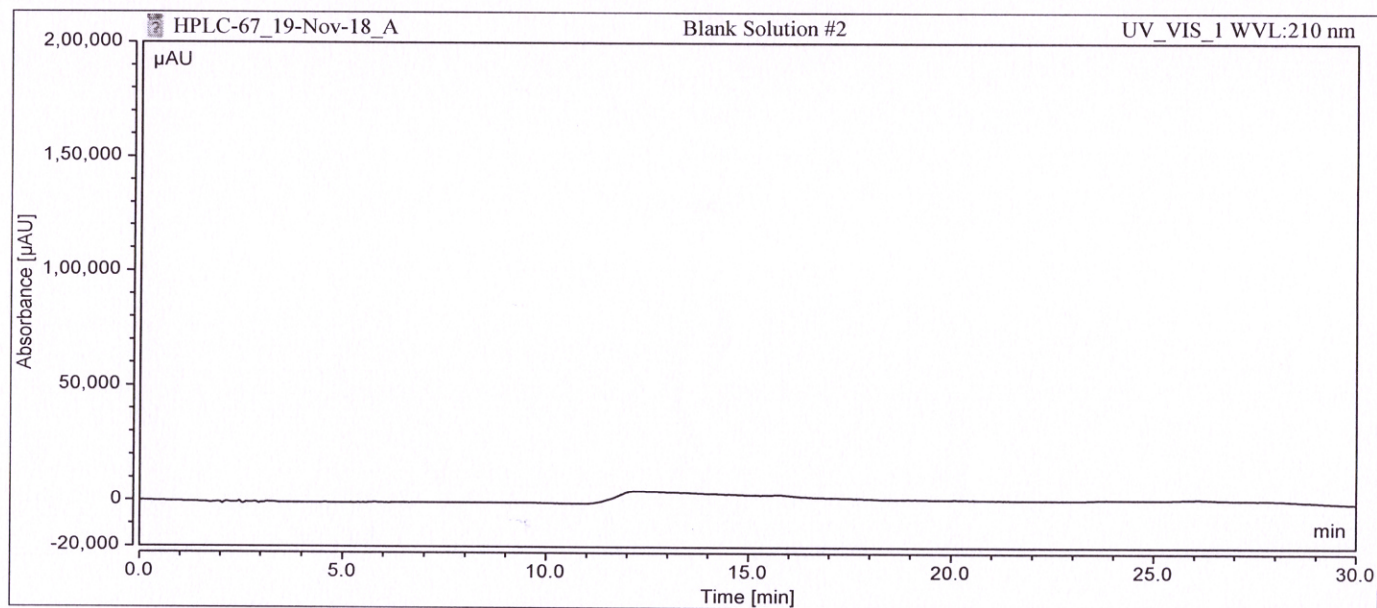


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
----------	-----------	---------------	--------------	--------	--------------------	--------------	-------------	------------------



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	2	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA1	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	27-11-2018 18:02:43
Injection Date & Time :-	19-11-2018 16:24:50	Experiment Name:-	Accuracy
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq		

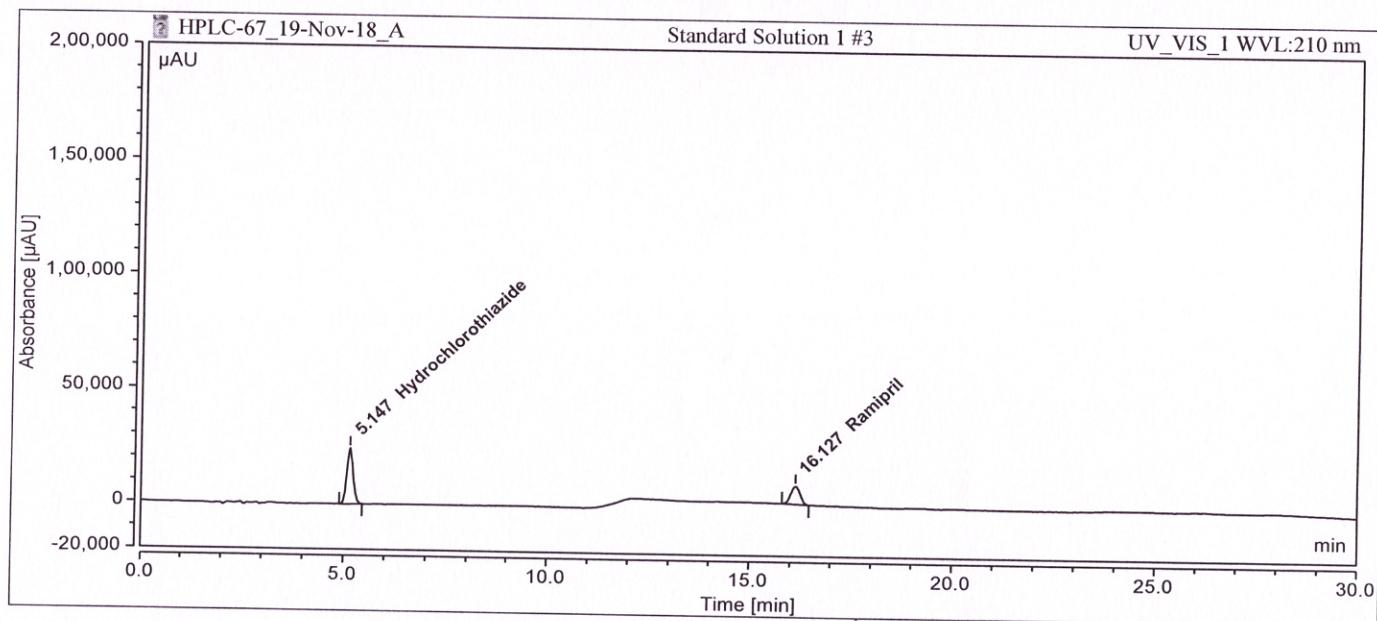


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
----------	-----------	---------------	--------------	--------	--------------------	--------------	-------------	------------------



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Standard Solution 1	AR. No. :-	D2404181993
Sample Number :-	3	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA2	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	27-11-2018 18:02:43
Injection Date & Time :-	19-11-2018 16:56:07	Experiment Name:-	Accuracy
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq		

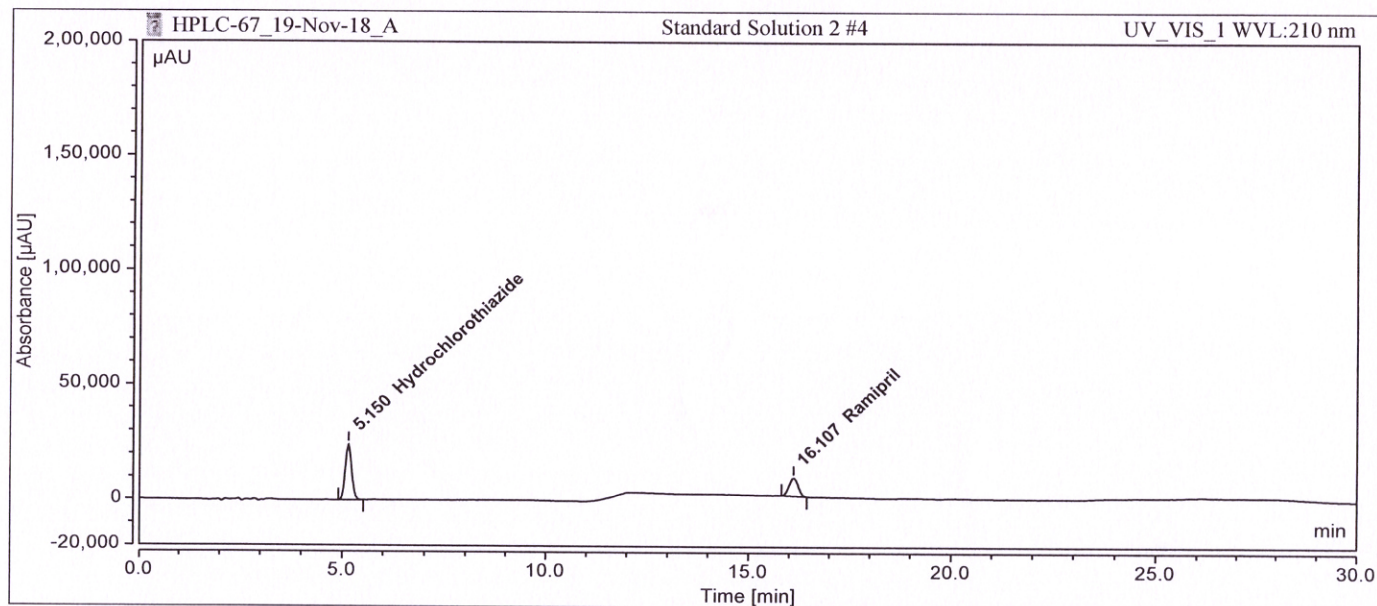


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.147	4385.000	67.62	1.12	5141	FALSE	n.a.
2	Ramipril	16.127	2099.722	32.38	1.03	23801	FALSE	31.14



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Standard Solution 2	AR. No. :-	D2404181993
Sample Number :-	4	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA2	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	27-11-2018 18:02:43
Injection Date & Time :-	19-11-2018 17:27:25	Experiment Name:-	Accuracy
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq		

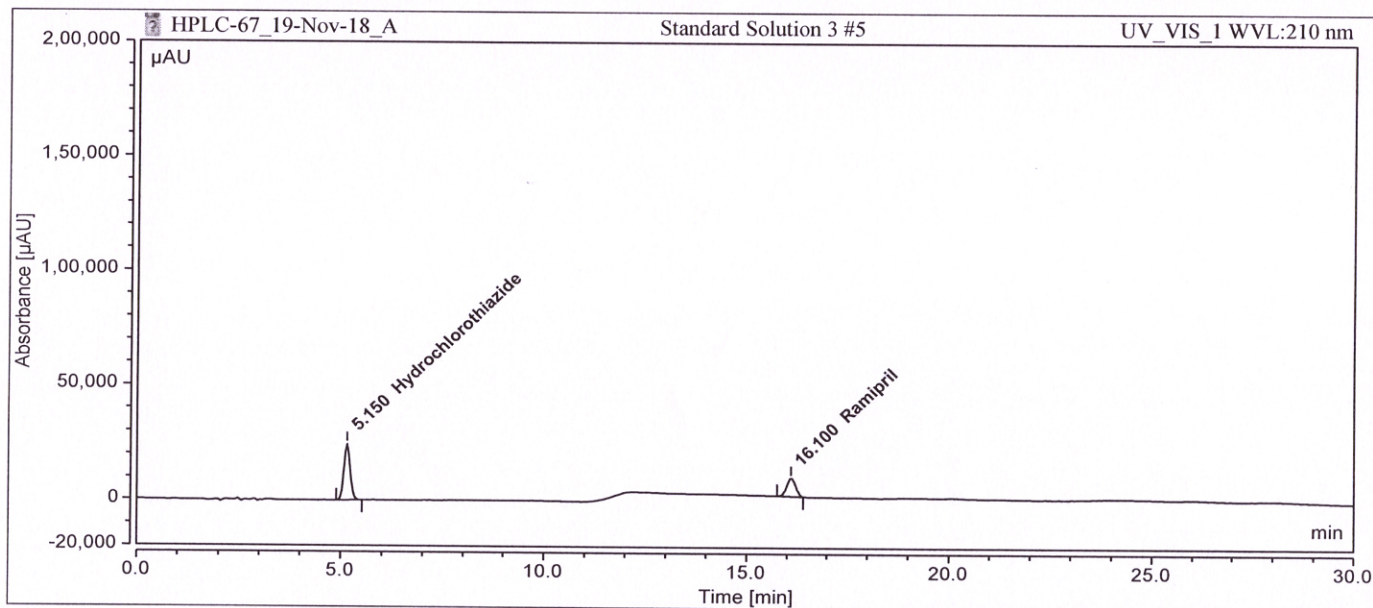


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.150	4397.046	67.90	1.12	5143	FALSE	n.a.
2	Ramipril	16.107	2079.038	32.10	1.03	23660	FALSE	31.03



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Standard Solution 3	AR. No. :-	D2404181993
Sample Number :-	5	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA2	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	27-11-2018 18:02:43
Injection Date & Time :-	19-11-2018 17:58:37	Experiment Name:-	Accuracy
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq		

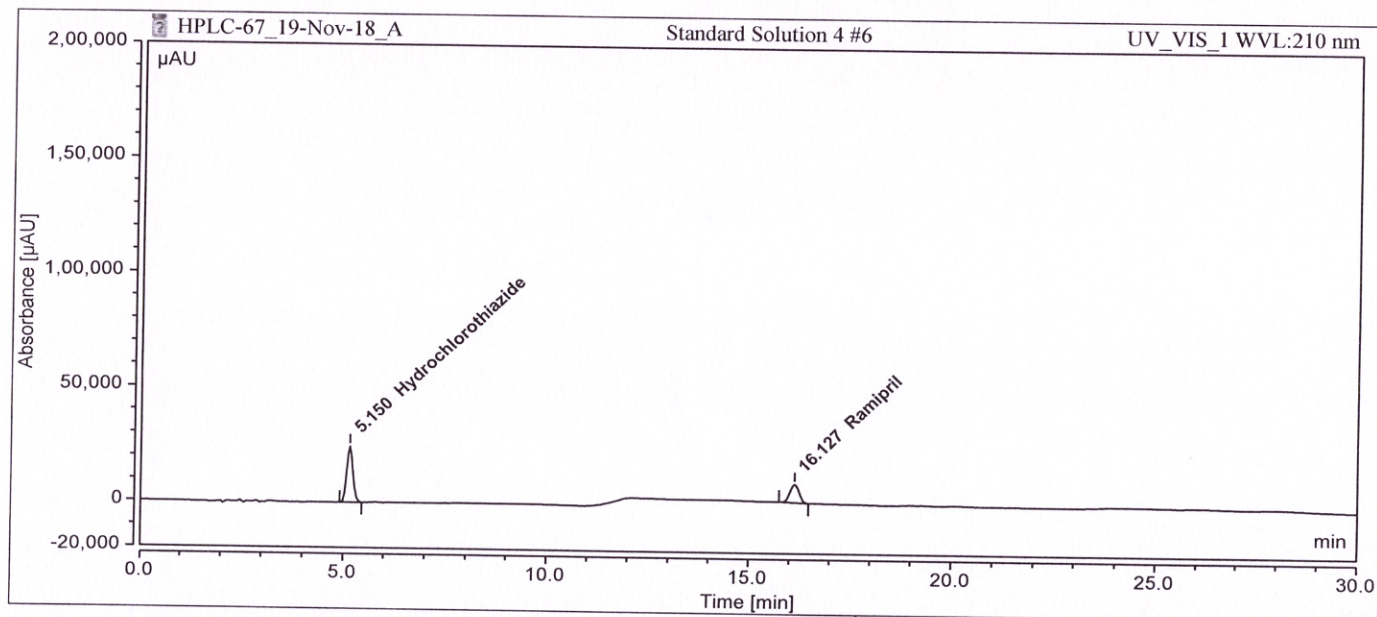


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.150	4397.991	67.85	1.13	5193	FALSE	n.a.
2	Ramipril	16.100	2083.587	32.15	1.02	23747	FALSE	31.12



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Standard Solution 4	AR. No. :-	D2404181993
Sample Number :-	6	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA2	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	27-11-2018 18:02:43
Injection Date & Time :-	19-11-2018 18:29:55	Experiment Name:-	Accuracy
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq		

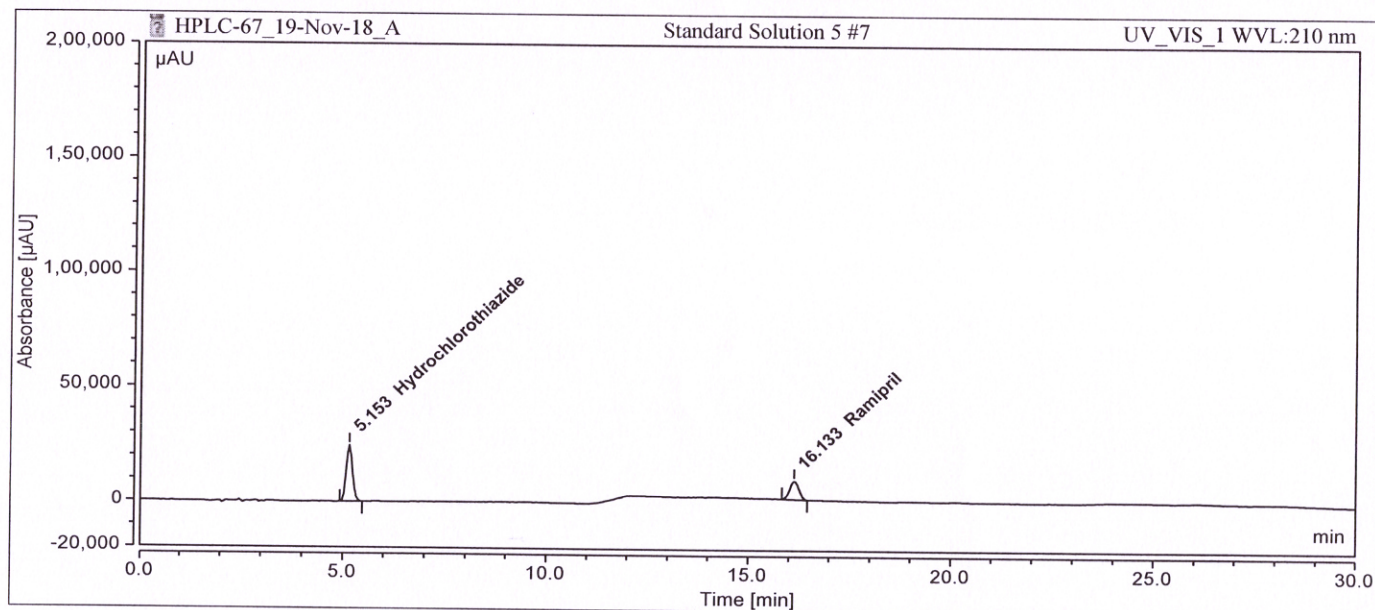


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.150	4388.904	67.59	1.13	5193	FALSE	n.a.
2	Ramipril	16.127	2104.412	32.41	1.02	24116	FALSE	31.31



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Standard Solution 5	AR. No. :-	D2404181993
Sample Number :-	7	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA2	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	27-11-2018 18:02:43
Injection Date & Time :-	19-11-2018 19:01:12	Experiment Name:-	Accuracy
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq		

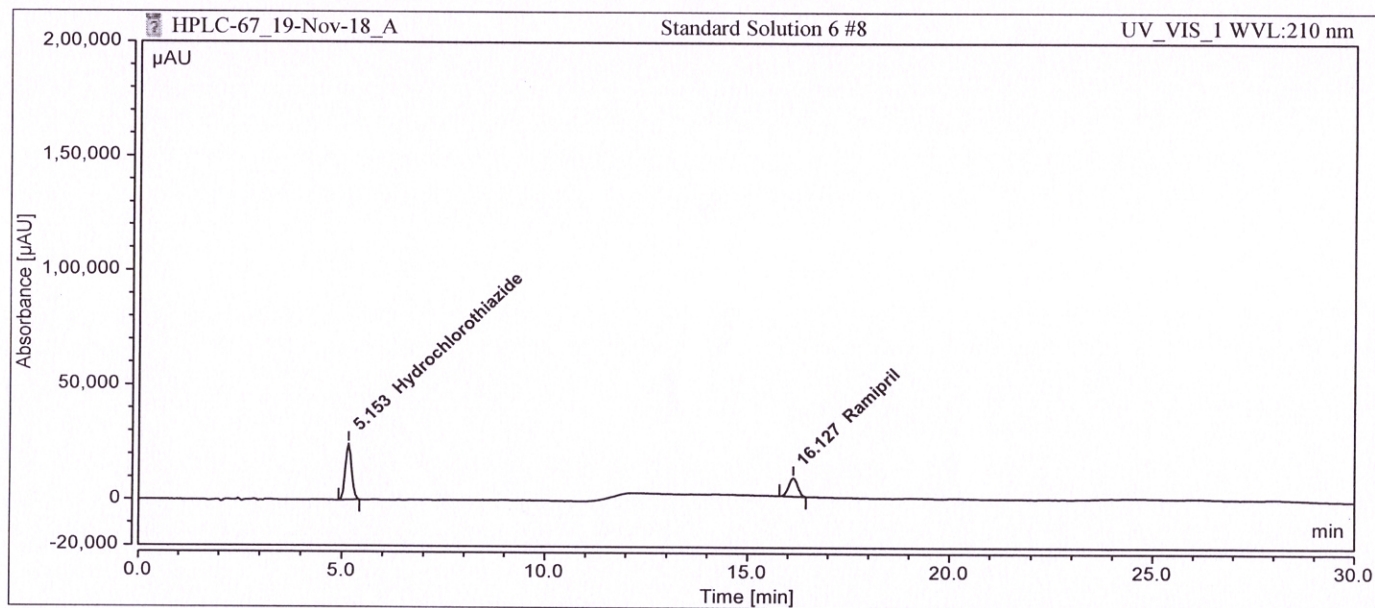


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.153	4387.979	67.77	1.13	5203	FALSE	n.a.
2	Ramipril	16.133	2086.427	32.23	1.02	23764	FALSE	31.17



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Standard Solution 6	AR. No. :-	D2404181993
Sample Number :-	8	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA2	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	27-11-2018 18:02:43
Injection Date & Time :-	19-11-2018 19:32:25	Experiment Name:-	Accuracy
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq		

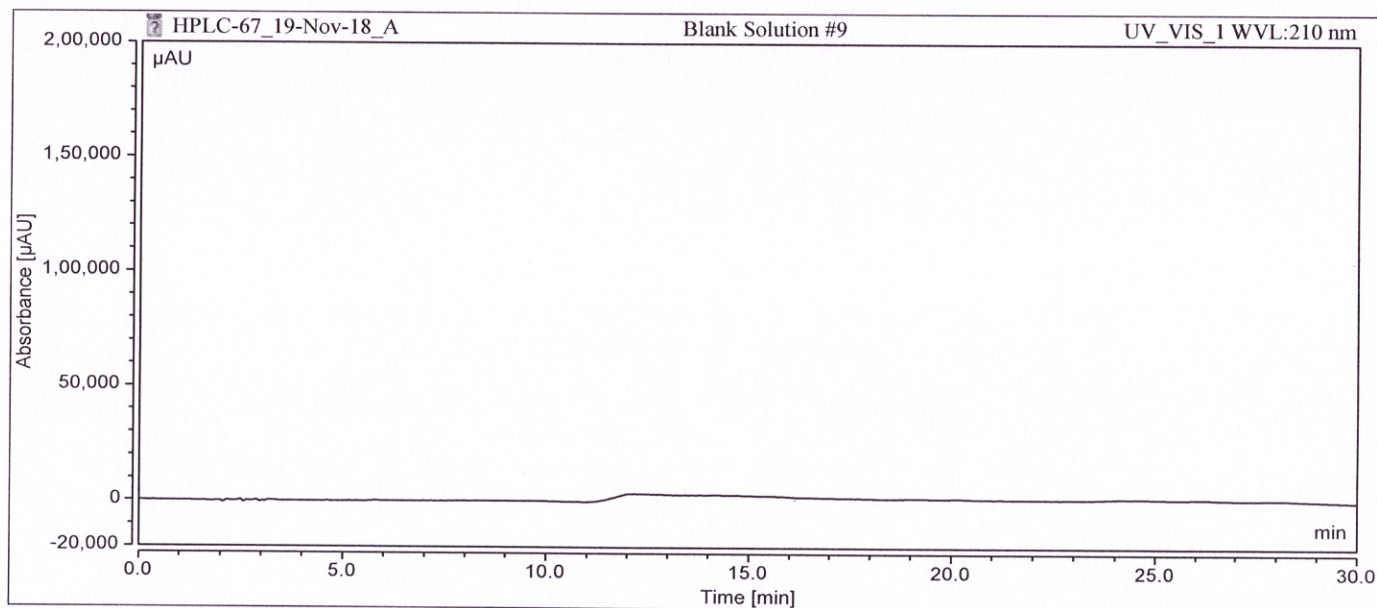


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.153	4367.186	67.63	1.11	5234	FALSE	n.a.
2	Ramipril	16.127	2090.498	32.37	1.01	24419	FALSE	31.46



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	9	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA1	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	27-11-2018 18:02:43
Injection Date & Time :-	19-11-2018 20:03:42	Experiment Name:-	Accuracy
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq		

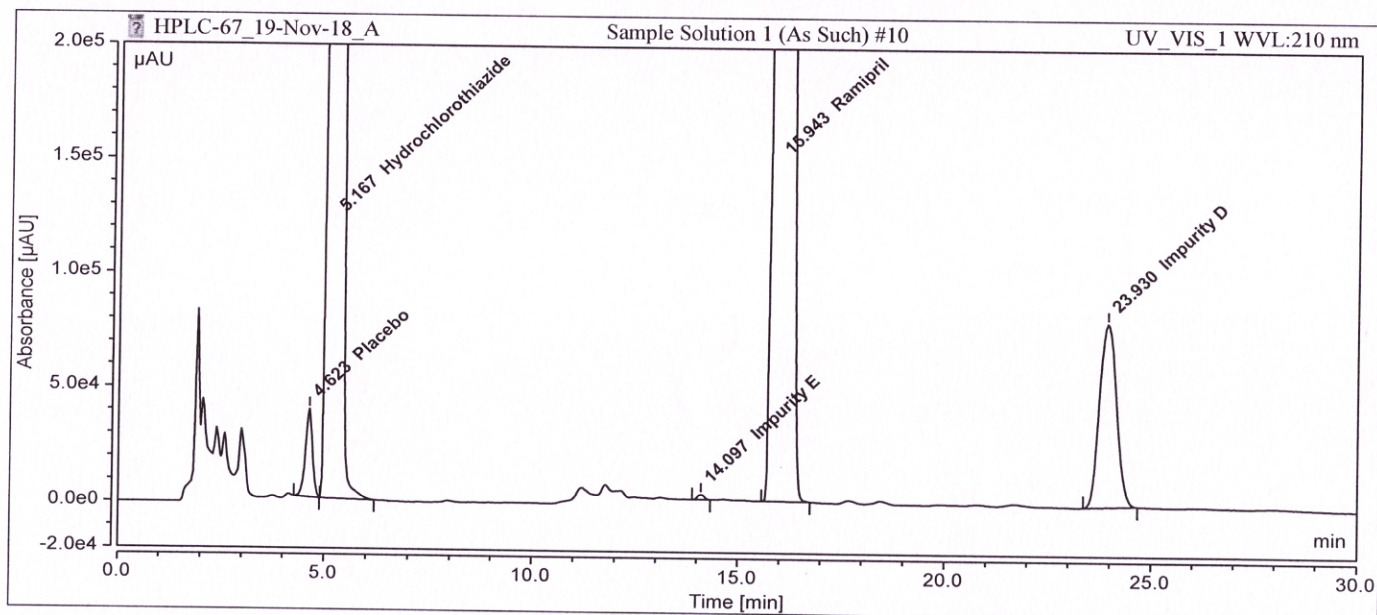


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
----------	-----------	---------------	--------------	--------	--------------------	--------------	-------------	------------------



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	GP180301
Sample Name :-	Sample Solution 1 (As Such)	AR. No. :-	D2404181993
Sample Number :-	10	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA3	Processing Method :-	Ramithiazide Tablets_RS_PR1
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	27-11-2018 18:56:59
Injection Date & Time :-	19-11-2018 20:34:55	Experiment Name:-	Accuracy
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq		

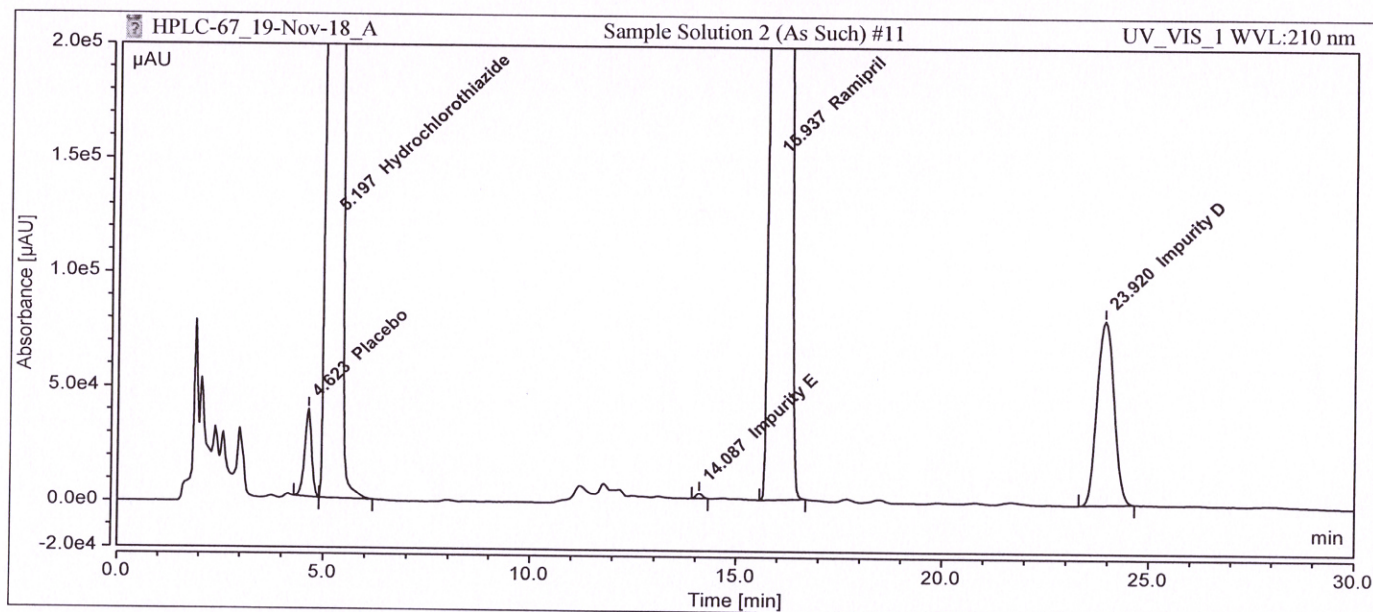


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Placebo	4.623	7464.256	0.44	0.97	3674	FALSE	n.a.
2	Hydrochlorothiazide	5.167	855974.061	50.01	1.19	2621	FALSE	1.53
3	Impurity E	14.097	418.297	0.02	1.08	38662	FALSE	25.87
4	Ramipril	15.943	809454.454	47.29	1.39	14174	FALSE	4.49
5	Impurity D	23.930	38262.601	2.24	1.11	16522	FALSE	12.48



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	GP180301
Sample Name :-	Sample Solution 2 (As Such)	AR. No. :-	D2404181993
Sample Number :-	11	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA4	Processing Method :-	Ramithiazide Tablets_RS_PR1
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	27-11-2018 18:56:59
Injection Date & Time :-	19-11-2018 21:06:08	Experiment Name:-	Accuracy
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq		

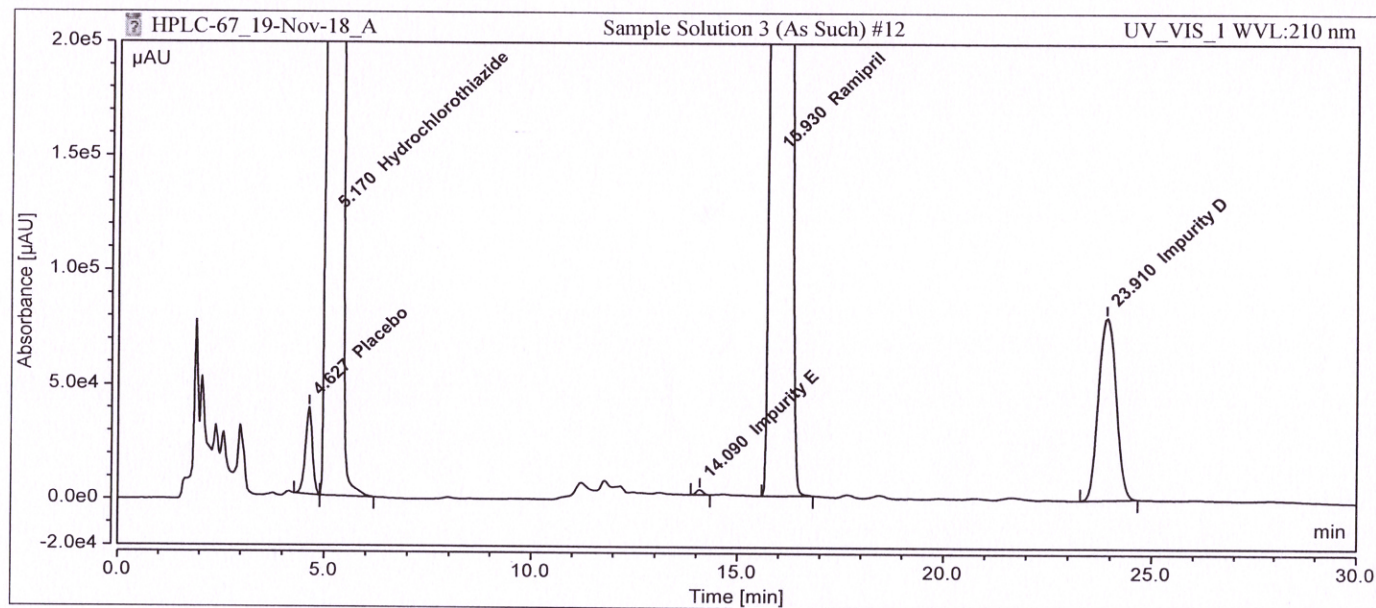


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Placebo	4.623	7467.428	0.44	0.96	3673	FALSE	n.a.
2	Hydrochlorothiazide	5.197	854044.172	49.99	1.04	2654	FALSE	1.62
3	Impurity E	14.087	414.109	0.02	1.15	36571	FALSE	25.47
4	Ramipril	15.937	808138.192	47.30	1.38	14153	FALSE	4.46
5	Impurity D	23.920	38302.940	2.24	1.11	16582	FALSE	12.49



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	GP180301
Sample Name :-	Sample Solution 3 (As Such)	AR. No. :-	D2404181993
Sample Number :-	12	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA5	Processing Method :-	Ramithiazide Tablets_RS_PR1
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	27-11-2018 18:56:59
Injection Date & Time :-	19-11-2018 21:37:20	Experiment Name:-	Accuracy
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq		

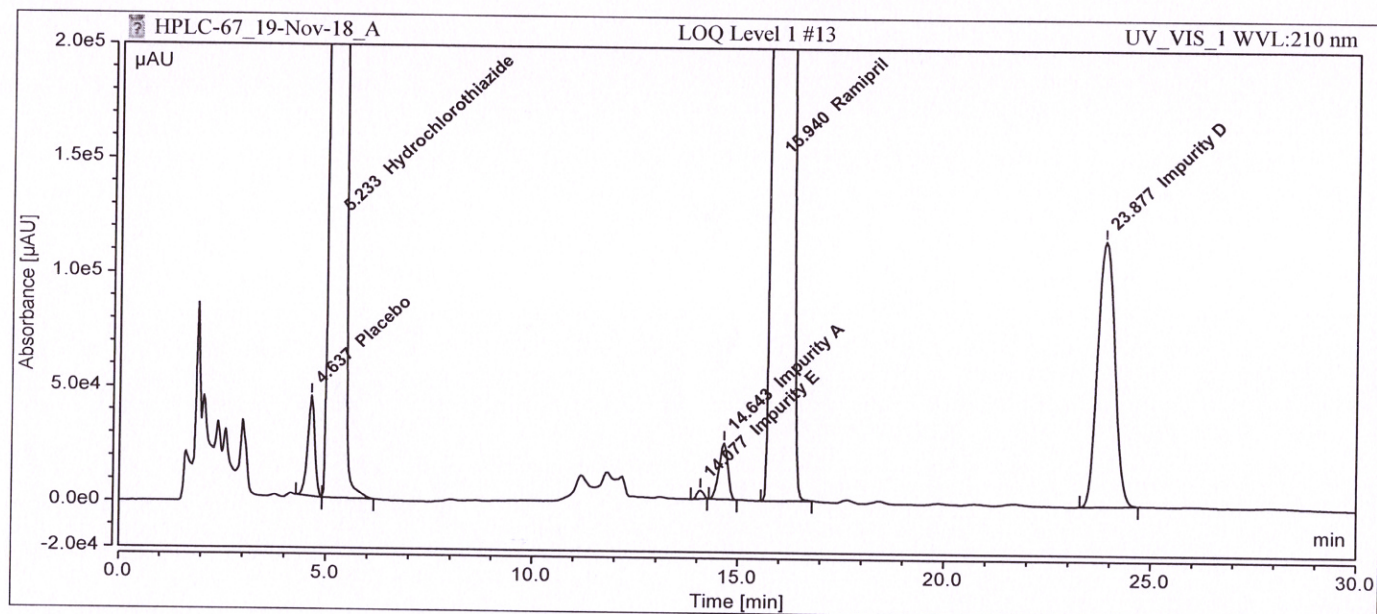


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Placebo	4.627	7459.179	0.43	0.96	3685	FALSE	n.a.
2	Hydrochlorothiazide	5.170	861688.604	50.12	1.19	2621	FALSE	1.53
3	Impurity E	14.090	425.468	0.02	1.05	37311	FALSE	25.64
4	Ramipril	15.930	811216.727	47.19	1.38	14107	FALSE	4.44
5	Impurity D	23.910	38341.274	2.23	1.11	16367	FALSE	12.43



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	LOQ Level 1	AR. No. :-	D2404181993
Sample Number :-	13	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA6	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	27-11-2018 18:02:43
Injection Date & Time :-	19-11-2018 22:08:33	Experiment Name:-	Accuracy
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq		

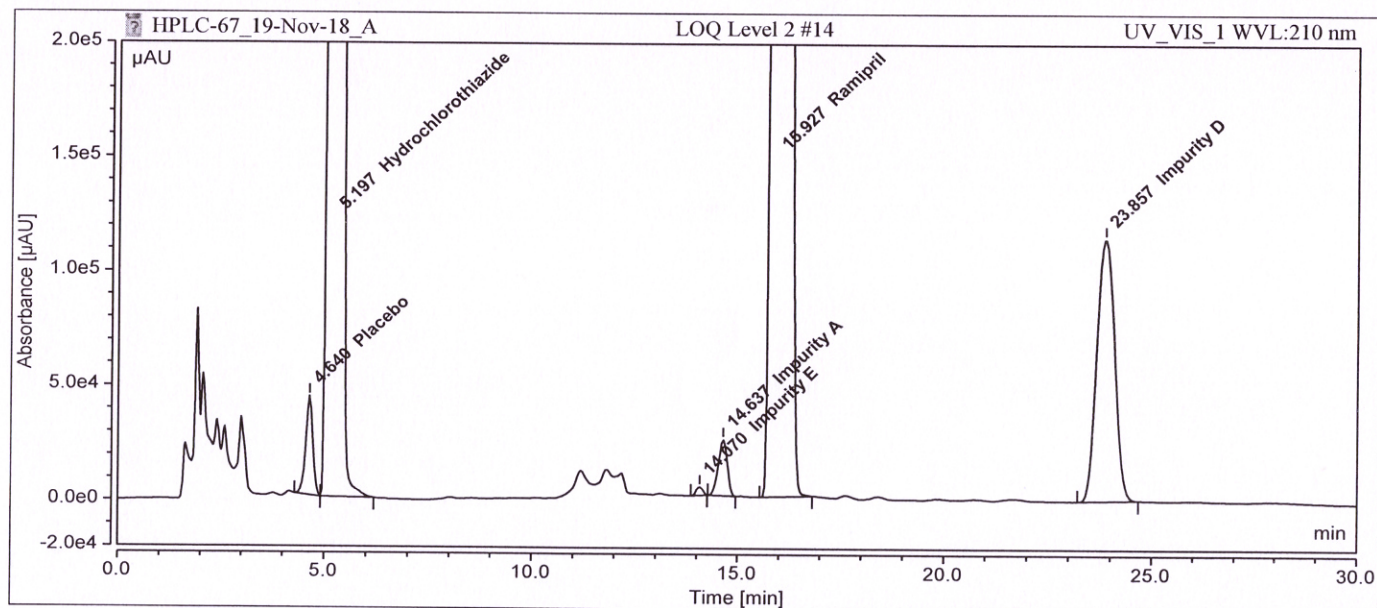


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Placebo	4.637	8655.224	0.49	0.95	3699	FALSE	n.a.
2	Hydrochlorothiazide	5.233	871885.020	49.41	0.96	2621	FALSE	1.67
3	Impurity E	14.077	687.928	0.04	1.01	41237	FALSE	25.78
4	Impurity A	14.643	6182.408	0.35	0.92	20488	FALSE	1.65
5	Ramipril	15.940	821001.745	46.52	1.37	13747	FALSE	2.72
6	Impurity D	23.877	56269.142	3.19	1.11	16016	FALSE	12.22



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	LOQ Level 2	AR. No. :-	D2404181993
Sample Number :-	14	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA7	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	27-11-2018 18:02:43
Injection Date & Time :-	19-11-2018 22:39:50	Experiment Name:-	Accuracy
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq		

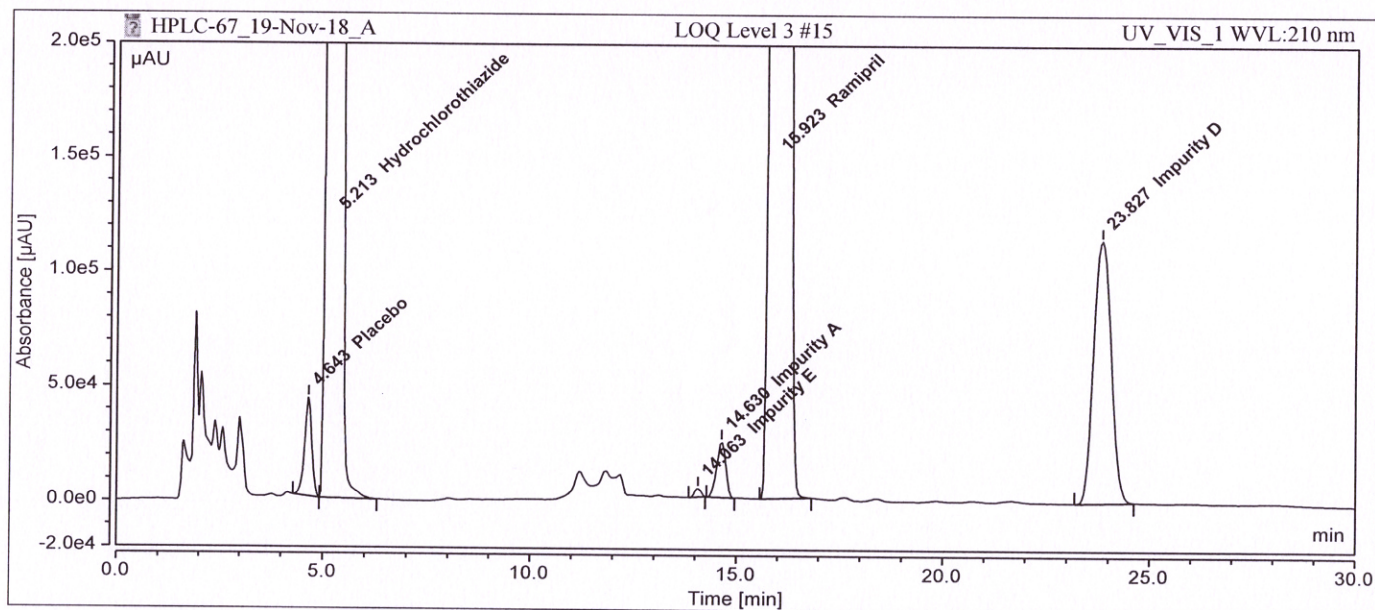


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Placebo	4.640	8550.788	0.48	0.94	3664	FALSE	n.a.
2	Hydrochlorothiazide	5.197	879866.747	49.62	1.15	2548	FALSE	1.55
3	Impurity E	14.070	704.799	0.04	1.03	37747	FALSE	25.30
4	Impurity A	14.637	6172.445	0.35	0.93	20293	FALSE	1.62
5	Ramipril	15.927	821555.382	46.34	1.41	13562	FALSE	2.69
6	Impurity D	23.857	56204.114	3.17	1.11	15766	FALSE	12.13



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	LOQ Level 3	AR. No. :-	D2404181993
Sample Number :-	15	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA8	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	27-11-2018 18:02:43
Injection Date & Time :-	19-11-2018 23:11:07	Experiment Name:-	Accuracy
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq		

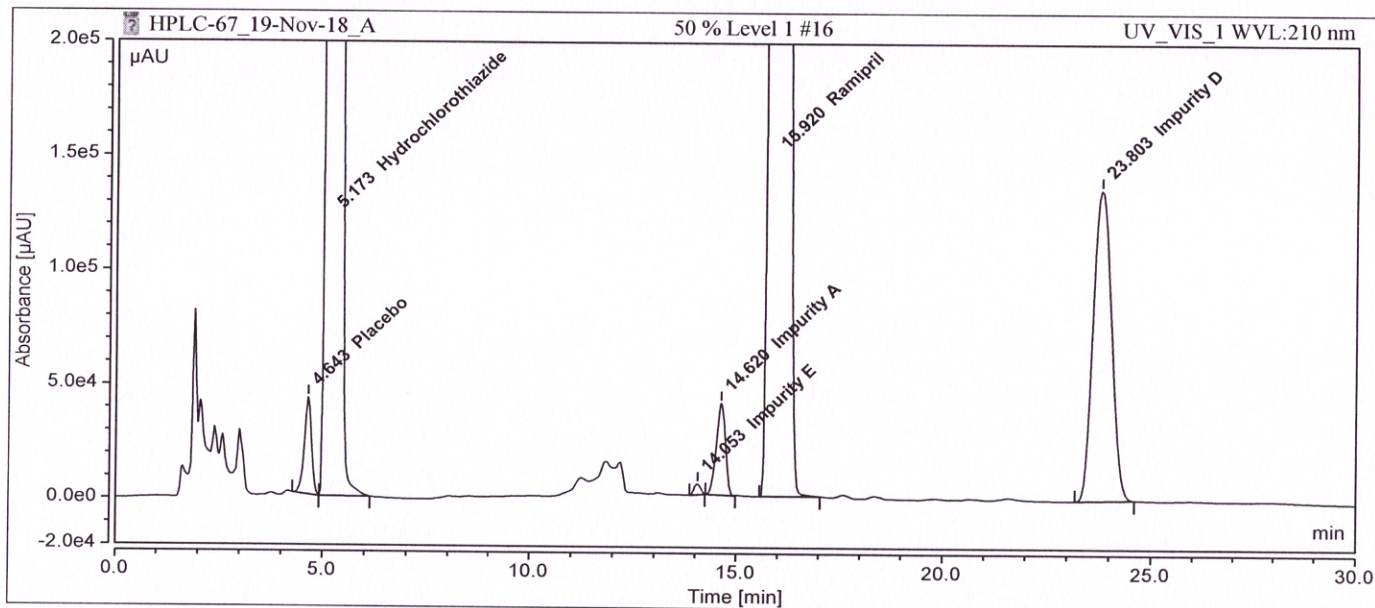


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Placebo	4.643	8547.013	0.48	0.94	3610	FALSE	n.a.
2	Hydrochlorothiazide	5.213	880913.699	49.66	1.08	2535	FALSE	1.58
3	Impurity E	14.063	692.966	0.04	1.01	39970	FALSE	25.45
4	Impurity A	14.630	6178.683	0.35	0.93	20367	FALSE	1.64
5	Ramipril	15.923	821140.637	46.29	1.39	13479	FALSE	2.70
6	Impurity D	23.827	56268.997	3.17	1.12	15612	FALSE	12.05



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	50 % Level 1	AR. No. :-	D2404181993
Sample Number :-	16	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RB1	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	27-11-2018 18:02:43
Injection Date & Time :-	19-11-2018 23:42:19	Experiment Name:-	Accuracy
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq		

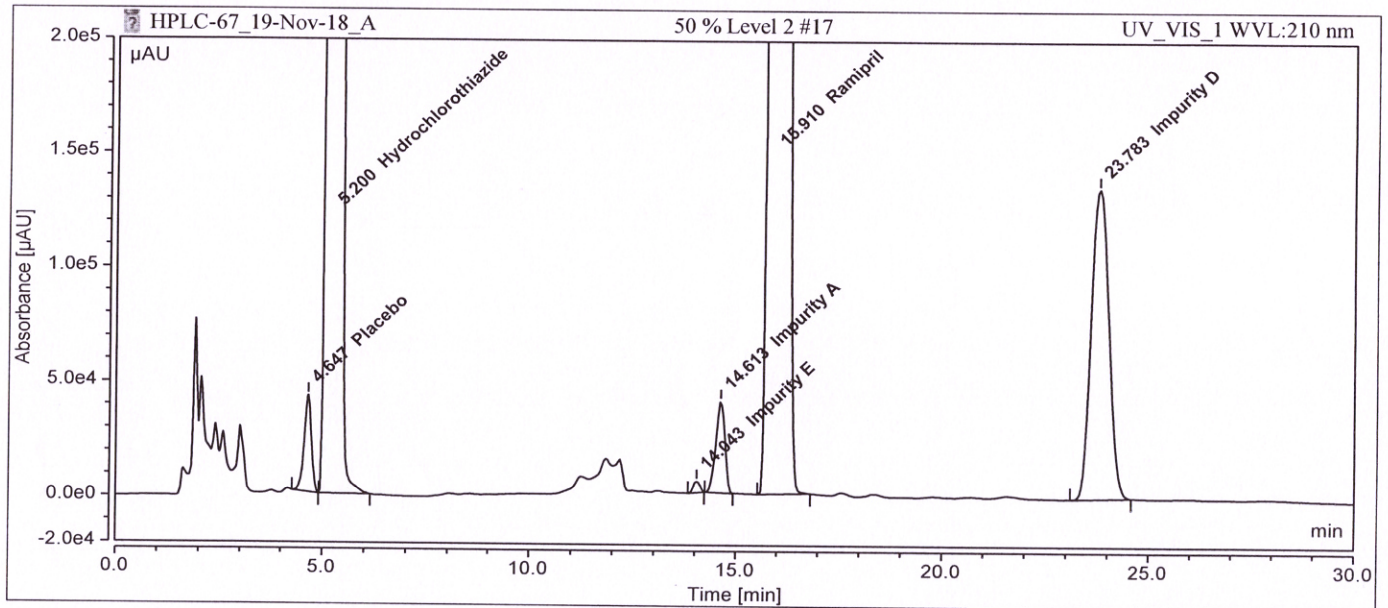


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Placebo	4.643	8544.251	0.48	0.93	3557	FALSE	n.a.
2	Hydrochlorothiazide	5.173	884416.131	49.23	1.33	2484	FALSE	1.46
3	Impurity E	14.053	903.913	0.05	1.02	37239	FALSE	25.14
4	Impurity A	14.620	10248.555	0.57	0.93	20204	FALSE	1.61
5	Ramipril	15.920	825412.027	45.94	1.34	13336	FALSE	2.70
6	Impurity D	23.803	67111.806	3.74	1.12	15495	FALSE	11.98



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	50 % Level 2	AR. No. :-	D2404181993
Sample Number :-	17	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RB2	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	27-11-2018 18:02:43
Injection Date & Time :-	20-11-2018 00:13:36	Experiment Name:-	Accuracy
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq		

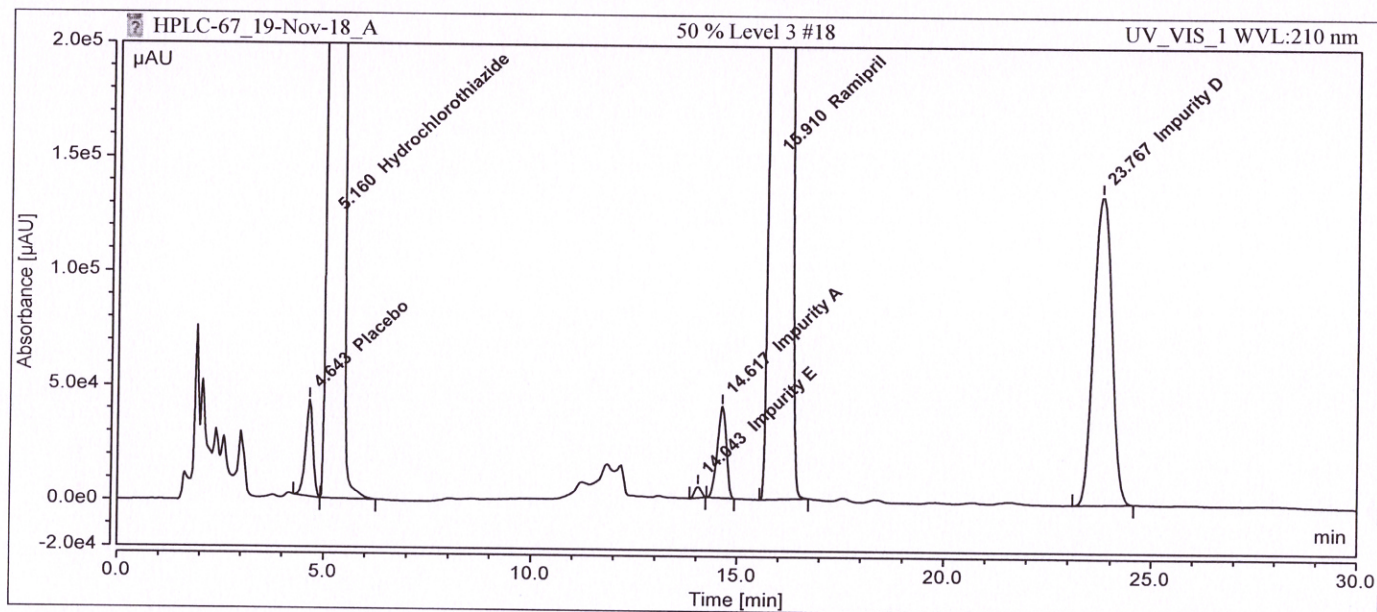


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Placebo	4.647	8515.168	0.48	0.93	3546	FALSE	n.a.
2	Hydrochlorothiazide	5.200	880235.864	49.13	1.18	2486	FALSE	1.52
3	Impurity E	14.043	914.204	0.05	1.04	37634	FALSE	25.02
4	Impurity A	14.613	10218.073	0.57	0.94	19974	FALSE	1.62
5	Ramipril	15.910	824506.073	46.02	1.35	13146	FALSE	2.68
6	Impurity D	23.783	67149.189	3.75	1.12	15295	FALSE	11.89



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	50 % Level 3	AR. No. :-	D2404181993
Sample Number :-	18	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RB3	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	27-11-2018 18:02:43
Injection Date & Time :-	20-11-2018 00:44:53	Experiment Name:-	Accuracy
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq		

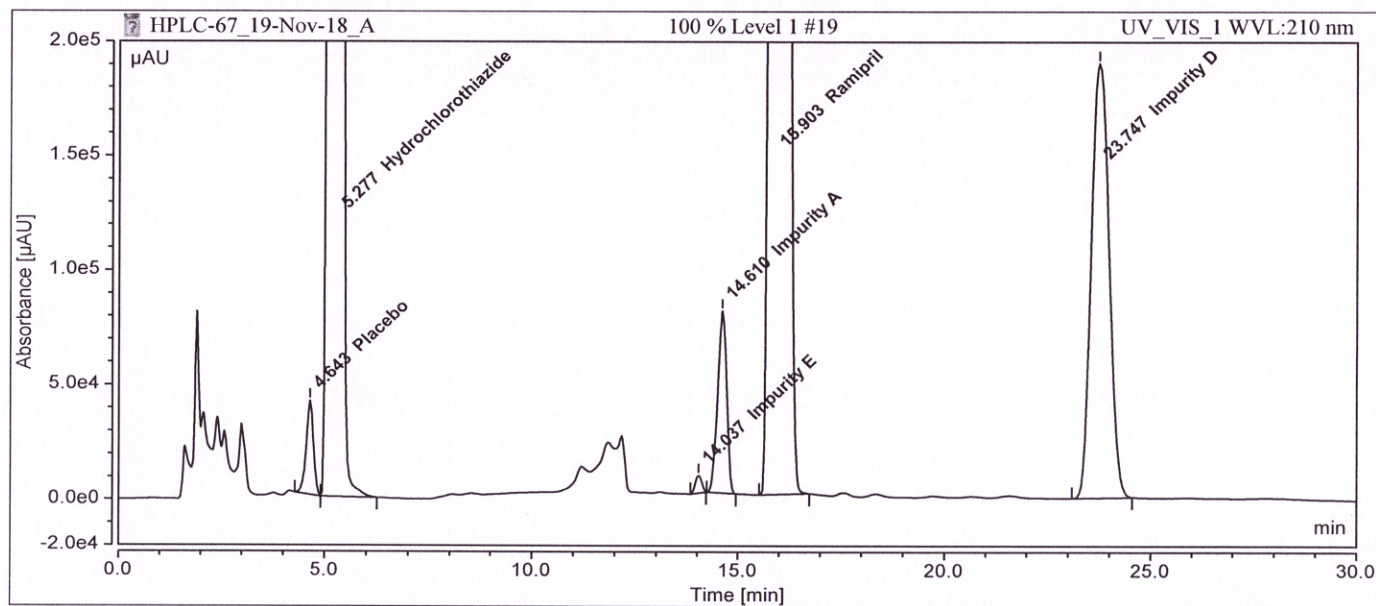


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Placebo	4.643	8504.630	0.47	0.94	3522	FALSE	n.a.
2	Hydrochlorothiazide	5.160	883313.469	49.21	1.47	2440	FALSE	1.41
3	Impurity E	14.043	908.864	0.05	1.02	37793	FALSE	25.14
4	Impurity A	14.617	10210.747	0.57	0.93	20054	FALSE	1.63
5	Ramipril	15.910	824924.243	45.96	1.36	13182	FALSE	2.67
6	Impurity D	23.767	67186.512	3.74	1.13	15160	FALSE	11.85



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	100 % Level 1	AR. No. :-	D2404181993
Sample Number :-	19	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RB4	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	27-11-2018 18:02:43
Injection Date & Time :-	20-11-2018 01:16:10	Experiment Name:-	Accuracy
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq		

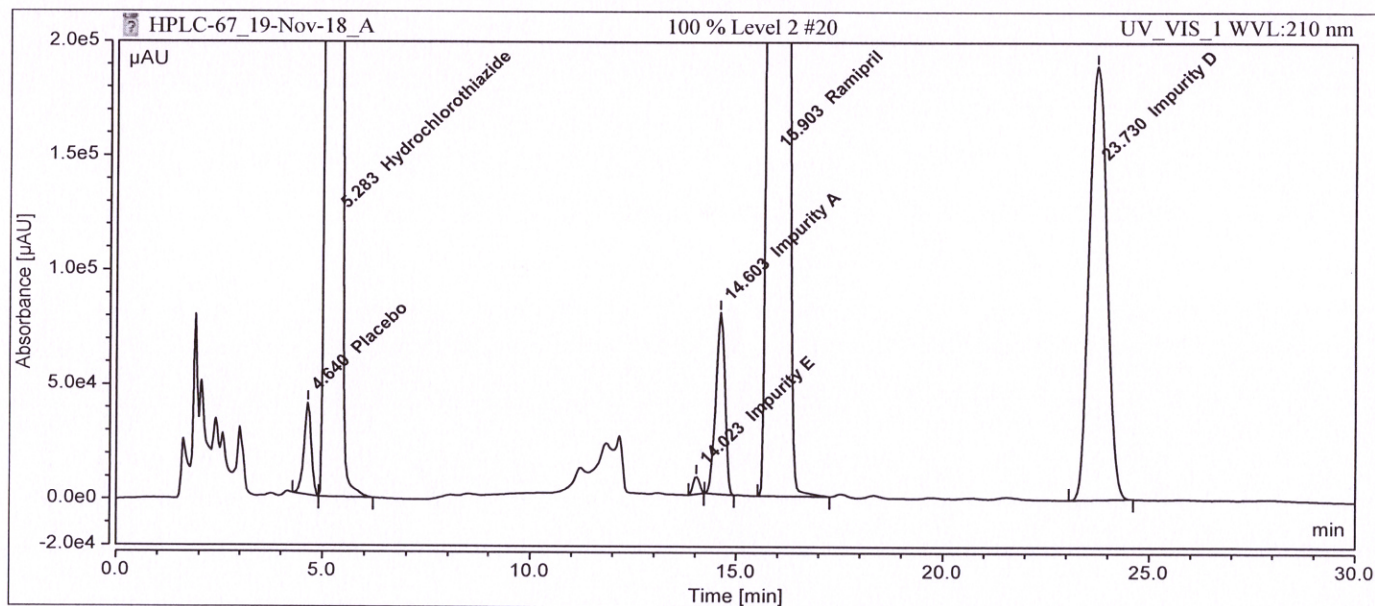


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Placebo	4.643	8359.611	0.45	0.93	3453	FALSE	n.a.
2	Hydrochlorothiazide	5.277	888958.528	48.27	0.85	2546	FALSE	1.72
3	Impurity E	14.037	1447.351	0.08	1.03	37541	FALSE	24.74
4	Impurity A	14.610	20487.535	1.11	0.94	19843	FALSE	1.63
5	Ramipril	15.903	827706.902	44.94	1.36	13143	FALSE	2.67
6	Impurity D	23.747	94831.406	5.15	1.13	15133	FALSE	11.82



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	100 % Level 2	AR. No. :-	D2404181993
Sample Number :-	20	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RB5	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	27-11-2018 18:02:43
Injection Date & Time :-	20-11-2018 01:47:22	Experiment Name:-	Accuracy
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq		

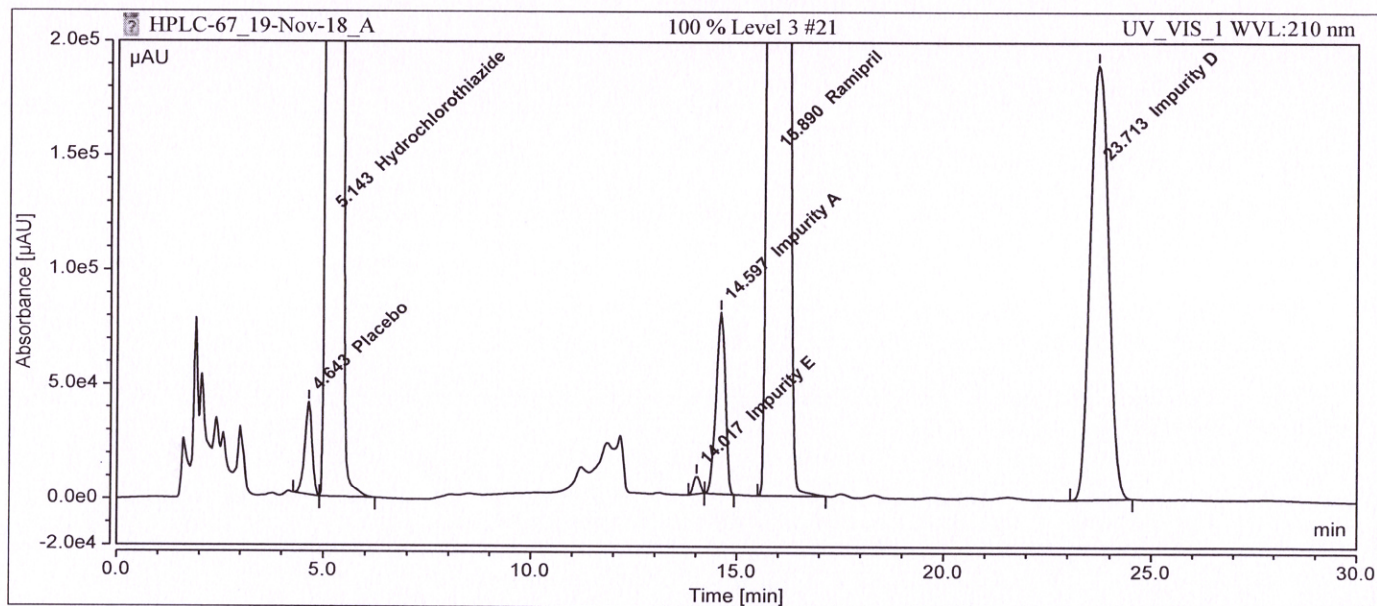


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Placebo	4.640	8256.984	0.45	0.93	3427	FALSE	n.a.
2	Hydrochlorothiazide	5.283	894836.098	48.43	0.83	2539	FALSE	1.75
3	Impurity E	14.023	1440.957	0.08	1.06	37793	FALSE	24.69
4	Impurity A	14.603	20471.264	1.11	0.94	19829	FALSE	1.65
5	Ramipril	15.903	827927.051	44.81	1.32	13126	FALSE	2.68
6	Impurity D	23.730	94865.375	5.13	1.13	15032	FALSE	11.77



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	100 % Level 3	AR. No. :-	D2404181993
Sample Number :-	21	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RB6	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	27-11-2018 18:02:43
Injection Date & Time :-	20-11-2018 02:18:35	Experiment Name:-	Accuracy
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq		

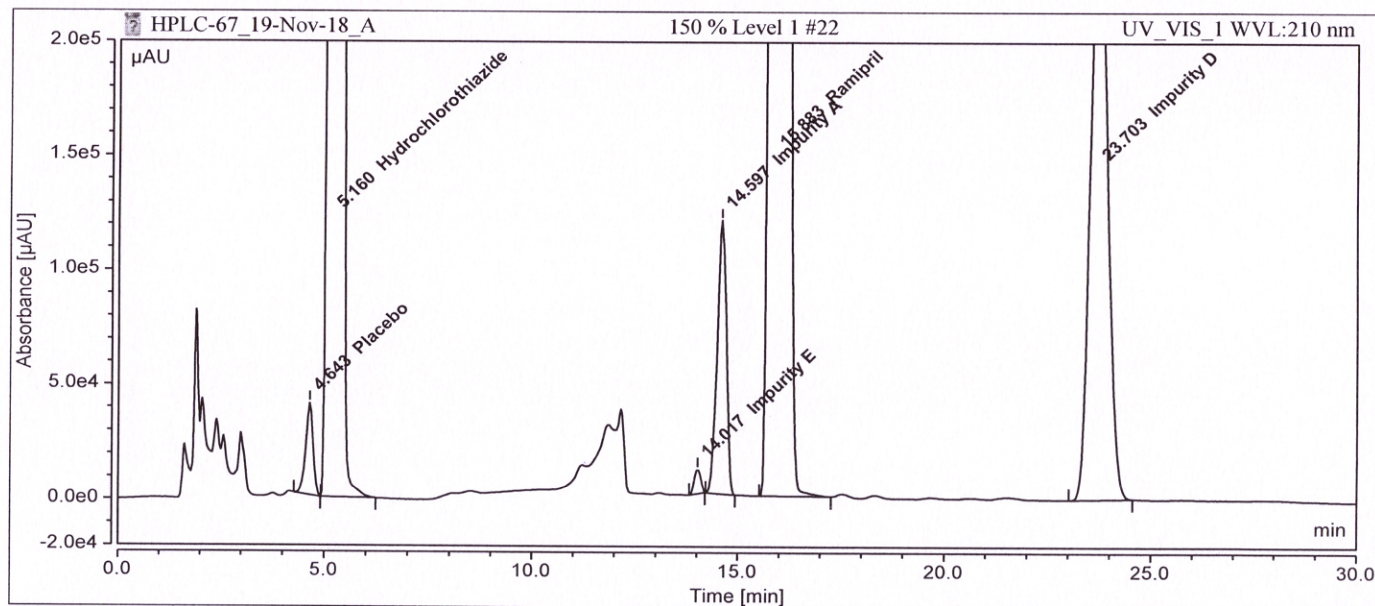


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Placebo	4.643	8309.109	0.45	0.92	3427	FALSE	n.a.
2	Hydrochlorothiazide	5.143	888795.375	48.22	1.62	2395	FALSE	1.36
3	Impurity E	14.017	1452.617	0.08	1.08	37066	FALSE	24.94
4	Impurity A	14.597	20504.030	1.11	0.94	19705	FALSE	1.64
5	Ramipril	15.890	828991.918	44.98	1.36	13017	FALSE	2.66
6	Impurity D	23.713	95030.461	5.16	1.14	15029	FALSE	11.76



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	150 % Level 1	AR. No. :-	D2404181993
Sample Number :-	22	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RB7	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	27-11-2018 18:02:43
Injection Date & Time :-	20-11-2018 02:49:47	Experiment Name:-	Accuracy
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq		

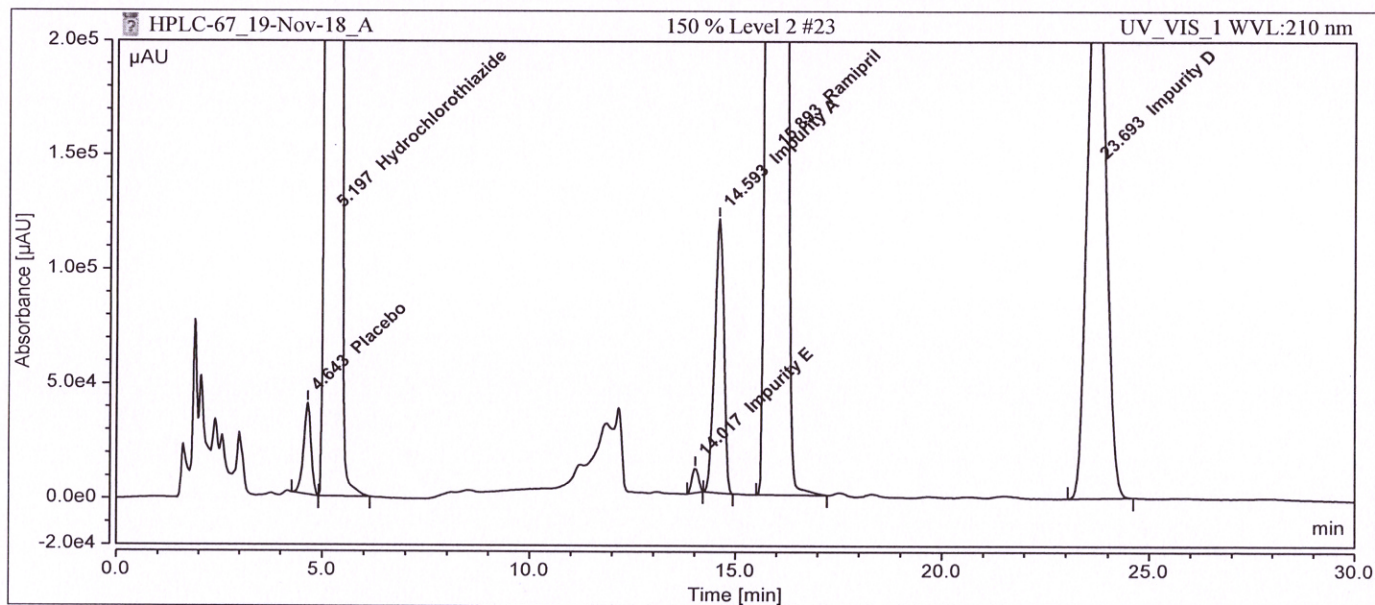


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Placebo	4.643	8292.282	0.44	0.92	3382	FALSE	n.a.
2	Hydrochlorothiazide	5.160	888293.928	47.19	1.45	2395	FALSE	1.39
3	Impurity E	14.017	1993.535	0.11	1.06	36908	FALSE	24.82
4	Impurity A	14.597	30939.252	1.64	0.94	19638	FALSE	1.64
5	Ramipril	15.883	830514.378	44.12	1.40	12898	FALSE	2.64
6	Impurity D	23.703	122365.078	6.50	1.14	14879	FALSE	11.70



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	150 % Level 2	AR. No. :-	D2404181993
Sample Number :-	23	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RB8	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	27-11-2018 18:02:43
Injection Date & Time :-	20-11-2018 03:20:59	Experiment Name:-	Accuracy
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq		

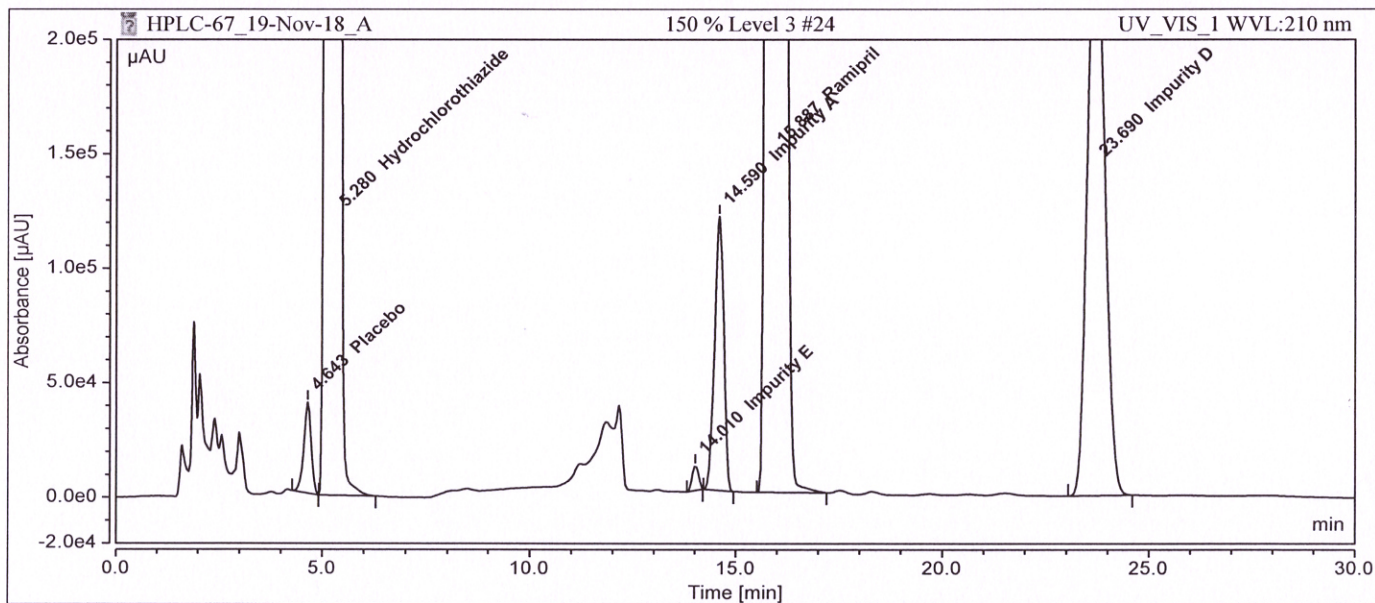


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Placebo	4.643	8252.322	0.44	0.92	3375	FALSE	n.a.
2	Hydrochlorothiazide	5.197	897178.559	47.36	1.19	2439	FALSE	1.49
3	Impurity E	14.017	2015.388	0.11	1.04	37143	FALSE	24.78
4	Impurity A	14.593	30962.018	1.63	0.95	19595	FALSE	1.63
5	Ramipril	15.893	833397.376	44.00	1.32	13065	FALSE	2.67
6	Impurity D	23.693	122440.906	6.46	1.14	14841	FALSE	11.69



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	150 % Level 3	AR. No. :-	D2404181993
Sample Number :-	24	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RC1	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	27-11-2018 18:02:43
Injection Date & Time :-	20-11-2018 03:52:11	Experiment Name:-	Accuracy
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq		

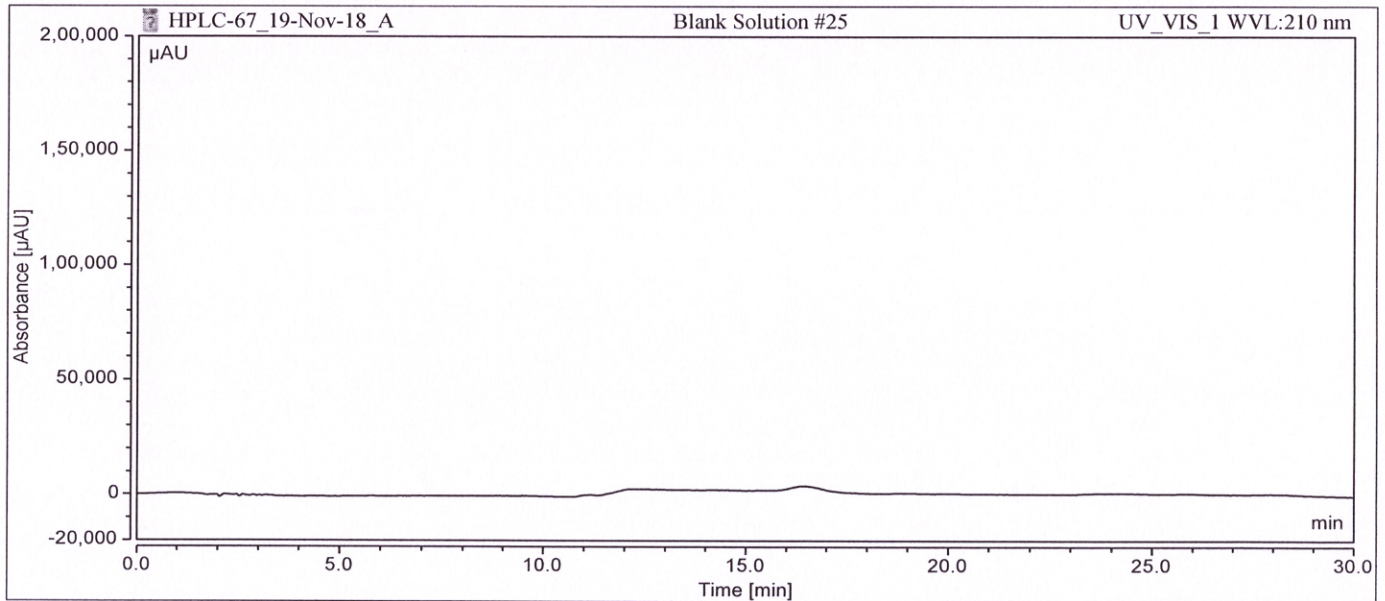


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Placebo	4.643	8227.837	0.44	0.92	3344	FALSE	n.a.
2	Hydrochlorothiazide	5.280	894673.930	47.35	0.85	2496	FALSE	1.71
3	Impurity E	14.010	2005.915	0.11	1.07	37622	FALSE	24.53
4	Impurity A	14.590	30950.782	1.64	0.94	19705	FALSE	1.65
5	Ramipril	15.887	830932.551	43.98	1.32	13095	FALSE	2.67
6	Impurity D	23.690	122567.945	6.49	1.14	14953	FALSE	11.73



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	25	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA1	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	27-11-2018 18:02:43
Injection Date & Time :-	20-11-2018 04:23:28	Experiment Name:-	Accuracy
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq		

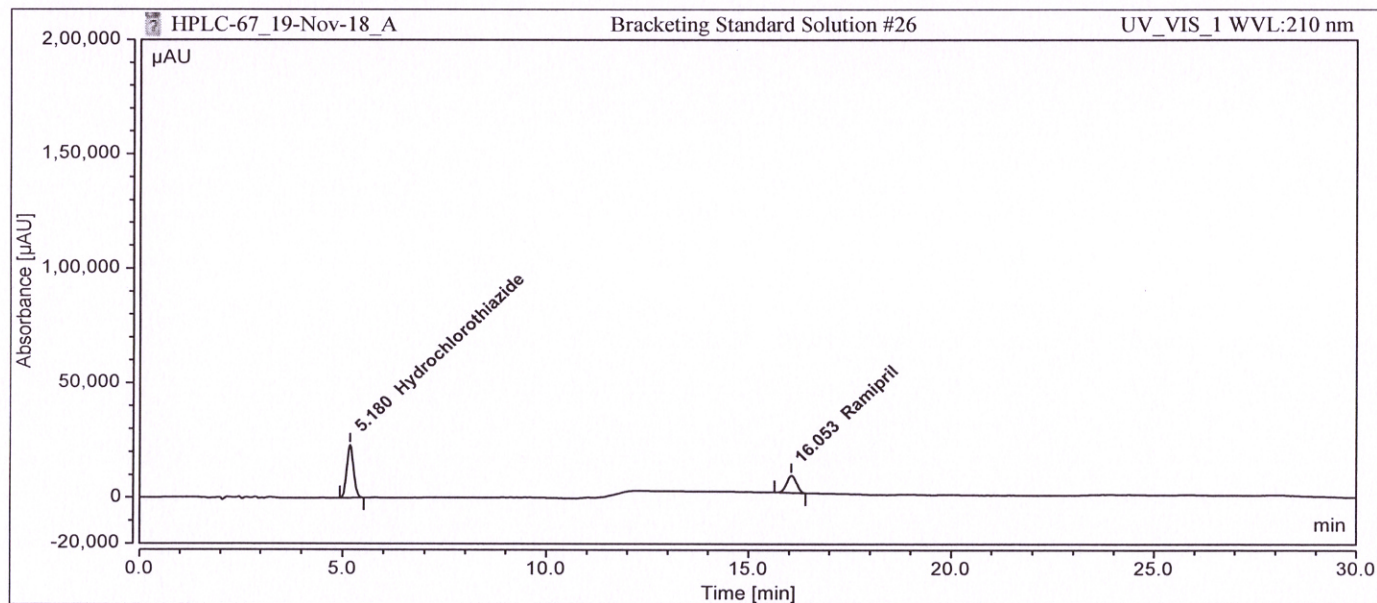


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
----------	-----------	---------------	--------------	--------	--------------------	--------------	-------------	------------------



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Bracketing Standard Solution	AR. No. :-	D2404181993
Sample Number :-	26	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA2	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	27-11-2018 18:02:43
Injection Date & Time :-	20-11-2018 04:54:46	Experiment Name:-	Accuracy
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq		



Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.180	4405.456	67.38	1.13	4590	FALSE	n.a.
2	Ramipril	16.053	2132.821	32.62	1.05	21377	FALSE	29.19



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Wash method created	Batch No. :-	N/A
Sample Name :-	Wash	AR. No. :-	N/A
Sample Number :-	27	Instrument Method :-	Wash method _HPLC 67_New
Sample Type :-	Unknown	Instrument Method Created By :-	Satish R Dodtale
Injection Volume :-	30.00 µL	Instrument Method Created On :-	11-11-2017 19:41:38
Vial Position :-	RA1	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	27-11-2018 18:02:43
Injection Date & Time :-	20-11-2018 05:29:58	Experiment Name:-	Accuracy
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq		

Channel UV_VIS_1 is not available for injection #27 - Wash.

Peak No.	Peak Name	Ret. Time min	Area n.a.	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
----------	-----------	---------------	-----------	--------	--------------------	--------------	-------------	------------------



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Shut method	Batch No. :-	N/A
Sample Name :-	Shut	AR. No. :-	N/A
Sample Number :-	28	Instrument Method :-	Shut method _HPLC 67_New-1
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmere
Injection Volume :-	30.00 µL	Instrument Method Created On :-	09-11-2017 20:07:07
Vial Position :-	RA1	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	27-11-2018 18:02:43
Injection Date & Time :-	20-11-2018 06:35:14	Experiment Name:-	Accuracy
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_19-Nov-18_A.seq		

Channel UV_VIS_1 is not available for injection #28 - Shut.

Peak No.	Peak Name	Ret. Time min	Area n.a.	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
----------	-----------	---------------	-----------	--------	--------------------	--------------	-------------	------------------