

RAW DATA OF

**(ROBUSTNESS- INCREASE
IN pH OF BUFFER
AND
ROBUSTNESS- DECREASE
IN pH OF BUFFER)**

RELATED SUBSTANCE VALIDATION

Product Name:	Ramithiazide Tablets
Label claim (mg):	10 mg And 25 mg
AR No:	D2404181193
Batch No.:	GPI180301
Parameter:	Robustness Decrease Buffer pH
LNB No./ Page No.	718/016

Analysis Date: 23-Nov-18

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

Preparation of standard solution for Ramipril	Weight of standard (mg)	Diluted (mL)	Concentration (nm)	Purity (As is Basis)
	25.24	25.0		
	2.0	100.0	2.02	99.64
	2.0	20.0		

Injection No.	Retention Time	Peak Area	Retention Time	Area of Bkt Standard
1	16.270	2448.932	16.278	2445.348
2	16.278	2456.892		
3	16.280	2453.597		
4	16.280	2459.340		
5	16.277	2440.273		
6	16.280	2452.475		
Average	16.278	2448.585	16.278	2446.694
SD	0.0039	7.2655	0.0036	8.3078
%RSD	0.02	0.30	0.02	0.34

System Suitability
%RSD of Area
0.30
NMT 5.0%

Preparation of standard solution for Hydrochlorothiazide	Weight of standard (mg)	Diluted (mL)	Concentration (nm)	Purity (As is Basis)
	25.31	25.0		
	2.5	100.0	2.53	99.24
	2.0	20.0		

Injection No.	Retention Time	Peak Area	Retention Time	Area of Bkt Standard
1	5.170	4143.884	5.177	4135.650
2	5.173	4150.561		
3	5.173	4150.489		
4	5.173	4139.976		
5	5.175	4140.506		
6	5.172	4141.728		
Average	5.173	4144.524	5.173	4143.256
SD	0.0016	4.8391	0.0022	5.5465
%RSD	0.03	0.12	0.04	0.13

System Suitability
%RSD of Area
0.12
NMT 5.0%

Sample solution 1	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	392.55	Unknown Impurity	3.788	0.24	100.110	0.01	BQL	4.99
		Unknown Impurity	7.867	0.49	182.150	0.01	BQL	
		Unknown Impurity	10.533	0.65	262.802	0.02	BQL	
		Unknown Impurity	18.045	1.12	462.374	0.04	BQL	
		Unknown Impurity	18.832	1.17	390.607	0.03	BQL	
		Ramipril Impurity E	14.433	0.90	436.411	0.79	0.79	
		Ramipril Impurity D	24.213	1.50	41982.260	4.20	4.20	
		Ramipril	16.113	1.00	702976.744	-	-	

Sample	Ramipril Impurity E	Ramipril Impurity D	Total % Impurities
Sample (Precision)	0.83	4.47	5.32
Sample Solution (Dec pH)	0.79	4.20	4.99
% Difference			
Sample	Ramipril Impurity E	Ramipril Impurity D	Total % Impurities
Sample (Precision)	-	-	-
Sample Solution (Dec pH)	0.06	0.27	0.33

Done by:

Date:

SD
20-Nov-18

Checked by:

Date:

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RELATED SUBSTANCE VALIDATION

Product Name:	Ramipril Tablets
Label claim (mg):	10 mg And 25 mg
AR No:	D2404181193
Batch No:	GP188301
Parameter:	Robustness Increase Buffer pH
LNB No / Page No:	718/016

Analysis Date: 23-Nov-18

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

Preparation of standard solution for Ramipril	Weight of standard (mg)	Diluted (mL)	Concentration (nm)	Purity (As is Basis)
	25.24	25.0		
	2.0	100.0	2.02	99.64
	2.0	20.0		

Injection No.	Retention Time	Peak Area	Retention Time	Area of Bkt Standard
1	16.355	2431.057	16.347	2427.447
2	16.355	2432.510		
3	16.358	2411.660		
4	16.357	2418.235		
5	16.360	2427.938		
6	16.353	2433.274		
Average	16.356	2425.790	16.355	2426.027
SD	0.0025	8.8448	0.0042	8.0984
%RSD	0.02	0.36	0.03	0.33

System Suitability	%RSD of Area	0.36	NMT 5.0%
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Preparation of standard solution for Hydrochlorothiazide	Weight of standard (mg)	Diluted (mL)	Concentration (nm)	Purity (As is Basis)
	25.31	25.0		
	2.5	100.0	2.53	99.24
	2.0	20.0		

Injection No.	Retention Time	Peak Area	Retention Time	Area of Bkt Standard
1	5.193	4152.844	5.195	4152.590
2	5.195	4154.945		
3	5.195	4160.028		
4	5.197	4157.492		
5	5.195	4159.078		
6	5.197	4155.044		
Average	5.195	4156.722	5.195	4156.132
SD	0.0015	2.9372	0.0014	3.1029
%RSD	0.03	0.07	0.03	0.07

System Suitability	%RSD of Area	0.07	NMT 5.0%
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Sample solution :	Eq to 20 mg	diluted to	20.0	ml, with Diluent
Average wt. (mg):	195.34			

Sample Details	Sample wt. (mg)	Impurity name	RT	RRT	Area	%Impurity	Reported impurity	Total % Impurity
Sample Solution	392.55	Unknown Impurity	3.798	0.23	109.613	0.01	BQL	5.00
		Unknown Impurity	7.915	0.49	252.183	0.02	BQL	
		Unknown Impurity	10.655	0.66	255.362	0.02	BQL	
		Unknown Impurity	18.125	1.12	539.292	0.04	BQL	
		Unknown Impurity	18.920	1.17	346.487	0.03	BQL	
		Ramipril Impurity E	14.480	0.89	429.737	0.79	0.79	
		Ramipril Impurity D	24.390	1.51	41714.920	4.21	4.21	
		Ramipril	16.180	1.00	691507.663	-	-	

Sample	Ramipril Impurity E	Ramipril Impurity D	Total % Impurities
Sample (Precision)	0.85	4.47	5.32
Sample Solution (Inc pH)	0.79	4.21	5.00
% Difference			
Sample	Ramipril Impurity E	Ramipril Impurity D	Total % Impurities
Sample (Precision)	-	-	-
Sample Solution (Inc pH)	0.06	0.26	0.32

Done by:

Date:

26-Nov-18

Checked by:

Date:

Patel



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Instrument ID : QbD-INST-HPLC-42

Sequence Name :

HPLC-42_23-Nov-18_A1

Data Vault :

QbD_2018

Sequence Path :

Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_A1.seq

Seq. Created By : Swaraj A. Jadhav

Seq. Last Updated By :

Seq. Created On : 23-11-2018 13:46:30

Seq. Last Updated On

23-11-2018 18:49:32

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

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

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Instrument ID : QbD-INST-HPLC-42

Sequence Name : HPLC-42_23-Nov-18_A

Data Vault : QbD_2018

Sequence Path : Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_A.seq

Seq. Created By : Swaraj A. Jadhav

Seq. Last Updated By : Swaraj A. Jadhav

Seq. Created On : 23-11-2018 13:46:30

Seq. Last Updated On : 23-11-2018 14:02:27

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

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

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Name	HPLC-42_Ramithiazide Tablet_RS_Met
Data Vault	QbD_2018
Path	chrom://qbdser03/QbD_2018/Method Validation/Generic Healthcare/Ramithiazide Tablet/Related Substances/HPLC-42_23- Nov-18_A.seq/HPLC-42_Ramithiazide Tablet_RS_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	21-Nov-18 15:24:45 +05:30 Mahesh Nikam

SP
23-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	1.000 [ml/min]	
		Pump.%B.Value	30.0 [%]	
		Pump.%C.Value	0.0 [%]	
		Pump.%D.Value	0.0 [%]	
	7.000	Pump.Flow	1.000 [ml/min]	
		Pump.%B.Value	30.0 [%]	
		Pump.%C.Value	0.0 [%]	
		Pump.%D.Value	0.0 [%]	
	9.000	Pump.Flow	1.000 [ml/min]	
		Pump.%B.Value	50.0 [%]	
		Pump.%C.Value	0.0 [%]	
		Pump.%D.Value	0.0 [%]	
	25.000	Pump.Flow	1.000 [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	1.000 [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		

23-NOV-18

Name	HPLC-42_Ramithiazide Tablet_RS_Dec pH_Met
Data Vault	QbD_2018
Path	chrom://qbdser03/QbD_2018/Method Validation/Generic Healthcare/Ramithiazide Tablet/Related Substances/HPLC-42_23- Nov-18_A.seq/HPLC-42_Ramithiazide Tablet_RS_Dec pH_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	23-Nov-18 13:51:55 +05:30 Santosh Padmure

SD
23-NOV-18

SD
23-NOV-18

Stage	Time min	Command	Value	Comment
Instrument Setup				
	initial	Pump.%A.Equate	"0"	
		Pump.%B.Equate	"Mobile Phase B"	
		Pump.%C.Equate	"Mobile Phase A"	
		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	1.000 [ml/min]	
		Pump.%B.Value	30.0 [%]	
		Pump.%C.Value	70.0 [%]	
		Pump.%D.Value	0.0 [%]	
	7.000	Pump.Flow	1.000 [ml/min]	
		Pump.%B.Value	30.0 [%]	
		Pump.%C.Value	70.0 [%]	
		Pump.%D.Value	0.0 [%]	
	9.000	Pump.Flow	1.000 [ml/min]	
		Pump.%B.Value	50.0 [%]	
		Pump.%C.Value	50.0 [%]	
		Pump.%D.Value	0.0 [%]	
	25.000	Pump.Flow	1.000 [ml/min]	

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	Pump.%B.Value	50.0 [%]
	Pump.%C.Value	50.0 [%]
	Pump.%D.Value	0.0 [%]
30.000		
	Pump.Flow	1.000 [ml/min]
	Pump.%B.Value	30.0 [%]
	Pump.%C.Value	70.0 [%]
	Pump.%D.Value	0.0 [%]
Stop Run		
30.000		
	UV.UV_VIS_1.AcqOff	
End		

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Instrument ID : QbD-INST-HPLC-42

Sequence Name : HPLC-42_23-Nov-18_AI

Data Vault : QbD_2018

Sequence Path : Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_AI.seq

Seq. Created By : Swaraj A. Jadhav

Seq. Created On : 23-11-2018 13:46:30

Seq. Last Updated By :

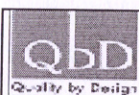
Seq. Last Updated On :

Swaraj A. Jadhav

26-11-2018 14:07:36

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	Finished	23-11-2018 19:11:38	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
2	Blank Solution	Unknown	30.00	1_1	Finished	23-11-2018 19:42:47	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
3	Standard Solution 1	Unknown	30.00	1_2	Finished	23-11-2018 20:13:58	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
4	Standard Solution 2	Unknown	30.00	1_2	Finished	23-11-2018 20:45:04	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
5	Standard Solution 3	Unknown	30.00	1_2	Finished	23-11-2018 21:16:13	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
6	Standard Solution 4	Unknown	30.00	1_2	Finished	23-11-2018 21:47:22	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
7	Standard Solution 5	Unknown	30.00	1_2	Finished	23-11-2018 22:18:31	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
8	Standard Solution 6	Unknown	30.00	1_2	Finished	23-11-2018 22:49:41	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
9	Blank Solution	Unknown	30.00	1_1	Finished	23-11-2018 23:20:51	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
10	Sample Solution	Unknown	30.00	1_3	Finished	23-11-2018 23:52:00	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
11	Blank Solution	Unknown	30.00	1_1	Finished	24-11-2018 00:23:08	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	GP180301	QbD/LC/COL/128
12	Bracketing Standard Solution	Unknown	30.00	1_2	Finished	24-11-2018 00:54:16	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
13	Blank Solution	Unknown	30.00	1_1	Finished	24-11-2018 01:25:25	Ramithiazide Tablet_RS_Damithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
14	Blank Solution	Unknown	30.00	1_1	Finished	24-11-2018 01:56:33	Ramithiazide Tablet_RS_Damithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
15	Blank Solution	Unknown	30.00	1_1	Finished	24-11-2018 02:27:40	Ramithiazide Tablet_RS_Damithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
16	Standard Solution 1	Unknown	30.00	1_2	Finished	24-11-2018 02:58:48	Ramithiazide Tablet_RS_Damithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
17	Standard Solution 2	Unknown	30.00	1_2	Finished	24-11-2018 03:29:59	Ramithiazide Tablet_RS_Damithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
18	Standard Solution 3	Unknown	30.00	1_2	Finished	24-11-2018 04:01:06	Ramithiazide Tablet_RS_Damithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
19	Standard Solution 4	Unknown	30.00	1_2	Finished	24-11-2018 04:32:15	Ramithiazide Tablet_RS_Damithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
20	Standard Solution 5	Unknown	30.00	1_2	Finished	24-11-2018 05:03:26	Ramithiazide Tablet_RS_Damithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
21	Standard Solution 6	Unknown	30.00	1_2	Finished	24-11-2018 05:34:31	Ramithiazide Tablet_RS_Damithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
22	Blank Solution	Unknown	30.00	1_1	Finished	24-11-2018 06:05:40	Ramithiazide Tablet_RS_Damithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
23	Sample Solution	Unknown	30.00	1_3	Finished	24-11-2018 06:36:48	Ramithiazide Tablet_RS_Damithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
24	Blank Solution	Unknown	30.00	1_1	Finished	24-11-2018 07:07:56	Ramithiazide Tablet_RS_Damithiazide Tablets_RS_Pf			D2404181993	GP180301	QbD/LC/COL/128
25	Bracketing Standard Solution	Unknown	30.00	1_2	Finished	24-11-2018 07:39:05	Ramithiazide Tablet_RS_Damithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
26	Wash	Unknown	30.00	1_1	Finished	24-11-2018 08:09:52	Wash method_HPLC 42	amithiazide Tablets_RS_Pf		N/A	N/A	QbD/LC/COL/128
27	Shut	Unknown	30.00	1_1	Finished	24-11-2018 09:10:26	Shut method_HPLC 42	amithiazide Tablets_RS_Pf		N/A	N/A	QbD/LC/COL/128

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



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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_23-Nov-18_A1.seq		
Processing Method Created By :	Swaraj A. Jadhav	Processing Method Last Updated By :	Swaraj A. Jadhav
Processing Method Created On :	23-11-2018 13:59:59	Processing Method Last Updated On :	24-11-2018 12:49:50

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	65.0000 [Signal*min]	Any	All Channels
0.000	Valley To Valley	On	Any	All Channels
0.000	Minimum Width	0.800 [min]	Any	All Channels
3.500	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
7.500	Peak Slice	0.80 [s]	Any	All Channels
8.500	Peak Slice	0.05 [s]	Any	All Channels
10.500	Peak Slice	2.00 [s]	Any	All Channels
11.188	Minimum Height	10000.000 [Signal]	Any	All Channels
13.500	Minimum Height	0.000 [Signal]	Any	All Channels
14.000	Valley To Valley	Off	Any	All Channels
14.712	Minimum Height	1000.000 [Signal]	Any	All Channels
15.648	Valley To Valley	On	Any	All Channels
26.000	Maximum Width	0.200 [min]	Any	All Channels

Peak Table

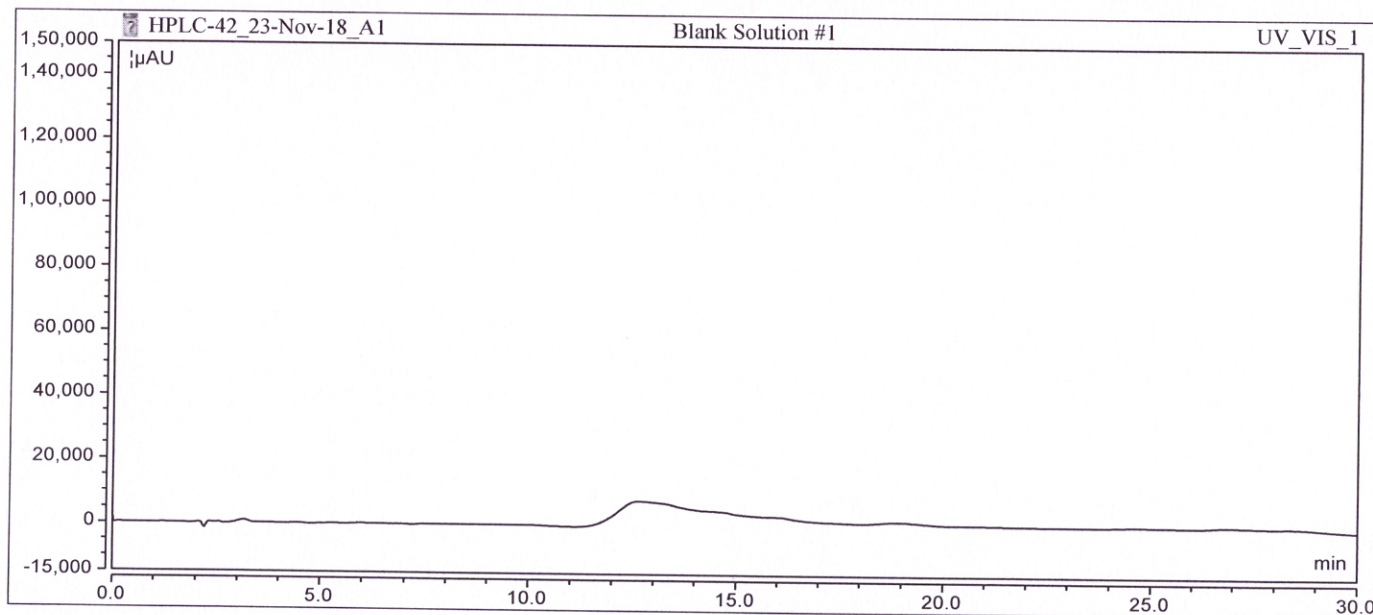
No.	Peak Name	Ret. Time
1	Unknown	3.800
2	Placebo	4.663
3	Hydrochlorothiazide	5.193
4	Unknown	7.915
5	Unknown	10.655
6	Placebo	11.197
7	Impurity E	14.480
8	Ramipril	16.355
9	Unknown	18.125
10	Unknown	18.920
11	Impurity D	24.390

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 :-	1	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_N
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	21-11-2018 15:24:45
Vial Position :-	1_1	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 :-	24-11-2018 12:49:50
Injection Date & Time :-	23-11-2018 19:11:38	Experiment Name:-	Robustness Inc pH 2.6 of Buffer
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_A1.seq		

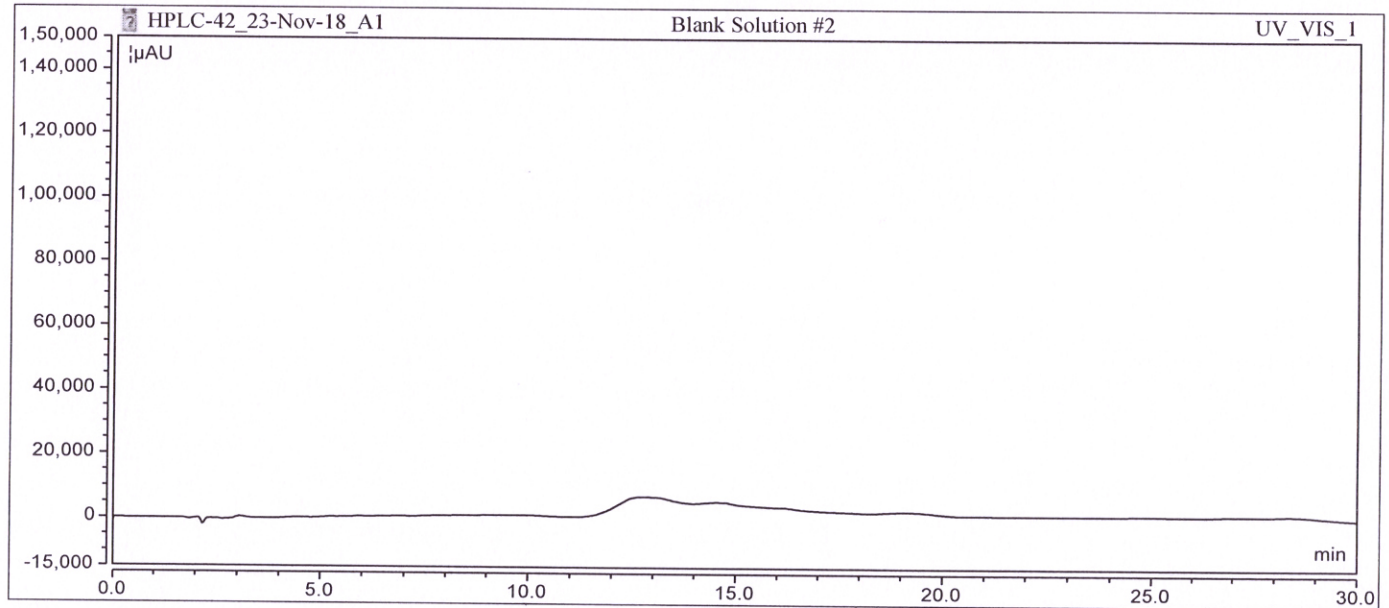


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	2	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Maresh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	21-11-2018 15:24:45
Vial Position :-	1_1	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 :-	24-11-2018 12:49:50
Injection Date & Time :-	23-11-2018 19:42:47	Experiment Name:-	Robustness Inc pH 2.6 of Buffer
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_A1.seq		

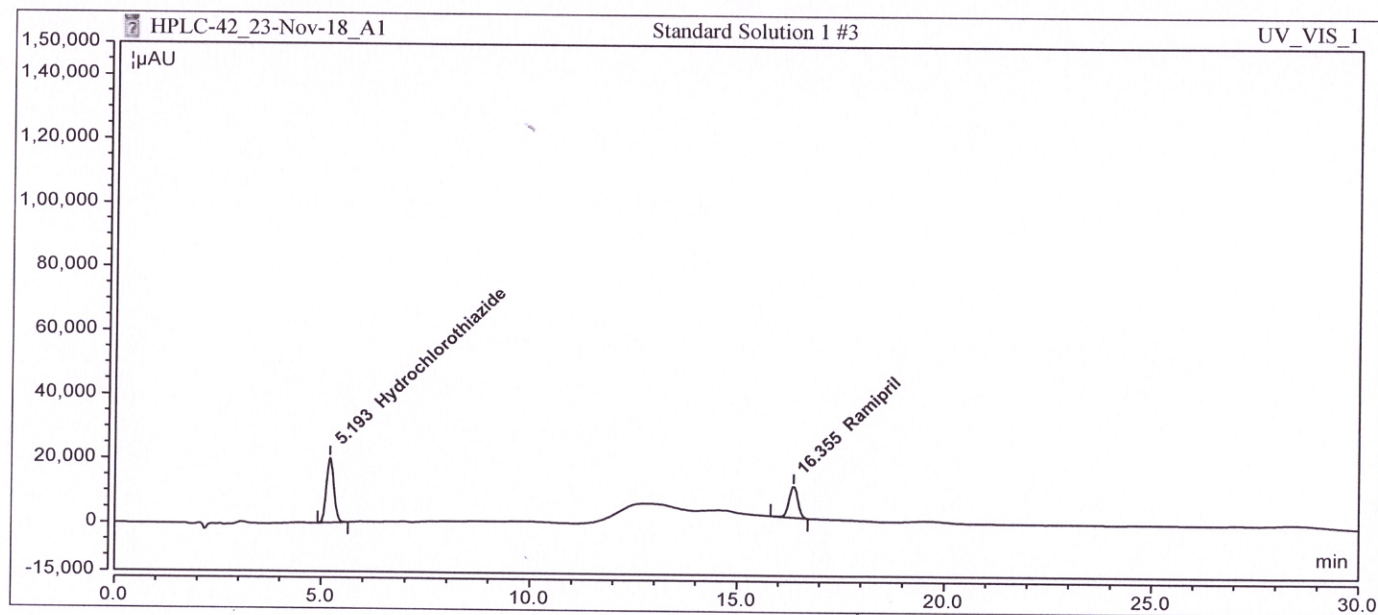


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Standard Solution 1	AR. No. :-	D2404181993
Sample Number :-	3	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	21-11-2018 15:24:45
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 :-	24-11-2018 12:49:50
Injection Date & Time :-	23-11-2018 20:13:58	Experiment Name:-	Robustness Inc pH 2.6 of Buffer
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_A1.seq		

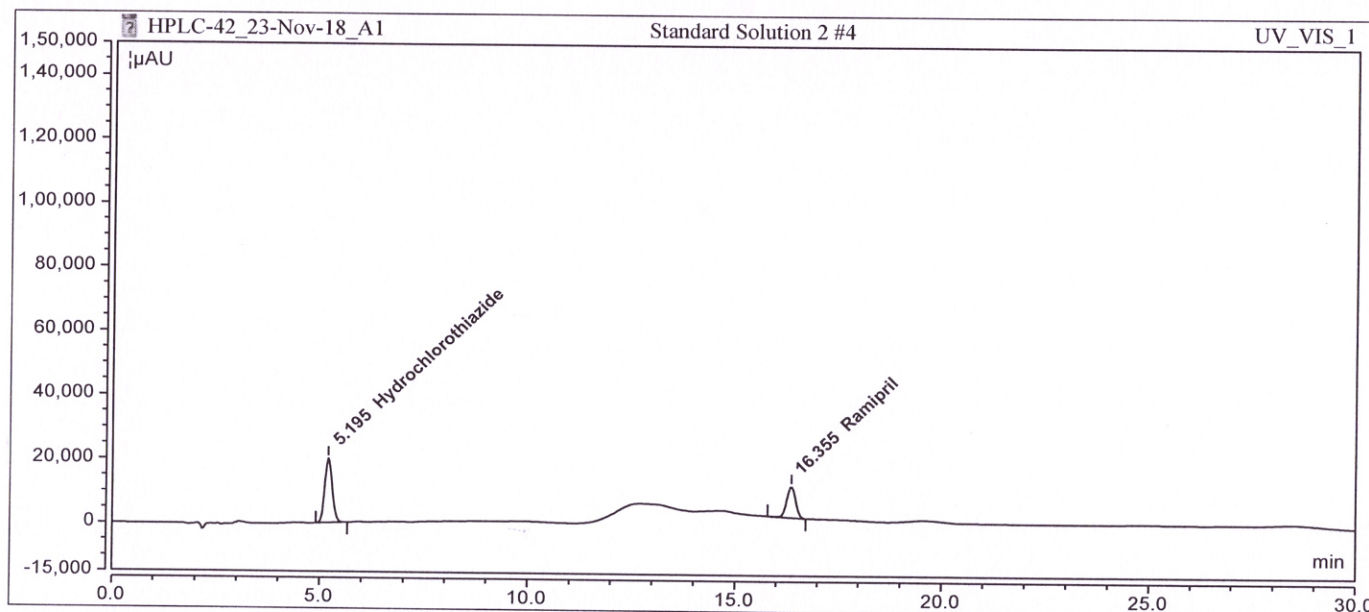


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.193	4152.844	63.08	1.14	3951	FALSE	n.a.
2	Ramipril	16.355	2431.052	36.92	1.01	27872	FALSE	30.90



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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_N
Sample Type :-	Unknown	Instrument Method Created By :-	Maresh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	21-11-2018 15:24:45
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 :-	24-11-2018 12:49:50
Injection Date & Time :-	23-11-2018 20:45:04	Experiment Name:-	Robustness Inc pH 2.6 of Buffer
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_A1.seq		

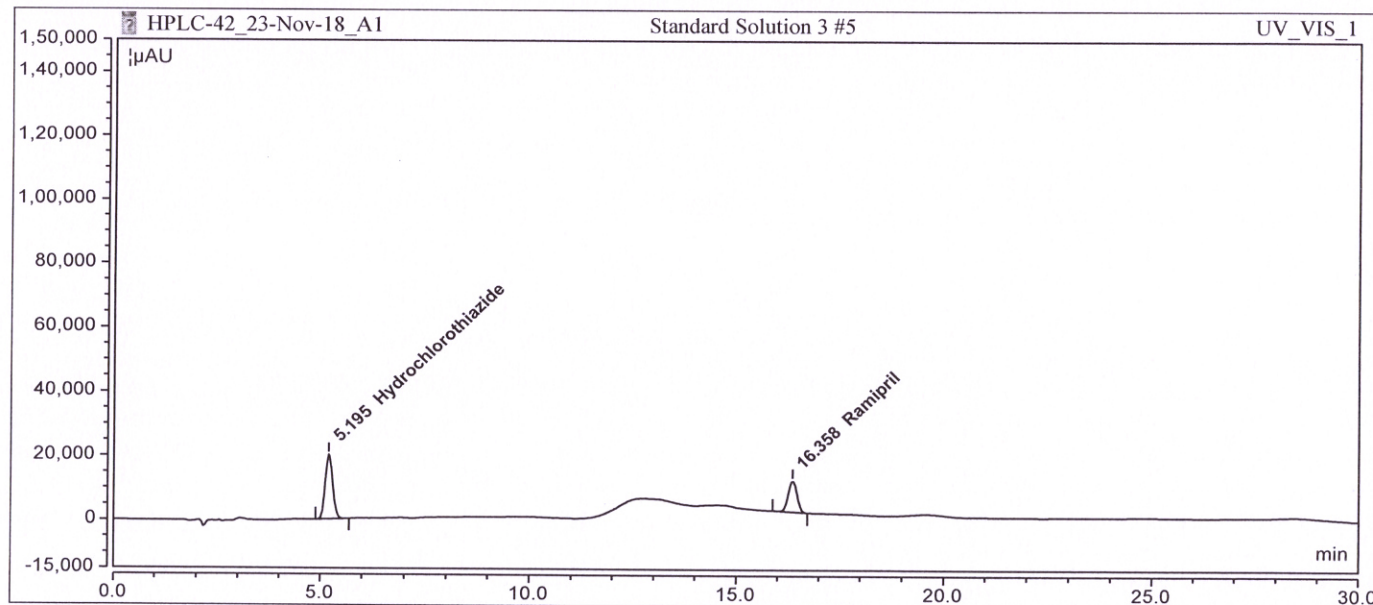


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.195	4154.945	63.07	1.14	3930	FALSE	n.a.
2	Ramipril	16.355	2432.580	36.93	1.01	27777	FALSE	30.83



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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_N
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	21-11-2018 15:24:45
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 :-	24-11-2018 12:49:50
Injection Date & Time :-	23-11-2018 21:16:13	Experiment Name:-	Robustness Inc pH 2.6 of Buffer
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_A1.seq		

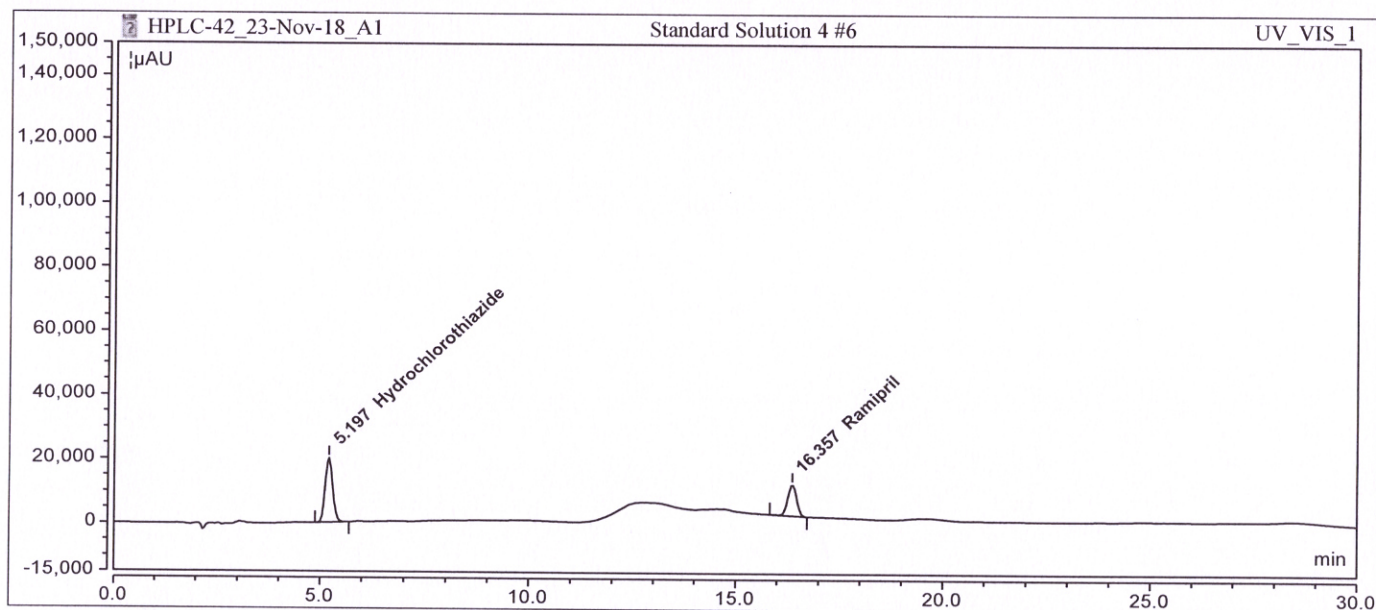


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.195	4160.028	63.30	1.14	3933	FALSE	n.a.
2	Ramipril	16.358	2411.660	36.70	1.02	27689	FALSE	30.81



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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_M
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	21-11-2018 15:24:45
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 :-	24-11-2018 12:49:50
Injection Date & Time :-	23-11-2018 21:47:22	Experiment Name:-	Robustness Inc pH 2.6 of Buffer
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_A1.seq		

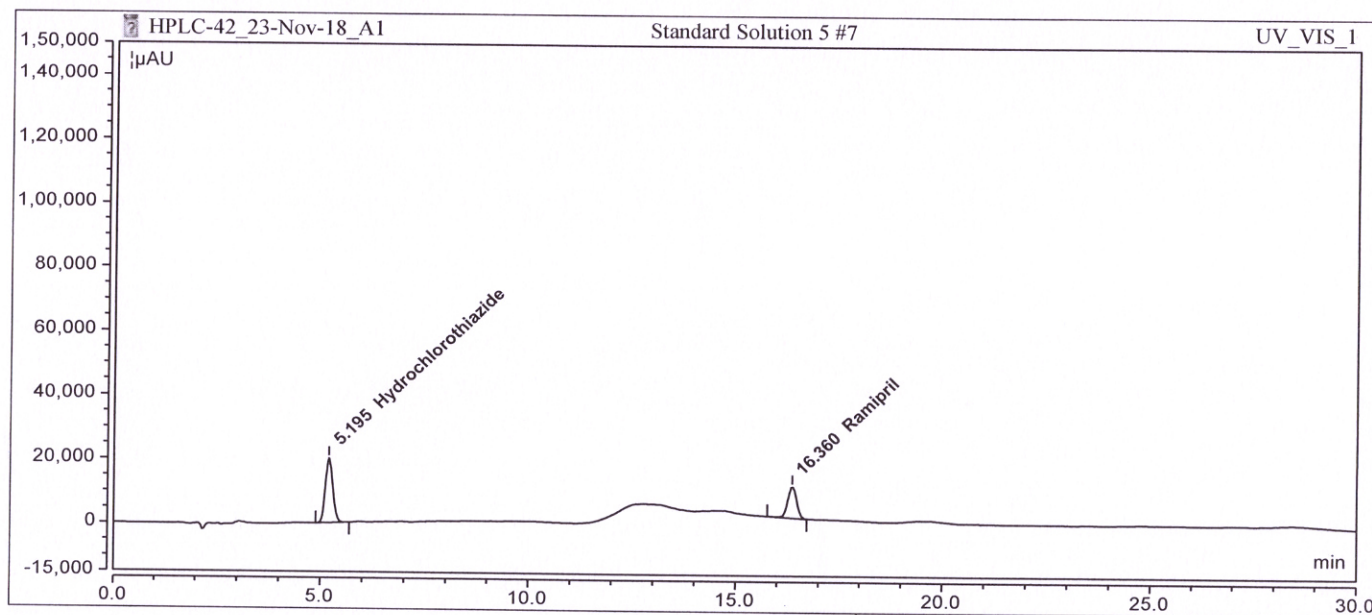


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.197	4157.492	63.22	1.14	3924	FALSE	n.a.
2	Ramipril	16.357	2418.235	36.78	1.03	27675	FALSE	30.78



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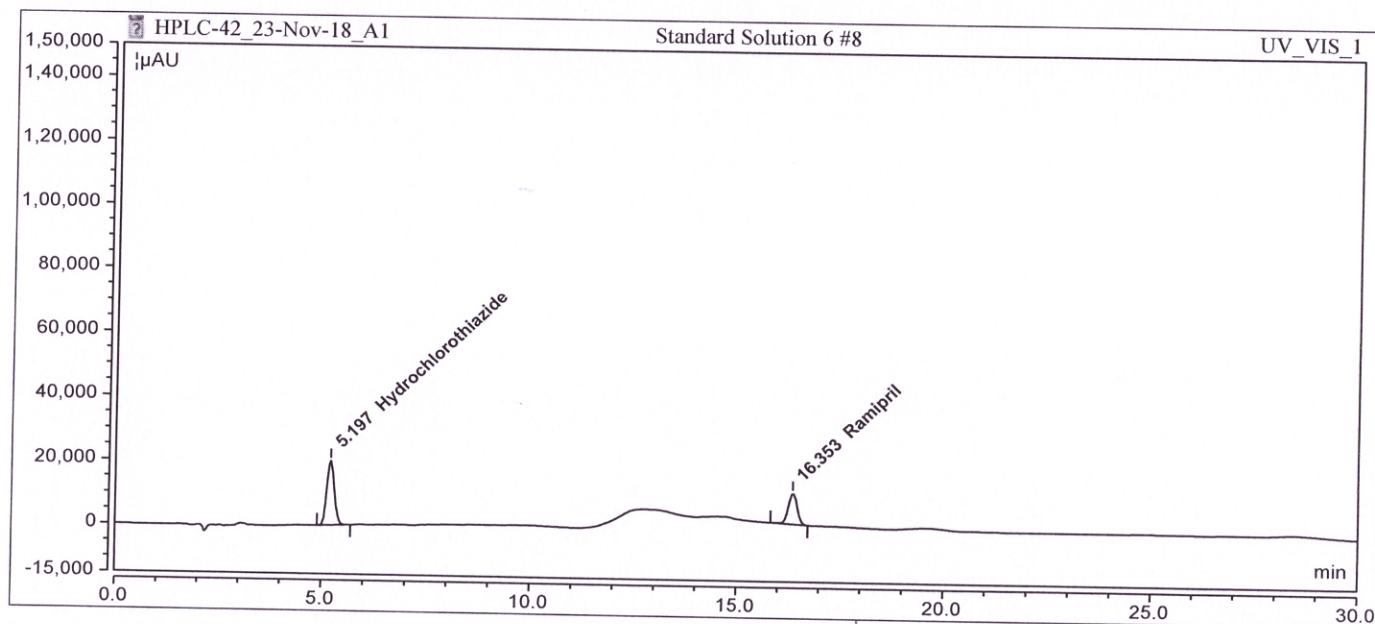
Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Standard Solution 5	AR. No. :-	D2404181993
Sample Number :-	7	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	21-11-2018 15:24:45
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 :-	24-11-2018 12:49:50
Injection Date & Time :-	23-11-2018 22:18:31	Experiment Name:-	Robustness Inc pH 2.6 of Buffer
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_A1.seq		



Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.195	4159.978	63.15	1.14	3920	FALSE	n.a.
2	Ramipril	16.360	2427.938	36.85	1.02	27555	FALSE	30.75


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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_M
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	21-11-2018 15:24:45
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 :-	24-11-2018 12:49:50
Injection Date & Time :-	23-11-2018 22:49:41	Experiment Name:-	Robustness Inc pH 2.6 of Buffer
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_A1.seq		

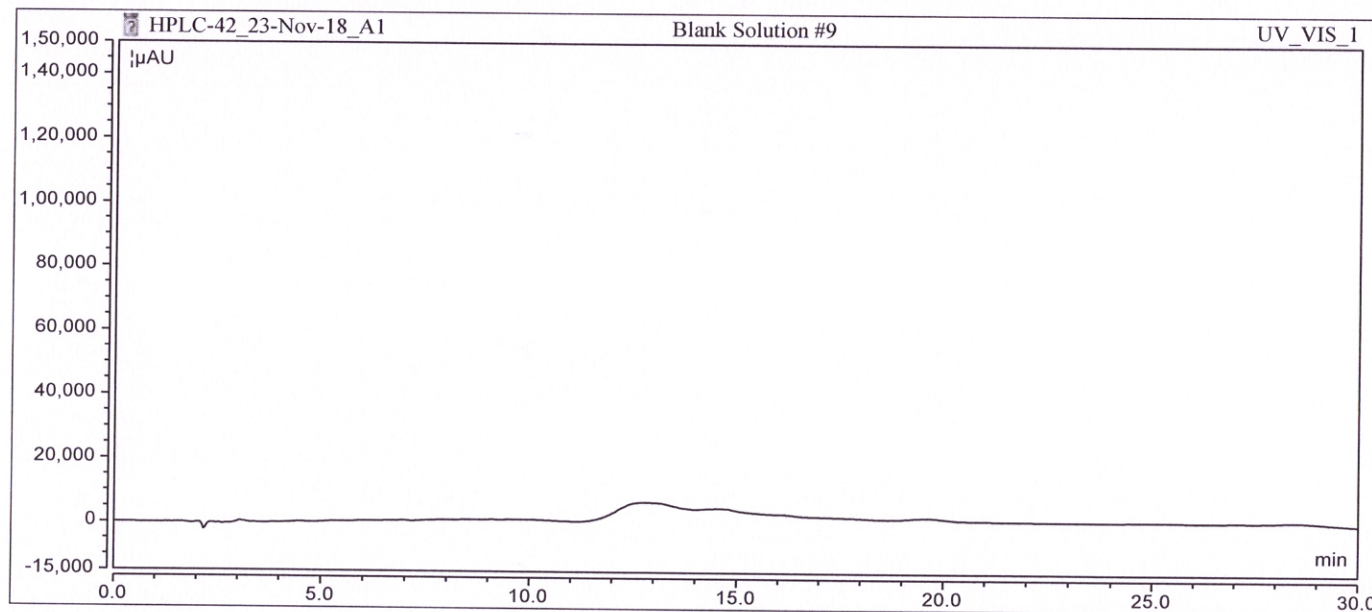


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.197	4155.044	63.07	1.14	3933	FALSE	n.a.
2	Ramipril	16.353	2433.274	36.93	1.02	27414	FALSE	30.71



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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_M
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	21-11-2018 15:24:45
Vial Position :-	1_1	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 :-	24-11-2018 12:49:50
Injection Date & Time :-	23-11-2018 23:20:51	Experiment Name:-	Robustness Inc pH 2.6 of Buffer
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_A1.seq		

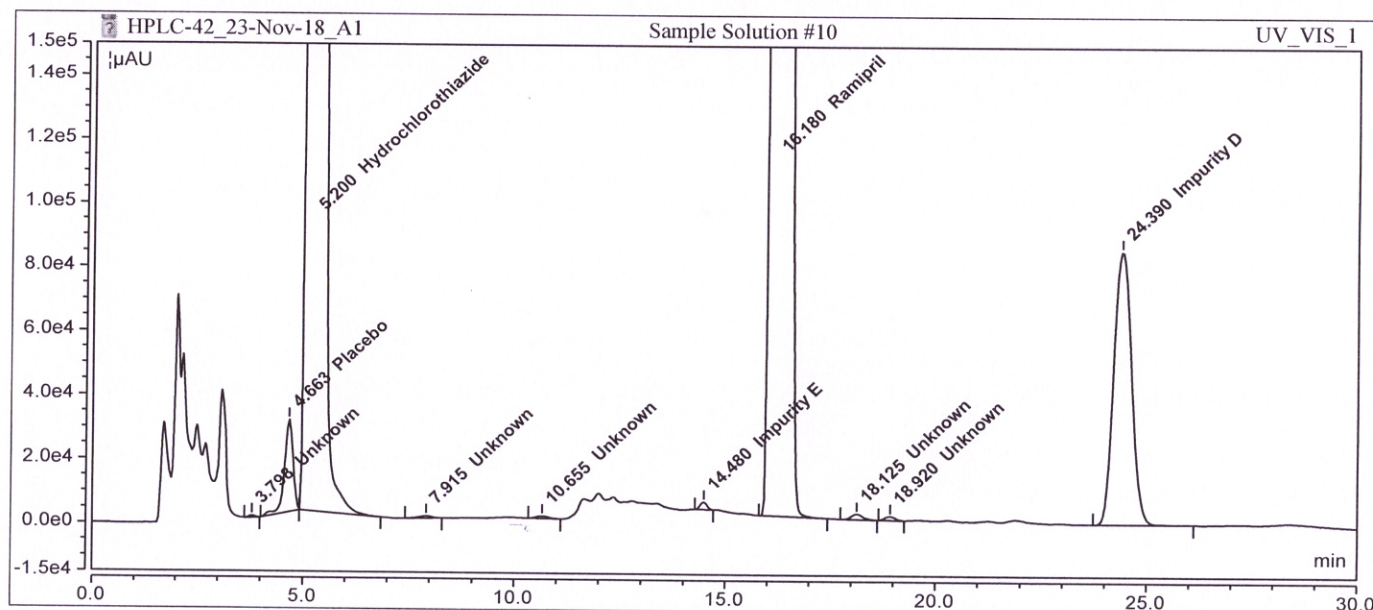


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	GP180301
Sample Name :-	Sample Solution	AR. No. :-	D2404181993
Sample Number :-	10	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	21-11-2018 15:24:45
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 :-	24-11-2018 12:49:50
Injection Date & Time :-	23-11-2018 23:52:00	Experiment Name:-	Robustness Inc pH 2.6 of Buffer
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_A1.seq		

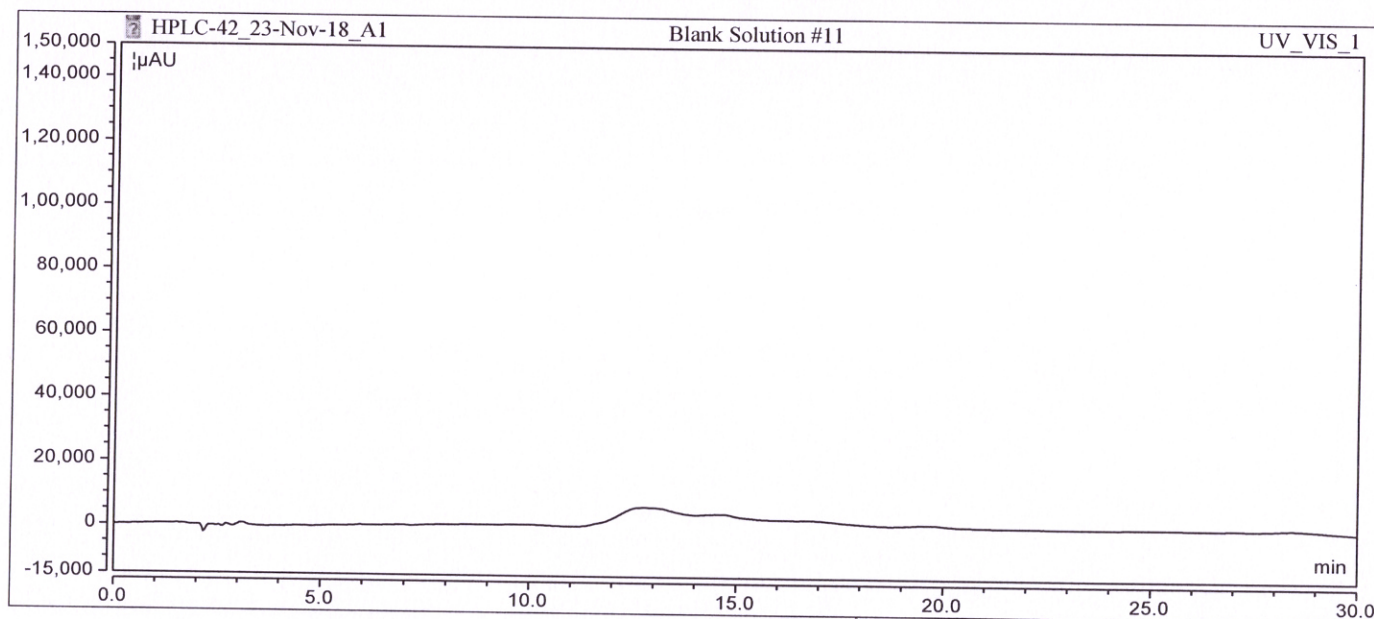


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Unknown	3.798	109.613	0.01	1.02	2631	FALSE	n.a.
2	Placebo	4.663	6712.972	0.39	0.89	2767	FALSE	2.66
3	Hydrochlorothiazide	5.200	983127.310	56.99	1.23	2114	FALSE	1.33
4	Unknown	7.915	252.183	0.01	0.85	2976	FALSE	5.26
5	Unknown	10.655	255.362	0.01	1.12	5209	FALSE	4.68
6	Impurity E	14.480	429.737	0.02	1.03	39232	FALSE	8.66
7	Ramipril	16.180	691507.663	40.09	1.42	13882	FALSE	4.04
8	Unknown	18.125	539.292	0.03	1.34	23092	FALSE	3.79
9	Unknown	18.920	346.487	0.02	1.06	28751	FALSE	1.72
10	Impurity D	24.390	41714.920	2.42	1.13	16774	FALSE	9.12



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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_N
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	21-11-2018 15:24:45
Vial Position :-	1_1	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 :-	24-11-2018 12:49:50
Injection Date & Time :-	24-11-2018 00:23:08	Experiment Name:-	Robustness Inc pH 2.6 of Buffer
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_A1.seq		

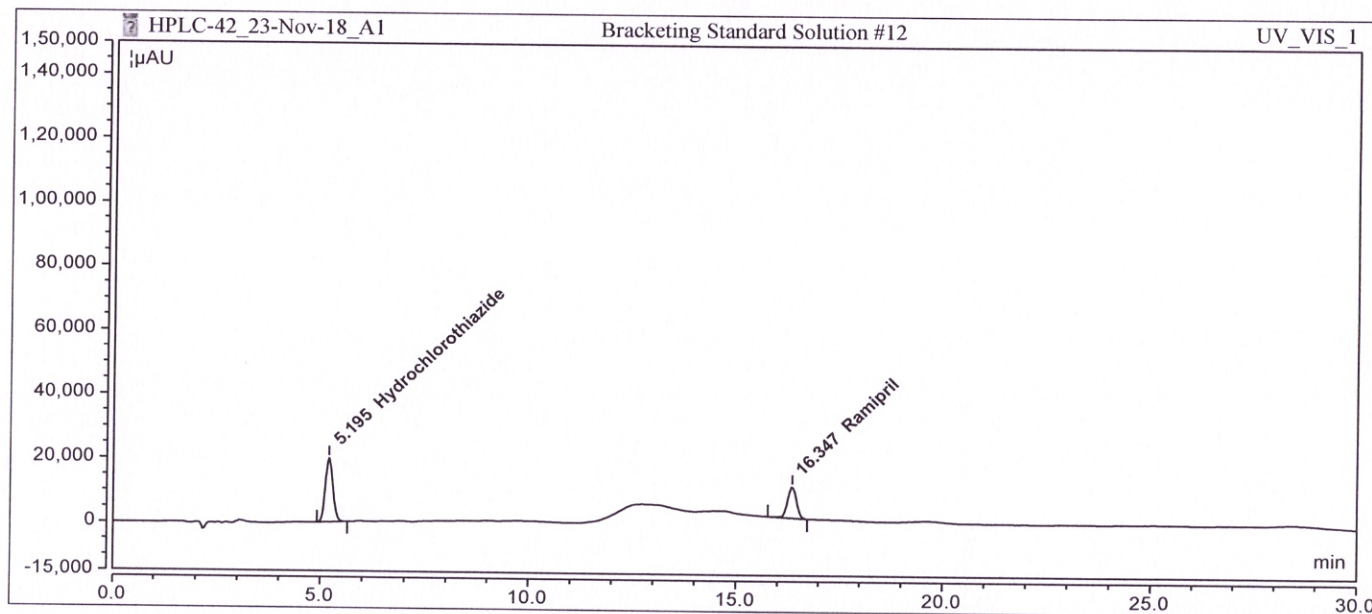


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

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_M
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	21-11-2018 15:24:45
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 :-	24-11-2018 12:49:50
Injection Date & Time :-	24-11-2018 00:54:16	Experiment Name:-	Robustness Inc pH 2.6 of Buffer
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_A1.seq		

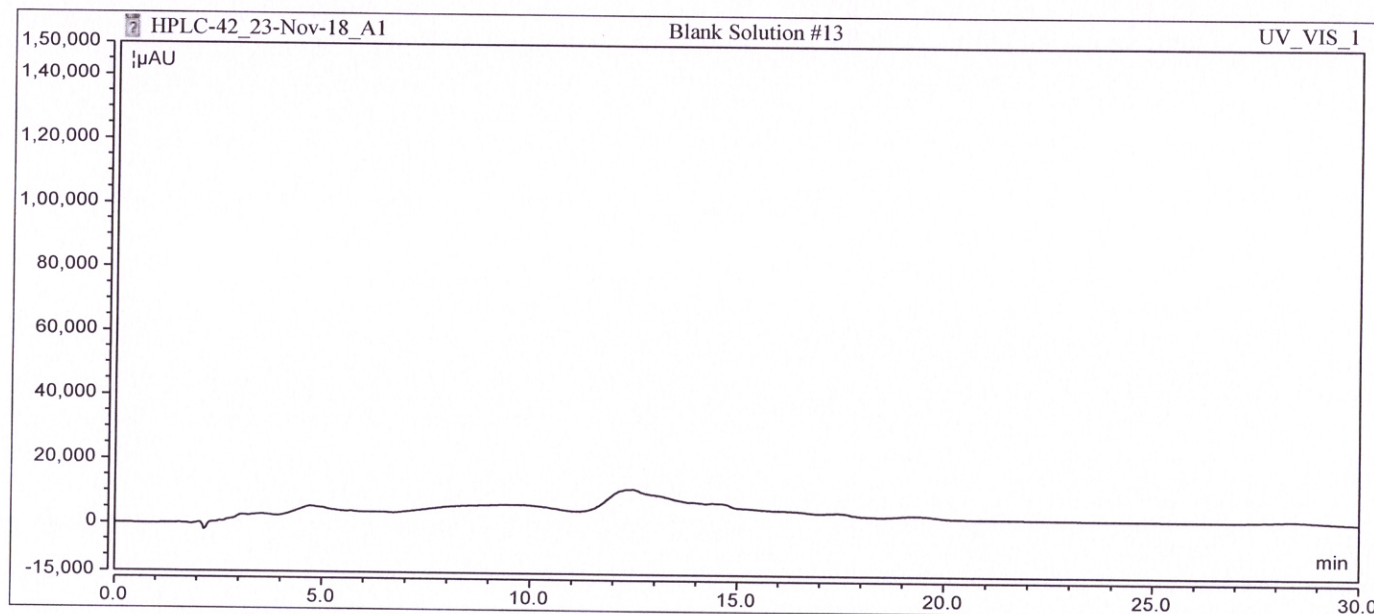


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.195	4152.590	63.11	1.14	3882	FALSE	n.a.
2	Ramipril	16.347	2427.447	36.89	1.02	27132	FALSE	30.53



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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 :-	23-11-2018 13:51:55
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 14:07:36
Injection Date & Time :-	24-11-2018 01:25:25	Experiment Name:-	Robustness Dec pH 2.4 of Buffer
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_A1.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-42_23-Nov-18_A1.seq		
Processing Method Created By :	Swaraj A. Jadhav	Processing Method Last Updated By :	Swaraj A. Jadhav
Processing Method Created On :	23-11-2018 13:59:59	Processing Method Last Updated On :	24-11-2018 12:49:50

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	60.0000 [Signal*min]	Any	All Channels
0.000	Valley To Valley	On	Any	All Channels
0.000	Minimum Width	0.600 [min]	Any	All Channels
0.000	Minimum Height	200.000 [Signal]	Any	All Channels
3.500	Minimum Width	0.000 [min]	Any	All Channels
5.000	Minimum Width	0.250 [min]	Any	All Channels
5.000	Minimum Height	0.000 [Signal]	Any	All Channels
5.500	Minimum Width	0.000 [min]	Any	All Channels
7.500	Peak Slice	0.80 [s]	Any	All Channels
8.500	Peak Slice	0.05 [s]	Any	All Channels
10.500	Peak Slice	2.00 [s]	Any	All Channels
11.188	Minimum Height	10000.000 [Signal]	Any	All Channels
13.500	Minimum Height	0.000 [Signal]	Any	All Channels
14.712	Minimum Height	1200.000 [Signal]	Any	All Channels
18.800	Tailing Sensitivity Factor	1.000	Any	All Channels
19.207	Tailing Sensitivity Factor	Off	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	4.647
3	Hydrochlorothiazide	5.170
4	Unknown	7.867
5	Unknown	10.533
6	Placebo	11.197
7	Impurity E	14.463
8	Impurity A	14.915
9	Ramipril	16.270
10	Unknown	18.045
11	Unknown	18.832
12	Impurity D	24.213

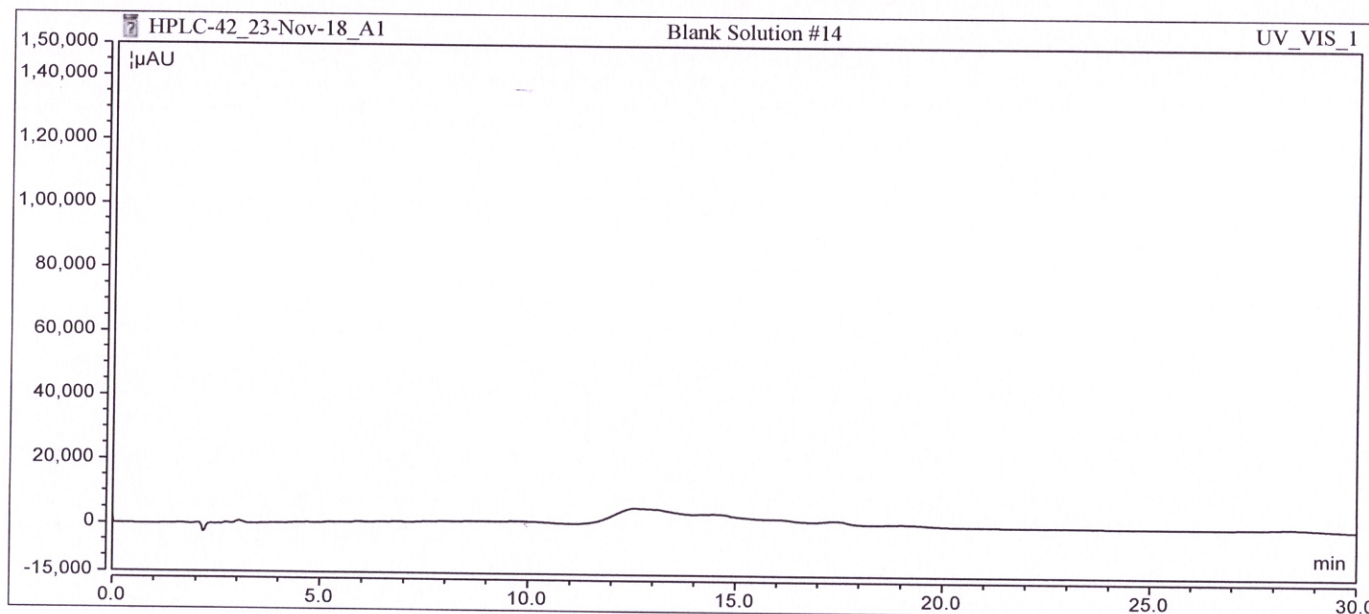
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Processing Method



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	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 :-	23-11-2018 13:51:55
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 :-	24-11-2018 12:49:50
Injection Date & Time :-	24-11-2018 01:56:33	Experiment Name:-	Robustness Dec pH 2.4 of Buffer
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_A1.seq		

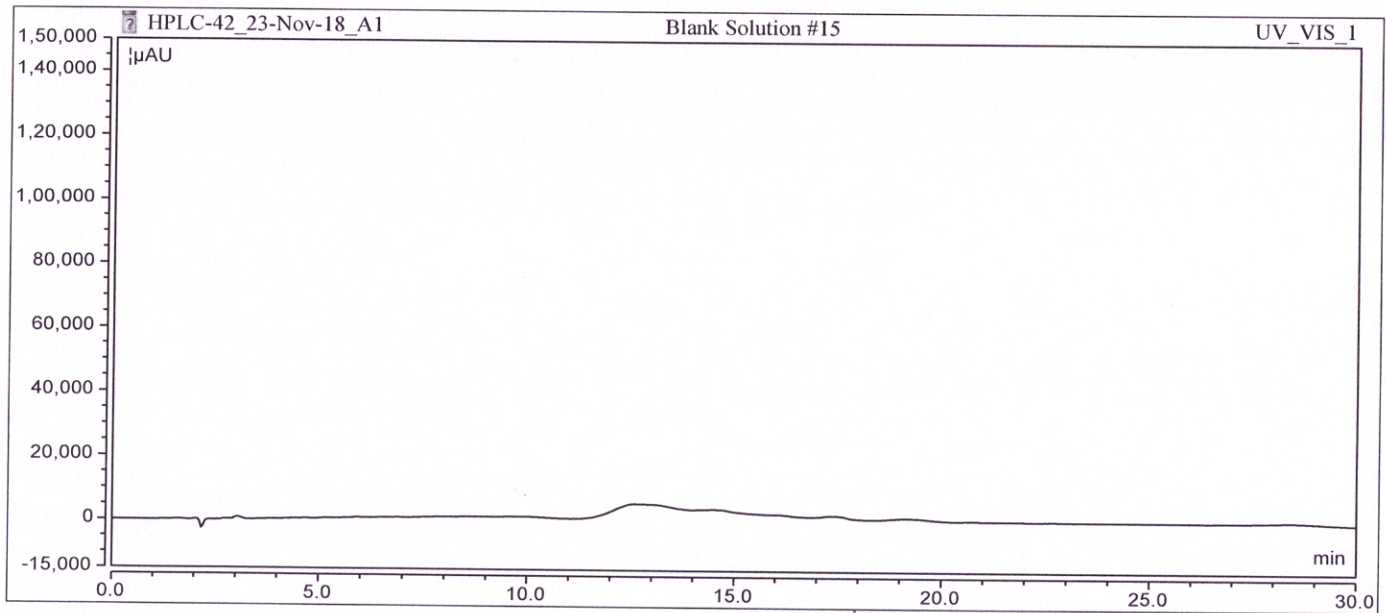


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	15	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_D
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	23-11-2018 13:51:55
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 :-	24-11-2018 12:49:50
Injection Date & Time :-	24-11-2018 02:27:40	Experiment Name:-	Robustness Dec pH 2.4 of Buffer
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_A1.seq		

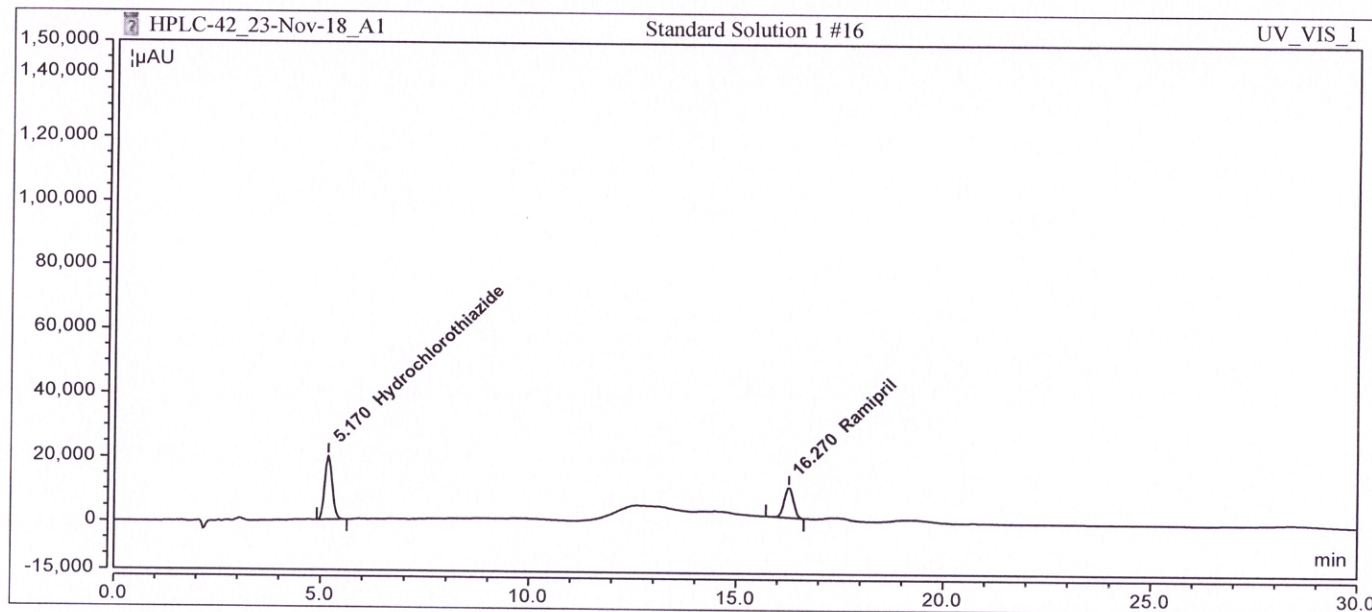


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Standard Solution 1	AR. No. :-	D2404181993
Sample Number :-	16	Instrument 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 :-	23-11-2018 13:51:55
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 :-	24-11-2018 12:49:50
Injection Date & Time :-	24-11-2018 02:58:48	Experiment Name:-	Robustness Dec pH 2.4 of Buffer
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_A1.seq		

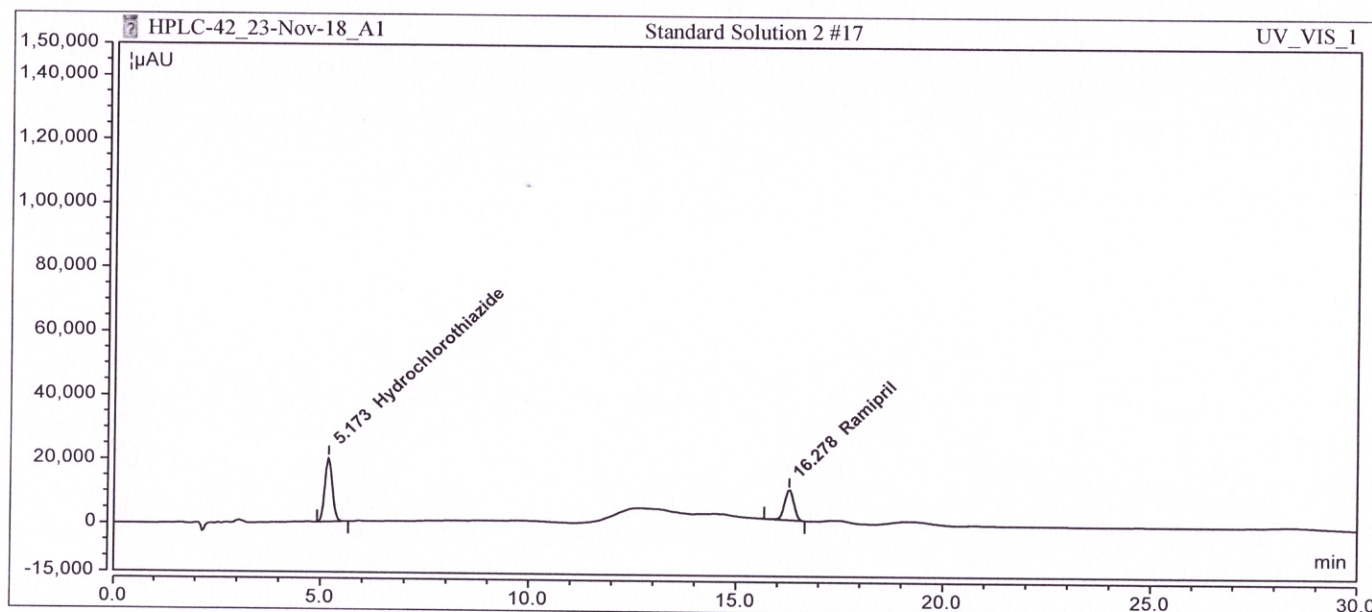


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.170	4143.884	62.85	1.15	3859	FALSE	n.a.
2	Ramipril	16.270	2448.932	37.15	1.02	24778	FALSE	29.74



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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 :-	23-11-2018 13:51:55
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 :-	24-11-2018 12:49:50
Injection Date & Time :-	24-11-2018 03:29:59	Experiment Name:-	Robustness Dec pH 2.4 of Buffer
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_A1.seq		

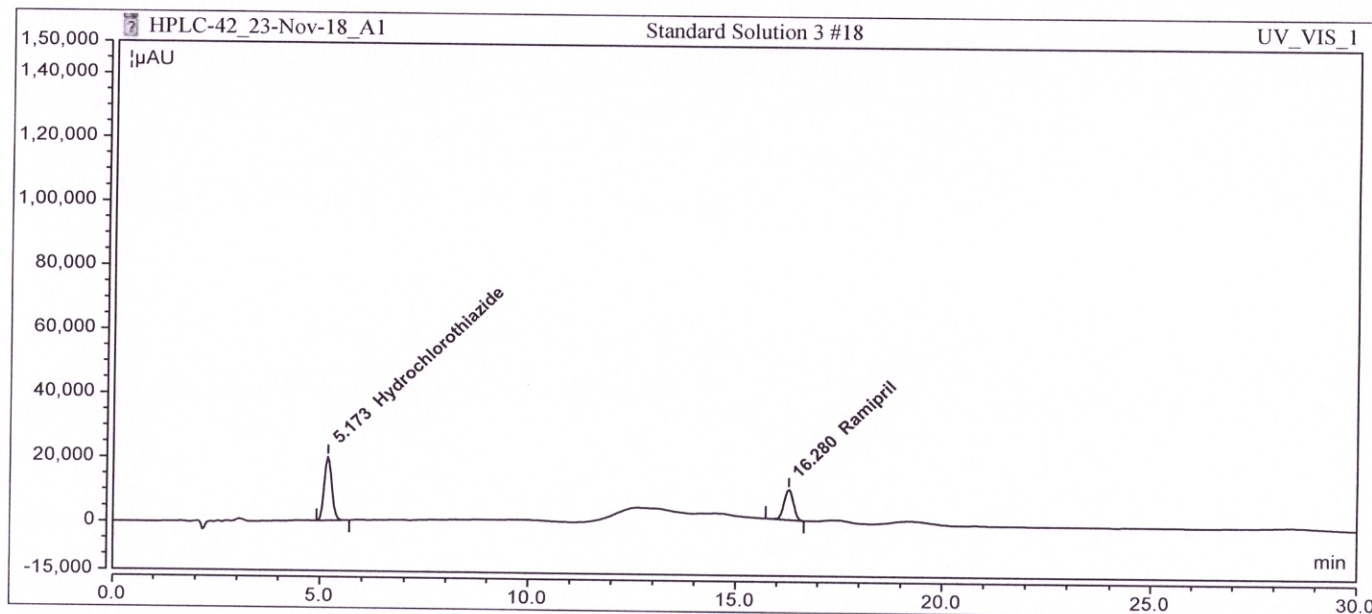


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.173	4150.561	62.82	1.15	3877	FALSE	n.a.
2	Ramipril	16.278	2456.892	37.18	1.01	24561	FALSE	29.70



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

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 :-	23-11-2018 13:51:55
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 :-	24-11-2018 12:49:50
Injection Date & Time :-	24-11-2018 04:01:06	Experiment Name:-	Robustness Dec pH 2.4 of Buffer
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_A1.seq		

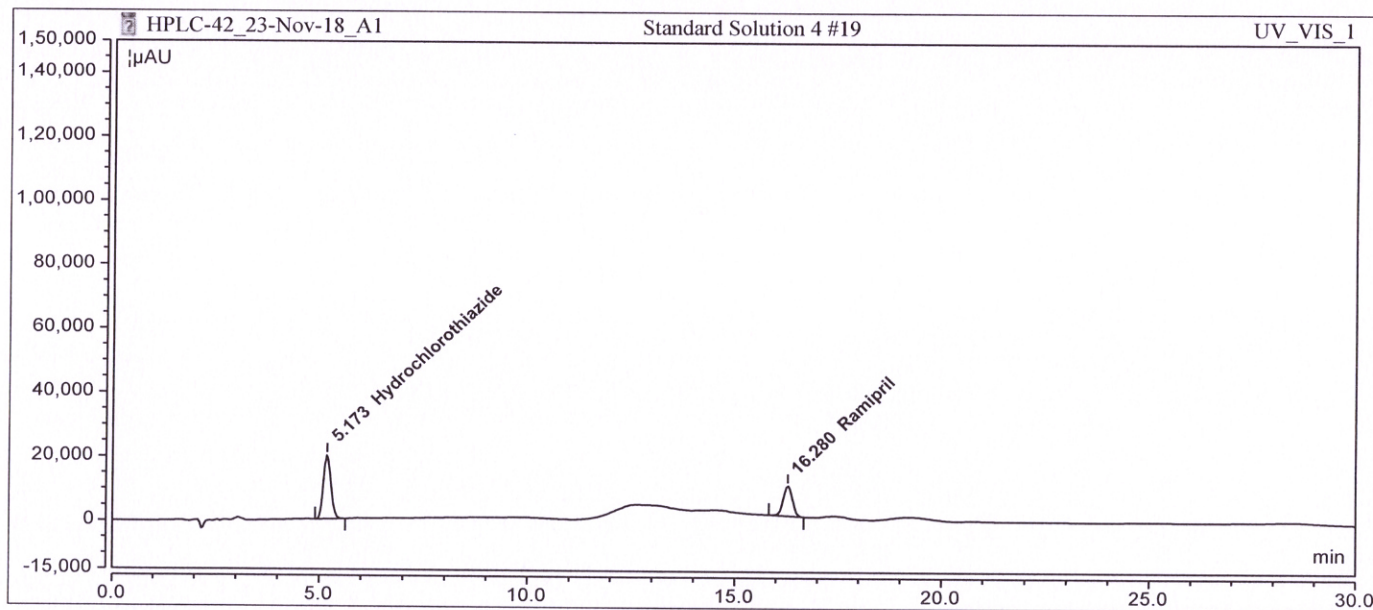


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.173	4150.489	62.85	1.15	3851	FALSE	n.a.
2	Ramipril	16.280	2453.597	37.15	1.01	24543	FALSE	29.65



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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 :-	23-11-2018 13:51:55
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 :-	24-11-2018 12:49:50
Injection Date & Time :-	24-11-2018 04:32:15	Experiment Name:-	Robustness Dec pH 2.4 of Buffer
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_A1.seq		

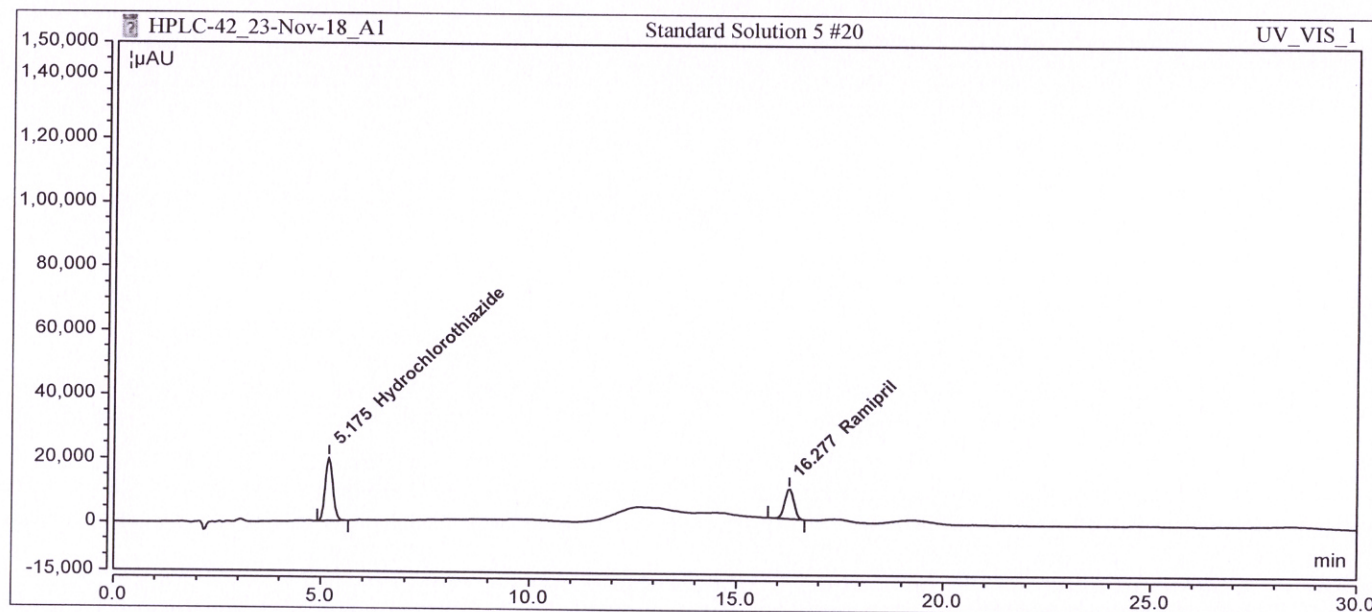


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.173	4139.976	62.92	1.15	3842	FALSE	n.a.
2	Ramipril	16.280	2439.340	37.08	1.02	24542	FALSE	29.64



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

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 :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	23-11-2018 13:51:55
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 :-	24-11-2018 12:49:50
Injection Date & Time :-	24-11-2018 05:03:26	Experiment Name:-	Robustness Dec pH 2.4 of Buffer
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_A1.seq		

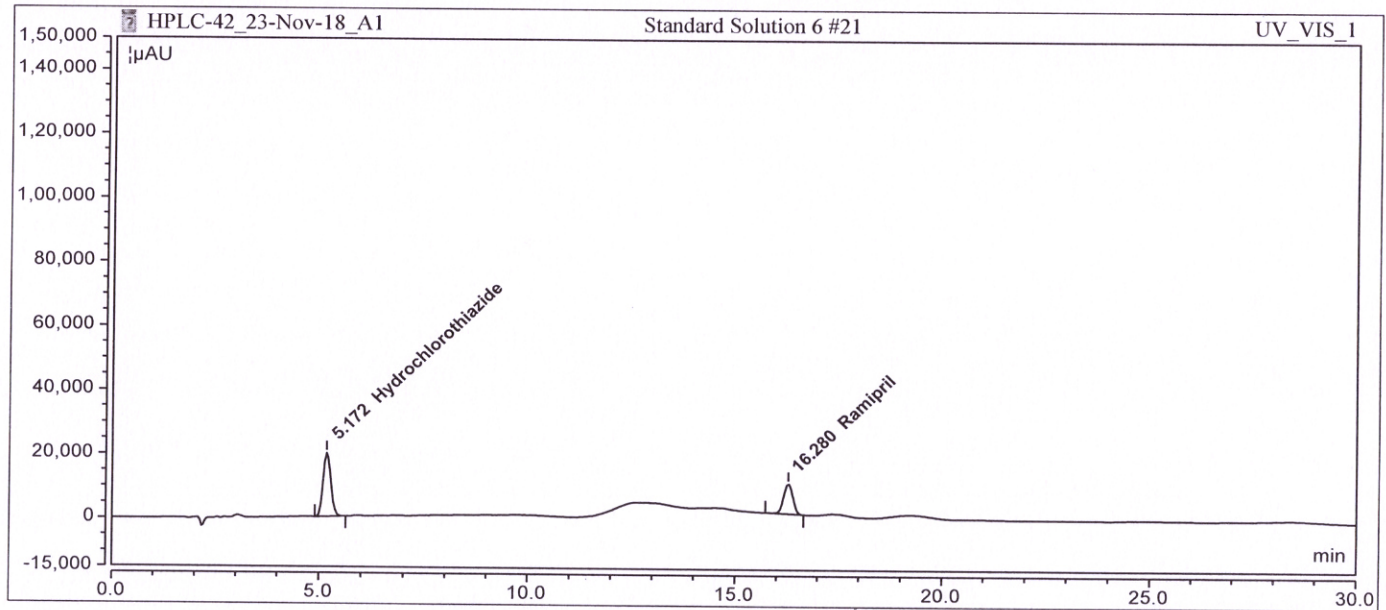


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.175	4140.506	62.92	1.15	3847	FALSE	n.a.
2	Ramipril	16.277	2440.273	37.08	1.02	24455	FALSE	29.60



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

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 :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	23-11-2018 13:51:55
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 :-	24-11-2018 12:49:50
Injection Date & Time :-	24-11-2018 05:34:31	Experiment Name:-	Robustness Dec pH 2.4 of Buffer
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_A1.seq		

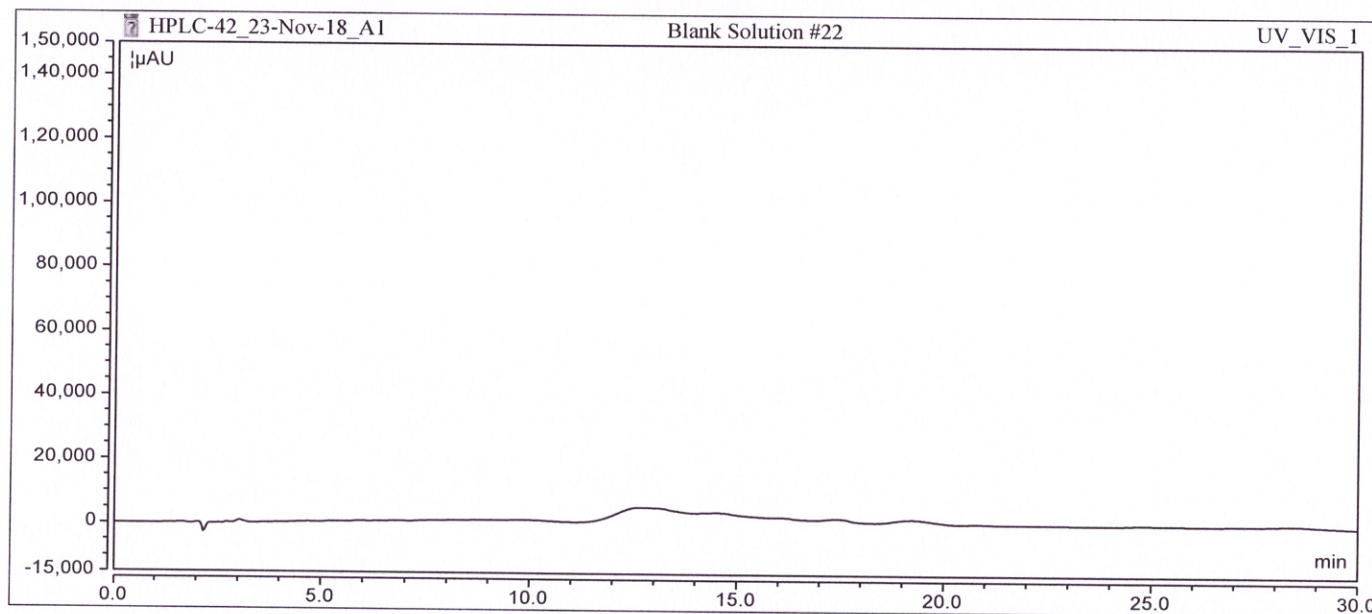


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.172	4141.728	62.81	1.15	3834	FALSE	n.a.
2	Ramipril	16.280	2452.475	37.19	1.02	24362	FALSE	29.57



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

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 :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	23-11-2018 13:51:55
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 :-	24-11-2018 12:49:50
Injection Date & Time :-	24-11-2018 06:05:40	Experiment Name:-	Robustness Dec pH 2.4 of Buffer
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_A1.seq		

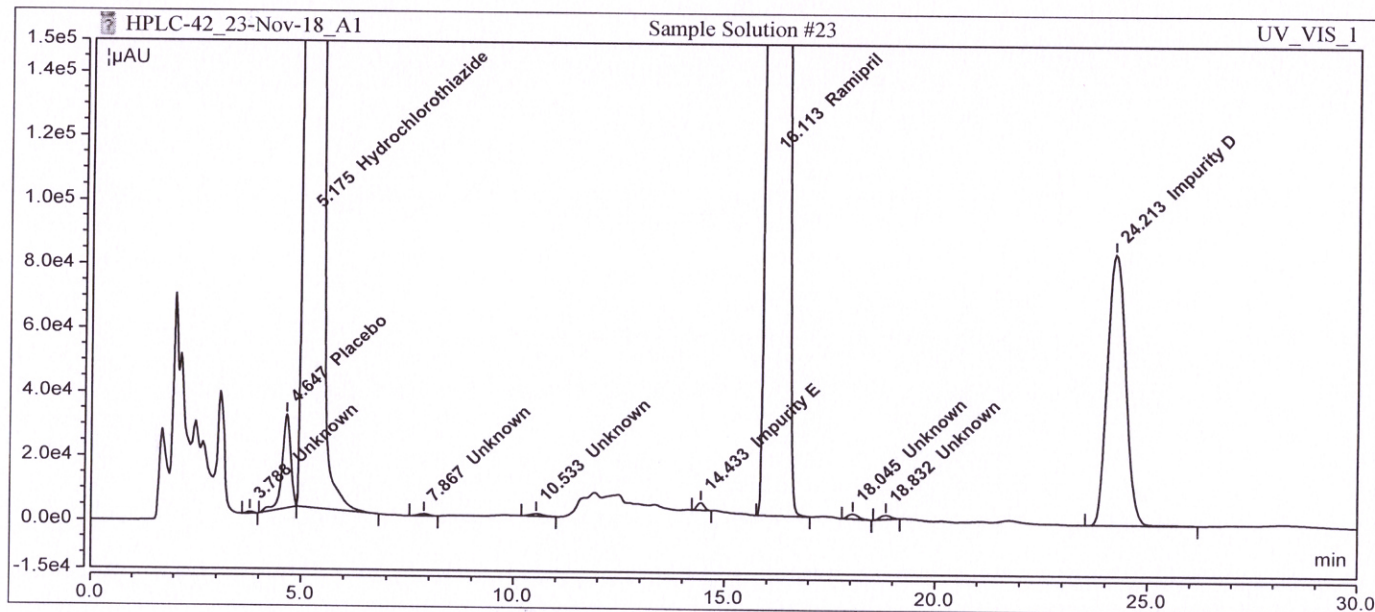


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	GP180301
Sample Name :-	Sample Solution	AR. No. :-	D2404181993
Sample Number :-	23	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 :-	23-11-2018 13:51:55
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 :-	24-11-2018 12:49:50
Injection Date & Time :-	24-11-2018 06:36:48	Experiment Name:-	Robustness Dec pH 2.4 of Buffer
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_A1.seq		

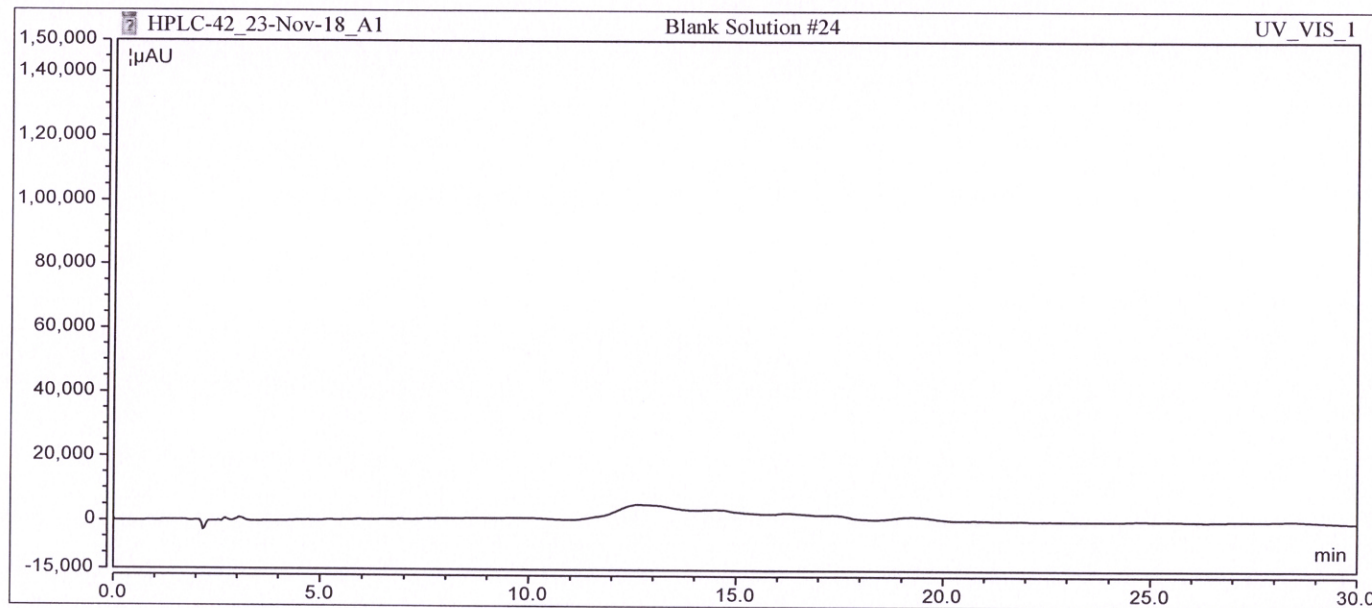


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Unknown	3.788	100.110	0.01	0.99	2544	FALSE	n.a.
2	Placebo	4.647	6854.846	0.39	0.87	2758	FALSE	2.62
3	Hydrochlorothiazide	5.175	987771.490	56.72	1.26	2066	FALSE	1.31
4	Unknown	7.867	182.150	0.01	0.96	5239	FALSE	6.05
5	Unknown	10.533	262.802	0.02	1.16	6046	FALSE	5.46
6	Impurity E	14.433	436.411	0.03	1.04	36871	FALSE	9.26
7	Ramipril	16.113	702976.744	40.37	1.38	13211	FALSE	3.90
8	Unknown	18.045	462.374	0.03	1.32	25140	FALSE	3.80
9	Unknown	18.832	390.607	0.02	1.08	25583	FALSE	1.70
10	Impurity D	24.213	41982.260	2.41	1.18	16247	FALSE	8.75



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 :-	23-11-2018 13:51:55
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 :-	24-11-2018 12:49:50
Injection Date & Time :-	24-11-2018 07:07:56	Experiment Name:-	Robustness Dec pH 2.4 of Buffer
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_A1.seq		

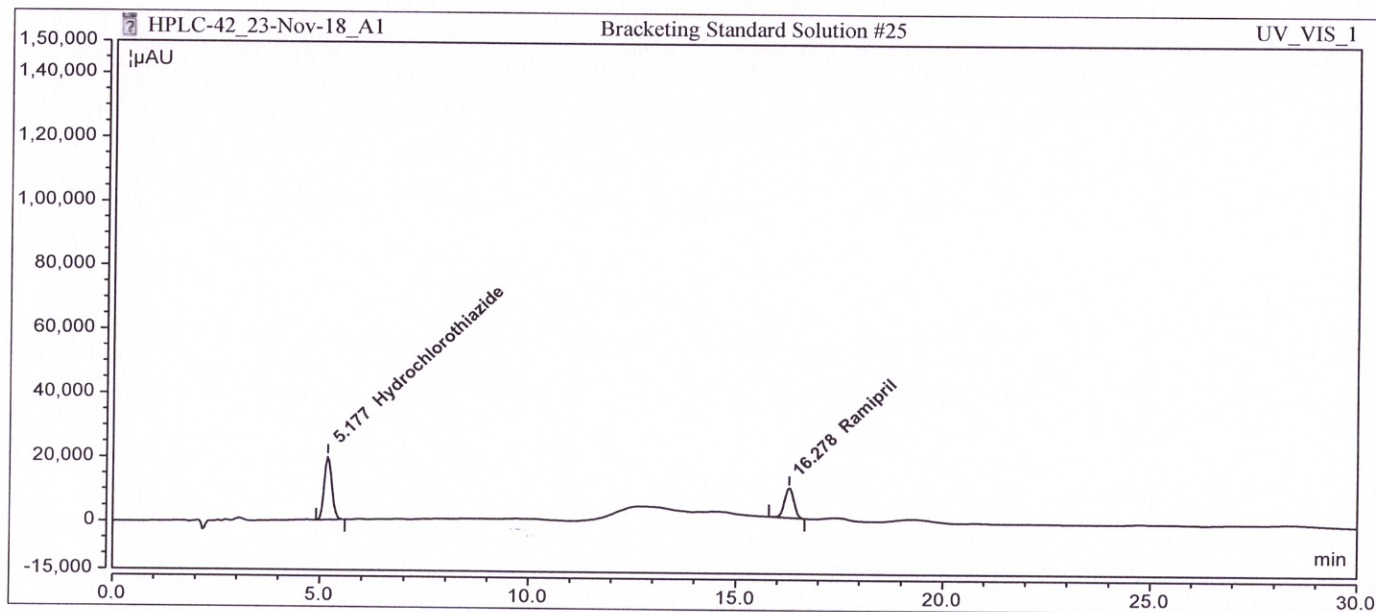


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Bracketing Standard Solution	AR. No. :-	D2404181993
Sample Number :-	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 :-	23-11-2018 13:51:55
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 :-	24-11-2018 12:49:50
Injection Date & Time :-	24-11-2018 07:39:05	Experiment Name:-	Robustness Dec pH 2.4 of Buffer
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_A1.seq		



Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.177	4135.650	62.94	1.15	3831	FALSE	n.a.
2	Ramipril	16.278	2435.348	37.06	1.03	24272	FALSE	29.51



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	metod created	Batch No. :-	N/A
Sample Name :-	Wash	AR. No. :-	N/A
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 :-	24-11-2018 12:49:50
Injection Date & Time :-	24-11-2018 08:09:52	Experiment Name:-	N/A
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_A1.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. :-	N/A
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_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 :-	24-11-2018 12:49:50
Injection Date & Time :-	24-11-2018 09:10:26	Experiment Name:-	N/A
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_23-Nov-18_A1.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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