

RAW DATA OF

(SPECIFICITY)

RELATED SUBSTANCE VALIDATION

Product Name:	Ramithiazide Tablets
Label claim (mg):	10 mg And 25 mg
AR No:	D2404181193
Batch No.:	GP180301
Parameter:	Specificity
LNB No./ Page No.	697/106

Analysis Date: 14-Nov-18

Preparation of standard solution for Ramipril	Weight of standard (mg)	Diluted (mL)	Concentration (ppm)	Purity (As is Basis)
	25.19	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	16.123	2191.679	16.117	2170.303
2	16.113	2225.651		
3	16.110	2208.984		
4	16.113	2185.436		
5	16.117	2181.993		
6	16.117	2165.894		
Average	16.116	2193.273	16.116	2189.991
SD	0.0045	21.1470	0.0042	21.1669
%RSD	0.03	0.96	0.03	0.97

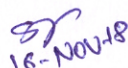
System Suitability		
%RSD of Area	0.96	NMT 5.0%

Preparation of standard solution for Hydrochlorothiazide	Weight of standard (mg)	Diluted (mL)	Concentration (ppm)	Purity (As is Basis)
	25.74	25.0		
	2.5	100.0	2.57	99.24
	2.0	20.0		

Hydrochlorothiazide				
Injection No.	Retention Time	Peak Area	Retention Time	Area of Bkt Standard
1	5.140	4377.810	5.163	4273.060
2	5.147	4276.994		
3	5.147	4333.180		
4	5.143	4271.156		
5	5.147	4370.513		
6	5.147	4271.229		
Average	5.145	4316.814	5.148	4310.563
SD	0.0030	50.2399	0.0073	48.7530
%RSD	0.06	1.16	0.14	1.13

System Suitability		
%RSD of Area	1.16	NMT 5.0%

Sample	RT (Individual impurity)	RT (As such Sample)	RT (Spiked Sample)
Blank Solution	ND	ND	ND
Hydrochlorothiazide	5.140	5.250	5.133
Ramipril Impurity E	14.063	14.067	14.057
Ramipril Impurity A	14.640	ND	14.647
Ramipril	16.123	15.977	15.980
Ramipril Impurity D	23.887	23.870	23.847

Done by: 
Date: 16-Nov-18

Checked by: 
Date: 16-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_14-Nov-18_A	Seq. Created On :	14-11-2018 16:51:27	Seq. Last Updated On :	14-11-2018 17:10:28
Data Vault :	QbD_2018				
Sequence Path :	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq				

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	RA1	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PF	67_Ramithiazide Tablets_RS_PF		D2404181993	N/A	QbD/ILC/COL/128
2	Standard Solution 1	Unknown	30.00	RA2	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PF	67_Ramithiazide Tablets_RS_PF		D2404181993	N/A	QbD/ILC/COL/128
3	Standard Solution 2	Unknown	30.00	RA2	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PF	67_Ramithiazide Tablets_RS_PF		D2404181993	N/A	QbD/ILC/COL/128
4	Standard Solution 3	Unknown	30.00	RA2	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PF	67_Ramithiazide Tablets_RS_PF		D2404181993	N/A	QbD/ILC/COL/128
5	Standard Solution 4	Unknown	30.00	RA2	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PF	67_Ramithiazide Tablets_RS_PF		D2404181993	N/A	QbD/ILC/COL/128
6	Standard Solution 5	Unknown	30.00	RA2	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PF	67_Ramithiazide Tablets_RS_PF		D2404181993	N/A	QbD/ILC/COL/128
7	Standard Solution 6	Unknown	30.00	RA2	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PF	67_Ramithiazide Tablets_RS_PF		D2404181993	N/A	QbD/ILC/COL/128
8	Blank Solution	Unknown	30.00	RA1	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PF	67_Ramithiazide Tablets_RS_PF		D2404181993	N/A	QbD/ILC/COL/128
9	Placebo Solution	Unknown	30.00	RA3	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PF	67_Ramithiazide Tablets_RS_PF		D2404181993	N/A	QbD/ILC/COL/128
10	Impurity A Identification Solution	Unknown	30.00	RA4	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PF	67_Ramithiazide Tablets_RS_PF		D2404181993	SP-023-164	QbD/ILC/COL/128
11	Impurity E Identification Solution	Unknown	30.00	RA5	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PF	67_Ramithiazide Tablets_RS_PF		D2404181993	SP-027-084	QbD/ILC/COL/128
12	Impurity D Identification Solution	Unknown	30.00	RA6	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PF	67_Ramithiazide Tablets_RS_PF		D2404181993	SP-028-152	QbD/ILC/COL/128
13	Blank Solution	Unknown	30.00	RA1	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PF	67_Ramithiazide Tablets_RS_PF		D2404181993	N/A	QbD/ILC/COL/128
14	Sample Solution (As Such)	Unknown	30.00	RA7	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PF	67_Ramithiazide Tablets_RS_PF		D2404181993	GP180301	QbD/ILC/COL/128
15	Blank Solution	Unknown	30.00	RA1	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PF	67_Ramithiazide Tablets_RS_PF		D2404181993	N/A	QbD/ILC/COL/128
16	Sample Solution (Spiked with Impu	Unknown	30.00	RA8	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PF	67_Ramithiazide Tablets_RS_PF		D2404181993	N/A	QbD/ILC/COL/128
17	Blank Solution	Unknown	30.00	RA1	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PF	67_Ramithiazide Tablets_RS_PF		D2404181993	N/A	QbD/ILC/COL/128
18	Bkt Standard Solution	Unknown	30.00	RA2	Idle	n.a.	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PF	67_Ramithiazide Tablets_RS_PF		D2404181993	N/A	QbD/ILC/COL/128
19	Wash	Unknown	30.00	RA1	Idle	n.a.	Wash method_HPLC 67_Nearamithiazide Tablets_RS_PF	Wash method_HPLC 67_Nearamithiazide Tablets_RS_PF		D2404181993	N/A	QbD/ILC/COL/128
20	Shut	Unknown	30.00	RA1	Idle	n.a.	Shut method_HPLC 67_Nearamithiazide Tablets_RS_PF	Shut method_HPLC 67_Nearamithiazide Tablets_RS_PF		D2404181993	N/A	QbD/ILC/COL/128

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

28-Nov-18

14-Nov-18

Name	HPLC-67_Ramithiazide Tablet_RS_Met
Data Vault	QbD_2018
Path	chrom://qbdser03/QbD_2018/Method Validation/Generic Healthcare/Ramithiazide Tablet/Related Substances/HPLC-67_14- Nov-18_A.seq/HPLC-67_Ramithiazide Tablet_RS_Met.instmeth
Comment	Ramithiazide Tablet
Description	Ramithiazide Tablet instrument method created
Run time	30.000 [min]
Instrument	QbD-INST-HPLC-67 on qbd-pc-19
Created	14-Nov-18 16:46:53 +05:30 Gauri Rane
Last Update	14-Nov-18 16:46:53 +05:30 Gauri Rane

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14-Nov-18

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14-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]	

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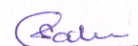
		DAD.UV_VIS_1.Wavelength	210.0 [nm] ✓
		DAD.UV_VIS_1.Bandwidth	4 [nm]
		DAD.UV_VIS_1.RefWavelength	Off
		DAD.UV_VIS_1.RefBandwidth	1 [nm]
		DAD.3DFIELD.RefWavelength	800.0 [nm]
		DAD.3DFIELD.RefBandwidth	1 [nm]
Inject Preparation	0.000	DAD.Autozero	
		Wait	DAD.Ready And ColumnOven.Re ady And Sampler.Ready And PumpModule.Pu mp.Ready
Inject	0.000	Sampler.Inject	
Start Run	0.000	DAD.UV_VIS_1.AcqOn	
		DAD.3DFIELD.AcqOn	
		DAD.Temp_Lamphouse.AcqOn	
		ColumnOven.ColumnOven_Temp.AcqOn	
		PumpModule.Pump.Pump_Pressure.AcqOn	
Run		Duration =	
	0.000		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
	7.000	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
	9.000	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
	25.000	PumpModule.Pump.Flow.Nominal	1.000 [ml/min] ✓
		PumpModule.Pump.%B.Value	50.0 [%] ✓
		PumpModule.Pump.%C.Value	0.0 [%]

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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 [%]
		PumpModule.Pump.Curve	5
		DAD.UV_VIS_1.AcqOff	
		DAD.3DFIELD.AcqOff	
		DAD.Temp_Lamphouse.AcqOff	
End	30.000	ColumnOven.ColumnOven_Temp.AcqOff	
		PumpModule.Pump.Pump_Pressure.AcqOf	

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14-Nov-18


14-Nov-18



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Instrument ID : QbD-INST-HPLC-67
Sequence Name : HPLC-67_14-Nov-18_A
Data Vault : QbD_2018
Sequence Path : Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq

Seq. Created By : Swaraj A. Jadhav
Seq. Created On : 14-11-2018 16:51:27

Inj No.	Injection Name	Injection Type	Volume μ L	Vial No.	Status	Injection Time	Instrument Method	Processing Method	Level
1	Blank Solution	Unknown	30.00	RA1	Finished	14-11-2018 17:28:52	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR		
2	Standard Solution 1	Unknown	30.00	RA2	Finished	14-11-2018 18:00:05	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR		
3	Standard Solution 2	Unknown	30.00	RA2	Finished	14-11-2018 18:31:23	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR		
4	Standard Solution 3	Unknown	30.00	RA2	Finished	14-11-2018 19:02:37	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR		
5	Standard Solution 4	Unknown	30.00	RA2	Finished	14-11-2018 19:33:50	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR		
6	Standard Solution 5	Unknown	30.00	RA2	Finished	14-11-2018 20:05:03	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR		
7	Standard Solution 6	Unknown	30.00	RA2	Finished	14-11-2018 20:36:16	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR		
8	Blank Solution	Unknown	30.00	RA1	Finished	14-11-2018 21:07:34	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR		
9	Placebo Solution	Unknown	30.00	RA3	Finished	14-11-2018 21:38:52	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR		
10	Impurity A identification Solution	Unknown	30.00	RA4	Finished	14-11-2018 22:10:05	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR		
11	Impurity E identification Solution	Unknown	30.00	RA5	Finished	14-11-2018 22:41:18	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR		
12	Impurity D identification Solution	Unknown	30.00	RA6	Finished	14-11-2018 23:12:31	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR		
13	Blank Solution	Unknown	30.00	RA1	Finished	14-11-2018 23:43:44	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR		
14	Sample Solution (As Such)	Unknown	30.00	RA7	Finished	15-11-2018 00:14:57	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR		
15	Blank Solution	Unknown	30.00	RA1	Finished	15-11-2018 00:46:11	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR		
16	Sample Solution (Spiked with Impu	Unknown	30.00	RA8	Finished	15-11-2018 01:17:24	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR		
17	Blank Solution	Unknown	30.00	RA1	Finished	15-11-2018 01:48:37	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR		
18	Bkt Standard Solution	Unknown	30.00	RA2	Finished	15-11-2018 02:19:55	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR		
19	Wash	Unknown	30.00	RA1	Finished	15-11-2018 02:54:58	Wash method _HPLC 67_Neamithiazide Tablets_RS_PR		
20	Shut	Unknown	30.00	RA1	Finished	15-11-2018 04:00:12	Shut method _HPLC 67_Neamithiazide Tablets_RS_PR		

Seq. Last Updated By : Swaraj A. Jadhav
Seq. Last Updated On : 16-11-2018 18:54:59

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	SP-023-164	QbD/LC/COL/128
D2404181993	SP-027-084	QbD/LC/COL/128
D2404181993	SP-028-152	QbD/LC/COL/128
D2404181993	N/A	QbD/LC/COL/128
D2404181993	GP180301	QbD/LC/COL/128
D2404181993	N/A	QbD/LC/COL/128
D2404181993	N/A	QbD/LC/COL/128
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D2404181993	N/A	QbD/LC/COL/128
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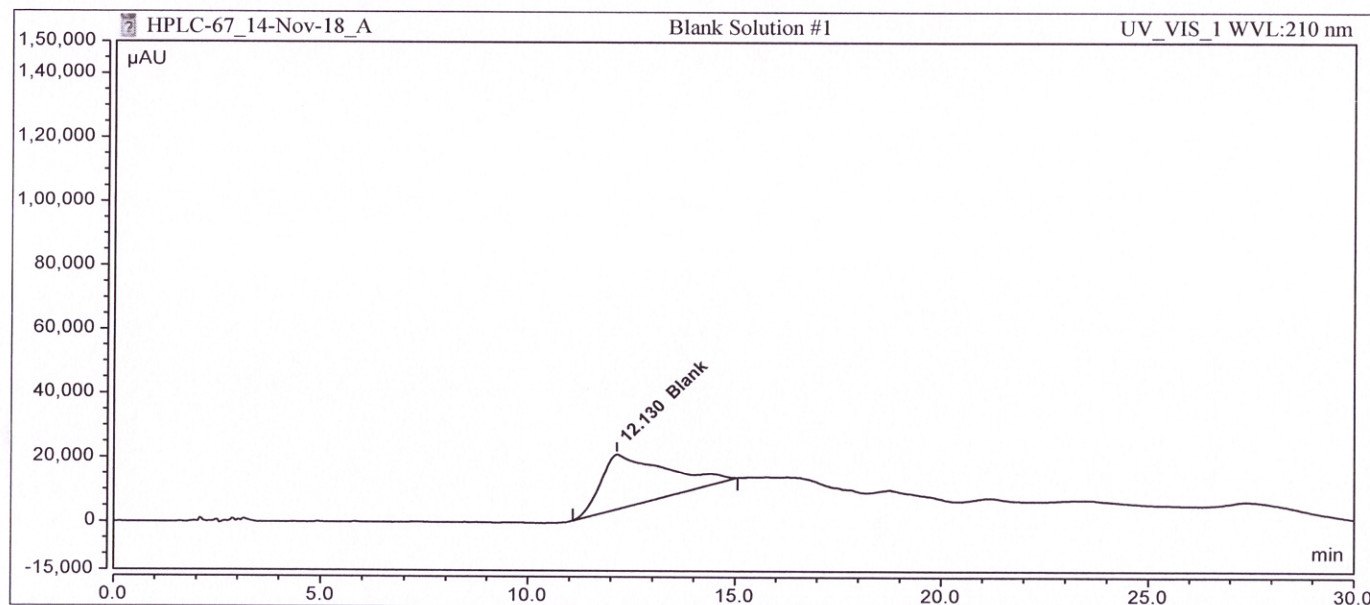
* Refer AR NO:- D2404181193 instead of AR NO:- D2404181993

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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 :-	16-11-2018 18:54:59
Injection Date & Time :-	14-11-2018 17:28:52	Experiment Name:-	Specificity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		

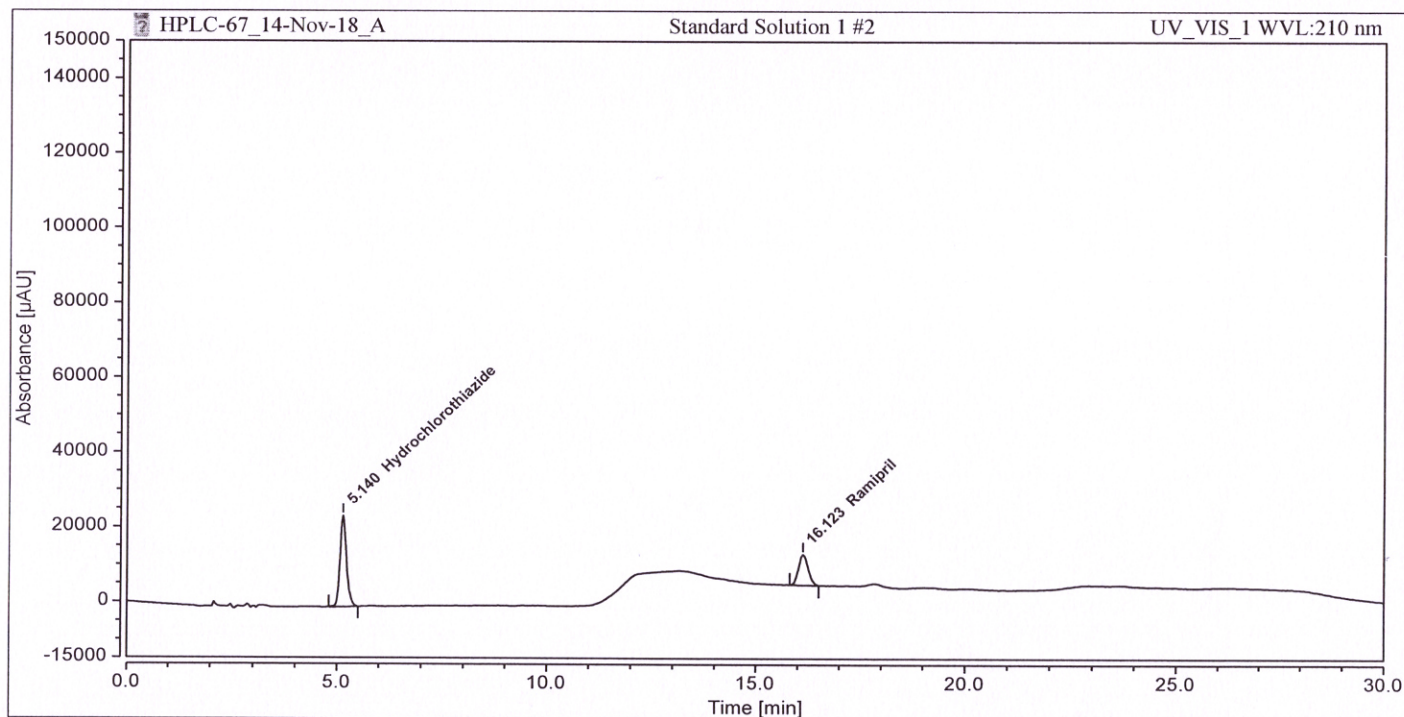


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Blank	12.130	29730.276	100.00	2.08	395	FALSE	n.a.



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Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Standard Solution 1	AR. No. :-	D2404181993
Sample Number :-	2	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS
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_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 :-	16-11-2018 18:54:59
Injection Date & Time :-	14-11-2018 18:00:05	Experiment Name:-	Specificity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		

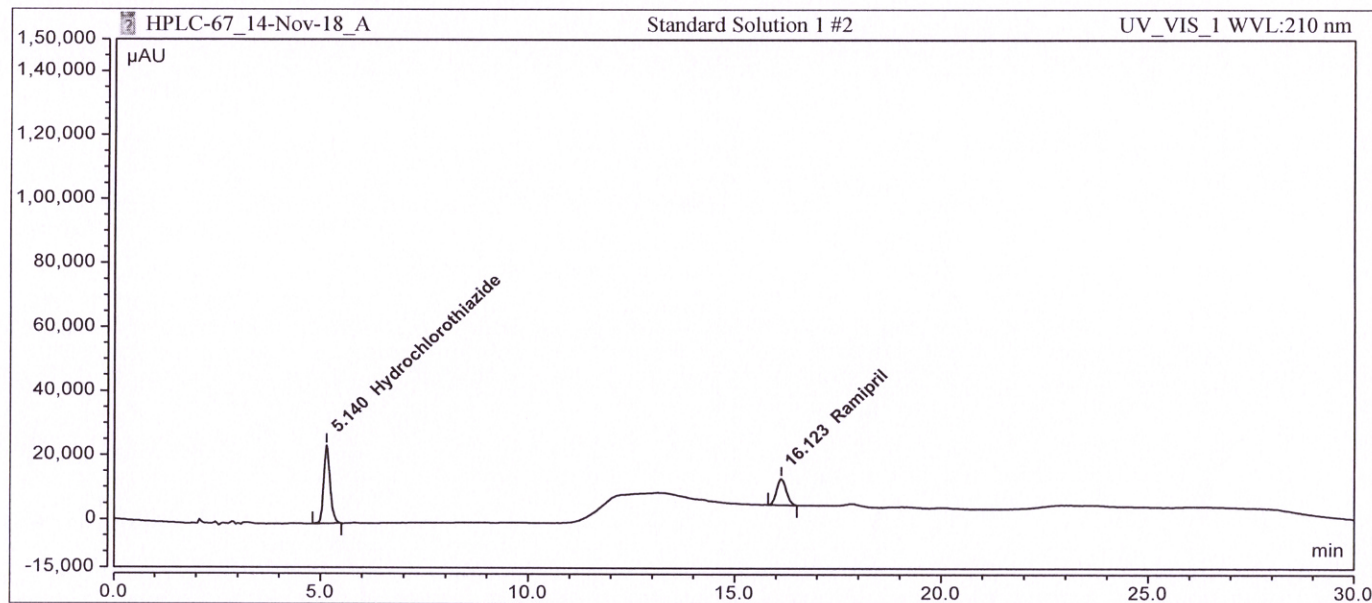


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Height µAU	Match Factor	Manipulated	Peak Type
1	Hydrochlorothiazide	5.140	4377.810	66.64	24328	1000	FALSE	BMB
2	Ramipril	16.123	2191.679	33.36	8174	1000	FALSE	BMB
Total				100.00				



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Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Standard Solution 1	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 :-	RA2	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 :-	16-11-2018 18:54:59
Injection Date & Time :-	14-11-2018 18:00:05	Experiment Name:-	Specificity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-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	5.140	4377.810	66.64	1.26	5529	FALSE	n.a.
2	Ramipril	16.123	2191.679	33.36	1.11	22827	FALSE	31.23



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Processing Method

Processing Method Name :	Ramithiazide Tablets_RS_PRI		
Processing Method Path :	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		
Processing Method Created By :	Swaraj A. Jadhav	Processing Method Last Updated By :	Swaraj A. Jadhav
Processing Method Created On :	14-11-2018 16:59:55	Processing Method Last Updated On :	16-11-2018 18:54:59

Detection Algorithm	Chromeleon 6	Version	4
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Detection Parameter

Ret. Time min	Param. Name	Param. Value	Inj. Type	Channel
0.000	Minimum Area	50.0000 [Signal*min]	Any	All Channels
0.000	Valley To Valley	On	Any	All Channels
0.000	Minimum Width	0.400 [min]	Any	All Channels
4.000	Minimum Width	0.000 [min]	Any	All Channels
11.000	Minimum Width	2.500 [min]	Any	All Channels
13.500	Minimum Width	0.000 [min]	Any	All Channels
16.000	Minimum Height	1600.000 [Signal]	Any	All Channels
18.000	Minimum Height	0.000 [Signal]	Any	All Channels

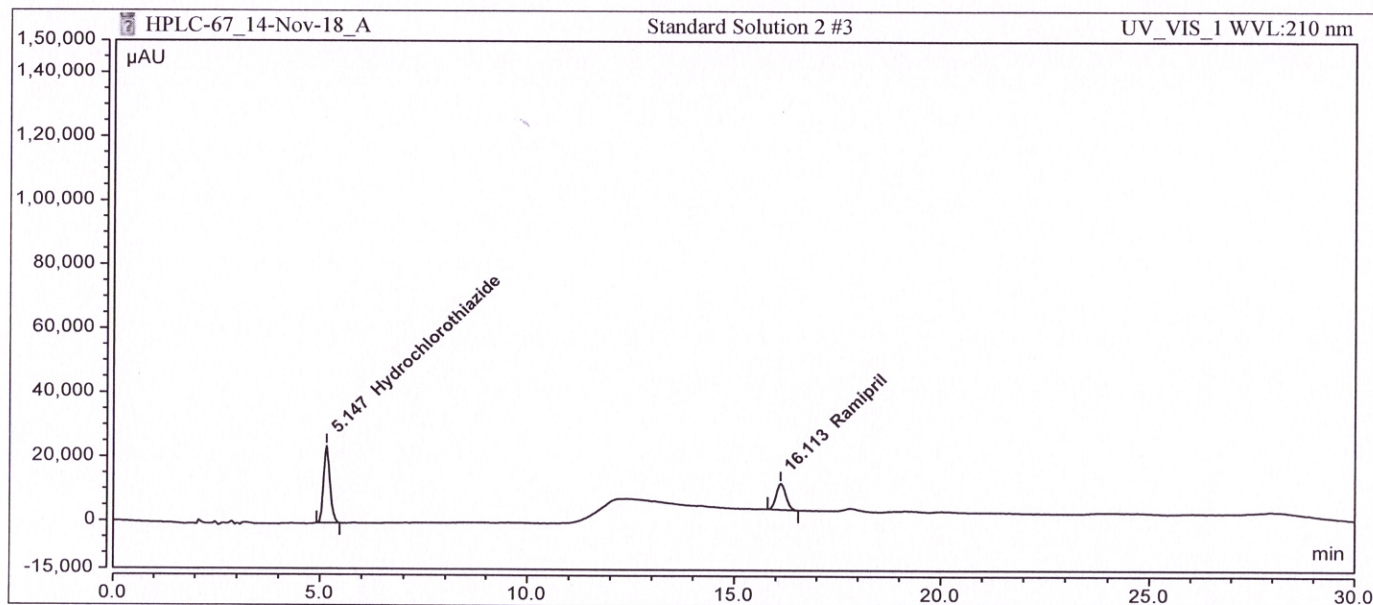
Peak Table

No.	Peak Name	Ret. Time
1	Hydrochlorothiazide	5.140
2	Impurity E	14.063
3	Impurity A	14.640
4	Ramipril	16.123
5	Impurity D	23.887



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Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Standard Solution 2	AR. No. :-	D2404181993
Sample Number :-	3	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_N
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_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 :-	16-11-2018 18:54:59
Injection Date & Time :-	14-11-2018 18:31:23	Experiment Name:-	Specificity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-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	4276.994	65.77	1.25	5545	FALSE	n.a.
2	Ramipril	16.113	2225.651	34.23	1.14	22223	FALSE	30.94



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Processing Method

Processing Method Name :	Ramithiazide Tablets_RS_PR1		
Processing Method Path :	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		
Processing Method Created By :	Swaraj A. Jadhav	Processing Method Last Updated By :	Swaraj A. Jadhav
Processing Method Created On :	14-11-2018 16:59:55	Processing Method Last Updated On :	16-11-2018 18:54:59

Detection Alogrithm	Chromeleon 6	Version	4
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Detection Parameter

Ret. Time min	Param. Name	Param. Value	Inj. Type	Channel
0.000	Minimum Area	50.0000 [Signal*min]	Any	All Channels
0.000	Valley To Valley	On	Any	All Channels
0.000	Minimum Width	0.400 [min]	Any	All Channels
4.000	Minimum Width	0.000 [min]	Any	All Channels
11.000	Minimum Width	2.500 [min]	Any	All Channels
13.500	Minimum Width	0.000 [min]	Any	All Channels
16.000	Minimum Height	1600.000 [Signal]	Any	All Channels
18.000	Minimum Height	0.000 [Signal]	Any	All Channels

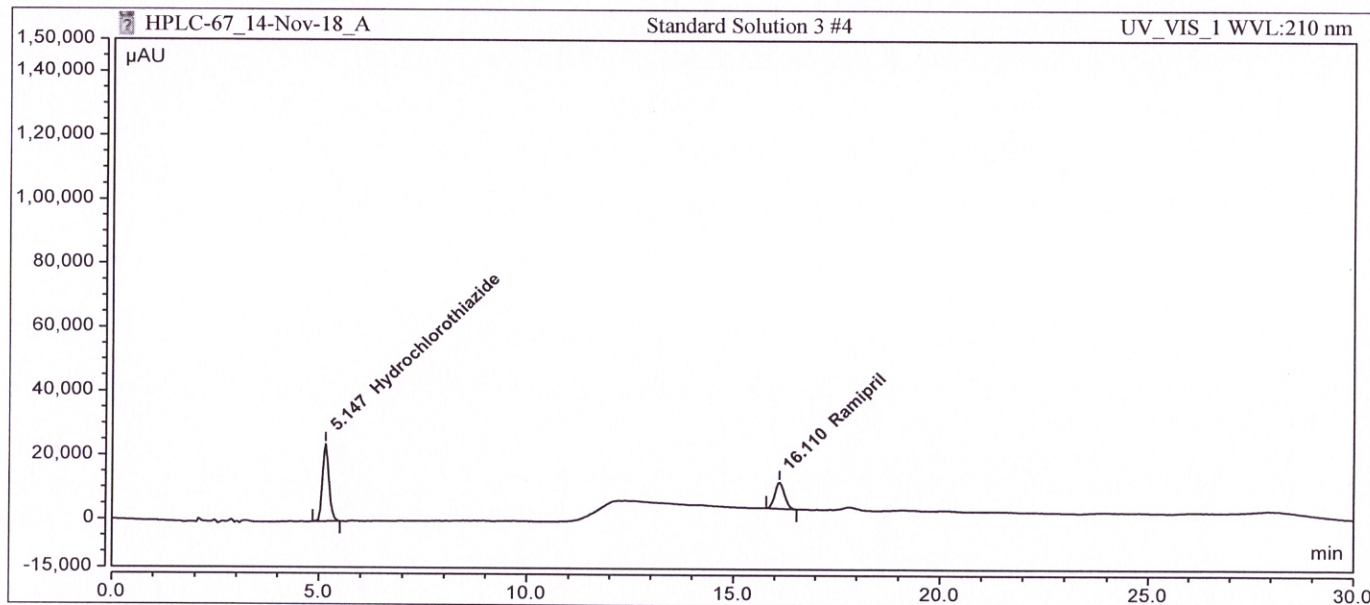
Peak Table

No.	Peak Name	Ret. Time
1	Hydrochlorothiazide	5.140
2	Impurity E	14.063
3	Impurity A	14.640
4	Ramipril	16.123
5	Impurity D	23.887



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Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Standard Solution 3	AR. No. :-	D2404181993
Sample Number :-	4	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_N
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_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 :-	16-11-2018 18:54:59
Injection Date & Time :-	14-11-2018 19:02:37	Experiment Name:-	Specificity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-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	4333.180	66.23	1.26	5498	FALSE	n.a.
2	Ramipril	16.110	2208.984	33.77	1.12	21841	FALSE	30.72



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Processing Method

Processing Method Name :	Ramithiazide Tablets_RS_PR1		
Processing Method Path :	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		
Processing Method Created By :	Swaraj A. Jadhav	Processing Method Last Updated By :	Swaraj A. Jadhav
Processing Method Created On :	14-11-2018 16:59:55	Processing Method Last Updated On :	16-11-2018 18:54:59

Detection Alogrithm	Chromeleon 6	Version	4
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Detection Parameter

Ret. Time min	Param. Name	Param. Value	Inj. Type	Channel
0.000	Minimum Area	50.0000 [Signal*min]	Any	All Channels
0.000	Valley To Valley	On	Any	All Channels
0.000	Minimum Width	0.400 [min]	Any	All Channels
4.000	Minimum Width	0.000 [min]	Any	All Channels
11.000	Minimum Width	2.500 [min]	Any	All Channels
13.500	Minimum Width	0.000 [min]	Any	All Channels
16.000	Minimum Height	1600.000 [Signal]	Any	All Channels
18.000	Minimum Height	0.000 [Signal]	Any	All Channels

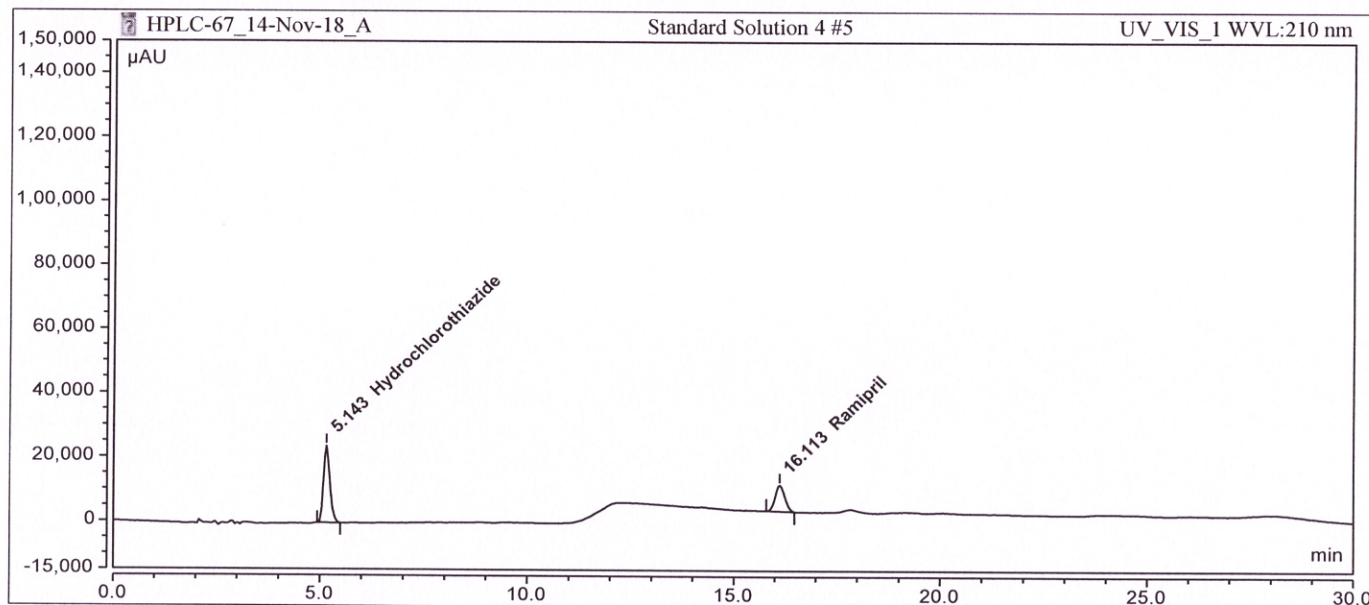
Peak Table

No.	Peak Name	Ret. Time
1	Hydrochlorothiazide	5.140
2	Impurity E	14.063
3	Impurity A	14.640
4	Ramipril	16.123
5	Impurity D	23.887



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Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Standard Solution 4	AR. No. :-	D2404181993
Sample Number :-	5	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_N
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_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 :-	16-11-2018 18:54:59
Injection Date & Time :-	14-11-2018 19:33:50	Experiment Name:-	Specificity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-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	5.143	4271.156	66.15	1.28	5503	FALSE	n.a.
2	Ramipril	16.113	2185.436	33.85	1.11	22364	FALSE	30.97



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Processing Method

Processing Method Name :	Ramithiazide Tablets_RS_PR1		
Processing Method Path :	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		
Processing Method Created By :	Swaraj A. Jadhav	Processing Method Last Updated By :	Swaraj A. Jadhav
Processing Method Created On :	14-11-2018 16:59:55	Processing Method Last Updated On :	16-11-2018 18:54:59

Detection Alogrithm	Chromeleon 6	Version	4
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Detection Parameter

Ret. Time min	Param. Name	Param. Value	Inj. Type	Channel
0.000	Minimum Area	50.0000 [Signal*min]	Any	All Channels
0.000	Valley To Valley	On	Any	All Channels
0.000	Minimum Width	0.400 [min]	Any	All Channels
4.000	Minimum Width	0.000 [min]	Any	All Channels
11.000	Minimum Width	2.500 [min]	Any	All Channels
13.500	Minimum Width	0.000 [min]	Any	All Channels
16.000	Minimum Height	1600.000 [Signal]	Any	All Channels
18.000	Minimum Height	0.000 [Signal]	Any	All Channels

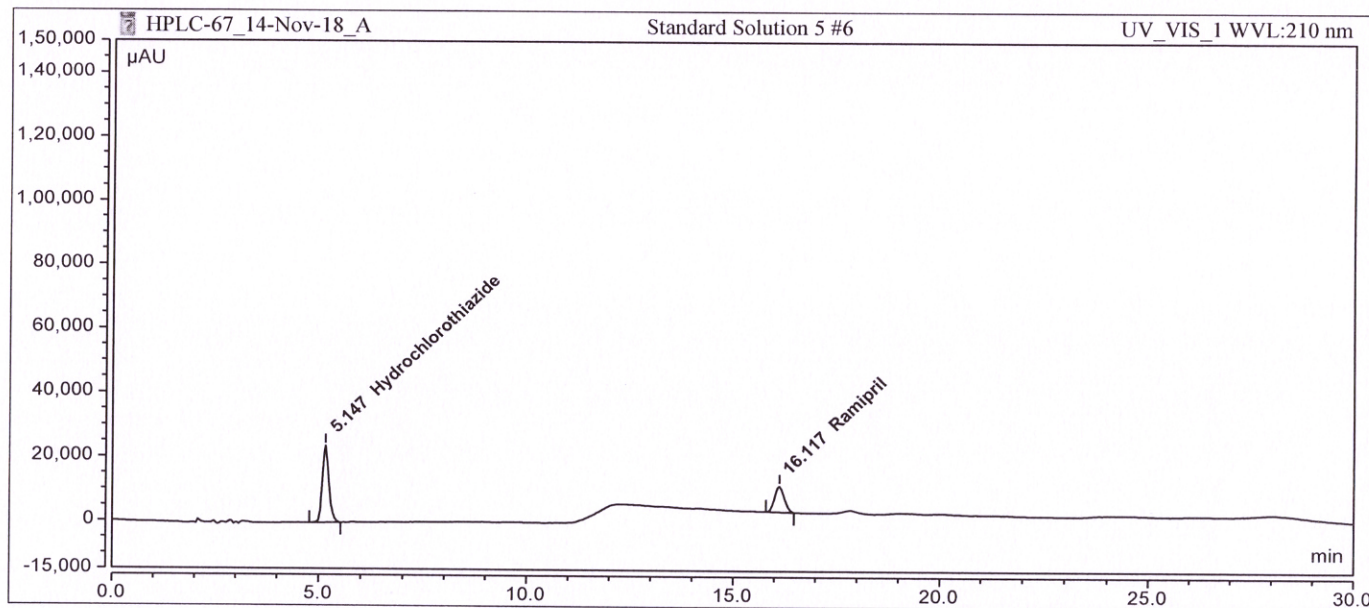
Peak Table

No.	Peak Name	Ret. Time
1	Hydrochlorothiazide	5.140
2	Impurity E	14.063
3	Impurity A	14.640
4	Ramipril	16.123
5	Impurity D	23.887



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 :-	6	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_N
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_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 :-	16-11-2018 18:54:59
Injection Date & Time :-	14-11-2018 20:05:03	Experiment Name:-	Specificity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-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	4370.513	66.70	1.26	5419	FALSE	n.a.
2	Ramipril	16.117	2181.993	33.30	1.10	21441	FALSE	30.48



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Processing Method

Processing Method Name :	Ramithiazide Tablets_RS_PR1		
Processing Method Path :	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		
Processing Method Created By :	Swaraj A. Jadhav	Processing Method Last Updated By :	Swaraj A. Jadhav
Processing Method Created On :	14-11-2018 16:59:55	Processing Method Last Updated On :	16-11-2018 18:54:59

Detection Alogrithm	Chromeleon 6	Version	4
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Detection Parameter

Ret. Time min	Param. Name	Param. Value	Inj. Type	Channel
0.000	Minimum Area	50.0000 [Signal*min]	Any	All Channels
0.000	Valley To Valley	On	Any	All Channels
0.000	Minimum Width	0.400 [min]	Any	All Channels
4.000	Minimum Width	0.000 [min]	Any	All Channels
11.000	Minimum Width	2.500 [min]	Any	All Channels
13.500	Minimum Width	0.000 [min]	Any	All Channels
16.000	Minimum Height	1600.000 [Signal]	Any	All Channels
18.000	Minimum Height	0.000 [Signal]	Any	All Channels

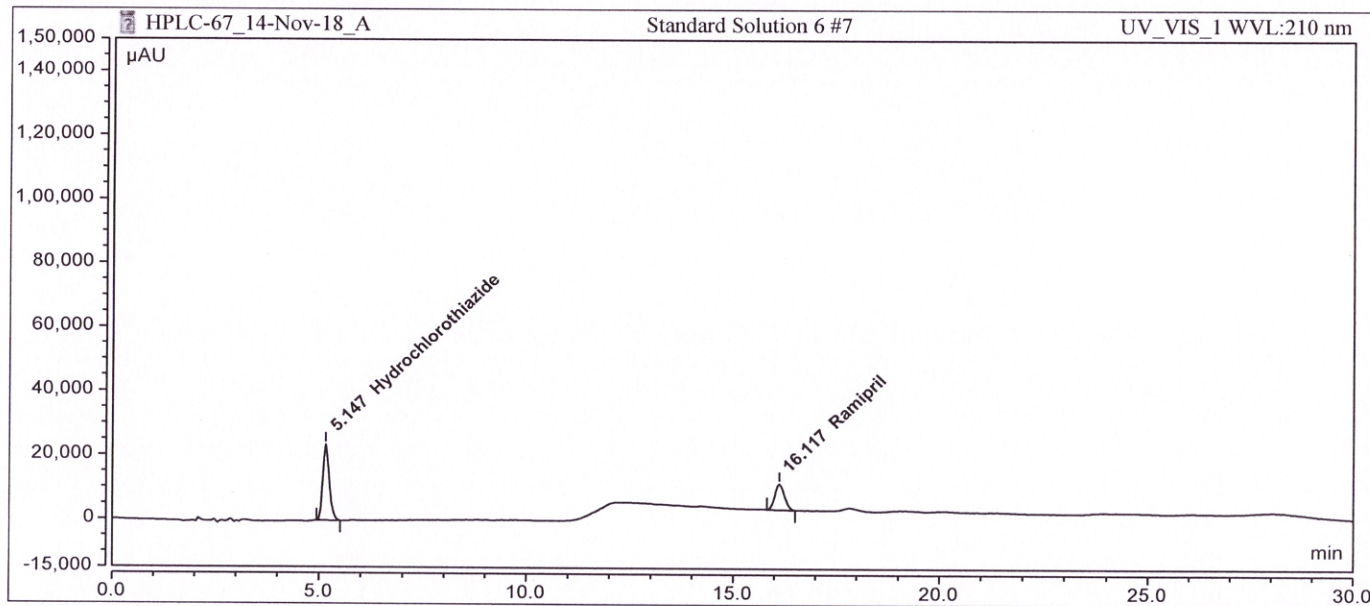
Peak Table

No.	Peak Name	Ret. Time
1	Hydrochlorothiazide	5.140
2	Impurity E	14.063
3	Impurity A	14.640
4	Ramipril	16.123
5	Impurity D	23.887

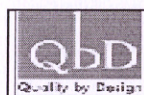


QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Standard Solution 6	AR. No. :-	D2404181993
Sample Number :-	7	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_N
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_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 :-	16-11-2018 18:54:59
Injection Date & Time :-	14-11-2018 20:36:16	Experiment Name:-	Specificity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-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	4271.229	66.35	1.30	5342	FALSE	n.a.
2	Ramipril	16.117	2165.894	33.65	1.14	21995	FALSE	30.63



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Processing Method

Processing Method Name :	Ramithiazide Tablets_RS_PR		
Processing Method Path :	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		
Processing Method Created By :	Swaraj A. Jadhav	Processing Method Last Updated By :	Swaraj A. Jadhav
Processing Method Created On :	14-11-2018 16:59:55	Processing Method Last Updated On :	16-11-2018 18:54:59

Detection Alogrithm	Chromeleon 6	Version	5
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Detection Parameter

Ret. Time min	Param. Name	Param. Value	Inj. Type	Channel
0.000	Minimum Area	50.0000 [Signal*min]	Any	All Channels
0.000	Valley To Valley	On	Any	All Channels
0.000	Minimum Width	0.450 [min]	Any	All Channels
4.000	Minimum Width	0.000 [min]	Any	All Channels
5.000	Minimum Width	0.250 [min]	Any	All Channels
5.500	Minimum Width	0.000 [min]	Any	All Channels
11.000	Minimum Height	6000.000 [Signal]	Any	All Channels
13.000	Minimum Height	0.000 [Signal]	Any	All Channels
17.500	Minimum Height	1000.000 [Signal]	Any	All Channels
19.000	Minimum Height	0.000 [Signal]	Any	All Channels

Peak Table

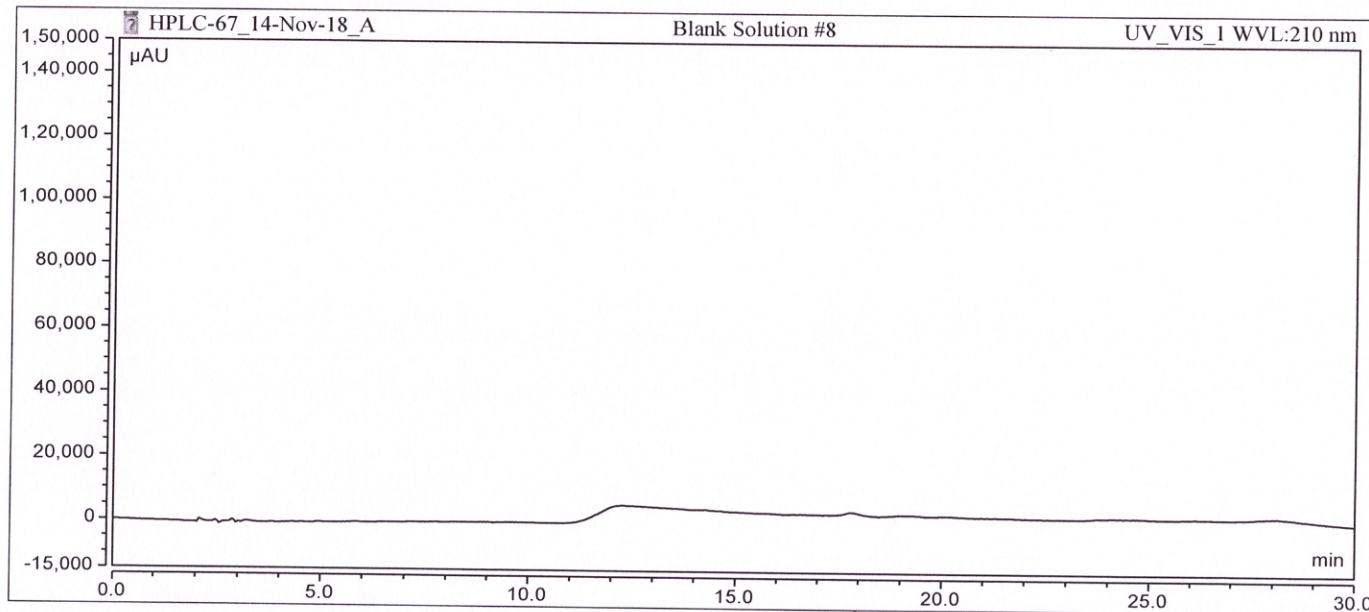
No.	Peak Name	Ret. Time
1	Unknown	4.133
2	Placebo	4.617
3	Hydrochlorothiazide	5.140
4	Unknown	7.963
5	Placebo	11.197
6	Blank	12.130
7	Impurity E	14.063
8	Impurity A	14.640
9	Ramipril	16.123
10	Impurity D	23.887

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 :-	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 :-	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 :-	16-11-2018 18:54:59
Injection Date & Time :-	14-11-2018 21:07:34	Experiment Name:-	Specificity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		



Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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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_14-Nov-18_A.seq		
Processing Method Created By :	Swaraj A. Jadhav	Processing Method Last Updated By :	Swaraj A. Jadhav
Processing Method Created On :	14-11-2018 16:59:55	Processing Method Last Updated On :	16-11-2018 18:54:59

Detection Alogrithm	Chromeleon 6	Version	5
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Detection Parameter

Ret. Time min	Param. Name	Param. Value	Inj. Type	Channel
0.000	Minimum Area	50.0000 [Signal*min]	Any	All Channels
0.000	Valley To Valley	On	Any	All Channels
0.000	Minimum Width	0.450 [min]	Any	All Channels
4.000	Minimum Width	0.000 [min]	Any	All Channels
5.000	Minimum Width	0.250 [min]	Any	All Channels
5.500	Minimum Width	0.000 [min]	Any	All Channels
11.000	Minimum Height	6000.000 [Signal]	Any	All Channels
13.000	Minimum Height	0.000 [Signal]	Any	All Channels
17.500	Minimum Height	1000.000 [Signal]	Any	All Channels
19.000	Minimum Height	0.000 [Signal]	Any	All Channels

Peak Table

No.	Peak Name	Ret. Time
1	Unknown	4.133
2	Placebo	4.617
3	Hydrochlorothiazide	5.140
4	Unknown	7.963
5	Placebo	11.197
6	Blank	12.130
7	Impurity E	14.063
8	Impurity A	14.640
9	Ramipril	16.123
10	Impurity D	23.887

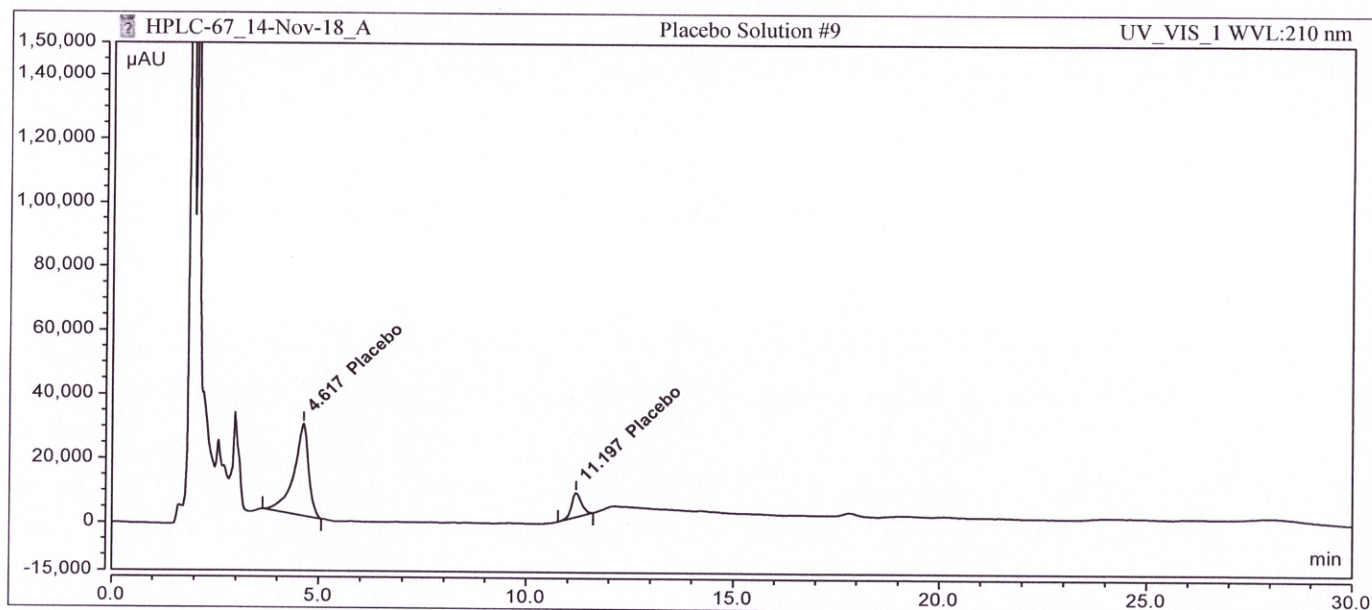
QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Processing Method



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Placebo Solution	AR. No. :-	D2404181993
Sample Number :-	9	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_N
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_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 :-	16-11-2018 18:54:59
Injection Date & Time :-	14-11-2018 21:38:52	Experiment Name:-	Specificity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-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	4.617	11684.913	84.50	0.73	1067	FALSE	n.a.
2	Placebo	11.197	2142.841	15.50	1.09	10778	FALSE	13.20

		QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.	
Processing Method			
Processing Method Name :		Ramithiazide Tablets_RS_PR1	
Processing Method Path :		Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq	
Processing Method Created By :		Swaraj A. Jadhav	Processing Method Last Updated By : Swaraj A. Jadhav
Processing Method Created On :		14-11-2018 16:59:55	Processing Method Last Updated On : 16-11-2018 18:54:59

Detection Alogrithm	Chromeleon 6	Version	4
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Detection Parameter

Ret. Time min	Param. Name	Param. Value	Inj. Type	Channel
0.000	Minimum Area	50.0000 [Signal*min]	Any	All Channels
0.000	Valley To Valley	On	Any	All Channels
0.000	Minimum Width	0.400 [min]	Any	All Channels
4.000	Minimum Width	0.000 [min]	Any	All Channels
11.000	Minimum Width	2.500 [min]	Any	All Channels
13.500	Minimum Width	0.000 [min]	Any	All Channels
16.000	Minimum Height	1600.000 [Signal]	Any	All Channels
18.000	Minimum Height	0.000 [Signal]	Any	All Channels

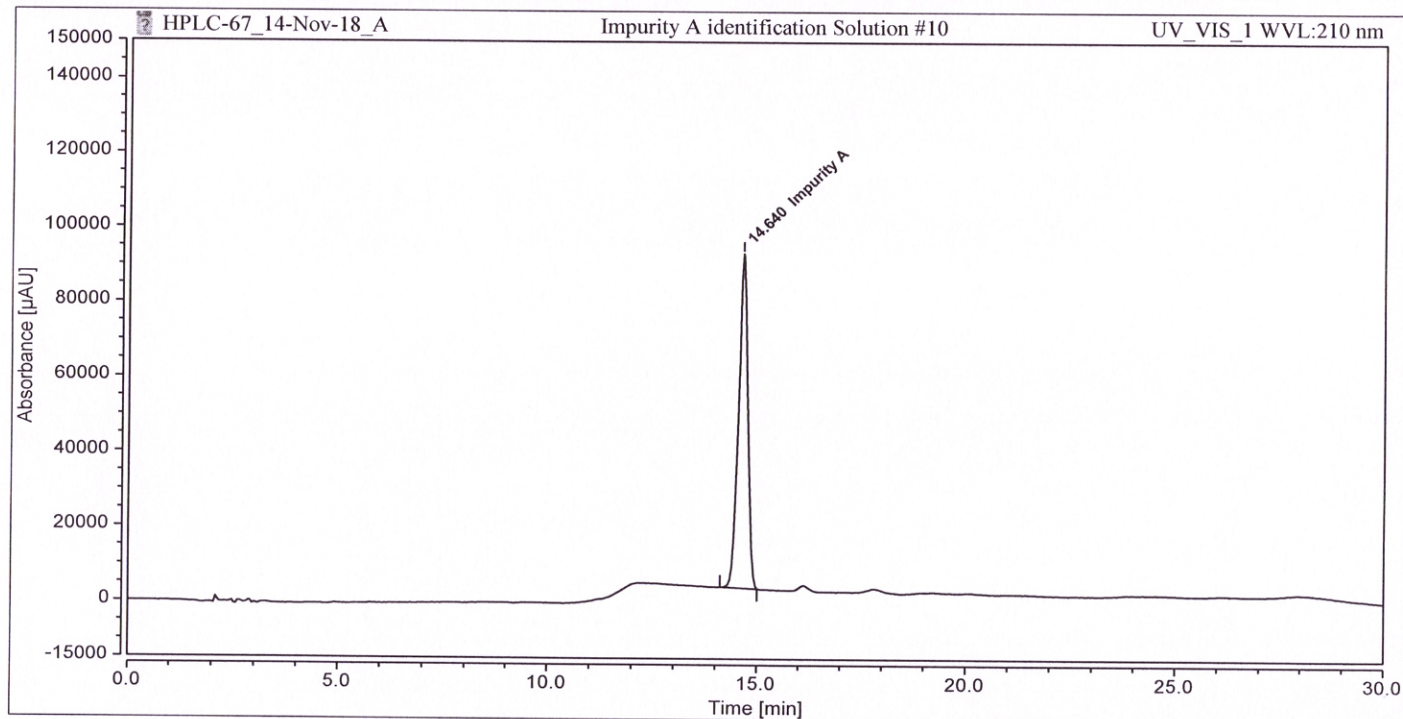
Peak Table

No.	Peak Name	Ret. Time
1	Hydrochlorothiazide	5.140
2	Impurity E	14.063
3	Impurity A	14.640
4	Ramipril	16.123
5	Impurity D	23.887



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	SP-023-164
Sample Name :-	Impurity A identification Solution	AR. No. :-	D2404181993
Sample Number :-	10	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS
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 :-	16-11-2018 18:54:59
Injection Date & Time :-	14-11-2018 22:10:05	Experiment Name:-	Specificity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		

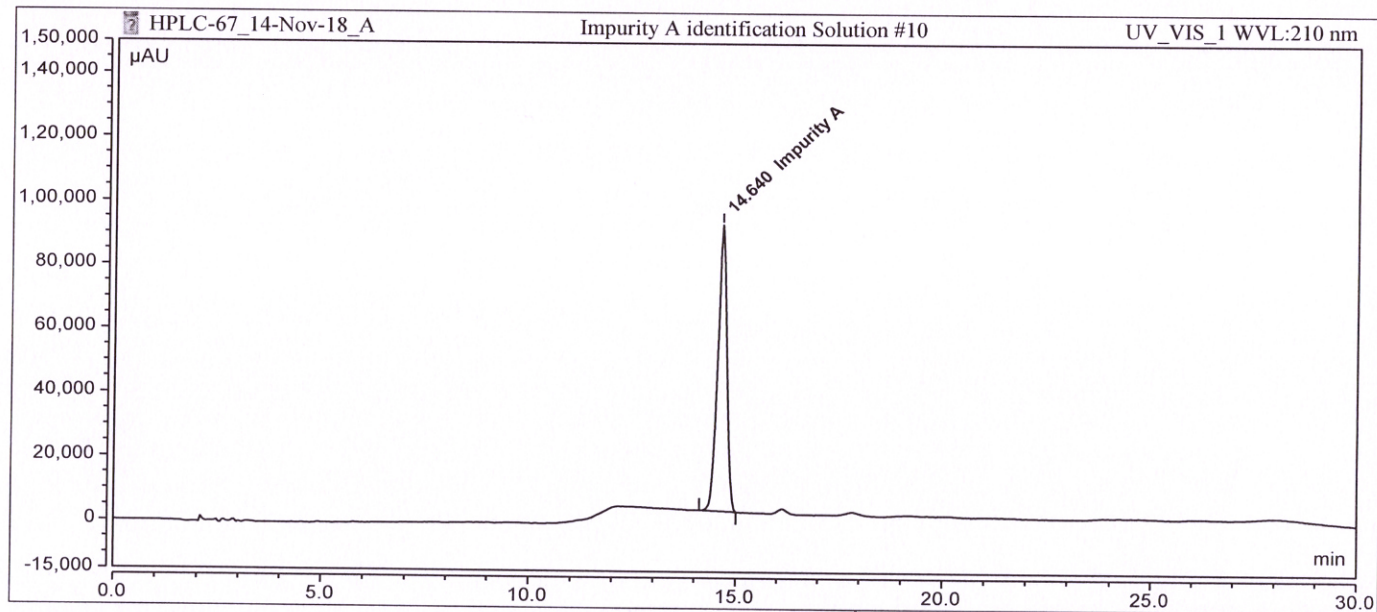


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Height µAU	Match Factor	Manipulated	Peak Type
1	Impurity A	14.640	22842.451	100.00	89291	1000	FALSE	BMB
Total				100.00				



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	SP-023-164
Sample Name :-	Impurity A identification Solution	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 :-	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 :-	16-11-2018 18:54:59
Injection Date & Time :-	14-11-2018 22:10:05	Experiment Name:-	Specificity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		



Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Impurity A	14.640	22842.451	100.00	0.99	20082	FALSE	n.a.



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Processing Method

Processing Method Name :	Ramithiazide Tablets_RS_PR1		
Processing Method Path :	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		
Processing Method Created By :	Swaraj A. Jadhav	Processing Method Last Updated By :	Swaraj A. Jadhav
Processing Method Created On :	14-11-2018 16:59:55	Processing Method Last Updated On :	16-11-2018 18:54:59

Detection Alogrithm	Chromeleon 6	Version	4
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Detection Parameter

Ret. Time min	Param. Name	Param. Value	Inj. Type	Channel
0.000	Minimum Area	50.0000 [Signal*min]	Any	All Channels
0.000	Valley To Valley	On	Any	All Channels
0.000	Minimum Width	0.400 [min]	Any	All Channels
4.000	Minimum Width	0.000 [min]	Any	All Channels
11.000	Minimum Width	2.500 [min]	Any	All Channels
13.500	Minimum Width	0.000 [min]	Any	All Channels
16.000	Minimum Height	1600.000 [Signal]	Any	All Channels
18.000	Minimum Height	0.000 [Signal]	Any	All Channels

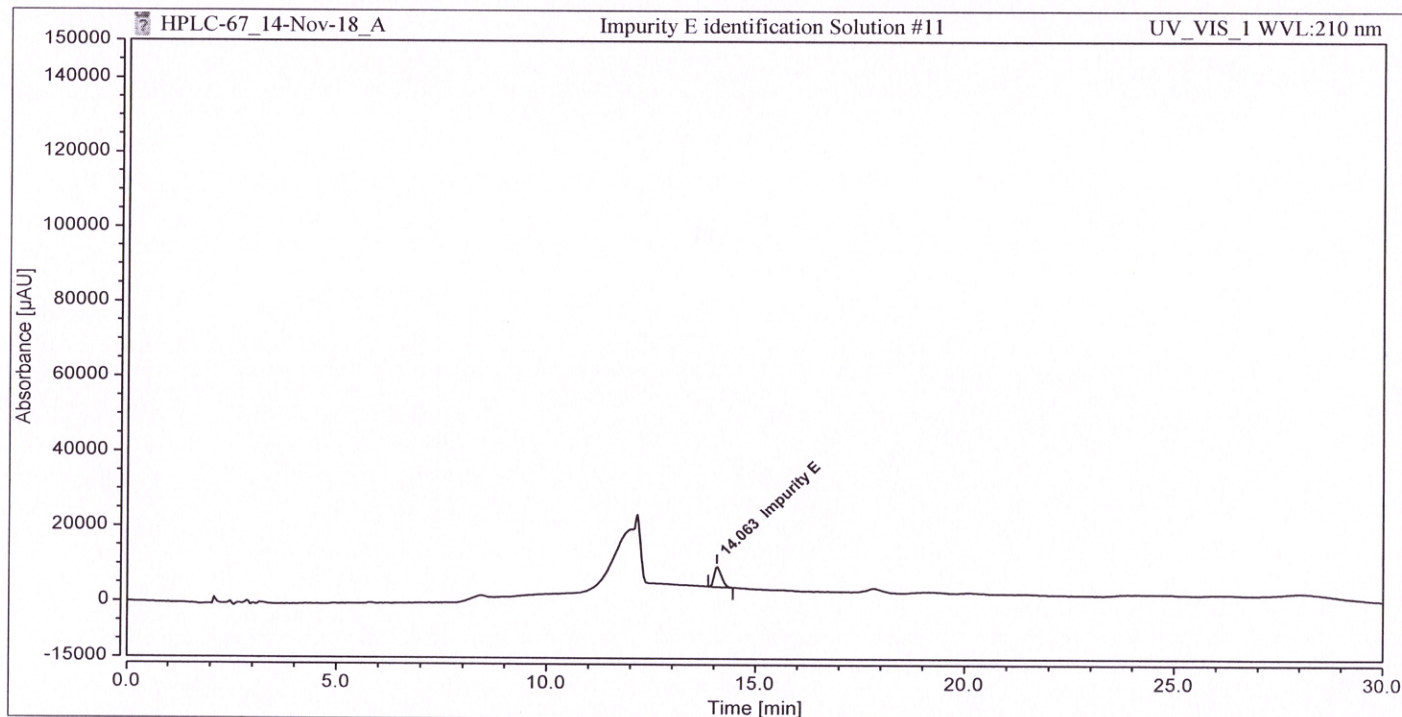
Peak Table

No.	Peak Name	Ret. Time
1	Hydrochlorothiazide	5.140
2	Impurity E	14.063
3	Impurity A	14.640
4	Ramipril	16.123
5	Impurity D	23.887



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	SP-027-084
Sample Name :-	Impurity E identification Solution	AR. No. :-	D2404181993
Sample Number :-	11	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS
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 :-	16-11-2018 18:54:59
Injection Date & Time :-	14-11-2018 22:41:18	Experiment Name:-	Specificity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		

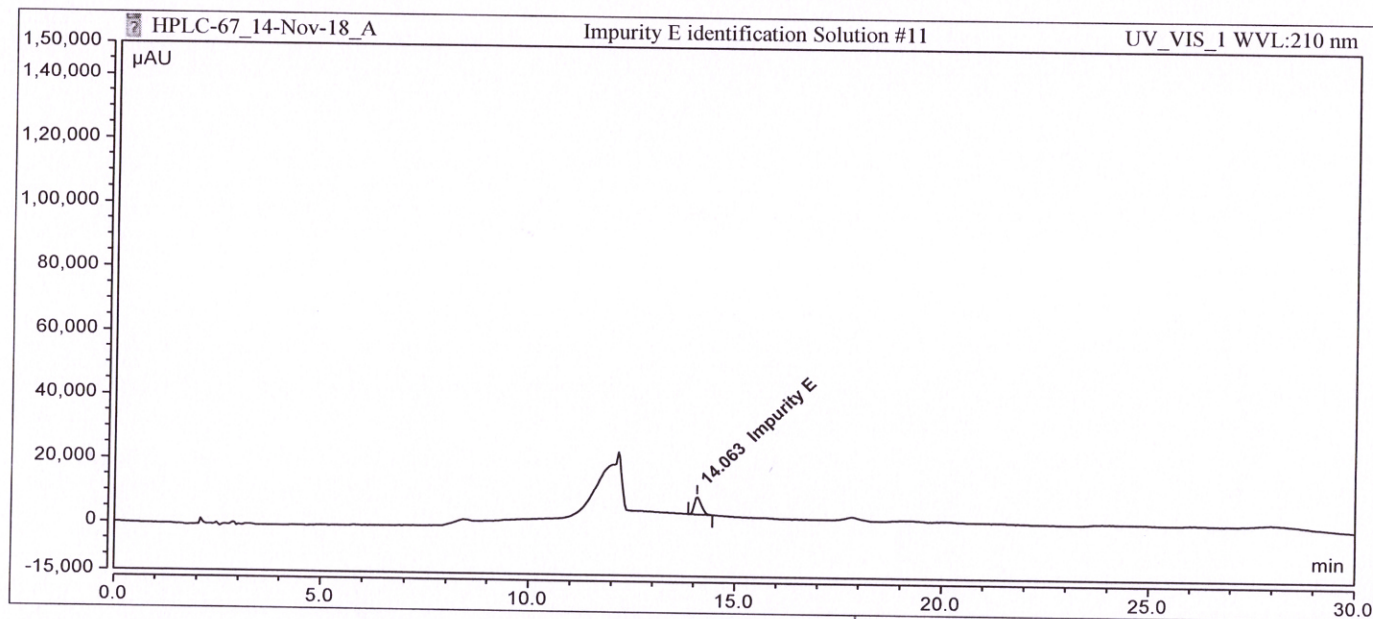


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Height µAU	Match Factor	Manipulated	Peak Type
1	Impurity E	14.063	1083.127	100.00	5467	1000	FALSE	BMB
Total				100.00				



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	SP-027-084
Sample Name :-	Impurity E identification Solution	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 :-	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 :-	16-11-2018 18:54:59
Injection Date & Time :-	14-11-2018 22:41:18	Experiment Name:-	Specificity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		



Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Impurity E	14.063	1083.127	100.00	1.47	26839	FALSE	n.a.



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Processing Method

Processing Method Name :	Ramithiazide Tablets_RS_PR1		
Processing Method Path :	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		
Processing Method Created By :	Swaraj A. Jadhav	Processing Method Last Updated By :	Swaraj A. Jadhav
Processing Method Created On :	14-11-2018 16:59:55	Processing Method Last Updated On :	16-11-2018 18:54:59

Detection Alogrithm	Chromeleon 6	Version	4
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Detection Parameter

Ret. Time min	Param. Name	Param. Value	Inj. Type	Channel
0.000	Minimum Area	50.0000 [Signal*min]	Any	All Channels
0.000	Valley To Valley	On	Any	All Channels
0.000	Minimum Width	0.400 [min]	Any	All Channels
4.000	Minimum Width	0.000 [min]	Any	All Channels
11.000	Minimum Width	2.500 [min]	Any	All Channels
13.500	Minimum Width	0.000 [min]	Any	All Channels
16.000	Minimum Height	1600.000 [Signal]	Any	All Channels
18.000	Minimum Height	0.000 [Signal]	Any	All Channels

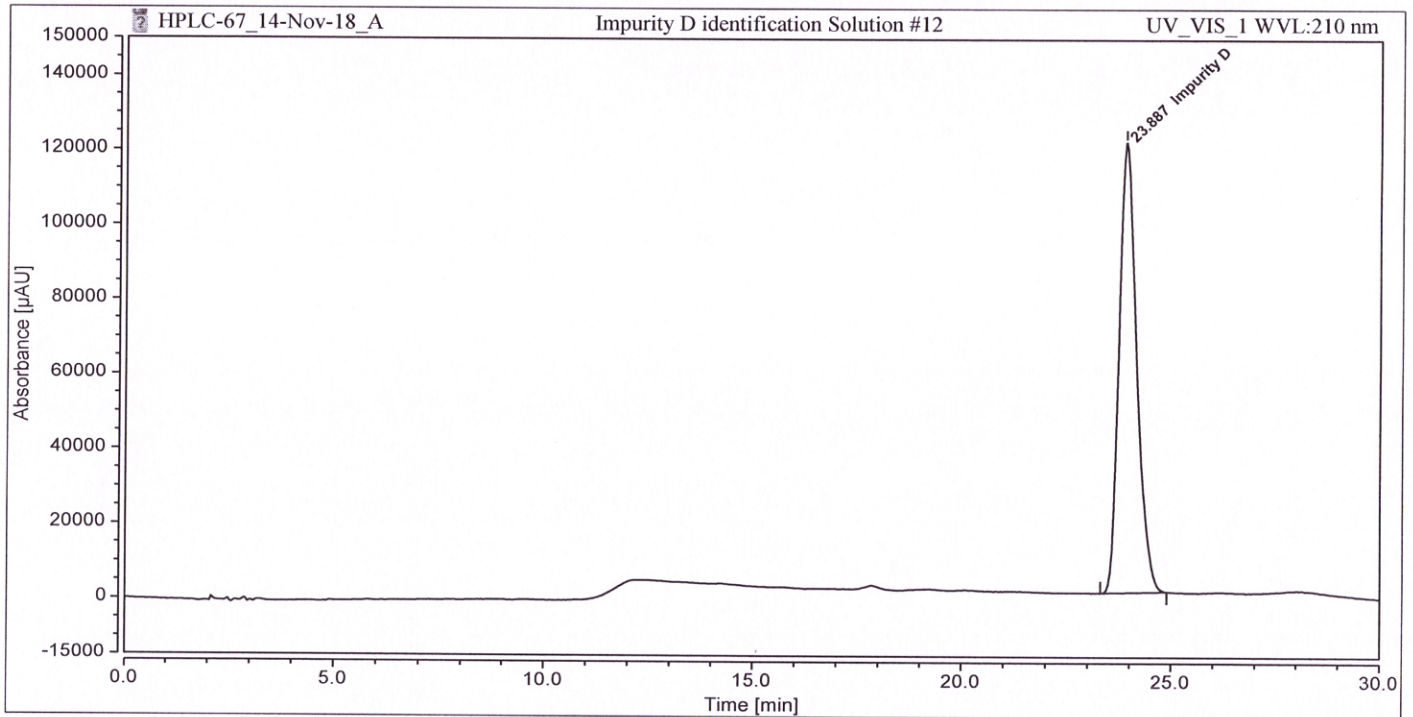
Peak Table

No.	Peak Name	Ret. Time
1	Hydrochlorothiazide	5.140
2	Impurity E	14.063
3	Impurity A	14.640
4	Ramipril	16.123
5	Impurity D	23.887



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	SP-028-152
Sample Name :-	Impurity D identification Solution	AR. No. :-	D2404181993
Sample Number :-	12	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS
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_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 :-	16-11-2018 18:54:59
Injection Date & Time :-	14-11-2018 23:12:31	Experiment Name:-	Specificity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		

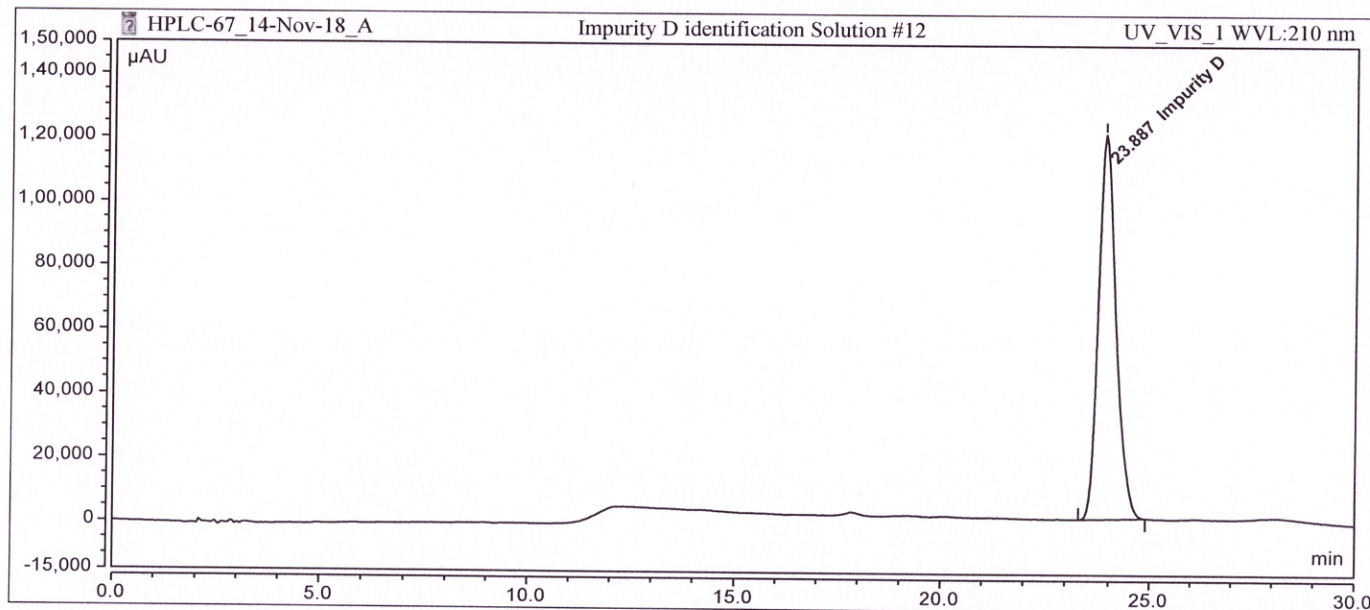


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Height µAU	Match Factor	Manipulated	Peak Type
1	Impurity D	23.887	58414.946	100.00	120125	1000	FALSE	BMB
Total				100.00				



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	SP-028-152
Sample Name :-	Impurity D identification Solution	AR. No. :-	D2404181993
Sample Number :-	12	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_N
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_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 :-	16-11-2018 18:54:59
Injection Date & Time :-	14-11-2018 23:12:31	Experiment Name:-	Specificity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		



Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Impurity D	23.887	58414.946	100.00	1.41	15572	FALSE	n.a.



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_14-Nov-18_A.seq		
Processing Method Created By :	Swaraj A. Jadhav	Processing Method Last Updated By :	Swaraj A. Jadhav
Processing Method Created On :	14-11-2018 16:59:55	Processing Method Last Updated On :	16-11-2018 18:54:59

Detection Alogrithm	Chromeleon 6	Version	5
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Detection Parameter

Ret. Time min	Param. Name	Param. Value	Inj. Type	Channel
0.000	Minimum Area	50.0000 [Signal*min]	Any	All Channels
0.000	Valley To Valley	On	Any	All Channels
0.000	Minimum Width	0.450 [min]	Any	All Channels
4.000	Minimum Width	0.000 [min]	Any	All Channels
5.000	Minimum Width	0.250 [min]	Any	All Channels
5.500	Minimum Width	0.000 [min]	Any	All Channels
11.000	Minimum Height	6000.000 [Signal]	Any	All Channels
13.000	Minimum Height	0.000 [Signal]	Any	All Channels
17.500	Minimum Height	1000.000 [Signal]	Any	All Channels
19.000	Minimum Height	0.000 [Signal]	Any	All Channels

Peak Table

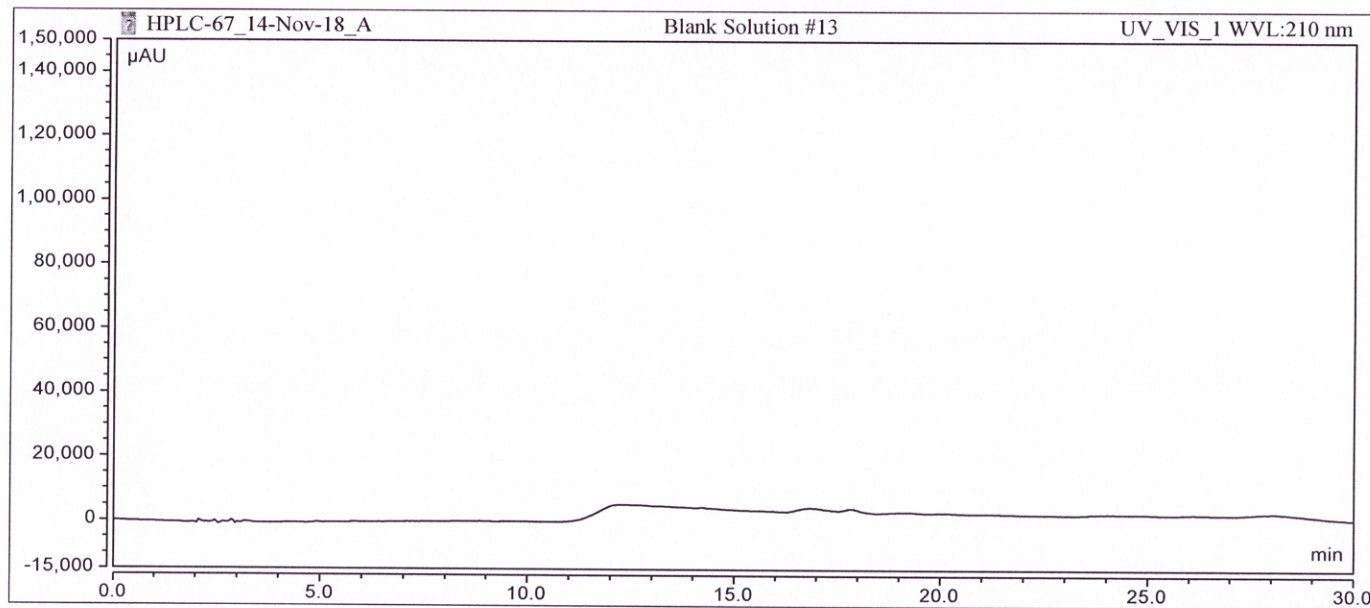
No.	Peak Name	Ret. Time
1	Unknown	4.133
2	Placebo	4.617
3	Hydrochlorothiazide	5.140
4	Unknown	7.963
5	Placebo	11.197
6	Blank	12.130
7	Impurity E	14.063
8	Impurity A	14.640
9	Ramipril	16.123
10	Impurity D	23.887

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 :-	13	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_N
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 :-	16-11-2018 18:54:59
Injection Date & Time :-	14-11-2018 23:43:44	Experiment Name:-	Specificity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		



Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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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_14-Nov-18_A.seq		
Processing Method Created By :	Swaraj A. Jadhav	Processing Method Last Updated By :	Swaraj A. Jadhav
Processing Method Created On :	14-11-2018 16:59:55	Processing Method Last Updated On :	16-11-2018 18:54:59

Detection Alogrithm	Chromeleon 6	Version	5
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Detection Parameter

Ret. Time min	Param. Name	Param. Value	Inj. Type	Channel
0.000	Minimum Area	50.0000 [Signal*min]	Any	All Channels
0.000	Valley To Valley	On	Any	All Channels
0.000	Minimum Width	0.450 [min]	Any	All Channels
4.000	Minimum Width	0.000 [min]	Any	All Channels
5.000	Minimum Width	0.250 [min]	Any	All Channels
5.500	Minimum Width	0.000 [min]	Any	All Channels
11.000	Minimum Height	6000.000 [Signal]	Any	All Channels
13.000	Minimum Height	0.000 [Signal]	Any	All Channels
17.500	Minimum Height	1000.000 [Signal]	Any	All Channels
19.000	Minimum Height	0.000 [Signal]	Any	All Channels

Peak Table

No.	Peak Name	Ret. Time
1	Unknown	4.133
2	Placebo	4.617
3	Hydrochlorothiazide	5.140
4	Unknown	7.963
5	Placebo	11.197
6	Blank	12.130
7	Impurity E	14.063
8	Impurity A	14.640
9	Ramipril	16.123
10	Impurity D	23.887

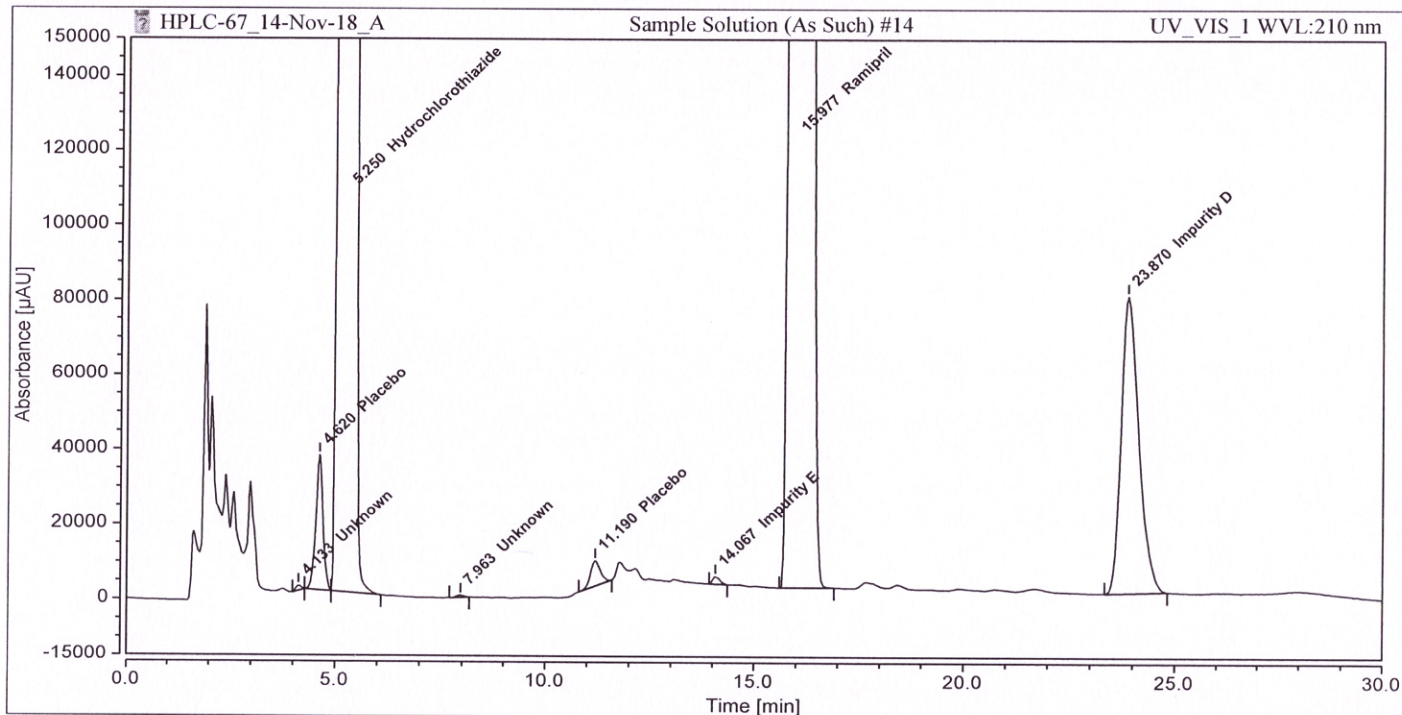
QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Processing Method



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	GP180301
Sample Name :-	Sample Solution (As Such)	AR. No. :-	D2404181993
Sample Number :-	14	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS
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 :-	16-11-2018 18:54:59
Injection Date & Time :-	15-11-2018 00:14:57	Experiment Name:-	Specificity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		

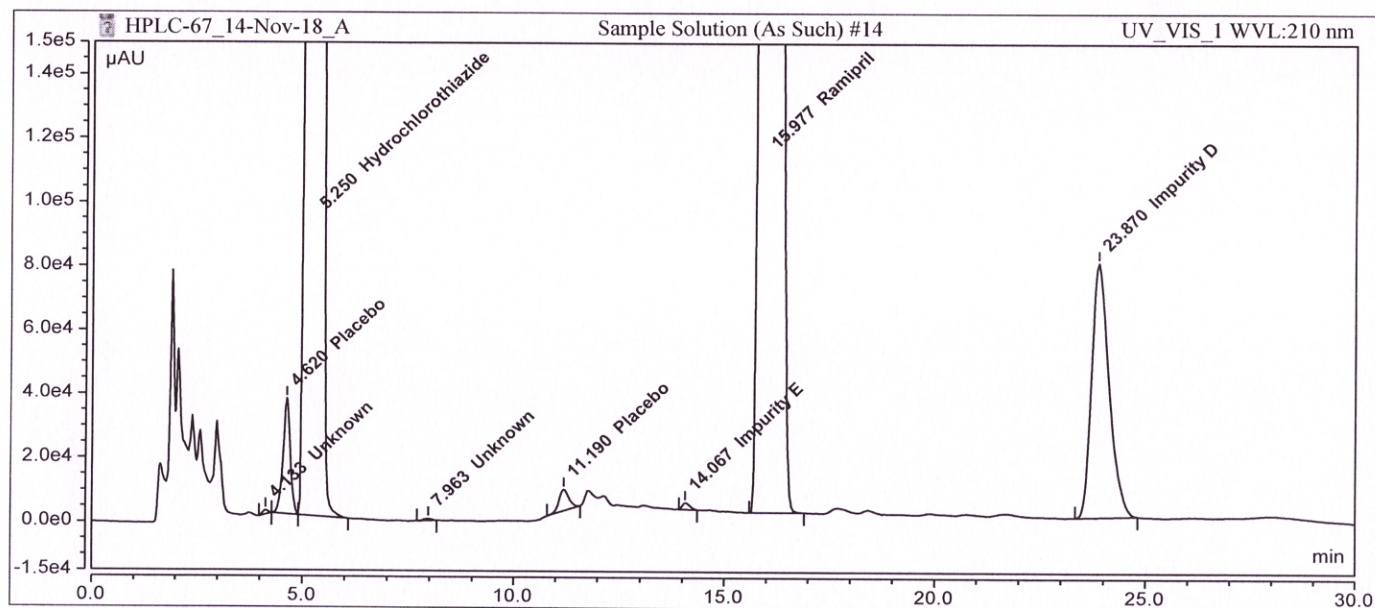


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Height µAU	Match Factor	Manipulated	Peak Type
1	Unknown	4.133	202.102	0.01	1358	995	FALSE	BMb
2	Placebo	4.620	7091.044	0.39	36073	1000	FALSE	bMb
3	Hydrochlorothiazide	5.250	935376.293	50.91	2479507	973	FALSE	bMB
4	Unknown	7.963	126.279	0.01	594	999	FALSE	BMB
5	Placebo	11.190	1830.436	0.10	6749	1000	FALSE	BMB
6	Impurity E	14.067	418.679	0.02	2088	999	FALSE	BMB
7	Ramipril	15.977	853968.840	46.48	2161853	1000	FALSE	BMB
8	Impurity D	23.870	38191.298	2.08	79375	1000	FALSE	BMB
Total				100.00				



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	GP180301
Sample Name :-	Sample Solution (As Such)	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 :-	16-11-2018 18:54:59
Injection Date & Time :-	15-11-2018 00:14:57	Experiment Name:-	Specificity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		



Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Unknown	4.133	202.102	0.01	1.03	4727	FALSE	n.a.
2	Placebo	4.620	7091.044	0.39	1.02	3778	FALSE	1.80
3	Hydrochlorothiazide	5.250	935376.293	50.91	0.94	2164	FALSE	1.68
4	Unknown	7.963	126.279	0.01	0.99	12446	FALSE	7.36
5	Placebo	11.190	1830.436	0.10	1.11	11155	FALSE	9.10
6	Impurity E	14.067	418.679	0.02	1.47	18796	FALSE	6.90
7	Ramipril	15.977	853968.840	46.48	1.36	12524	FALSE	3.89
8	Impurity D	23.870	38191.298	2.08	1.42	15919	FALSE	11.89



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_14-Nov-18_A.seq		
Processing Method Created By :	Swaraj A. Jadhav	Processing Method Last Updated By :	Swaraj A. Jadhav
Processing Method Created On :	14-11-2018 16:59:55	Processing Method Last Updated On :	16-11-2018 18:54:59

Detection Alogrithm	Chromeleon 6	Version	5
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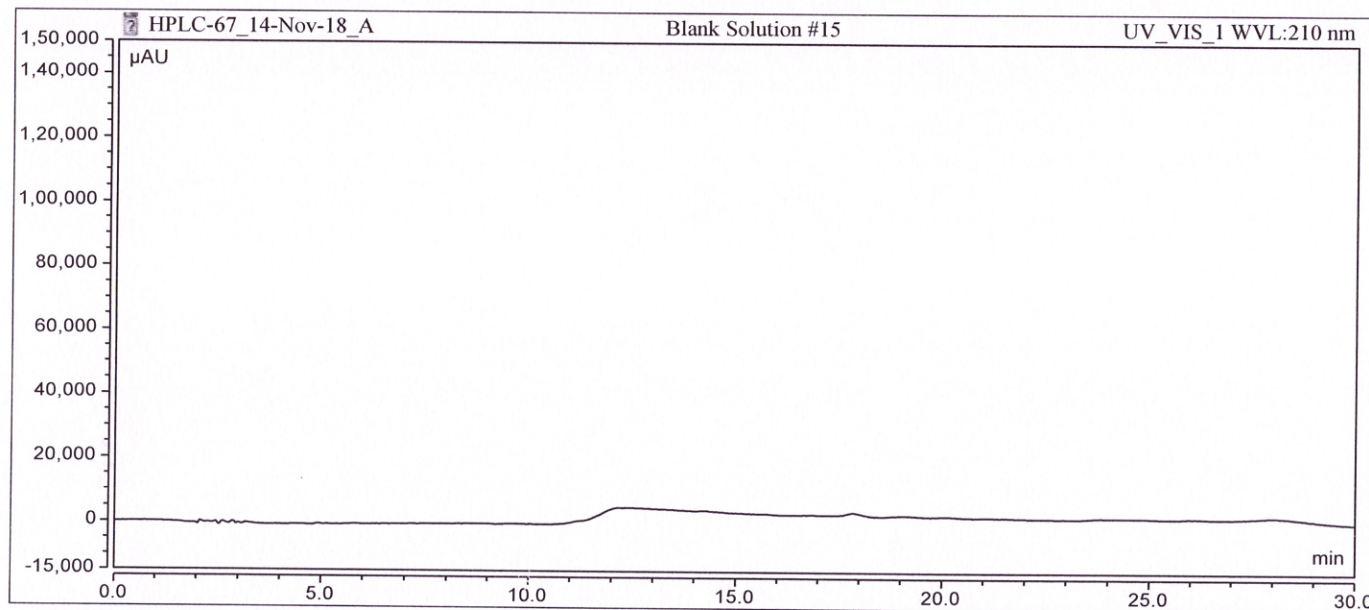
Detection Parameter

Ret. Time min	Param. Name	Param. Value	Inj. Type	Channel
0.000	Minimum Area	50.0000 [Signal*min]	Any	All Channels
0.000	Valley To Valley	On	Any	All Channels
0.000	Minimum Width	0.450 [min]	Any	All Channels
4.000	Minimum Width	0.000 [min]	Any	All Channels
5.000	Minimum Width	0.250 [min]	Any	All Channels
5.500	Minimum Width	0.000 [min]	Any	All Channels
11.000	Minimum Height	6000.000 [Signal]	Any	All Channels
13.000	Minimum Height	0.000 [Signal]	Any	All Channels
17.500	Minimum Height	1000.000 [Signal]	Any	All Channels
19.000	Minimum Height	0.000 [Signal]	Any	All Channels

Peak Table

No.	Peak Name	Ret. Time
1	Unknown	4.133
2	Placebo	4.617
3	Hydrochlorothiazide	5.140
4	Unknown	7.963
5	Placebo	11.197
6	Blank	12.130
7	Impurity E	14.063
8	Impurity A	14.640
9	Ramipril	16.123
10	Impurity D	23.887

 QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.			
Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Blank Solution	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 :-	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 :-	16-11-2018 18:54:59
Injection Date & Time :-	15-11-2018 00:46:11	Experiment Name:-	Specificity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		



Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.**Processing Method**



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_14-Nov-18_A.seq		
Processing Method Created By :	Swaraj A. Jadhav	Processing Method Last Updated By :	Swaraj A. Jadhav
Processing Method Created On :	14-11-2018 16:59:55	Processing Method Last Updated On :	16-11-2018 18:54:59

Detection Alogrithm	Chromeleon 6	Version	5
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Detection Parameter

Ret. Time min	Param. Name	Param. Value	Inj. Type	Channel
0.000	Minimum Area	50.0000 [Signal*min]	Any	All Channels
0.000	Valley To Valley	On	Any	All Channels
0.000	Minimum Width	0.450 [min]	Any	All Channels
4.000	Minimum Width	0.000 [min]	Any	All Channels
5.000	Minimum Width	0.250 [min]	Any	All Channels
5.500	Minimum Width	0.000 [min]	Any	All Channels
11.000	Minimum Height	6000.000 [Signal]	Any	All Channels
13.000	Minimum Height	0.000 [Signal]	Any	All Channels
17.500	Minimum Height	1000.000 [Signal]	Any	All Channels
19.000	Minimum Height	0.000 [Signal]	Any	All Channels

Peak Table

No.	Peak Name	Ret. Time
1	Unknown	4.133
2	Placebo	4.617
3	Hydrochlorothiazide	5.140
4	Unknown	7.963
5	Placebo	11.197
6	Blank	12.130
7	Impurity E	14.063
8	Impurity A	14.640
9	Ramipril	16.123
10	Impurity D	23.887

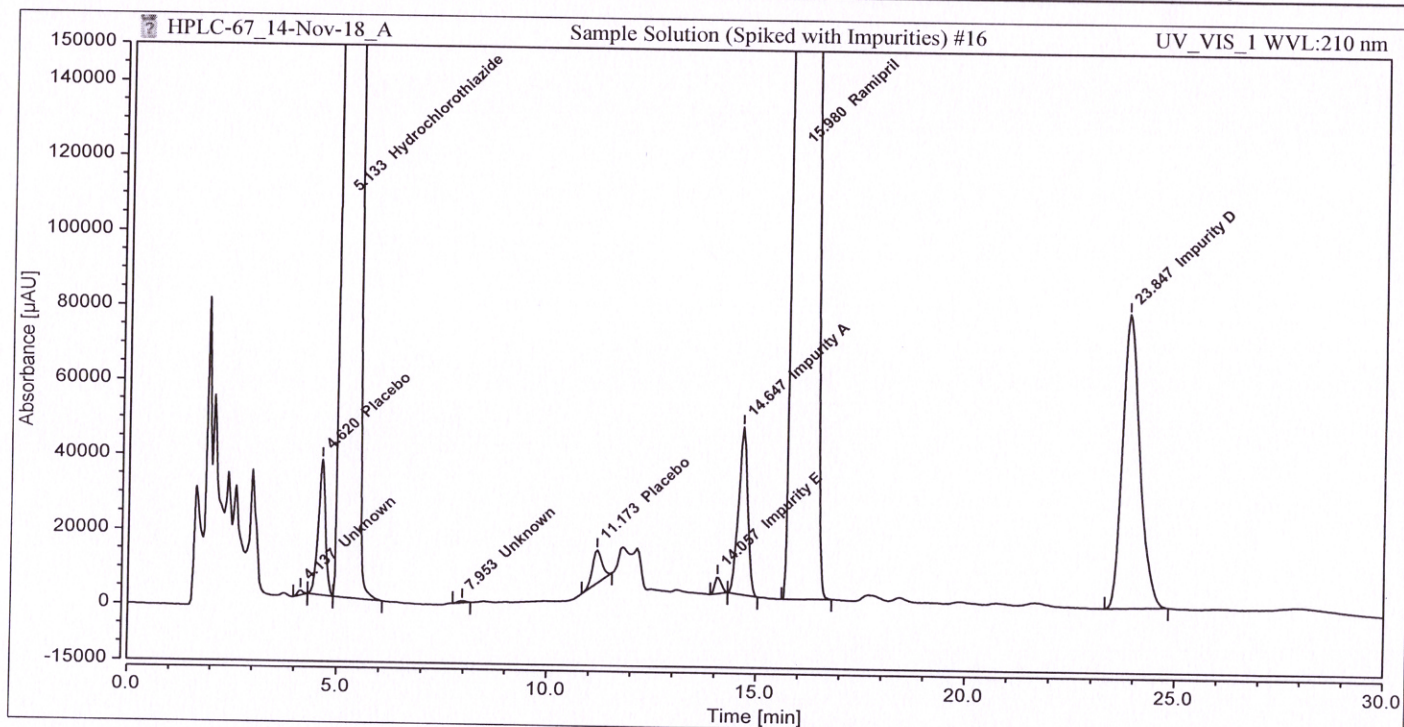
QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Processing Method



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Sample Solution (Spiked with Impurities)	AR. No. :-	D2404181993
Sample Number :-	16	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS
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 :-	16-11-2018 18:54:59
Injection Date & Time :-	15-11-2018 01:17:24	Experiment Name:-	Specificity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		

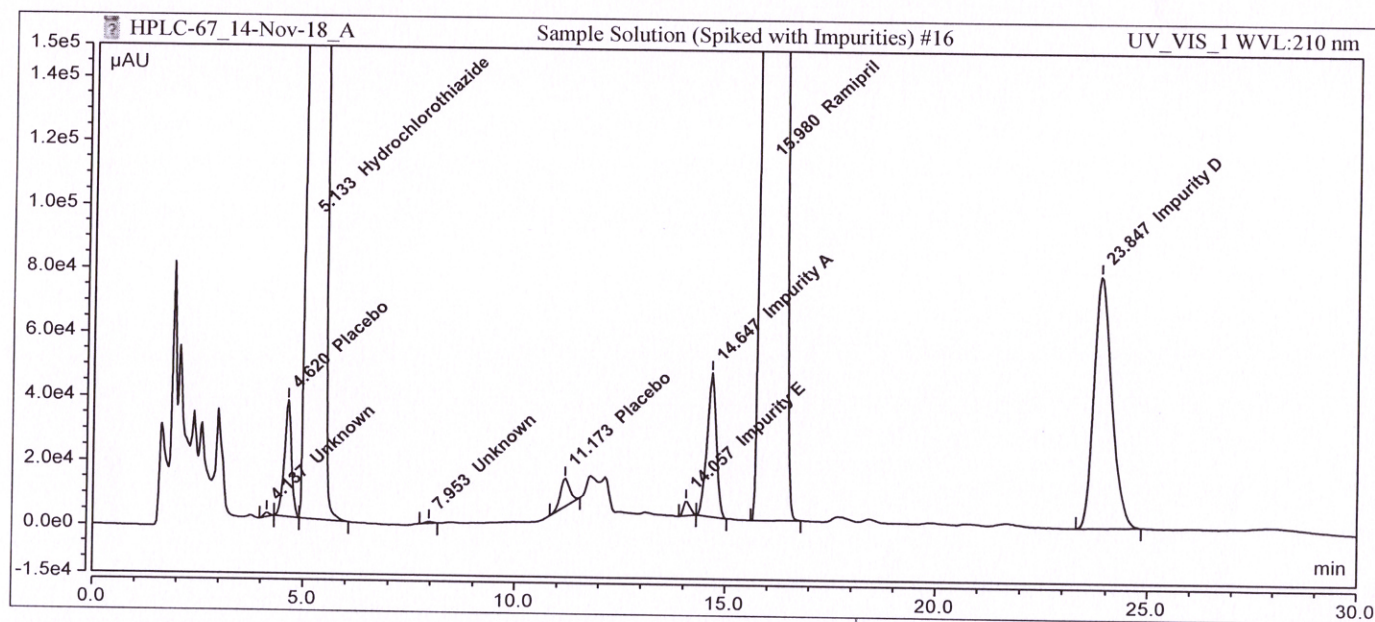


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Height µAU	Match Factor	Manipulated	Peak Type
1	Unknown	4.137	194.776	0.01	1302	997	FALSE	BMB
2	Placebo	4.620	7071.940	0.38	36238	1000	FALSE	bMB
3	Hydrochlorothiazide	5.133	934604.589	50.80	2472839	952	FALSE	BMB
4	Unknown	7.953	118.781	0.01	583	1000	FALSE	BMB
5	Placebo	11.173	2317.601	0.13	8880	1000	FALSE	BMB
6	Impurity E	14.057	813.001	0.04	4542	1000	FALSE	BMB
7	Impurity A	14.647	11386.109	0.62	44804	1000	FALSE	bMB
8	Ramipril	15.980	845250.780	45.95	2140317	1000	FALSE	BMB
9	Impurity D	23.847	37850.978	2.06	78472	1000	FALSE	BMB
Total				100.00				



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Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Sample Solution (Spiked with Impurities)	AR. No. :-	D2404181993
Sample Number :-	16	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_N
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 :-	16-11-2018 18:54:59
Injection Date & Time :-	15-11-2018 01:17:24	Experiment Name:-	Specificity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		



Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Unknown	4.137	194.776	0.01	1.08	5180	FALSE	n.a.
2	Placebo	4.620	7071.940	0.38	1.01	3837	FALSE	1.83
3	Hydrochlorothiazide	5.133	934604.589	50.80	1.67	2049	FALSE	1.37
4	Unknown	7.953	118.781	0.01	0.94	8112	FALSE	6.99
5	Placebo	11.173	2317.601	0.13	1.08	11659	FALSE	8.39
6	Impurity E	14.057	813.001	0.04	1.34	34630	FALSE	8.05
7	Impurity A	14.647	11386.109	0.62	1.01	20157	FALSE	1.65
8	Ramipril	15.980	845250.780	45.95	1.33	12513	FALSE	2.71
9	Impurity D	23.847	37850.978	2.06	1.43	15800	FALSE	11.83



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Processing Method

Processing Method Name :	Ramithiazide Tablets_RS_PR		
Processing Method Path :	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		
Processing Method Created By :	Swaraj A. Jadhav	Processing Method Last Updated By :	Swaraj A. Jadhav
Processing Method Created On :	14-11-2018 16:59:55	Processing Method Last Updated On :	16-11-2018 18:54:59

Detection Alogrithm	Chromeleon 6	Version	5
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Detection Parameter

Ret. Time min	Param. Name	Param. Value	Inj. Type	Channel
0.000	Minimum Area	50.0000 [Signal*min]	Any	All Channels
0.000	Valley To Valley	On	Any	All Channels
0.000	Minimum Width	0.450 [min]	Any	All Channels
4.000	Minimum Width	0.000 [min]	Any	All Channels
5.000	Minimum Width	0.250 [min]	Any	All Channels
5.500	Minimum Width	0.000 [min]	Any	All Channels
11.000	Minimum Height	6000.000 [Signal]	Any	All Channels
13.000	Minimum Height	0.000 [Signal]	Any	All Channels
17.500	Minimum Height	1000.000 [Signal]	Any	All Channels
19.000	Minimum Height	0.000 [Signal]	Any	All Channels

Peak Table

No.	Peak Name	Ret. Time
1	Unknown	4.133
2	Placebo	4.617
3	Hydrochlorothiazide	5.140
4	Unknown	7.963
5	Placebo	11.197
6	Blank	12.130
7	Impurity E	14.063
8	Impurity A	14.640
9	Ramipril	16.123
10	Impurity D	23.887

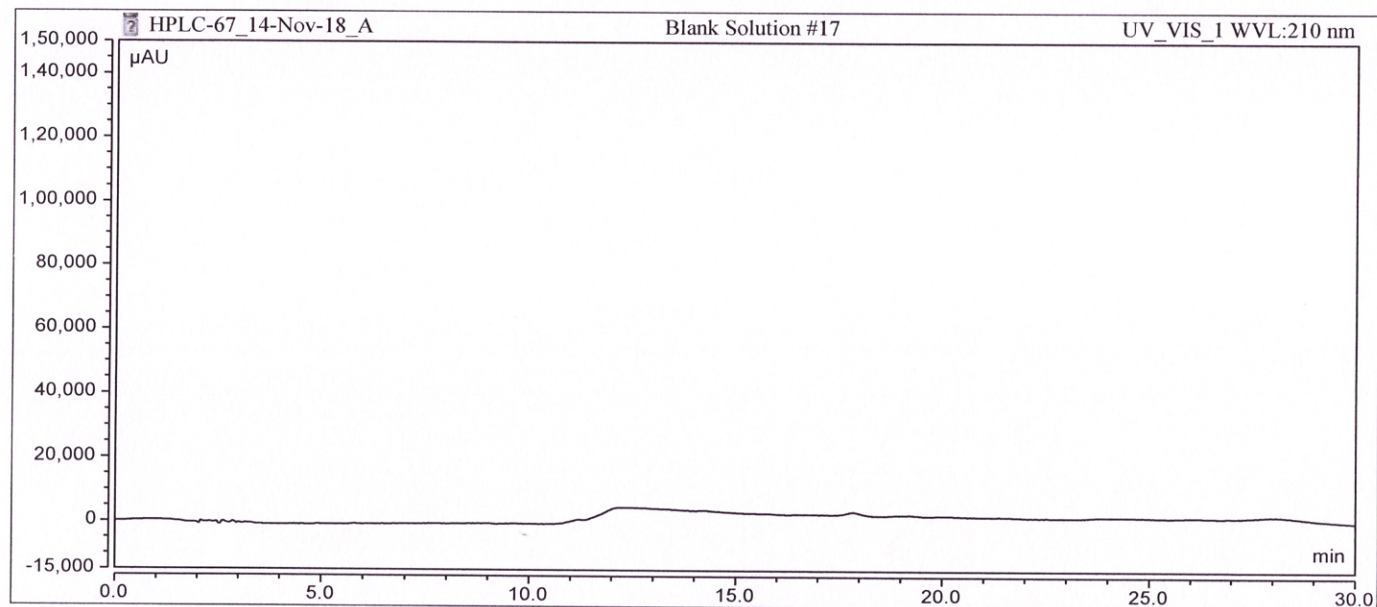
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Processing Method



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Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Blank Solution	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 :-	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 :-	16-11-2018 18:54:59
Injection Date & Time :-	15-11-2018 01:48:37	Experiment Name:-	Specificity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		



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

Processing Method Name :	Ramithiazide Tablets_RS_PR1		
Processing Method Path :	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		
Processing Method Created By :	Swaraj A. Jadhav	Processing Method Last Updated By :	Swaraj A. Jadhav
Processing Method Created On :	14-11-2018 16:59:55	Processing Method Last Updated On :	16-11-2018 18:54:59

Detection Alogrithm	Chromeleon 6	Version	4
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Detection Parameter

Ret. Time min	Param. Name	Param. Value	Inj. Type	Channel
0.000	Minimum Area	50.0000 [Signal*min]	Any	All Channels
0.000	Valley To Valley	On	Any	All Channels
0.000	Minimum Width	0.400 [min]	Any	All Channels
4.000	Minimum Width	0.000 [min]	Any	All Channels
11.000	Minimum Width	2.500 [min]	Any	All Channels
13.500	Minimum Width	0.000 [min]	Any	All Channels
16.000	Minimum Height	1600.000 [Signal]	Any	All Channels
18.000	Minimum Height	0.000 [Signal]	Any	All Channels

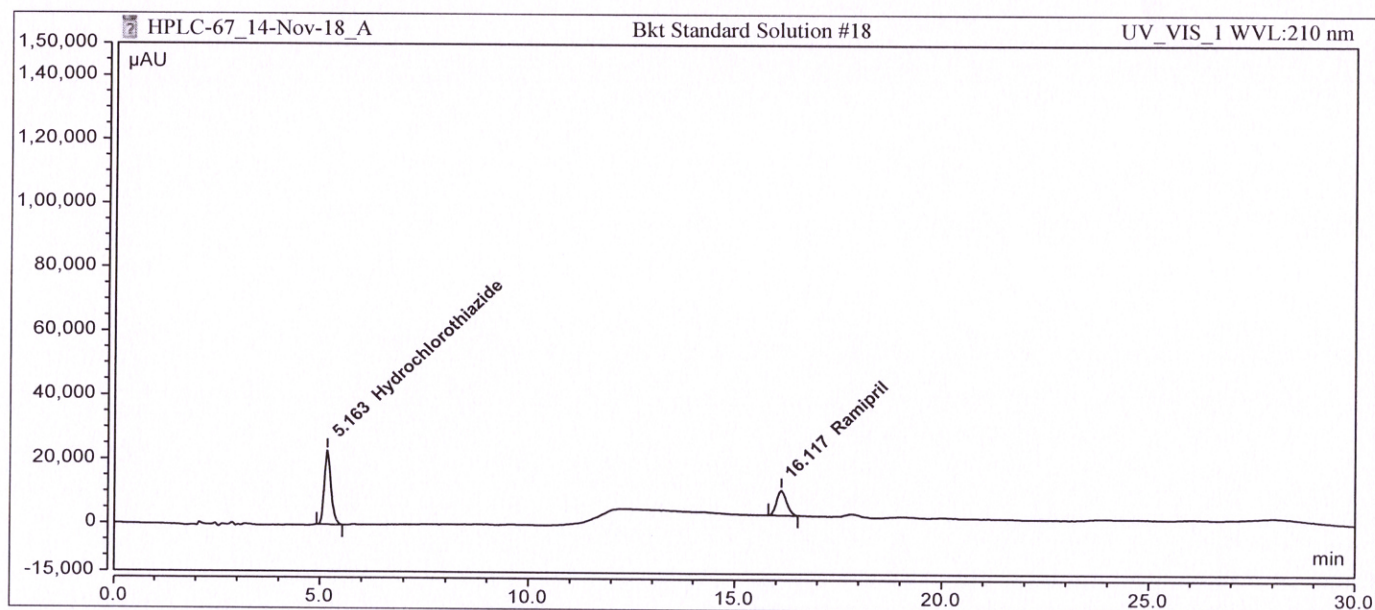
Peak Table

No.	Peak Name	Ret. Time
1	Hydrochlorothiazide	5.140
2	Impurity E	14.063
3	Impurity A	14.640
4	Ramipril	16.123
5	Impurity D	23.887



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Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Bkt Standard Solution	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 :-	RA2	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 :-	16-11-2018 18:54:59
Injection Date & Time :-	15-11-2018 02:19:55	Experiment Name:-	Specificity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-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	5.163	4273.060	66.32	1.31	5214	FALSE	n.a.
2	Ramipril	16.117	2170.303	33.68	1.16	21498	FALSE	30.19



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Processing Method

Processing Method Name :	Ramithiazide Tablets_RS_PR1		
Processing Method Path :	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		
Processing Method Created By :	Swaraj A. Jadhav	Processing Method Last Updated By :	Swaraj A. Jadhav
Processing Method Created On :	14-11-2018 16:59:55	Processing Method Last Updated On :	16-11-2018 18:54:59

Detection Alogrithm	Chromeleon 6	Version	4
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Detection Parameter

Ret. Time min	Param. Name	Param. Value	Inj. Type	Channel
0.000	Minimum Area	50.0000 [Signal*min]	Any	All Channels
0.000	Valley To Valley	On	Any	All Channels
0.000	Minimum Width	0.400 [min]	Any	All Channels
4.000	Minimum Width	0.000 [min]	Any	All Channels
11.000	Minimum Width	2.500 [min]	Any	All Channels
13.500	Minimum Width	0.000 [min]	Any	All Channels
16.000	Minimum Height	1600.000 [Signal]	Any	All Channels
18.000	Minimum Height	0.000 [Signal]	Any	All Channels

Peak Table

No.	Peak Name	Ret. Time
1	Hydrochlorothiazide	5.140
2	Impurity E	14.063
3	Impurity A	14.640
4	Ramipril	16.123
5	Impurity D	23.887



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Wash method created	Batch No. :-	N/A
Sample Name :-	Wash	AR. No. :-	D2404181993
Sample Number :-	19	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_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 :-	16-11-2018 18:54:59
Injection Date & Time :-	15-11-2018 02:54:58	Experiment Name:-	Specificity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		

Channel UV_VIS_1 is not available for injection #19 - Wash.

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

Processing Method Name :	Ramithiazide Tablets_RS_PR1		
Processing Method Path :	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		
Processing Method Created By :	Swaraj A. Jadhav	Processing Method Last Updated By :	Swaraj A. Jadhav
Processing Method Created On :	14-11-2018 16:59:55	Processing Method Last Updated On :	16-11-2018 18:54:59

Detection Alogrithm	Chromeleon 6	Version	4
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Detection Parameter

Ret. Time min	Param. Name	Param. Value	Inj. Type	Channel
0.000	Minimum Area	50.0000 [Signal*min]	Any	All Channels
0.000	Valley To Valley	On	Any	All Channels
0.000	Minimum Width	0.400 [min]	Any	All Channels
4.000	Minimum Width	0.000 [min]	Any	All Channels
11.000	Minimum Width	2.500 [min]	Any	All Channels
13.500	Minimum Width	0.000 [min]	Any	All Channels
16.000	Minimum Height	1600.000 [Signal]	Any	All Channels
18.000	Minimum Height	0.000 [Signal]	Any	All Channels

Peak Table

No.	Peak Name	Ret. Time
1	Hydrochlorothiazide	5.140
2	Impurity E	14.063
3	Impurity A	14.640
4	Ramipril	16.123
5	Impurity D	23.887



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Shut method	Batch No. :-	N/A
Sample Name :-	Shut	AR. No. :-	D2404181993
Sample Number :-	20	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_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 :-	16-11-2018 18:54:59
Injection Date & Time :-	15-11-2018 04:00:12	Experiment Name:-	Specificity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_14-Nov-18_A.seq		

Channel UV_VIS_1 is not available for injection #20 - Shut.

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