

RAW DATA OF
(ROBUSTNESS- INCREASE
IN FLOW RATE
AND
ROBUSTNESS- DECREASE
IN FLOW RATE)

RELATED SUBSTANCE VALIDATION

Analysis Date: 24-Nov-18

Product Name:	Ramithiazide Tablets
Label claim (mg):	10 mg And 25 mg
AR No:	D2404181193
Batch No:	GP180501
Parameter:	Robustness Decrease Flow Rate (0.9 mL/min)
INB No./ Page No.	718/021

Name	RHP
Ramipril Impurity A	1.15
Ramipril Impurity D	1.22
Ramipril Impurity E	22.09

	Weight of standard (mg)	Diluted (mL)	Concentration (mg/mL)	Purity (As is Basis)
Preparation of standard solution for Ramipril	25.21	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	17.257	2856.396	17.220	2864.456
2	17.258	2814.506		
3	17.260	2868.118		
4	17.248	2864.010		
5	17.243	2812.913		
6	17.245	2824.345		
Average	17.252	2843.451	17.247	2866.452
SD	0.0074	22.6723	0.0128	22.1673
%RSD	0.04	0.88	0.08	0.78

System Suitability		
%RSD of Area	0.88	NMT 5.0%

	Weight of standard (mg)	Diluted (mL)	Concentration (mg/mL)	Purity (As is Basis)
Preparation of standard solution for Hydrochlorothiazide	25.34	25.0		
	2.5	100.0	2.53	99.24
	2.0	20.0		

Hydrochlorothiazide				
Injection No.	Retention Time	Peak Area	Retention Time	Area of Bkt Standard
1	5.740	4404.299	5.732	4425.379
2	5.742	4405.378		
3	5.745	4401.963		
4	5.743	4414.646		
5	5.743	4419.398		
6	5.743	4411.327		
Average	5.743	4409.582	5.741	4411.270
SD	0.0016	6.7622	0.0043	8.6092
%RSD	0.03	0.15	0.07	0.20

System Suitability		
%RSD of Area	0.15	NMT 5.0%

Sample solution :	Eq to 20 mg	diluted to	20.0	ml. with Diluent
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Average wt. (mg):	195.84
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Sample Details	Sample wt. (mg)	Impurity name	RT	RRT	Area	%Impurity	Reported impurity	Total % Impurity
Sample Solution	392.12	Unknown Impurity	4.643	0.27	176.422	0.01	BQL	4.94
		Unknown Impurity	8.740	0.51	206.120	0.01	BQL	
		Unknown Impurity	12.162	0.72	767.964	0.05	BQL	
		Unknown Impurity	19.227	1.13	828.870	0.06	BQL	
		Unknown Impurity	20.057	1.18	524.004	0.04	BQL	
		Ramipril Impurity E	15.208	0.90	519.261	0.81	0.81	
		Ramipril Impurity D	26.033	1.53	48004.230	4.13	4.13	
		Ramipril	16.983	1.00	686172.771	-	-	

Sample	Ramipril Impurity E	Ramipril Impurity D	Total % Impurities
Sample (Precision)	0.85	4.47	5.32
Sample Solution (Dec. flow rate)	0.81	4.13	4.94
Sample	Ramipril Impurity E	Ramipril Impurity D	Total % Impurities
Sample (Precision)	0.04	0.34	0.38
Sample Solution (Dec. flow rate)			

Done by:
Date:

26-Nov-18

Checked by:
Date:

26-Nov-18

RELATED SUBSTANCE VALIDATION

Product Name:	Ramithiazide Tablets
Label claim (mg):	10 mg And 25 mg
AR No:	D2404181193
Batch No.:	GP180301
Parameter:	Robustness Increase Flow Rate (1.1 ml/min).
LSR No./ Page No.	718/921

Analysis Date: 24-Nov-18

Name	RRF
Ramipril Impurity A	1.15
Ramipril Impurity D	1.22
Ramipril Impurity E	21.09

Preparation of standard solution for Ramipril	Weight of standard (mg)	Diluted (mL)	Concentration (nmol)	Purity (As is Basis)
	25.31	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	15.513	2259.037	15.525	2269.591
2	15.518	2260.725		
3	15.517	2254.860		
4	15.527	2350.586		
5	15.515	2328.998		
6	15.525	2290.007		
Average	15.519	2291.699	15.520	2289.541
SD	0.0056	42.4083	0.0056	39.5982
%RSD	0.04	1.85	0.04	1.73

System Suitability		
%RSD of Area	1.85	NMT 5.0%

Preparation of standard solution for Hydrochlorothiazide	Weight of standard (mg)	Diluted (mL)	Concentration (nmol)	Purity (As is Basis)
	25.34	25.0		
	2.5	100.0	2.53	99.24
	2.0	20.0		

Hydrochlorothiazide				
Injection No.	Retention Time	Peak Area	Retention Time	Area of Bkt Standard
1	4.717	3586.857	4.718	3596.931
2	4.717	3604.715		
3	4.715	3596.818		
4	4.722	3594.271		
5	4.713	3600.321		
6	4.713	3595.054		
Average	4.716	3596.339	4.716	3596.424
SD	0.0024	6.8346	0.0032	5.5123
%RSD	0.07	0.17	0.07	0.15

System Suitability		
%RSD of Area	0.17	NMT 5.0%

Sample solution :	10 to 20 mg	diluted to	20.0	ml. with Diluent
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Average wt. (mg):	195.84
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Sample Details	Sample wt. (mg)	Impurity name	RT	RRT	Area	%Impurity	Reported impurity	Total % Impurity
Sample Solution	192.12	Unknown Impurity	3.812	0.25	107.383	0.01	BQL	5.01
		Unknown Impurity	7.183	0.47	167.223	0.01	BQL	
		Unknown Impurity	9.045	0.63	416.074	0.04	BQL	
		Unknown Impurity	17.040	1.11	531.704	0.05	BQL	
		Unknown Impurity	17.795	1.16	384.599	0.03	BQL	
		Ramipril Impurity E	13.792	0.90	435.111	0.84	0.84	
		Ramipril Impurity D	22.753	1.48	39026.096	4.17	4.17	
		Ramipril	15.330	1.00	567894.761	-	-	

Sample	Ramipril Impurity E	Ramipril Impurity D	Total % Impurities
Sample (Precision)	0.85	4.47	5.32
Sample Solution (In flow rate)	0.84	4.17	5.01
% Difference			
Sample	Ramipril Impurity E	Ramipril Impurity D	Total % Impurities
Sample (Precision)	-	-	-
Sample Solution (In flow rate)	0.01	0.30	0.31

Done by:

Date:

26-Nov-18

Checked by:

Date:

26-Nov-18



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Instrument ID : QbD-INST-HPLC-42

Sequence Name : HPLC-42_24-Nov-18_A

Data Vault : QbD_2018

Sequence Path : Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_24-Nov-18_A.seq

Seq. Created By : Swaraj A. Jadhav

Seq. Last Updated By : Scheduler

Seq. Created On : 24-11-2018 13:27:16

Seq. Last Updated On : 24-11-2018 13:35:22

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	1_1	Idle	n.a.	Ramithiazide Tablet_RS_Ramithiazide	Tablets_RS_PI		D2404181993	N/A	QbD/LC/COL/128
2	Blank Solution	Unknown	30.00	1_1	Idle	n.a.	Ramithiazide Tablet_RS_Ramithiazide	Tablets_RS_PI		D2404181993	N/A	QbD/LC/COL/128
3	Standard Solution 1	Unknown	30.00	1_2	Idle	n.a.	Ramithiazide Tablet_RS_Ramithiazide	Tablets_RS_PI		D2404181993	N/A	QbD/LC/COL/128
4	Standard Solution 2	Unknown	30.00	1_2	Idle	n.a.	Ramithiazide Tablet_RS_Ramithiazide	Tablets_RS_PI		D2404181993	N/A	QbD/LC/COL/128
5	Standard Solution 3	Unknown	30.00	1_2	Idle	n.a.	Ramithiazide Tablet_RS_Ramithiazide	Tablets_RS_PI		D2404181993	N/A	QbD/LC/COL/128
6	Standard Solution 4	Unknown	30.00	1_2	Idle	n.a.	Ramithiazide Tablet_RS_Ramithiazide	Tablets_RS_PI		D2404181993	N/A	QbD/LC/COL/128
7	Standard Solution 5	Unknown	30.00	1_2	Idle	n.a.	Ramithiazide Tablet_RS_Ramithiazide	Tablets_RS_PI		D2404181993	N/A	QbD/LC/COL/128
8	Standard Solution 6	Unknown	30.00	1_2	Idle	n.a.	Ramithiazide Tablet_RS_Ramithiazide	Tablets_RS_PI		D2404181993	N/A	QbD/LC/COL/128
9	Blank Solution	Unknown	30.00	1_1	Idle	n.a.	Ramithiazide Tablet_RS_Ramithiazide	Tablets_RS_PI		D2404181993	N/A	QbD/LC/COL/128
10	Sample Solution	Unknown	30.00	1_3	Idle	n.a.	Ramithiazide Tablet_RS_Ramithiazide	Tablets_RS_PI		D2404181993	GP180301	QbD/LC/COL/128
11	Blank Solution	Unknown	30.00	1_1	Idle	n.a.	Ramithiazide Tablet_RS_Ramithiazide	Tablets_RS_PI		D2404181993	N/A	QbD/LC/COL/128
12	Bracketing Standard Solution	Unknown	30.00	1_2	Idle	n.a.	Ramithiazide Tablet_RS_Ramithiazide	Tablets_RS_PI		D2404181993	N/A	QbD/LC/COL/128
13	Blank Solution	Unknown	30.00	1_1	Idle	n.a.	Ramithiazide Tablet_RS_Ramithiazide	Tablets_RS_PI		D2404181993	N/A	QbD/LC/COL/128
14	Blank Solution	Unknown	30.00	1_1	Idle	n.a.	Ramithiazide Tablet_RS_Ramithiazide	Tablets_RS_PI		D2404181993	N/A	QbD/LC/COL/128
15	Blank Solution	Unknown	30.00	1_1	Idle	n.a.	Ramithiazide Tablet_RS_Ramithiazide	Tablets_RS_PI		D2404181993	N/A	QbD/LC/COL/128
16	Standard Solution 1	Unknown	30.00	1_2	Idle	n.a.	Ramithiazide Tablet_RS_Ramithiazide	Tablets_RS_PI		D2404181993	N/A	QbD/LC/COL/128
17	Standard Solution 2	Unknown	30.00	1_2	Idle	n.a.	Ramithiazide Tablet_RS_Ramithiazide	Tablets_RS_PI		D2404181993	N/A	QbD/LC/COL/128
18	Standard Solution 3	Unknown	30.00	1_2	Idle	n.a.	Ramithiazide Tablet_RS_Ramithiazide	Tablets_RS_PI		D2404181993	N/A	QbD/LC/COL/128
19	Standard Solution 4	Unknown	30.00	1_2	Idle	n.a.	Ramithiazide Tablet_RS_Ramithiazide	Tablets_RS_PI		D2404181993	N/A	QbD/LC/COL/128
20	Standard Solution 5	Unknown	30.00	1_2	Idle	n.a.	Ramithiazide Tablet_RS_Ramithiazide	Tablets_RS_PI		D2404181993	N/A	QbD/LC/COL/128
21	Standard Solution 6	Unknown	30.00	1_2	Idle	n.a.	Ramithiazide Tablet_RS_Ramithiazide	Tablets_RS_PI		D2404181993	N/A	QbD/LC/COL/128
22	Blank Solution	Unknown	30.00	1_1	Idle	n.a.	Ramithiazide Tablet_RS_Ramithiazide	Tablets_RS_PI		D2404181993	N/A	QbD/LC/COL/128
23	Sample Solution	Unknown	30.00	1_3	Idle	n.a.	Ramithiazide Tablet_RS_Ramithiazide	Tablets_RS_PI		D2404181993	GP180301	QbD/LC/COL/128
24	Blank Solution	Unknown	30.00	1_1	Idle	n.a.	Ramithiazide Tablet_RS_Ramithiazide	Tablets_RS_PI		D2404181993	N/A	QbD/LC/COL/128
25	Bracketing Standard Solution	Unknown	30.00	1_2	Idle	n.a.	Ramithiazide Tablet_RS_Ramithiazide	Tablets_RS_PI		D2404181993	N/A	QbD/LC/COL/128
26	Wash	Unknown	30.00	1_1	Idle	n.a.	Wash method_HPLC 42	amithiazide Tablets_RS_PI		D2404181993	N/A	QbD/LC/COL/128
27	Shut	Unknown	30.00	1_1	Idle	n.a.	Shut method_HPLC 42	amithiazide Tablets_RS_PI		D2404181993	N/A	QbD/LC/COL/128

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

24-Nov-18
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Name	HPLC-42_Ramithiazide Tablet_RS_Dec FR_Met
Data Vault	XVault
Path	chrom://qbd-pc-03/XVault/QbD-INST-HPLC-42/1310/HPLC-42_24-Nov-18_A.seq/HPLC-42_Ramithiazide Tablet_RS_Dec FR_Met.instmeth
Comment	Ramithiazide Tablets
Description	Ramithiazide Tablets-Related Substance
Run time	30.000 [min]
Instrument	QbD-INST-HPLC-42 on qbd-pc-03
Created	21-Nov-18 15:24:45 +05:30 Mahesh Nikam
Last Update	24-Nov-18 13:25:54 +05:30 Mahesh Nikam

SP
24-Nov-18

SP
24-Nov-18

Stage	Time min	Command	Value	Comment
Instrument Setup	initial	Pump.%A.Equate	"Mobile Phase A"	
		Pump.%B.Equate	"Mobile Phase B"	
		Pump.%C.Equate	"0"	
		Pump.%D.Equate	"0"	
		Pump.Pressure.LowerLimit	0 [bar]	
		Pump.Pressure.UpperLimit	378 [bar]	
		Sampler.Temperature.Nominal	25 [°C]	
		Sampler.WashMode	Both	
		Sampler.WashVolume	200 [µl]	
		Sampler.WashDuration	5 [s]	
		Sampler.SyringeSpeed	15.0 [µl/s]	
		Sampler.NeedleStroke	52 [mm]	
		ColumnOven.TempCtrl	On	
		ColumnOven.Temperature.Nominal	25 [°C]	
		ColumnOven.Temperature.UpperLimit	60 [°C]	
		UV.CellTemp.Nominal	Low	
		UV.Response	0.50 [s]	
		UV.UV_VIS_1.Wavelength	210 [nm]	
		UV.Mode	Single	
Inject Preparation	0.000	UV.Autozero		
Inject	0.000	Sampler.Inject		
Start Run	0.000	UV.UV_VIS_1.AcqOn		
Run			Duration = 30.000 [min]	
	0.000	Pump.Flow	0.900 [ml/min]	
		Pump.%B.Value	30.0 [%]	
		Pump.%C.Value	0.0 [%]	
		Pump.%D.Value	0.0 [%]	
	7.000	Pump.Flow	0.900 [ml/min]	
		Pump.%B.Value	30.0 [%]	
		Pump.%C.Value	0.0 [%]	
		Pump.%D.Value	0.0 [%]	
	9.000	Pump.Flow	0.900 [ml/min]	
		Pump.%B.Value	50.0 [%]	
		Pump.%C.Value	0.0 [%]	
		Pump.%D.Value	0.0 [%]	
	25.000	Pump.Flow	0.900 [ml/min]	

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	Pump.%B.Value	50.0 [%]
	Pump.%C.Value	0.0 [%]
	Pump.%D.Value	0.0 [%]
30.000	Pump.Flow	0.900 [ml/min]
	Pump.%B.Value	30.0 [%]
	Pump.%C.Value	0.0 [%]
	Pump.%D.Value	0.0 [%]
Stop Run		
30.000	UV.UV_VIS_1.AcqOff	
End		

SD
24-Nov-18

SD
24-Nov-18

Name	HPLC-42_Ramithiazide Tablet_RS_Inc FR_Met
Data Vault	XVault
Path	chrom://qbd-pc-03/XVault/QbD-INST-HPLC-42/1310/HPLC-42_24-Nov-18_A.seq/HPLC-42_Ramithiazide Tablet_RS_Inc FR_Met.instmeth
Comment	Ramithiazide Tablets
Description	Ramithiazide Tablets-Related Substance
Run time	30.000 [min]
Instrument	QbD-INST-HPLC-42 on qbd-pc-03
Created	21-Nov-18 15:24:45 +05:30 Mahesh Nikam
Last Update	24-Nov-18 13:24:47 +05:30 Mahesh Nikam

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Stage	Time min	Command	Value	Comment
Instrument Setup	initial	Pump.%A.Equate	"Mobile Phase A"	
		Pump.%B.Equate	"Mobile Phase B"	
		Pump.%C.Equate	"0"	
		Pump.%D.Equate	"0"	
		Pump.Pressure.LowerLimit	0 [bar]	
		Pump.Pressure.UpperLimit	378 [bar]	
		Sampler.Temperature.Nominal	25 [°C]	
		Sampler.WashMode	Both	
		Sampler.WashVolume	200 [µl]	
		Sampler.WashDuration	5 [s]	
		Sampler.SyringeSpeed	15.0 [µl/s]	
		Sampler.NeedleStroke	52 [mm]	
		ColumnOven.TempCtrl	On	
		ColumnOven.Temperature.Nominal	25 [°C]	
		ColumnOven.Temperature.UpperLimit	60 [°C]	
		UV.CellTemp.Nominal	Low	
		UV.Response	0.50 [s]	
		UV.UV_VIS_1.Wavelength	210 [nm]	
		UV.Mode	Single	
Inject Preparation	0.000	UV.Autozero		
Inject	0.000	Sampler.Inject		
Start Run	0.000	UV.UV_VIS_1.AcqOn		
Run			Duration = 30.000 [min]	
	0.000	Pump.Flow	1.100 [ml/min]	
		Pump.%B.Value	30.0 [%]	
		Pump.%C.Value	0.0 [%]	
		Pump.%D.Value	0.0 [%]	
	7.000	Pump.Flow	1.100 [ml/min]	
		Pump.%B.Value	30.0 [%]	
		Pump.%C.Value	0.0 [%]	
		Pump.%D.Value	0.0 [%]	
	9.000	Pump.Flow	1.100 [ml/min]	
		Pump.%B.Value	50.0 [%]	
		Pump.%C.Value	0.0 [%]	
		Pump.%D.Value	0.0 [%]	
	25.000	Pump.Flow	1.100 [ml/min]	

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P1
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	Pump.%B.Value	50.0 [%]
	Pump.%C.Value	0.0 [%]
	Pump.%D.Value	0.0 [%]
30.000		
	Pump.Flow	1.100 [ml/min]
	Pump.%B.Value	30.0 [%]
	Pump.%C.Value	0.0 [%]
	Pump.%D.Value	0.0 [%]
Stop Run		
30.000		
	UV.UV_VIS_1.AcqOff	
End		

SD
24-Nov-18

PJ
24-Nov-18



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Instrument ID :

QbD-INST-HPLC-42

Sequence Name :

HPLC-42_24-Nov-18_A

Data Vault :

QbD_2018

Sequence Path :

Method Validation\Generic Healthcare\Tablet\Related Substances\HPLC-42_24-Nov-18_A.seq

Seq. Created By : Swaraj A. Jadhav

Seq. Last Updated By : Swaraj A. Jadhav

Seq. Created On : 24-11-2018 13:27:16

Seq. Last Updated On : 26-11-2018 14:10:56

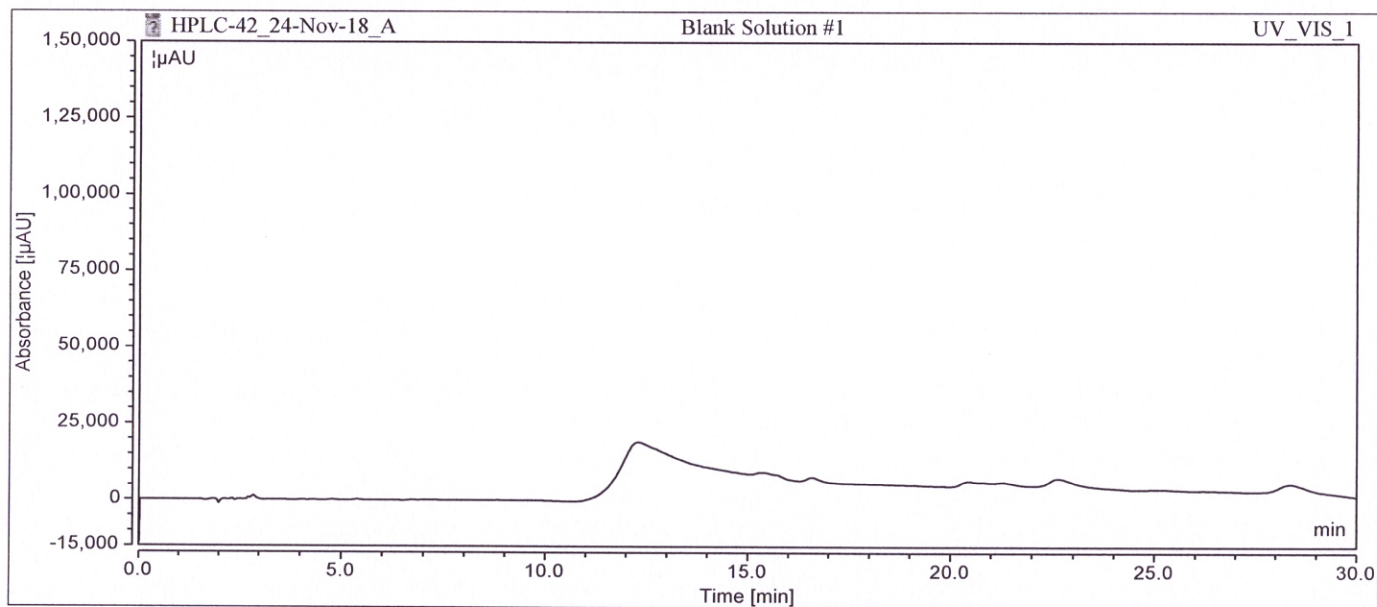
Inj No.	Injection Name	Injection Type	Volume μ L	Vial No.	Status	Injection Time	Instrument Method	Processing Method	Level	AR_NO	BATCH_NO	COLUMN_NO
1	Blank Solution	Unknown	30.00	1_1	Finished	24-11-2018 14:04:20	Ramithiazide Tablet_RS_	Ramithiazide Tablets_RS_PR		D2404181993	N/A	QbD/LC/COL/128
2	Blank Solution	Unknown	30.00	1_1	Finished	24-11-2018 14:35:30	Ramithiazide Tablet_RS_	Ramithiazide Tablets_RS_PR		D2404181993	N/A	QbD/LC/COL/128
3	Standard Solution 1	Unknown	30.00	1_2	Finished	24-11-2018 15:06:38	Ramithiazide Tablet_RS_	Ramithiazide Tablets_RS_PR		D2404181993	N/A	QbD/LC/COL/128
4	Standard Solution 2	Unknown	30.00	1_2	Finished	24-11-2018 15:37:47	Ramithiazide Tablet_RS_	Ramithiazide Tablets_RS_PR		D2404181993	N/A	QbD/LC/COL/128
5	Standard Solution 3	Unknown	30.00	1_2	Finished	24-11-2018 16:08:56	Ramithiazide Tablet_RS_	Ramithiazide Tablets_RS_PR		D2404181993	N/A	QbD/LC/COL/128
6	Standard Solution 4	Unknown	30.00	1_2	Finished	24-11-2018 16:40:08	Ramithiazide Tablet_RS_	Ramithiazide Tablets_RS_PR		D2404181993	N/A	QbD/LC/COL/128
7	Standard Solution 5	Unknown	30.00	1_2	Finished	24-11-2018 17:11:14	Ramithiazide Tablet_RS_	Ramithiazide Tablets_RS_PR		D2404181993	N/A	QbD/LC/COL/128
8	Standard Solution 6	Unknown	30.00	1_2	Finished	24-11-2018 17:42:23	Ramithiazide Tablet_RS_	Ramithiazide Tablets_RS_PR		D2404181993	N/A	QbD/LC/COL/128
9	Blank Solution	Unknown	30.00	1_1	Finished	24-11-2018 18:13:31	Ramithiazide Tablet_RS_	Ramithiazide Tablets_RS_PR		D2404181993	N/A	QbD/LC/COL/128
10	Sample Solution	Unknown	30.00	1_3	Finished	24-11-2018 18:44:40	Ramithiazide Tablet_RS_	Ramithiazide Tablets_RS_PR		D2404181993	N/A	QbD/LC/COL/128
11	Blank Solution	Unknown	30.00	1_1	Finished	24-11-2018 19:15:50	Ramithiazide Tablet_RS_	Ramithiazide Tablets_RS_PR		D2404181993	GP180301	QbD/LC/COL/128
12	Bracketing Standard Solution	Unknown	30.00	1_2	Finished	24-11-2018 19:47:00	Ramithiazide Tablet_RS_	Ramithiazide Tablets_RS_PR		D2404181993	N/A	QbD/LC/COL/128
13	Blank Solution	Unknown	30.00	1_1	Finished	24-11-2018 20:18:10	Ramithiazide Tablet_RS_	Ramithiazide Tablets_RS_PR		D2404181993	N/A	QbD/LC/COL/128
14	Blank Solution	Unknown	30.00	1_1	Finished	24-11-2018 20:49:20	Ramithiazide Tablet_RS_	Ramithiazide Tablets_RS_PR		D2404181993	N/A	QbD/LC/COL/128
15	Blank Solution	Unknown	30.00	1_1	Finished	24-11-2018 21:20:30	Ramithiazide Tablet_RS_	Ramithiazide Tablets_RS_PR		D2404181993	N/A	QbD/LC/COL/128
16	Standard Solution 1	Unknown	30.00	1_2	Finished	24-11-2018 21:51:39	Ramithiazide Tablet_RS_	Ramithiazide Tablets_RS_PR		D2404181993	N/A	QbD/LC/COL/128
17	Standard Solution 2	Unknown	30.00	1_2	Finished	24-11-2018 22:22:48	Ramithiazide Tablet_RS_	Ramithiazide Tablets_RS_PR		D2404181993	N/A	QbD/LC/COL/128
18	Standard Solution 3	Unknown	30.00	1_2	Finished	24-11-2018 22:53:56	Ramithiazide Tablet_RS_	Ramithiazide Tablets_RS_PR		D2404181993	N/A	QbD/LC/COL/128
19	Standard Solution 4	Unknown	30.00	1_2	Finished	24-11-2018 23:25:04	Ramithiazide Tablet_RS_	Ramithiazide Tablets_RS_PR		D2404181993	N/A	QbD/LC/COL/128
20	Standard Solution 5	Unknown	30.00	1_2	Finished	24-11-2018 23:56:15	Ramithiazide Tablet_RS_	Ramithiazide Tablets_RS_PR		D2404181993	N/A	QbD/LC/COL/128
21	Standard Solution 6	Unknown	30.00	1_2	Finished	25-11-2018 00:27:22	Ramithiazide Tablet_RS_	Ramithiazide Tablets_RS_PR		D2404181993	N/A	QbD/LC/COL/128
22	Blank Solution	Unknown	30.00	1_1	Finished	25-11-2018 00:58:32	Ramithiazide Tablet_RS_	Ramithiazide Tablets_RS_PR		D2404181993	N/A	QbD/LC/COL/128
23	Sample Solution	Unknown	30.00	1_3	Finished	25-11-2018 01:29:40	Ramithiazide Tablet_RS_	Ramithiazide Tablets_RS_PR		D2404181993	GP180301	QbD/LC/COL/128
24	Blank Solution	Unknown	30.00	1_1	Finished	25-11-2018 02:00:50	Ramithiazide Tablet_RS_	Ramithiazide Tablets_RS_PR		D2404181993	N/A	QbD/LC/COL/128
25	Bracketing Standard Solution	Unknown	30.00	1_2	Finished	25-11-2018 02:31:57	Ramithiazide Tablet_RS_	Ramithiazide Tablets_RS_PR		D2404181993	N/A	QbD/LC/COL/128
26	Wash	Unknown	30.00	1_1	Finished	25-11-2018 03:02:45	Wash method_HPLC 42	amithiazide Tablets_RS_PR		D2404181993	N/A	QbD/LC/COL/128
27	Shut	Unknown	30.00	1_1	Finished	25-11-2018 04:03:20	Shut method_HPLC 42	amithiazide Tablets_RS_PR		D2404181993	N/A	QbD/LC/COL/128

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



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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	1	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_In
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	24-11-2018 13:24:48
Vial Position :-	1_1	Processing Method :-	Ramithiazide Tablets_RS_PR2
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-42	Processing Method Last Updated On :-	26-11-2018 14:10:56
Injection Date & Time :-	24-11-2018 14:04:20	Experiment Name:-	Robustness Inc Flow Rate (1.1 ml/min)
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_24-Nov-18_A.seq		

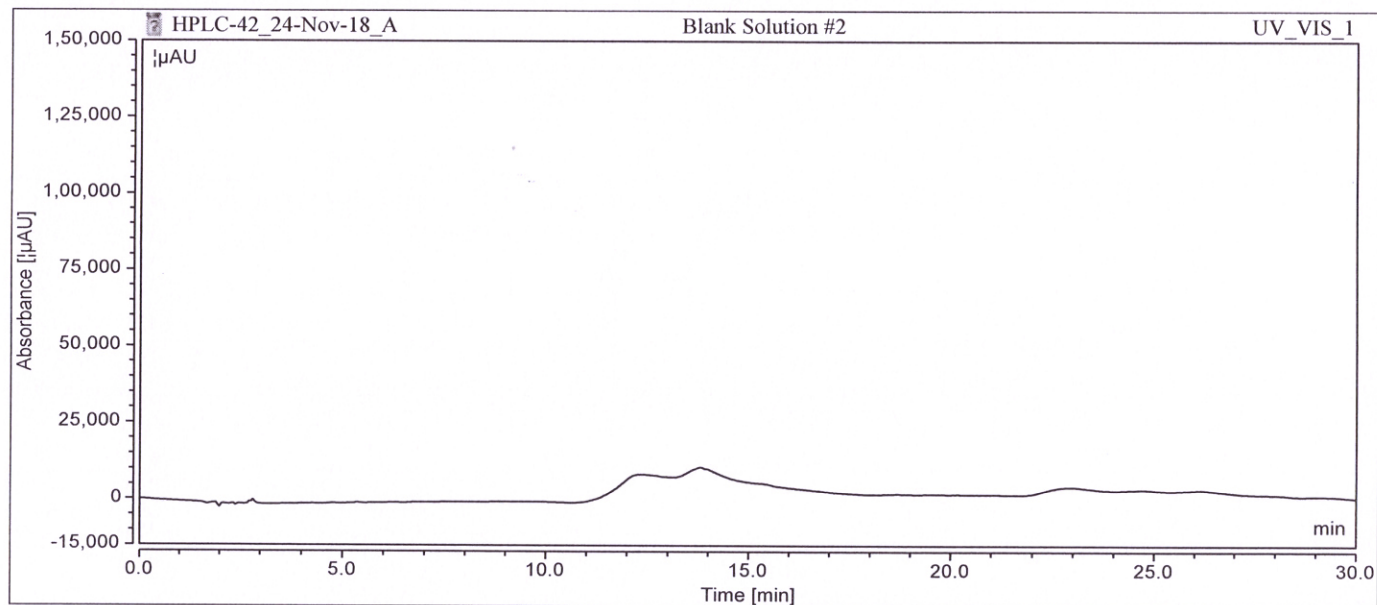


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	2	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_In
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	24-11-2018 13:24:48
Vial Position :-	1_1	Processing Method :-	Ramithiazide Tablets_RS_PR2
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-42	Processing Method Last Updated On :-	26-11-2018 14:10:56
Injection Date & Time :-	24-11-2018 14:35:30	Experiment Name:-	Robustness Inc Flow Rate (1.1 ml/min)
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_24-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_PR		
Processing Method Path :	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_24-Nov-18_A.seq		
Processing Method Created By :	Swaraj A. Jadhav	Processing Method Last Updated By :	Swaraj A. Jadhav
Processing Method Created On :	24-11-2018 13:34:29	Processing Method Last Updated On :	26-11-2018 09:47:03

Detection Alogrithm	Chromeleon 6	Version	3
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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	0.800 [min]	Any	All Channels
0.000	Minimum Height	500.000 [Signal]	Any	All Channels
3.697	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
11.188	Minimum Height	17000.000 [Signal]	Any	All Channels
13.500	Minimum Height	500.000 [Signal]	Any	All Channels
14.712	Minimum Height	2000.000 [Signal]	Any	All Channels
26.000	Maximum Width	0.200 [min]	Any	All Channels

Peak Table

No.	Peak Name	Ret. Time
1	Unknown	3.800
2	Placebo	4.238
3	Hydrochlorothiazide	4.715
4	Unknown	7.183
5	Unknown	9.645
6	Placebo	11.197
7	Impurity E	13.792
8	Ramipril	15.517
9	Unknown	17.080
10	Unknown	17.795
11	Impurity D	22.753

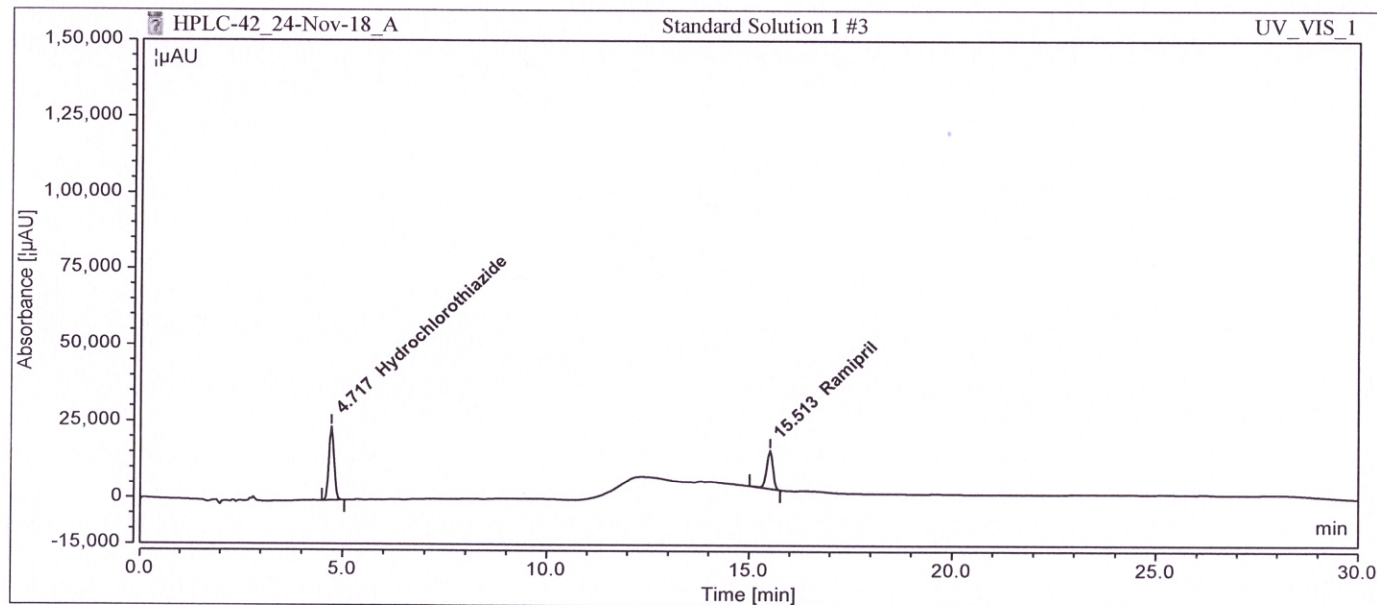
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Processing Method



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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Standard Solution 1	AR. No. :-	D2404181993
Sample Number :-	3	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_In
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	24-11-2018 13:24:48
Vial Position :-	1_2	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-42	Processing Method Last Updated On :-	26-11-2018 09:47:03
Injection Date & Time :-	24-11-2018 15:06:38	Experiment Name:-	Robustness Inc Flow Rate (1.1 ml/min)
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_24-Nov-18_A.seq		

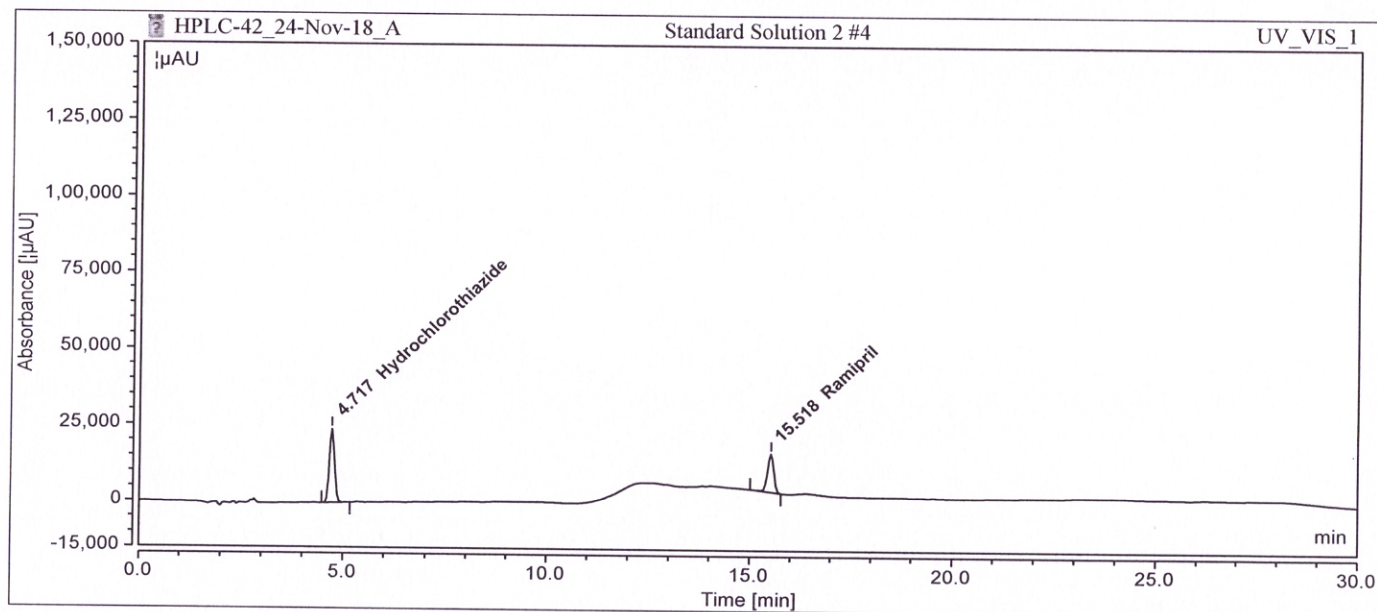


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	4.717	3586.857	61.36	1.14	6336	FALSE	n.a.
2	Ramipril	15.513	2259.037	38.64	0.94	47570	FALSE	41.40



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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Standard Solution 2	AR. No. :-	D2404181993
Sample Number :-	4	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_In
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	24-11-2018 13:24:48
Vial Position :-	1_2	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-42	Processing Method Last Updated On :-	26-11-2018 09:47:03
Injection Date & Time :-	24-11-2018 15:37:47	Experiment Name:-	Robustness Inc Flow Rate (1.1 ml/min)
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_24-Nov-18_A.seq		

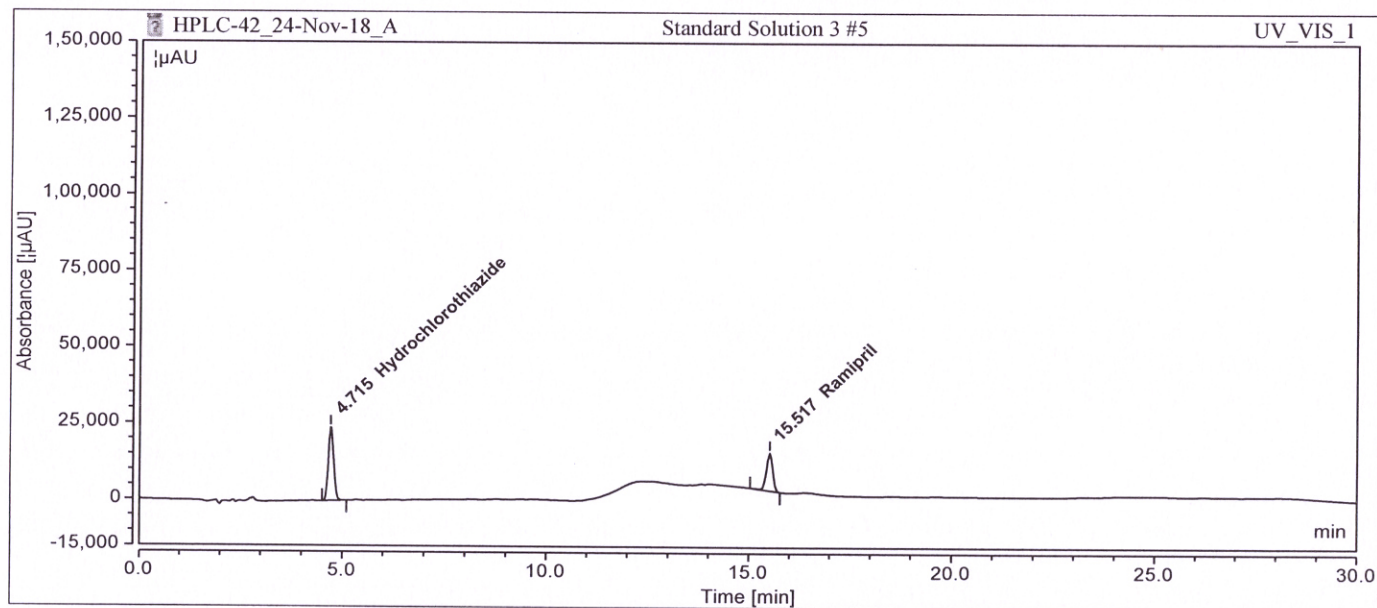


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	4.717	3604.715	61.46	1.15	6314	FALSE	n.a.
2	Ramipril	15.518	2260.725	38.54	0.94	47216	FALSE	41.30



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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Standard Solution 3	AR. No. :-	D2404181993
Sample Number :-	5	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_In
Sample Type :-	Unknown	Instrument Method Created By :-	Maresh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	24-11-2018 13:24:48
Vial Position :-	1_2	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-42	Processing Method Last Updated On :-	26-11-2018 09:47:03
Injection Date & Time :-	24-11-2018 16:08:56	Experiment Name:-	Robustness Inc Flow Rate (1.1 ml/min)
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_24-Nov-18_A.seq		

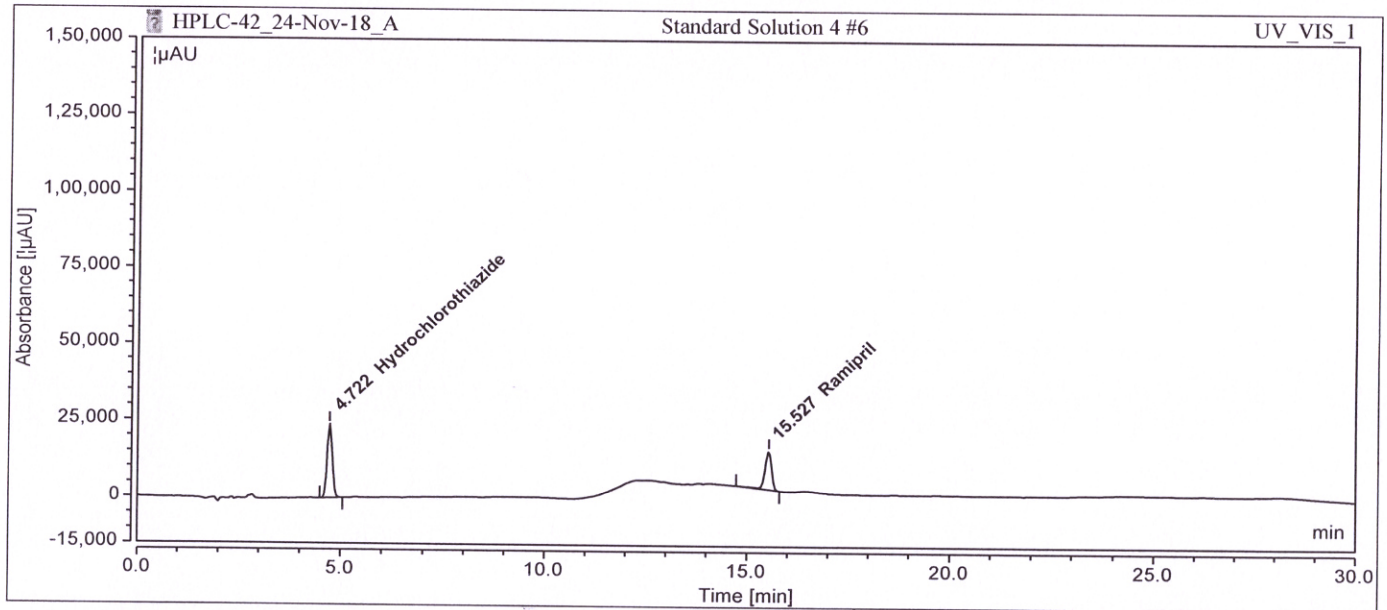


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	4.715	3596.818	61.47	1.15	6269	FALSE	n.a.
2	Ramipril	15.517	2254.840	38.53	0.94	46874	FALSE	41.16



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Standard Solution 4	AR. No. :-	D2404181993
Sample Number :-	6	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_It
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	24-11-2018 13:24:48
Vial Position :-	1_2	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-42	Processing Method Last Updated On :-	26-11-2018 09:47:03
Injection Date & Time :-	24-11-2018 16:40:08	Experiment Name:-	Robustness Inc Flow Rate (1.1 ml/min)
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_24-Nov-18_A.seq		

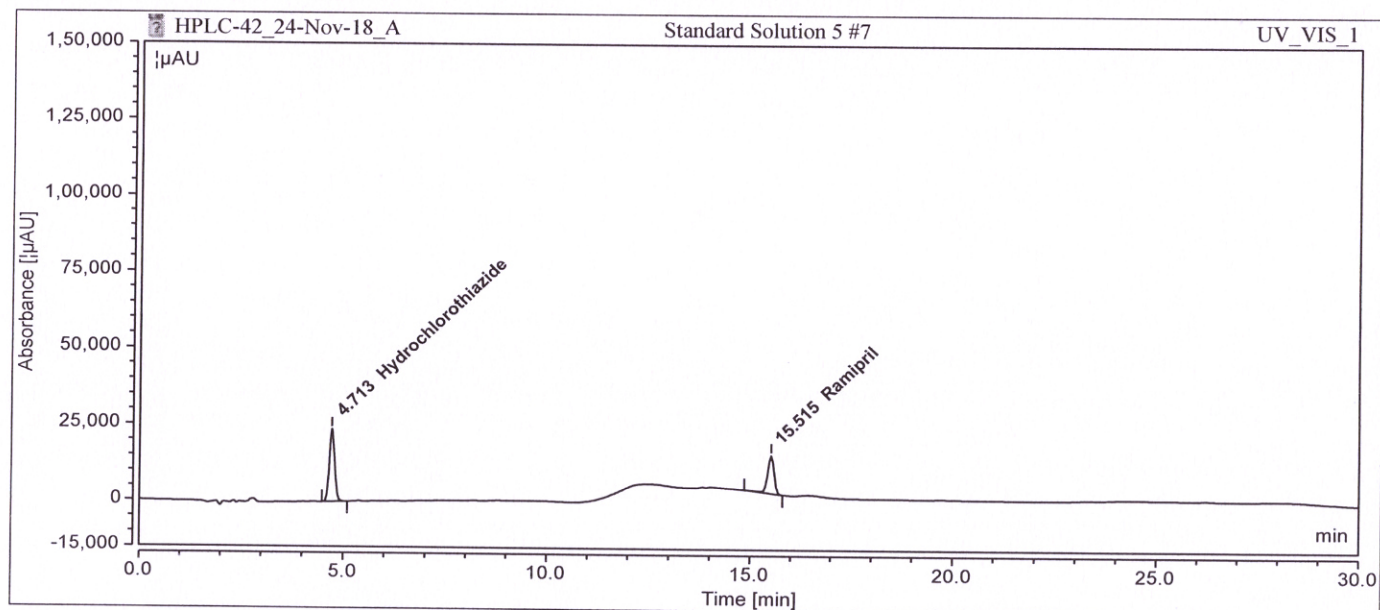


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	4.722	3594.271	60.40	1.15	6320	FALSE	n.a.
2	Ramipril	15.527	2356.586	39.60	0.92	46466	FALSE	41.11



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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Standard Solution 5	AR. No. :-	D2404181993
Sample Number :-	7	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_In
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	24-11-2018 13:24:48
Vial Position :-	1_2	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-42	Processing Method Last Updated On :-	26-11-2018 09:47:03
Injection Date & Time :-	24-11-2018 17:11:14	Experiment Name:-	Robustness Inc Flow Rate (1.1 ml/min)
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_24-Nov-18_A.seq		

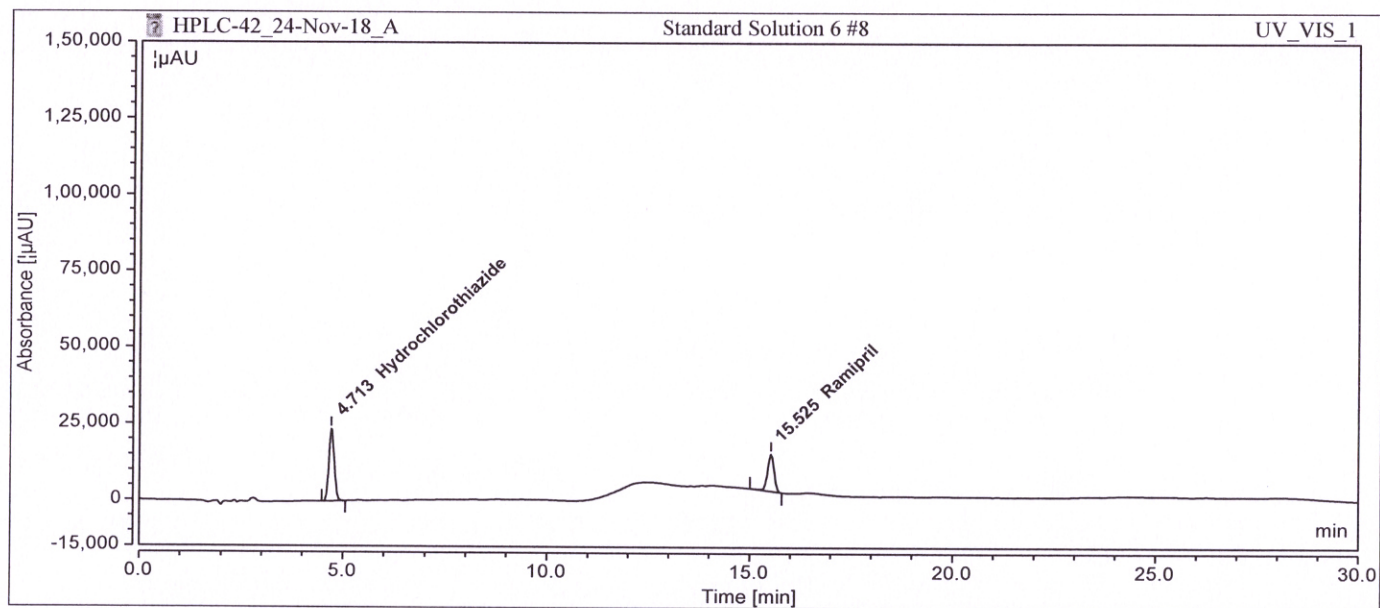


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	4.713	3600.321	60.72	1.14	6138	FALSE	n.a.
2	Ramipril	15.515	2328.998	39.28	0.93	45785	FALSE	40.71



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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Standard Solution 6	AR. No. :-	D2404181993
Sample Number :-	8	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_In
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	24-11-2018 13:24:48
Vial Position :-	1_2	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-42	Processing Method Last Updated On :-	26-11-2018 09:47:03
Injection Date & Time :-	24-11-2018 17:42:23	Experiment Name:-	Robustness Inc Flow Rate (1.1 ml/min)
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_24-Nov-18_A.seq		

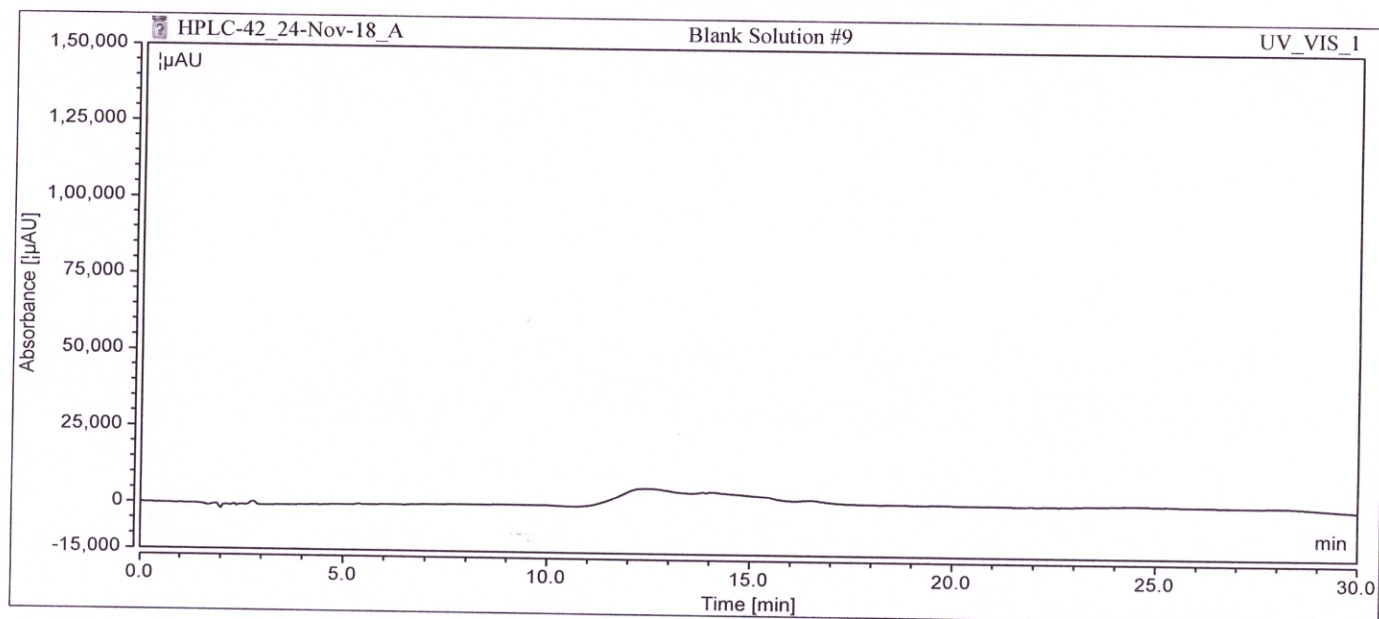


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	4.713	3595.054	61.09	1.14	6090	FALSE	n.a.
2	Ramipril	15.525	2290.007	38.91	0.94	45611	FALSE	40.62



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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	9	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_It
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	24-11-2018 13:24:48
Vial Position :-	1_1	Processing Method :-	Ramithiazide Tablets_RS_PR2
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-42	Processing Method Last Updated On :-	26-11-2018 14:10:56
Injection Date & Time :-	24-11-2018 18:13:31	Experiment Name:-	Robustness Inc Flow Rate (1.1 ml/min)
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_24-Nov-18_A.seq		

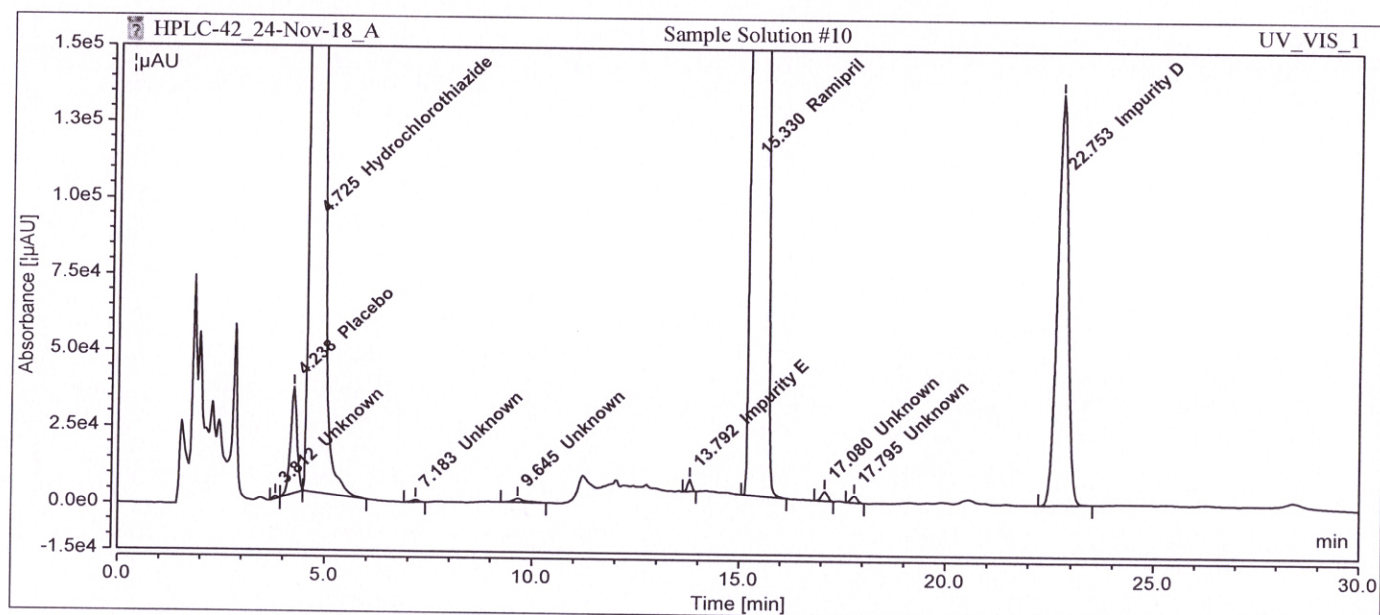


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	GP180301
Sample Name :-	Sample Solution	AR. No. :-	D2404181993
Sample Number :-	10	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_In
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	24-11-2018 13:24:48
Vial Position :-	1_3	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-42	Processing Method Last Updated On :-	26-11-2018 09:47:03
Injection Date & Time :-	24-11-2018 18:44:40	Experiment Name:-	Robustness Inc Flow Rate (1.1 ml/min)
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_24-Nov-18_A.seq		

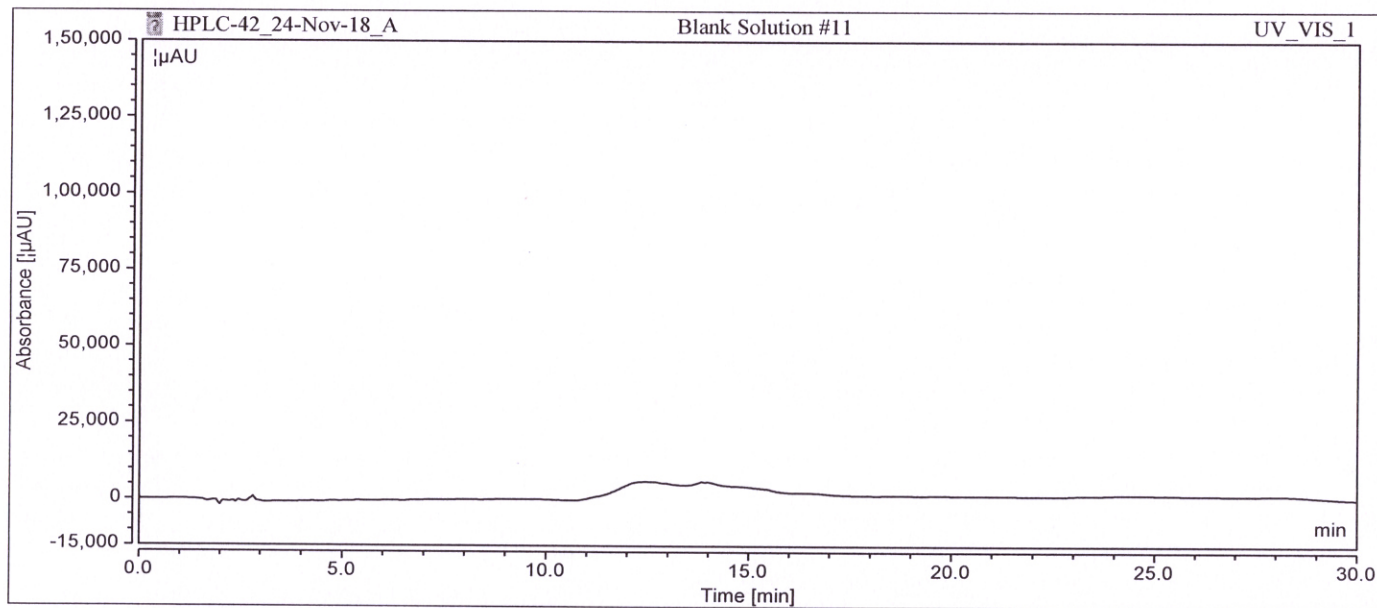


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Unknown	3.812	107.583	0.01	0.95	6093	FALSE	n.a.
2	Placebo	4.238	6095.262	0.45	1.00	3894	FALSE	1.83
3	Hydrochlorothiazide	4.725	746906.982	54.84	1.17	3128	FALSE	1.60
4	Unknown	7.183	167.223	0.01	0.88	8688	FALSE	7.61
5	Unknown	9.645	416.074	0.03	1.48	7739	FALSE	6.59
6	Impurity E	13.792	435.111	0.03	1.01	97486	FALSE	13.48
7	Ramipril	15.330	567894.761	41.70	1.78	20511	FALSE	5.09
8	Unknown	17.080	533.704	0.04	1.00	59657	FALSE	4.94
9	Unknown	17.795	394.599	0.03	1.07	58943	FALSE	2.50
10	Impurity D	22.753	39026.096	2.87	1.03	38820	FALSE	13.13



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	11	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_In
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	24-11-2018 13:24:48
Vial Position :-	1_1	Processing Method :-	Ramithiazide Tablets_RS_PR2
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-42	Processing Method Last Updated On :-	26-11-2018 14:10:56
Injection Date & Time :-	24-11-2018 19:15:50	Experiment Name:-	Robustness Inc Flow Rate (1.1 ml/min)
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_24-Nov-18_A.seq		

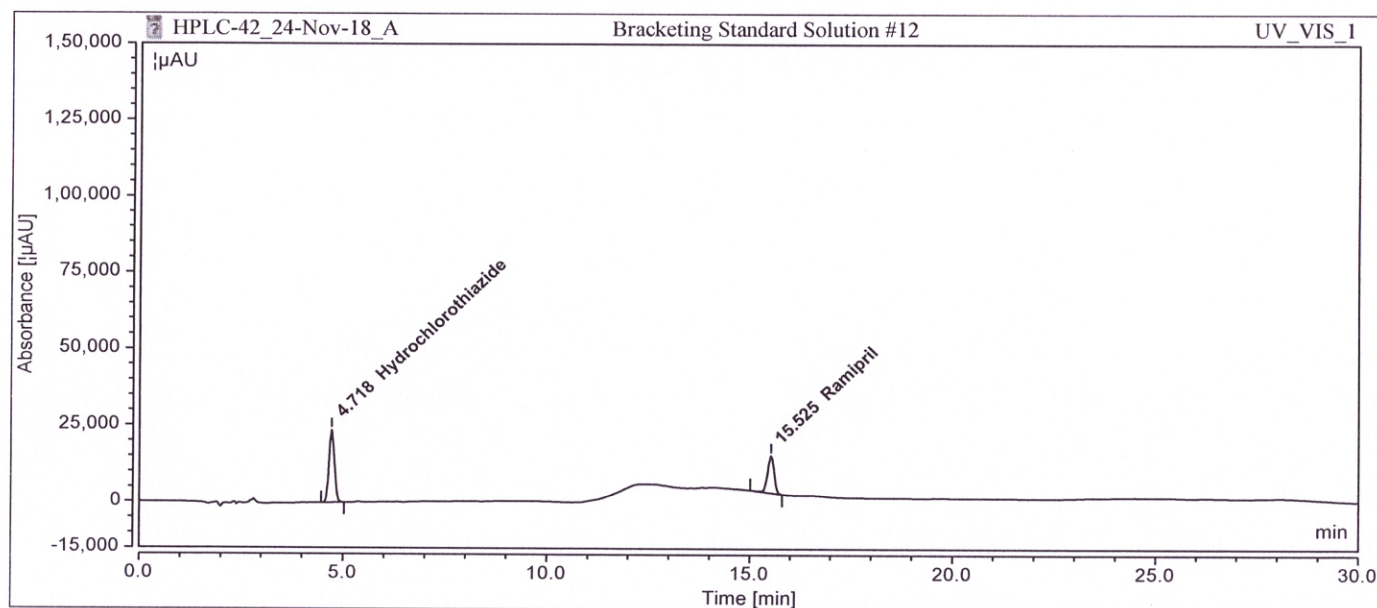


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Bracketing Standard Solution	AR. No. :-	D2404181993
Sample Number :-	12	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_In
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	24-11-2018 13:24:48
Vial Position :-	1_2	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-42	Processing Method Last Updated On :-	26-11-2018 09:47:03
Injection Date & Time :-	24-11-2018 19:47:00	Experiment Name:-	Robustness Inc Flow Rate (1.1 ml/min)
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_24-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	4.718	3596.931	61.31	1.13	6117	FALSE	n.a.
2	Ramipril	15.525	2269.591	38.69	0.94	45027	FALSE	40.48



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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-42_24-Nov-18_A.seq		
Processing Method Created By :	Swaraj A. Jadhav	Processing Method Last Updated By :	Swaraj A. Jadhav
Processing Method Created On :	24-11-2018 13:34:29	Processing Method Last Updated On :	26-11-2018 10:16:50

Detection Algorithm	Chromleon 6	Version	3
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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	0.800 [min]	Any	All Channels
4.397	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
12.500	Minimum Height	10000.000 [Signal]	Any	All Channels
14.000	Valley To Valley	Off	Any	All Channels
14.200	Minimum Height	0.000 [Signal]	Any	All Channels
14.712	Minimum Height	1100.000 [Signal]	Any	All Channels
15.648	Valley To Valley	On	Any	All Channels
27.000	Maximum Width	0.000 [min]	Any	All Channels

Peak Table

No.	Peak Name	Ret. Time
1	Unknown	4.643
2	Placebo	5.148
3	Hydrochlorothiazide	5.740
4	Unknown	8.740
5	Unknown	12.162
6	Impurity E	15.208
7	Ramipril	17.257
8	Unknown	19.227
9	Unknown	20.057
10	Impurity D	26.033

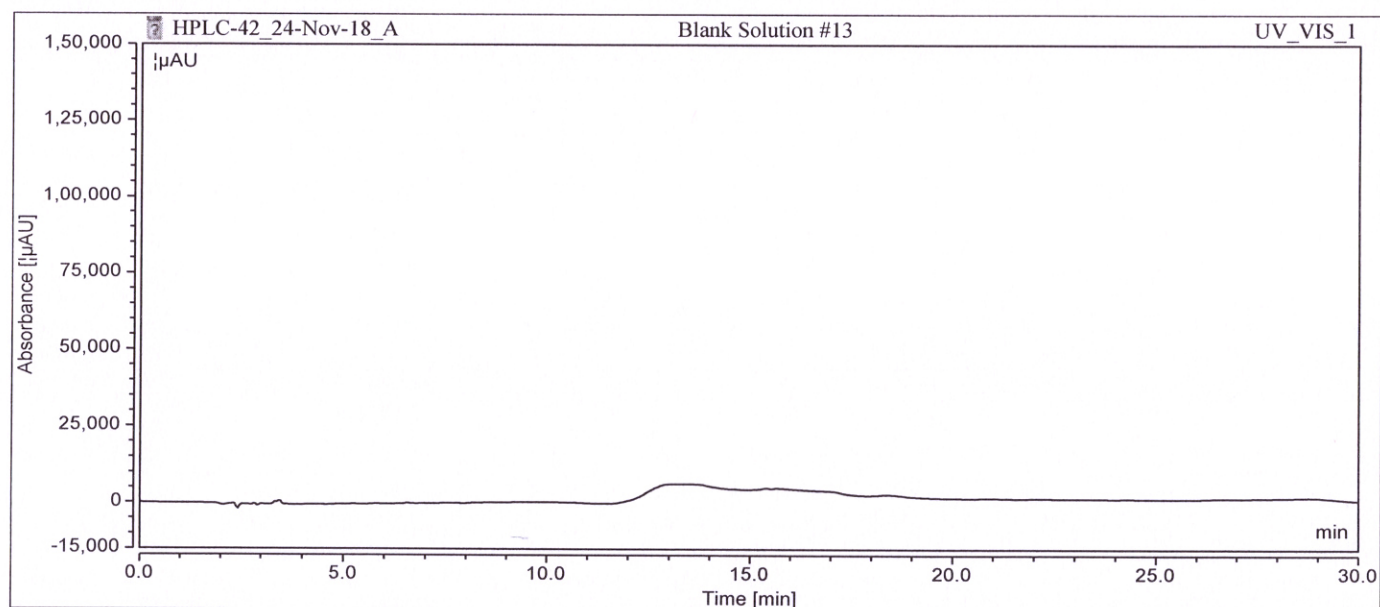
QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Processing Method



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	13	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_D
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	24-11-2018 13:25:54
Vial Position :-	1_1	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-42	Processing Method Last Updated On :-	26-11-2018 10:16:50
Injection Date & Time :-	24-11-2018 20:18:10	Experiment Name:-	Robustness Dec Flow Rate (0.9 ml/min)
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_24-Nov-18_A.seq		

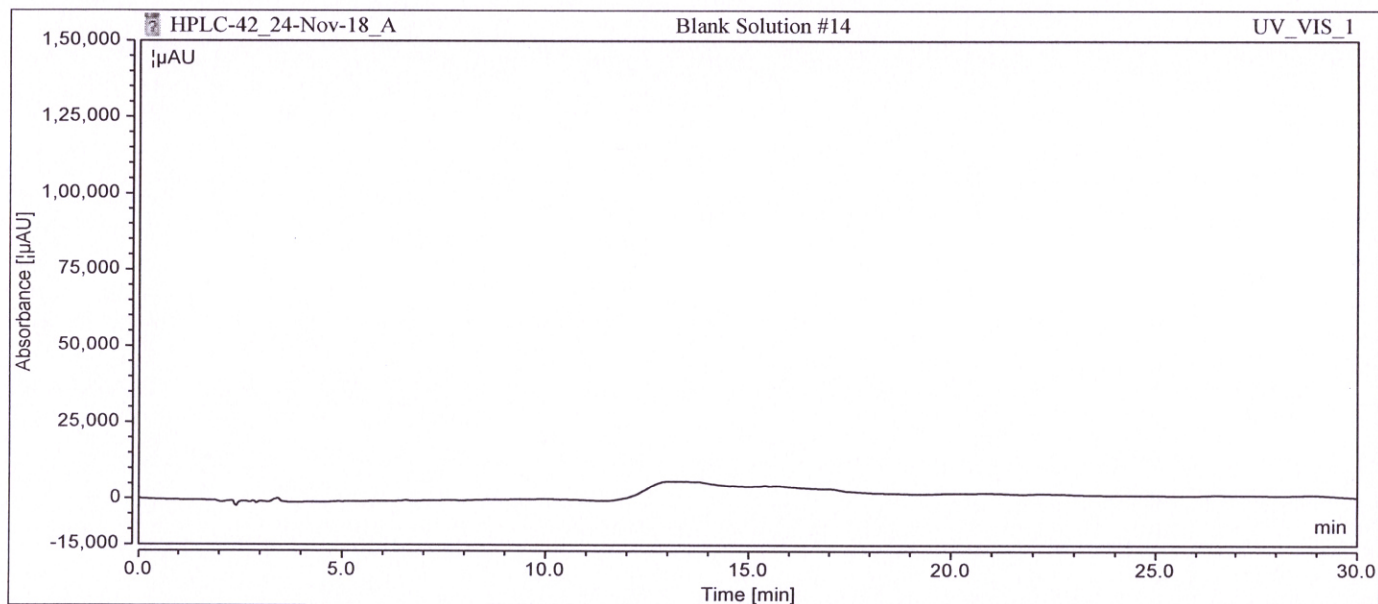


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	14	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_D
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	24-11-2018 13:25:54
Vial Position :-	1_1	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-42	Processing Method Last Updated On :-	26-11-2018 10:16:50
Injection Date & Time :-	24-11-2018 20:49:20	Experiment Name:-	Robustness Dec Flow Rate (0.9 ml/min)
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_24-Nov-18_A.seq		

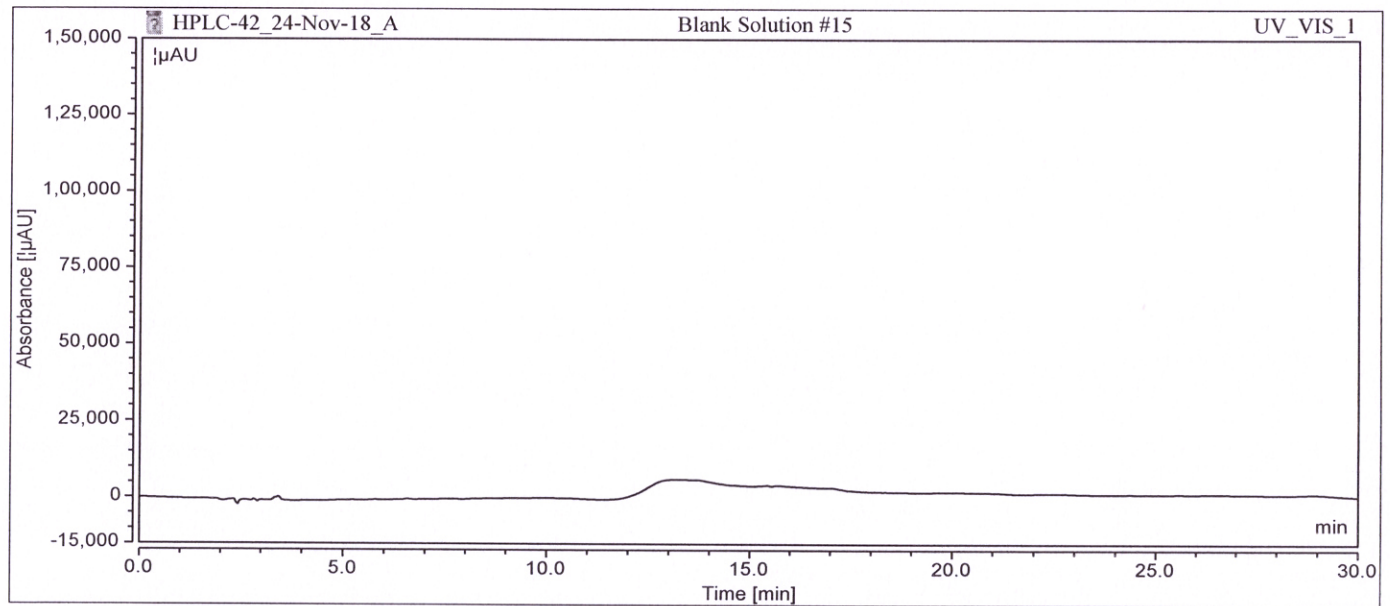


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	15	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_D
Sample Type :-	Unknown	Instrument Method Created By :-	Maresh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	24-11-2018 13:25:54
Vial Position :-	1_1	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-42	Processing Method Last Updated On :-	26-11-2018 10:16:50
Injection Date & Time :-	24-11-2018 21:20:30	Experiment Name:-	Robustness Dec Flow Rate (0.9 ml/min)
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_24-Nov-18_A.seq		

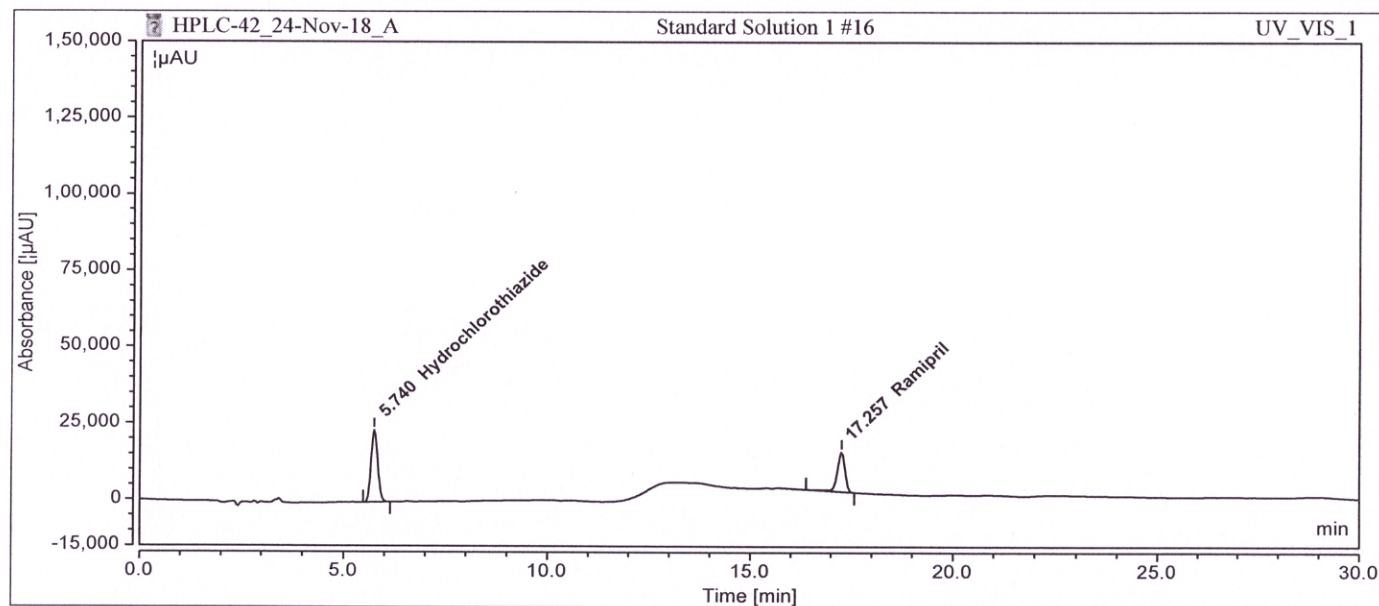


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Standard Solution 1	AR. No. :-	D2404181993
Sample Number :-	16	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_D
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	24-11-2018 13:25:54
Vial Position :-	1_2	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-42	Processing Method Last Updated On :-	26-11-2018 10:16:50
Injection Date & Time :-	24-11-2018 21:51:39	Experiment Name:-	Robustness Dec Flow Rate (0.9 ml/min)
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_24-Nov-18_A.seq		

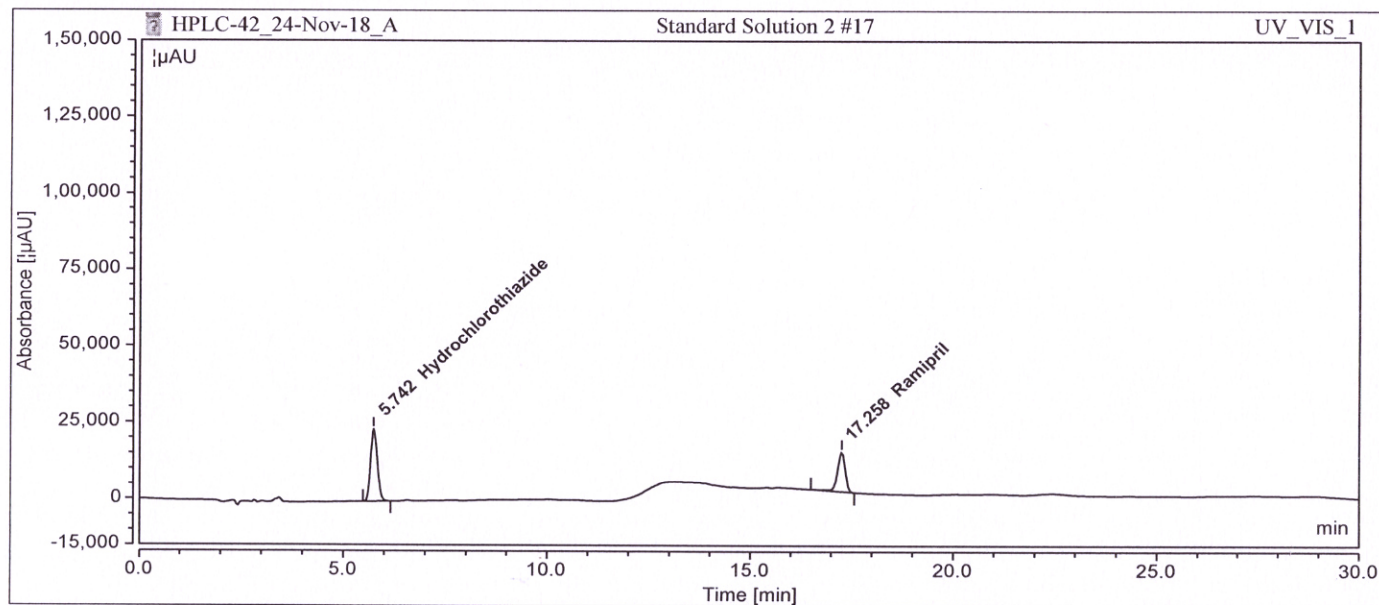


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.740	4404.299	60.66	1.16	5960	FALSE	n.a.
2	Ramipril	17.257	2856.396	39.34	0.92	41776	FALSE	36.27



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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Standard Solution 2	AR. No. :-	D2404181993
Sample Number :-	17	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_D
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	24-11-2018 13:25:54
Vial Position :-	1_2	Processing Method :-	Ramithiazide Tablets_RS_PRI
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-42	Processing Method Last Updated On :-	26-11-2018 10:16:50
Injection Date & Time :-	24-11-2018 22:22:48	Experiment Name:-	Robustness Dec Flow Rate (0.9 ml/min)
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_24-Nov-18_A.seq		

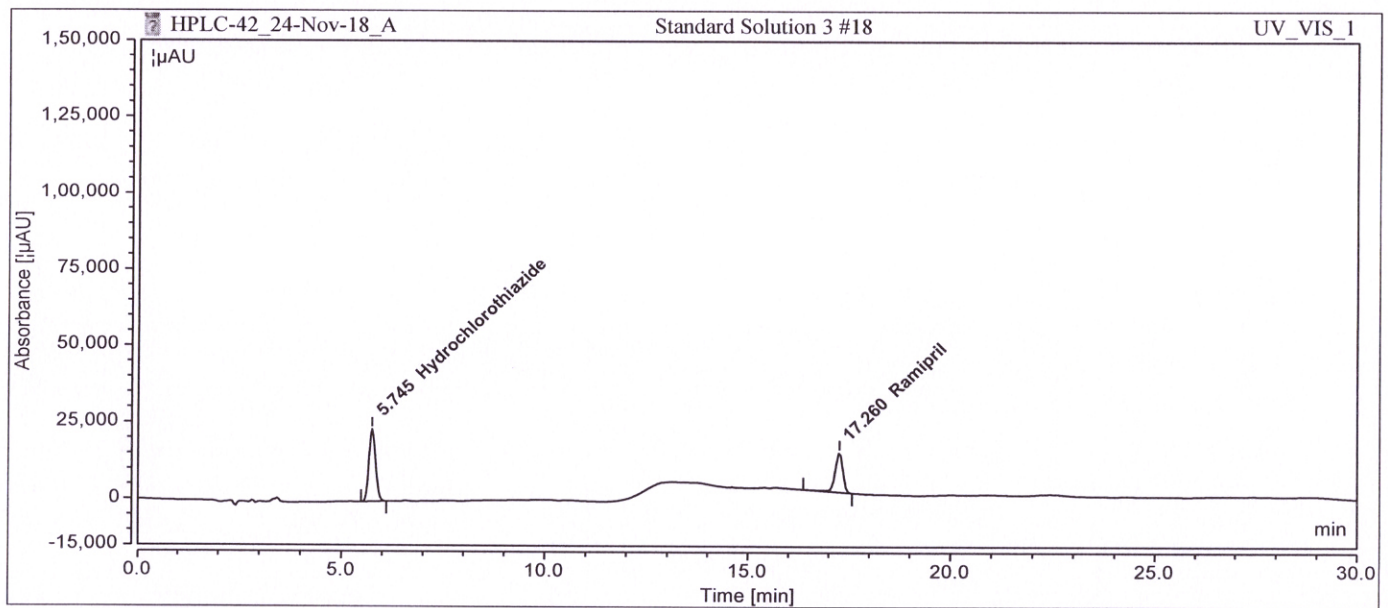


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.742	4405.378	60.85	1.17	5948	FALSE	n.a.
2	Ramipril	17.258	2834.906	39.15	0.92	41590	FALSE	36.20



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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Standard Solution 3	AR. No. :-	D2404181993
Sample Number :-	18	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_D
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	24-11-2018 13:25:54
Vial Position :-	1_2	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-42	Processing Method Last Updated On :-	26-11-2018 10:16:50
Injection Date & Time :-	24-11-2018 22:53:56	Experiment Name:-	Robustness Dec Flow Rate (0.9 ml/min)
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_24-Nov-18_A.seq		

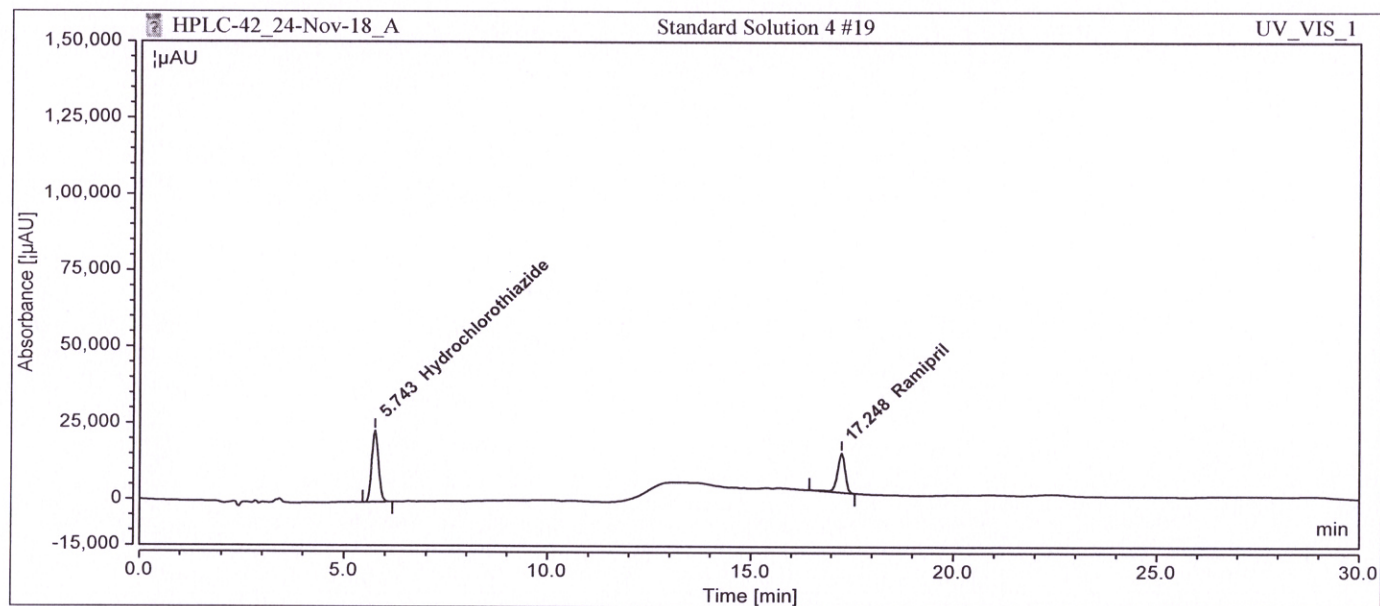


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.745	4401.963	60.55	1.16	5949	FALSE	n.a.
2	Ramipril	17.260	2868.118	39.45	0.92	41240	FALSE	36.10



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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Standard Solution 4	AR. No. :-	D2404181993
Sample Number :-	19	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_D
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	24-11-2018 13:25:54
Vial Position :-	1_2	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-42	Processing Method Last Updated On :-	26-11-2018 10:16:50
Injection Date & Time :-	24-11-2018 23:25:04	Experiment Name:-	Robustness Dec Flow Rate (0.9 ml/min)
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_24-Nov-18_A.seq		

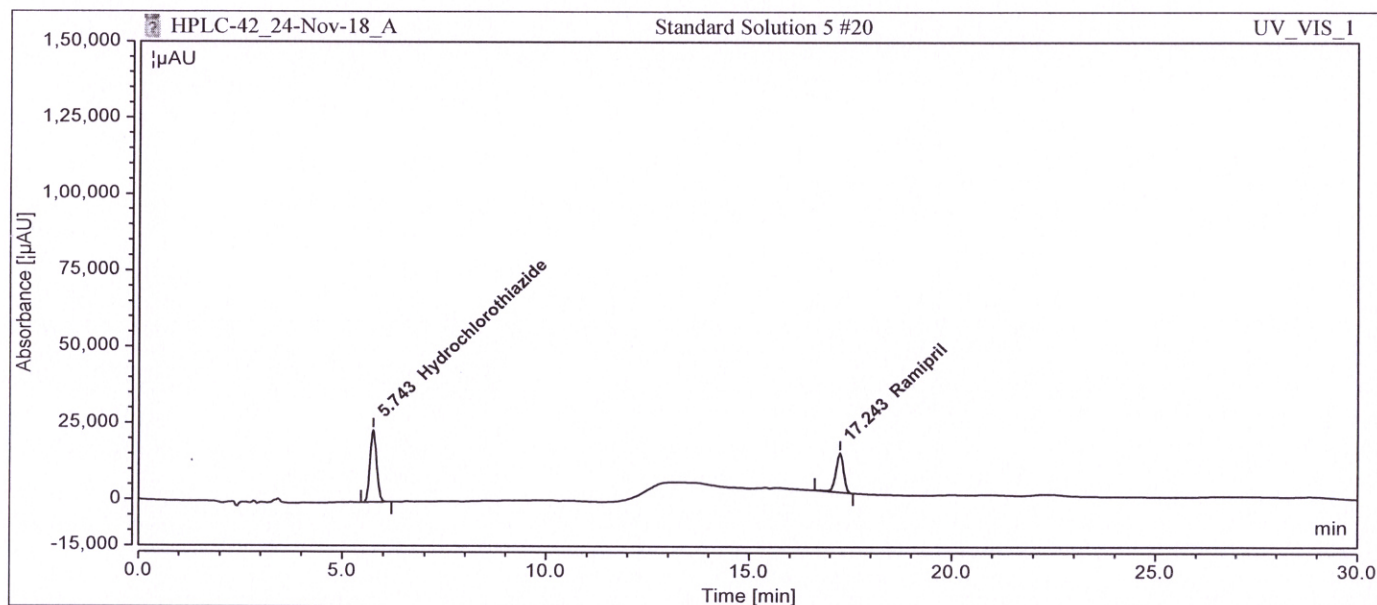


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.743	4414.646	60.65	1.16	5891	FALSE	n.a.
2	Ramipril	17.248	2864.030	39.35	0.92	41147	FALSE	35.98



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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Standard Solution 5	AR. No. :-	D2404181993
Sample Number :-	20	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_D
Sample Type :-	Unknown	Instrument Method Created By :-	Maresh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	24-11-2018 13:25:54
Vial Position :-	1_2	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-42	Processing Method Last Updated On :-	26-11-2018 10:16:50
Injection Date & Time :-	24-11-2018 23:56:15	Experiment Name:-	Robustness Dec Flow Rate (0.9 ml/min)
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_24-Nov-18_A.seq		

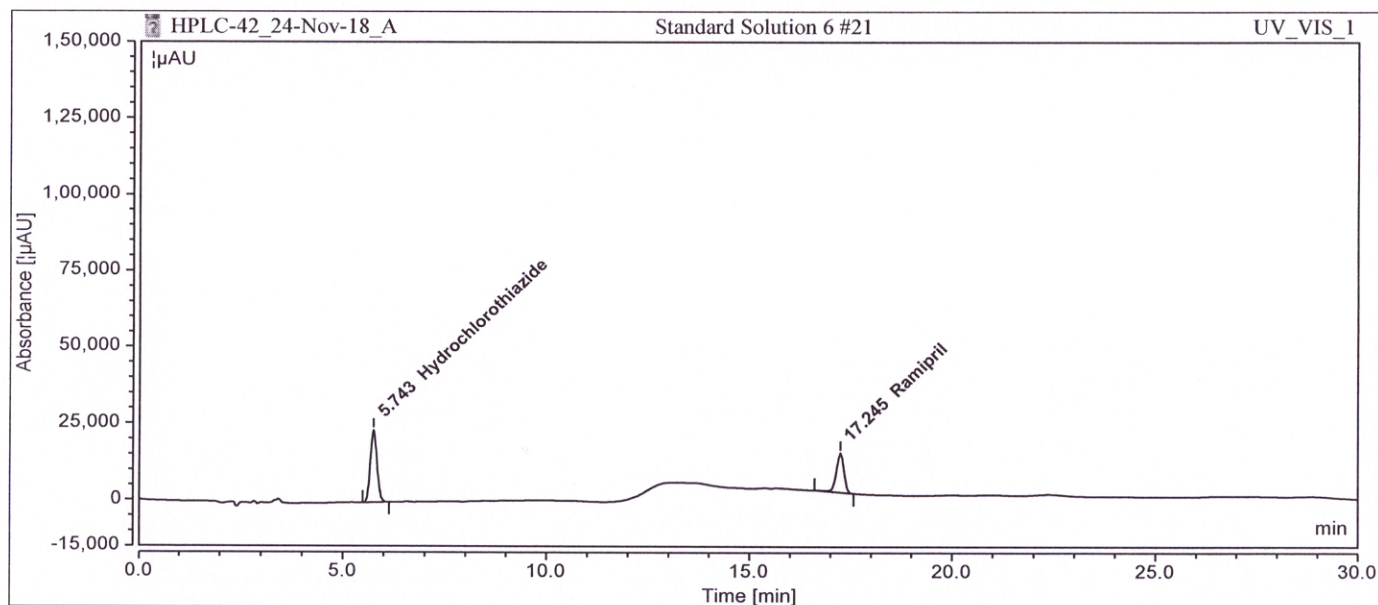


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.743	4419.398	61.11	1.16	5952	FALSE	n.a.
2	Ramipril	17.243	2812.913	38.89	0.92	41128	FALSE	36.06



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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Standard Solution 6	AR. No. :-	D2404181993
Sample Number :-	21	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_D
Sample Type :-	Unknown	Instrument Method Created By :-	Maresh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	24-11-2018 13:25:54
Vial Position :-	1_2	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-42	Processing Method Last Updated On :-	26-11-2018 10:16:50
Injection Date & Time :-	25-11-2018 00:27:22	Experiment Name:-	Robustness Dec Flow Rate (0.9 ml/min)
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_24-Nov-18_A.seq		

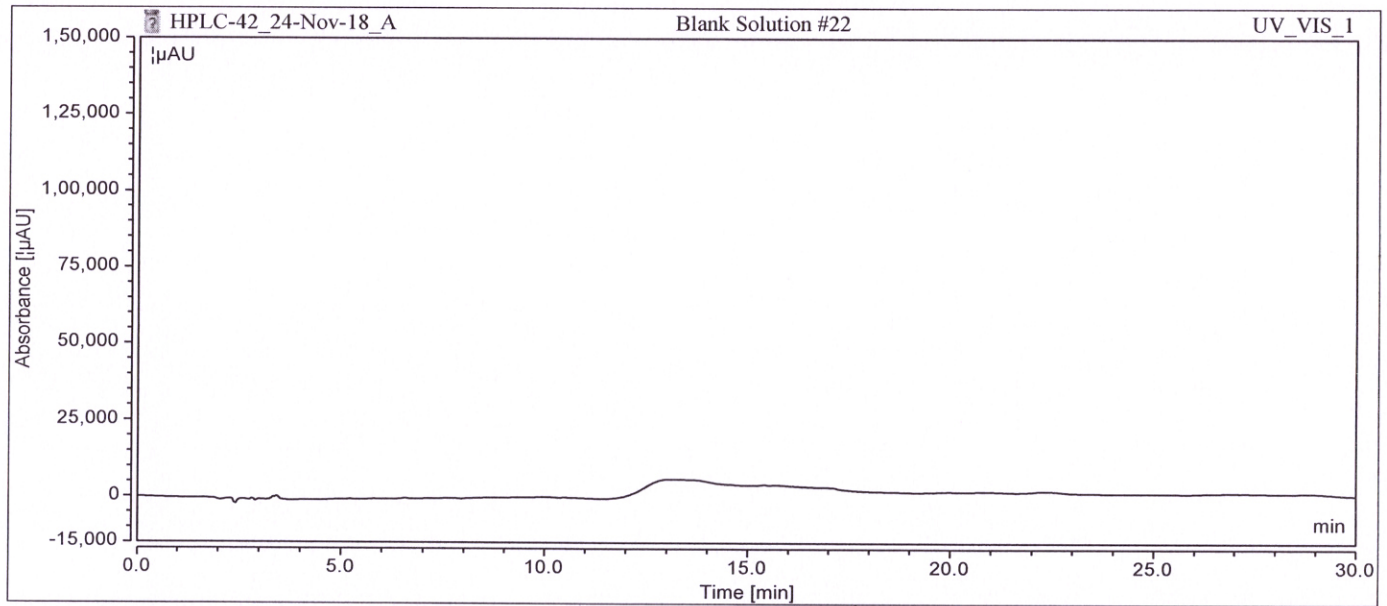


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.743	4411.327	60.97	1.16	5918	FALSE	n.a.
2	Ramipril	17.245	2824.345	39.03	0.92	40818	FALSE	35.94



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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	22	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_D
Sample Type :-	Unknown	Instrument Method Created By :-	Maresh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	24-11-2018 13:25:54
Vial Position :-	1_1	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-42	Processing Method Last Updated On :-	26-11-2018 10:16:50
Injection Date & Time :-	25-11-2018 00:58:32	Experiment Name:-	Robustness Dec Flow Rate (0.9 ml/min)
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_24-Nov-18_A.seq		

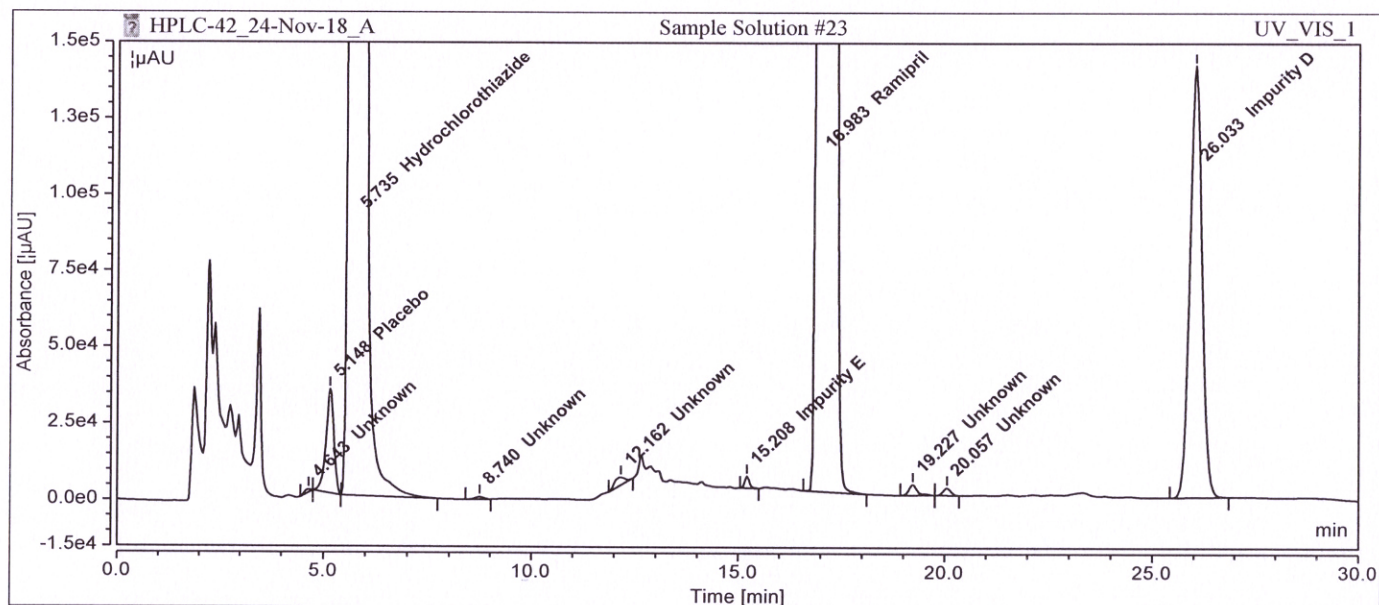


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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Product Name :-	Ramithiazide Tablets	Batch No. :-	GP180301
Sample Name :-	Sample Solution	AR. No. :-	D2404181993
Sample Number :-	23	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_D
Sample Type :-	Unknown	Instrument Method Created By :-	Maresh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	24-11-2018 13:25:54
Vial Position :-	1_3	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-42	Processing Method Last Updated On :-	26-11-2018 10:16:50
Injection Date & Time :-	25-11-2018 01:29:40	Experiment Name:-	Robustness Dec Flow Rate (0.9 ml/min)
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_24-Nov-18_A.seq		

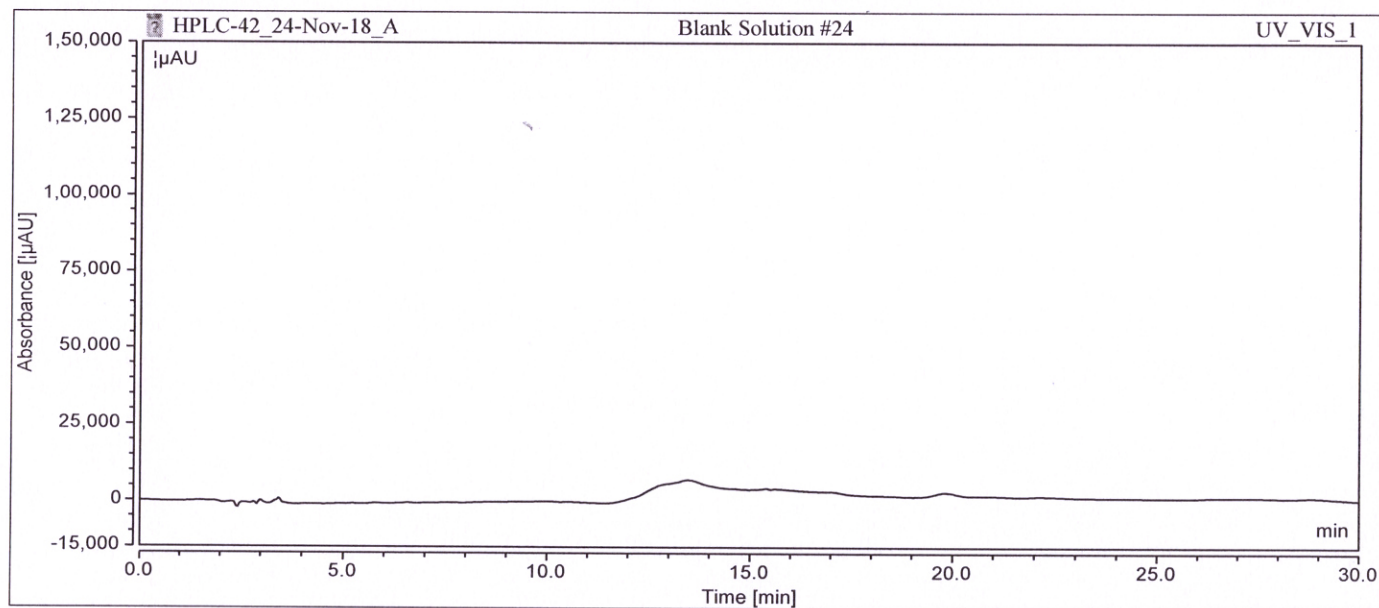


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Unknown	4.643	176.422	0.01	0.77	5155	FALSE	n.a.
2	Placebo	5.148	7300.957	0.44	0.89	3911	FALSE	1.72
3	Hydrochlorothiazide	5.735	926461.808	55.44	1.23	3026	FALSE	1.57
4	Unknown	8.740	206.120	0.01	0.89	8593	FALSE	7.57
5	Unknown	12.162	767.964	0.05	0.94	13528	FALSE	8.60
6	Impurity E	15.208	519.261	0.03	1.32	88340	FALSE	9.78
7	Ramipril	16.983	686172.771	41.06	1.84	17464	FALSE	4.94
8	Unknown	19.227	828.870	0.05	1.55	51162	FALSE	5.25
9	Unknown	20.057	524.004	0.03	1.01	52523	FALSE	2.41
10	Impurity D	26.033	48004.230	2.87	1.04	37553	FALSE	13.47



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	24	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_D
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	24-11-2018 13:25:54
Vial Position :-	1_1	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-42	Processing Method Last Updated On :-	26-11-2018 10:16:50
Injection Date & Time :-	25-11-2018 02:00:50	Experiment Name:-	Robustness Dec Flow Rate (0.9 ml/min)
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_24-Nov-18_A.seq		

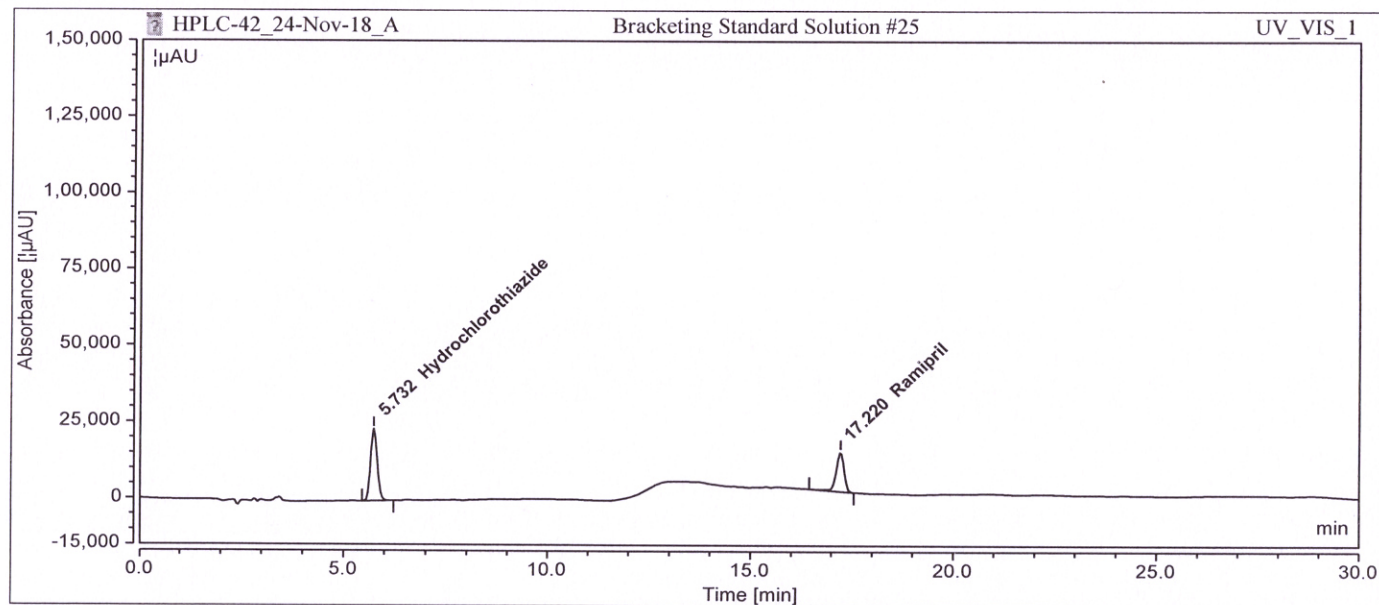


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Bracketing Standard Solution	AR. No. :-	D2404181993
Sample Number :-	25	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_D
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	24-11-2018 13:25:54
Vial Position :-	1_2	Processing Method :-	Ramithiazide Tablets_RS_PRI
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-42	Processing Method Last Updated On :-	26-11-2018 10:16:50
Injection Date & Time :-	25-11-2018 02:31:57	Experiment Name:-	Robustness Dec Flow Rate (0.9 ml/min)
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_24-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	5.732	4425.379	60.71	1.16	5890	FALSE	n.a.
2	Ramipril	17.220	2864.456	39.29	0.92	40303	FALSE	35.80



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Product Name :-	metod created	Batch No. :-	N/A
Sample Name :-	Wash	AR. No. :-	D2404181993
Sample Number :-	26	Instrument Method :-	Wash method _HPLC 42
Sample Type :-	Unknown	Instrument Method Created By :-	Ravi R Birajdar
Injection Volume :-	30.00 µL	Instrument Method Created On :-	29-04-2017 12:40:44
Vial Position :-	1_1	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-42	Processing Method Last Updated On :-	26-11-2018 10:16:50
Injection Date & Time :-	25-11-2018 03:02:45	Experiment Name:-	N/A
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_24-Nov-18_A.seq		

Channel UV_VIS_1 is not available for injection #26 - Wash.

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

Product Name :-	metod created	Batch No. :-	N/A
Sample Name :-	Shut	AR. No. :-	D2404181993
Sample Number :-	27	Instrument Method :-	Shut method _HPLC 42
Sample Type :-	Unknown	Instrument Method Created By :-	Ravi R Birajdar
Injection Volume :-	30.00 µL	Instrument Method Created On :-	16-03-2017 12:39:53
Vial Position :-	1_1	Processing Method :-	Ramithiazide Tablets_RS_PRI
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-42	Processing Method Last Updated On :-	26-11-2018 10:16:50
Injection Date & Time :-	25-11-2018 04:03:20	Experiment Name:-	N/A
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_24-Nov-18_A.seq		

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

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