

RAW DATA OF

(LINEARITY)

Analysis Date: 17-Nov-18

Product Name:	Ramiprilide Tablets
Manufacturer:	QBD Research & Development Lab. Pvt. Ltd.
AR No.:	DA44181159
Batch No.:	GT180301
Parameter:	Linearity for Ramipril Impurity E
Lab No./Page No.:	697/133

Preparation of standard solution for Ramipril	Weight of standard (mg)	Diluted (mL)	Concentration (ppm)	Purity (As it Basis)
	25.49	25.0	2.04	99.64
	2.0	100.0		
	2.0	20.0		

Ramipril				
Injection No.	Retention Time	Peak Area	Retention Time	Area of IIS Standard
1	16.133	2091.691	16.087	2074.657
2	16.150	2087.062		
3	16.167	2082.432		
4	16.184	2077.548		
5	16.140	2089.524		
6	16.130	2076.230		
Average	16.141	2086.132	16.133	1979.416
%RSD	16.141	11.118	0.018	11.118
%RSD	0.85	6.77	0.14	0.53

System Suitability		
%RSD of Area	0.57	NMT 5.0%

Preparation of standard solution for Hydrochlorothiazide	Weight of standard (mg)	Diluted (mL)	Concentration (ppm)	Purity (As it Basis)
	25.83	25.0	1.58	99.24
	2.5	100.0		
	2.0	20.0		

Hydrochlorothiazide				
Injection No.	Retention Time	Peak Area	Retention Time	Area of IIS Standard
1	5.163	4392.226	5.107	4340.857
2	5.173	4397.939		
3	5.183	4393.523		
4	5.190	4392.629		
5	5.183	4386.128		
6	5.180	4389.416		
Average	5.180	4387.075	5.178	4386.238
%RSD	0.072	2.668	0.078	16.9234
%RSD	0.14	0.17	0.15	0.39

System Suitability		
%RSD of Area	0.17	NMT 5.0%

Preparation of Linearity Standard Solution for Ramipril Imp E	Batch No.	Weight of standard (mg)	Diluted (mL)	Concentration (ppm)
	SP-427-484	5.93	20.0	251.49
		1.0	1.0	

Level (%)	mL of Linearity Stock Solution	Diluted to volume (mL)	Actual Concentration (ppm)	Area of sample	Mean Area
LQ	0.6	25.0	6.04	284.601	298.975
				300.922	
50	1.0	25.0	10.06	520.246	538.168
				520.000	
80	1.6	25.0	16.10	836.407	838.060
				839.639	
100	2.0	25.0	20.12	1047.135	1050.973
				1047.142	
120	2.4	25.0	24.14	1245.242	1274.700
				1248.187	
150	3.0	25.0	30.18	1520.256	1615.688
				1520.244	
				1617.723	

Linearity of Ramipril Impurity E



Slope	54.38
y-intercept	-21.27
Correlation coefficient	0.9999
R ²	0.9999

Done by: 19-Nov-18
Date:Checked by: 19-Nov-18
Date:Slope of Analyte
Slope of Impurity

Analysis Date: 17-Nov-18

Product Name:	Ramipril Tablets
Label claim (mg):	10 mg And 25 mg
SR No.:	D2404181153
Batch No.:	GP180901
Material:	Impurity for Ramipril
LRD No./Page No.:	07/11/18

Preparation of standard solution for Ramipril	Weight of standard (mg)	Diluted (mL)	Concentration (ppm)	Purity (As is Basis)
	25.49	25.0	2.84	99.64
	2.0	100.0		
	2.0	20.0		

Injection No.	Retention Time	Peak Area	Retention Time	Area of this Standard
1	16.133	2091.691	16.087	2076.057
2	16.133	2091.692		
3	16.147	2077.548		
4	16.147	2077.548		
5	16.140	2089.534		
Average	16.130	2076.330		
SD	0.004	2089.312		
%RSD	0.05	16.133		
		2076.418		
		11.188		
		0.53		

%RSD of Area	System Suitability	0.57	NMT 5.0%
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Preparation of standard solution for Hydrochloride	Weight of standard (mg)	Diluted (mL)	Concentration (ppm)	Purity (As is Basis)
	25.83	25.0	2.58	99.24
	2.5	100.0		
	2.0	20.0		

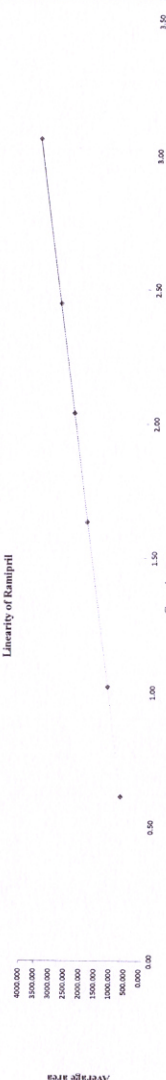
Injection No.	Retention Time	Peak Area	Retention Time	Area of this Standard
1	5.163	4302.226	5.187	4340.257
2	5.173	4297.689		
3	5.180	4292.673		
4	5.180	4306.128		
5	5.183	4295.416		
Average	5.180	4299.388		
SD	0.007	4305.486		
%RSD	0.14	5.178		
		0.0078		
		1.12		
		16.924		
		8.39		

%RSD of Area	System Suitability	0.17	NMT 5.0%
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Preparation of Linearity Standard Solution for Ramipril	Weight of standard (mg)	Diluted (mL)	Concentration (ppm)
	25.49	25.0	20.39
	10.0	25.0	
	10.0	25.0	

Level (%)	mL of Linearity Stock Solution	Diluted to volume (mL)	Actual Concentration (ppm)	Area of sample	Mean Area
LOQ	0.75	25.0	0.61	631.627	671.024
				654.499	
50	1.25	25.0	1.02	1181.781	1151.944
				1134.445	
80	2.00	25.0	1.63	1918.460	1907.225
				1890.667	
100	2.50	25.0	2.04	1971.607	2383.395
				2366.662	
120	3.00	25.0	2.45	2376.389	2865.842
				2483.472	
140	3.75	25.0	3.06	2842.809	3607.607
				3632.881	
				3593.575	
				3596.385	

Linearity of Ramipril



Slope	1199.91
y-intercept	-43.54
Correlation coefficient	1.0000
RRF	1.00

Slope of Analyte
Slope of Impurity

RRF =

Date by: 19-Nov-18
Date:

Checked by: *Ram*
Date:

Product Name: Ramipril Tablets

Label claim (mg): 10 mg And 25 mg

Lot No.: 19-00000000

Batch No.: 19-00000000

Parameter: Linearity for Ramipril Impurity A

Lab No./Page No.: 6977123

Analysis Date: 17-Nov-18

Preparation of standard solution for Ramipril	Weight of standard (mg)	Diluted (mL)	Concentration (ppm)	Purity (As is Basis)
	25.49	25.0	2.64	99.44
	2.0	20.0		

Injection No.	Retention Time	Peak Area	Retention Time	Area of Ref. Standard
1	16.147	2087.602	16.147	2079.075
2	16.150	2087.602		
3	16.147	2059.705		
4	16.147	2077.444		
5	16.147	2077.444		
6	16.130	2076.330		
Average	16.141	2088.312	16.133	2079.418
SD	0.0083	11.9012	0.018	11.188
%RSD	0.05	0.57	0.14	0.53

%RSD of Area	System Suitability
0.57	NMT 5.0%

Preparation of standard solution for Hydrochlorothiazide	Weight of standard (mg)	Diluted (mL)	Concentration (ppm)	Purity (As is Basis)
	25.81	25.0	2.58	99.24
	2.0	20.0		

Injection No.	Retention Time	Peak Area	Retention Time	Area of Ref. Standard
1	5.163	4302.226	5.167	4340.157
2	5.173	4297.689		
3	5.173	4297.689		
4	5.180	4297.679		
5	5.183	4306.128		
6	5.180	4297.416		
Average	5.175	4299.388	5.178	4285.348
SD	0.017	10.474	0.017	10.474
%RSD	0.14	0.17	0.15	0.39

%RSD of Area	System Suitability
0.17	NMT 5.0%

Preparation of Linearity Standard Solution for Ramipril Imp A	Batch No.	Weight of standard (mg)	Diluted (mL)	Concentration (ppm)
	SP-423-164	4.81	25.0	246.50
		1.0	1.0	

Level (%)	mL of Linearity Stock Solution	Diluted to volume (mL)	Actual Concentration (ppm)	Area of sample	Mean Area
LOQ	0.6	25.0	5.77	5953.617	5985.763
				5921.314	
50	1.0	25.0	9.62	10103.214	10107.600
				10145.670	
				10104.716	
80	1.6	25.0	15.39	15982.488	15988.854
				15981.949	
				15984.124	
100	2.0	25.0	19.24	20661.336	20653.914
				20619.508	
120	2.4	25.0	23.09	23979.960	23995.800
				23979.960	
				24010.189	
150	3.0	25.0	28.46	30264.148	30284.844
				30260.129	
				30300.275	

Linearity of Ramipril Impurity A



Slope	1847.310
y-intercept	-63.410
Correlation coefficient	0.9999
R ²	1.15

R² =

Checked by: Balu
Date: 19-Nov-18

Done by: SP-423-164
Date: 19-Nov-18

Analytical Date: 17-Nov-18

Product Name:	Ramipril Tablets
Label claim (mg):	10 mg, 25 mg, 50 mg
Lot No.:	D244411193
Batch No.:	GP180301
Tested by:	Dr. Ramipril Impurity D
Lab No./Page No.:	697123

Preparation of standard solution for Ramipril	Weight of standard (mg)	Diluted (mL)	Concentration (ppm)	Purity (As is Basis)
	25.49	25.0	2.04	99.64
	2.0	100.0		
	2.0	20.0		

Injection No.	Retention Time	Peak Area	Retention Time	Area of IIS Standard
1	16.133	2091.691	16.087	2074.057
2	16.133	2091.691		
3	16.147	2095.505		
4	16.147	2077.548		
5	16.140	2089.534		
6	16.140	2089.534		
Average	16.141	2088.122	16.133	2078.418
SD	0.0082	11.9015	0.0218	11.1188
%RSD	0.05	0.57	0.14	0.53

%RSD of Area	System Suitability
6.57	NMT 5.0%

Preparation of standard solution for Hydrochlorothiazide	Weight of standard (mg)	Diluted (mL)	Concentration (ppm)	Purity (As is Basis)
	25.83	25.0	2.58	99.24
	2.5	100.0		
	2.5	20.0		

Injection No.	Retention Time	Peak Area	Retention Time	Area of IIS Standard
1	5.173	4297.459	5.157	4320.377
2	5.173	4297.459		
3	5.177	4308.221		
4	5.180	4292.629		
5	5.180	4292.629		
6	5.180	4289.416		
Average	5.176	4299.885	5.178	4285.238
SD	0.0072	7.4768	0.0078	16.9234
%RSD	0.14	0.17	0.15	0.39

%RSD of Area	System Suitability
6.17	NMT 5.0%

Preparation of Linearity Standard Solution for Ramipril Imp D	Batch No.	Weight of standard (mg)	Diluted (mL)	Concentration (ppm)
	SP-028-152	1.0	10.0	100.0
		1.0	1.0	999.50

Level (%)	mL of Linearity Stock Solution	Diluted to volume (mL)	Actual Concentration (ppm)	Area of sample	Mean Area
LOQ	0.75	25.0	17.99	18113.100	18059.972
50	1.25	25.0	29.98	18084.532	18084.532
80	2.00	25.0	47.96	29912.541	29916.060
100	2.50	25.0	59.95	29917.663	29917.663
120	3.00	25.0	71.94	47776.801	47716.881
150	3.75	25.0	89.93	47762.570	47762.570
				58928.184	58947.361
				58983.775	58983.775
				58983.775	58983.775
				70900.499	70918.114
				70907.075	70907.075
				88910.631	88910.631
				88910.631	88910.631
				88948.005	88923.318

Linearity of Ramipril Impurity D



Slope	982.74
y-intercept	290.19
Correlation coefficient	1.0000
RRF	1.22

Date by: 17-Nov-18
Date:Checked by: *Calu*
Date: 17-Nov-18Slope of Analyte
Slope of Impurity



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Instrument ID : QbD-INST-HPLC-67

Sequence Name : HPLC-67_17-Nov-18_A1

Data Vault : QbD_2018

Sequence Path : Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq

Seq. Created By : Swaraj A. Jadhav

Seq. Last Updated By :

Seq. Created On : 17-11-2018 12:49:53

Seq. Last Updated On

Scheduler

17-11-2018 20:26:17

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	RA1	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
2	Blank Solution	Unknown	30.00	RA1	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
3	Standard Solution 1	Unknown	30.00	RA2	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
4	Standard Solution 2	Unknown	30.00	RA2	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
5	Standard Solution 3	Unknown	30.00	RA2	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
6	Standard Solution 4	Unknown	30.00	RA2	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
7	Standard Solution 5	Unknown	30.00	RA2	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
8	Standard Solution 6	Unknown	30.00	RA2	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
9	Blank Solution	Unknown	30.00	RA1	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
10	LOQ Level 1	Unknown	30.00	RA3	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
11	LOQ Level 2	Unknown	30.00	RA3	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
12	LOQ Level 3	Unknown	30.00	RA3	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
13	50 % Level 1	Unknown	30.00	RA4	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
14	50 % Level 2	Unknown	30.00	RA4	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
15	50 % Level 3	Unknown	30.00	RA4	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
16	80 % Level 1	Unknown	30.00	RA5	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
17	80 % Level 2	Unknown	30.00	RA5	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
18	80 % Level 3	Unknown	30.00	RA5	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
19	100 % Level 1	Unknown	30.00	RA6	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
20	100 % Level 2	Unknown	30.00	RA6	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
21	100 % Level 3	Unknown	30.00	RA6	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
22	120 % Level 1	Unknown	30.00	RA7	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
23	120 % Level 2	Unknown	30.00	RA7	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
24	120 % Level 3	Unknown	30.00	RA7	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
25	150 % Level 1	Unknown	30.00	RA8	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
26	150 % Level 2	Unknown	30.00	RA8	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
27	150 % Level 3	Unknown	30.00	RA8	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
28	Blank Solution	Unknown	30.00	RA1	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128

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

17-Nov-18
28-Nov-18

QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Instrument ID : QbD-INST-HPLC-67										
Sequence Name : HPLC-67_17-Nov-18_A1										
Data Vault : QbD_2018										
Sequence Path : Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq										
29	Bracketing Standard Solution	Unknown	30.00	RA2	Idle	n.a.	67_Ramithiazide Tablet_RS_Pl	D2404181993	N/A	QbD/LC/COL/128
30	Wash	Unknown	30.00	RA1	Idle	n.a.	67_HPLC 67_NewRamithiazide Tablets_RS_Pl	N/A	N/A	QbD/LC/COL/128
31	Shut	Unknown	30.00	RA1	Idle	n.a.	67_HPLC 67_NewRamithiazide Tablets_RS_Pl	N/A	N/A	QbD/LC/COL/128
Seq. Created By : Swaraj A. Jadhav							Seq. Last Updated By : Scheduler			
Seq. Created On : 17-11-2018 12:49:53							Seq. Last Updated On : 17-11-2018 20:26:17			

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

28-Nov-18

28-Nov-18

17-Nov-18



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Instrument ID : QbD-INST-HPLC-67
Sequence Name : HPLC-67_17-Nov-18_A
Data Vault : QbD_2018
Sequence Path : Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A.seq

Seq. Created By : Swaraj A. Jadhav
Seq. Created On : 17-11-2018 12:49:53
Seq. Last Updated By : Swaraj A. Jadhav
Seq. Last Updated On : 17-11-2018 13:45:16

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	RA1	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
2	Blank Solution	Unknown	30.00	RA1	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
3	Standard Solution 1	Unknown	30.00	RA2	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
4	Standard Solution 2	Unknown	30.00	RA2	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
5	Standard Solution 3	Unknown	30.00	RA2	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
6	Standard Solution 4	Unknown	30.00	RA2	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
7	Standard Solution 5	Unknown	30.00	RA2	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
8	Standard Solution 6	Unknown	30.00	RA2	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
9	Blank Solution	Unknown	30.00	RA1	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
10	LOQ Level 1	Unknown	30.00	RA3	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
11	LOQ Level 2	Unknown	30.00	RA3	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
12	LOQ Level 3	Unknown	30.00	RA3	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
13	50 % Level 1	Unknown	30.00	RA4	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
14	50 % Level 2	Unknown	30.00	RA4	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
15	50 % Level 3	Unknown	30.00	RA4	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
16	80 % Level 1	Unknown	30.00	RA5	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
17	80 % Level 2	Unknown	30.00	RA5	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
18	80 % Level 3	Unknown	30.00	RA5	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
19	100 % Level 1	Unknown	30.00	RA6	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
20	100 % Level 2	Unknown	30.00	RA6	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
21	100 % Level 3	Unknown	30.00	RA6	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
22	120 % Level 1	Unknown	30.00	RA7	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
23	120 % Level 2	Unknown	30.00	RA7	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
24	120 % Level 3	Unknown	30.00	RA7	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
25	150 % Level 1	Unknown	30.00	RA8	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
26	150 % Level 2	Unknown	30.00	RA8	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
27	150 % Level 3	Unknown	30.00	RA8	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128
28	Blank Solution	Unknown	30.00	RA1	Idle	n.a.	-67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf			D2404181993	N/A	QbD/LC/COL/128

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

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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Instrument ID : QbD-INST-HPLC-67											
Sequence Name : HPLC-67_17-Nov-18_A											
Data Vault : QbD_2018											
Sequence Path : Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A.seq											
29	Bracketing Standard Solution	Unknown	30.00	RA2	Idle	n.a.	67_Ramithiazide Tablet_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
30	Wash	Unknown	30.00	RA1	Idle	n.a.	Wash method_HPLC 67_NewRamithiazide Tablets_RS_Pf		N/A	N/A	QbD/LC/COL/128
31	Shut	Unknown	30.00	RA1	Idle	n.a.	Shut method_HPLC 67_NewRamithiazide Tablets_RS_Pf		N/A	N/A	QbD/LC/COL/128
							Seq. Created By : Swaraj A. Jadhav		Seq. Last Updated By :		
							Seq. Created On : 17-11-2018 12:49:53		Seq. Last Updated On		17-11-2018 13:45:16

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

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<i>Name</i>	HPLC-67_Ramithiazide Tablet_RS_Met
<i>Data Vault</i>	QbD_2018
<i>Path</i>	chrom://qbdser03/QbD_2018/Method Validation/Generic Healthcare/Ramithiazide Tablet/Related Substances/HPLC-67_17- Nov-18_A.seq/HPLC-67_Ramithiazide Tablet_RS_Met.instmeth
<i>Comment</i>	Ramithiazide Tablet
<i>Description</i>	Ramithiazide Tablet instrument method created
<i>Run time</i>	30.000 [min]
<i>Instrument</i>	QbD-INST-HPLC-67 on qbd-pc-19
<i>Created</i>	14-Nov-18 16:46:53 +05:30 Gauri Rane
<i>Last Update</i>	14-Nov-18 16:46:53 +05:30 Gauri Rane

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17-Nov-18

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Stage	Time min	Command	Value	Comment
Instrument Setup				
	initial	DAD.3DFIELD.MinWavelength	190.0 [nm]	
		DAD.3DFIELD.MaxWavelength	400.0 [nm]	
		DAD.3DFIELD.BunchWidth	1 [nm]	
		DAD.ResponseTime	1.000 [s]	
		DAD.Data_Collection_Rate	5 [Hz]	
		ColumnOven.TempCtrl	On	
		ColumnOven.Temperature.Nominal	25.0 [°C]	
		ColumnOven.Temperature.LowerLimit	5.0 [°C]	
		ColumnOven.Temperature.UpperLimit	80.0 [°C]	
		ColumnOven.EquilibrationTime	0.5 [min]	
		ColumnOven.ReadyTempDelta	1.0 [°C]	
		ColumnOven.Column_A.ActiveColumn	No	
		ColumnOven.Column_A.SystemPressure	"Pump"	
		ColumnOven.Column_B.ActiveColumn	No	
		ColumnOven.Column_B.SystemPressure	"Pump"	
		Sampler.InjectWash	Both	
		Sampler.WashSpeed	20.000 [µl/s]	
		Sampler.WashVolume	75.000 [µl]	
		Sampler.SampleHeight	2.000 [mm]	
		Sampler.WasteSpeed	32.000 [µl/s]	
		Sampler.DispenseDelay	0.000 [s]	
		Sampler.DispSpeed	20.000 [µl/s]	
		Sampler.DrawSpeed	5.000 [µl/s]	
		Sampler.DrawDelay	3.000 [s]	
		Sampler.InjectMode	Normal	
		Sampler.PumpDevice	"Pump"	
		Sampler.SyncWithPump	On	
		Sampler.LoopWashFactor	2.000	
		Sampler.TempCtrl	On	
		Sampler.Temperature.Nominal	25.0 [°C]	
		Sampler.ReadyTempDelta	1.5 [°C]	
		Sampler.Temperature.LowerLimit	4.0 [°C]	
		Sampler.Temperature.UpperLimit	45.0 [°C]	
		PumpModule.Pump.%A.Equate	"Mobile Phase A"	
		PumpModule.Pump.%B.Equate	"Mobile Phase B"	
		PumpModule.Pump.%C.Equate	"%C"	
		PumpModule.Pump.%D.Equate	"%D"	
		PumpModule.Pump.Pressure.LowerLimit	0 [bar]	
		PumpModule.Pump.Pressure.UpperLimit	600 [bar]	
		PumpModule.Pump.MaximumFlowRampUp	6.000 [ml/min ²]	
		PumpModule.Pump.MaximumFlowRampDown	5.998 [ml/min ²]	

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

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

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Instrument ID : QbD-INST-HPLC-67
Sequence Name : HPLC-67_17-Nov-18_A1
Data Vault : QbD_2018
Sequence Path : Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq

Seq. Created By : Swaraj A. Jadhav
Seq. Created On : 17-11-2018 12:49:53

Inj No.	Injection Name	Injection Type	Volume µL	Vial No.	Status	Injection Time	Instrument Method	Processing Method	Level
1	Blank Solution	Unknown	30.00	RA1	Finished	17-11-2018 20:28:57	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf		
2	Blank Solution	Unknown	30.00	RA1	Finished	17-11-2018 21:00:10	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf		
3	Standard Solution 1	Unknown	30.00	RA2	Finished	17-11-2018 21:31:22	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf		
4	Standard Solution 2	Unknown	30.00	RA2	Finished	17-11-2018 22:02:40	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf		
5	Standard Solution 3	Unknown	30.00	RA2	Finished	17-11-2018 22:33:57	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf		
6	Standard Solution 4	Unknown	30.00	RA2	Finished	17-11-2018 23:05:15	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf		
7	Standard Solution 5	Unknown	30.00	RA2	Finished	17-11-2018 23:36:32	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf		
8	Standard Solution 6	Unknown	30.00	RA2	Finished	18-11-2018 00:07:45	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf		
9	Blank Solution	Unknown	30.00	RA1	Finished	18-11-2018 00:39:02	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf		
10	LOQ Level 1	Unknown	30.00	RA3	Finished	18-11-2018 01:10:15	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf		
11	LOQ Level 2	Unknown	30.00	RA3	Finished	18-11-2018 01:41:28	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf		
12	LOQ Level 3	Unknown	30.00	RA3	Finished	18-11-2018 02:12:41	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf		
13	50 % Level 1	Unknown	30.00	RA4	Finished	18-11-2018 02:43:54	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf		
14	50 % Level 2	Unknown	30.00	RA4	Finished	18-11-2018 03:15:07	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf		
15	50 % Level 3	Unknown	30.00	RA4	Finished	18-11-2018 03:46:19	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf		
16	80 % Level 1	Unknown	30.00	RA5	Finished	18-11-2018 04:17:32	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf		
17	80 % Level 2	Unknown	30.00	RA5	Finished	18-11-2018 04:48:45	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf		
18	80 % Level 3	Unknown	30.00	RA5	Finished	18-11-2018 05:19:58	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf		
19	100 % Level 1	Unknown	30.00	RA6	Finished	18-11-2018 05:51:11	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf		
20	100 % Level 2	Unknown	30.00	RA6	Finished	18-11-2018 06:22:23	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf		
21	100 % Level 3	Unknown	30.00	RA6	Finished	18-11-2018 06:53:36	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf		
22	120 % Level 1	Unknown	30.00	RA7	Finished	18-11-2018 07:24:54	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf		
23	120 % Level 2	Unknown	30.00	RA7	Finished	18-11-2018 07:56:06	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf		
24	120 % Level 3	Unknown	30.00	RA7	Finished	18-11-2018 08:27:24	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf		
25	150 % Level 1	Unknown	30.00	RA8	Finished	18-11-2018 08:58:36	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf		
26	150 % Level 2	Unknown	30.00	RA8	Finished	18-11-2018 09:29:49	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf		
27	150 % Level 3	Unknown	30.00	RA8	Finished	18-11-2018 10:01:02	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf		
28	Blank Solution	Unknown	30.00	RA1	Finished	18-11-2018 10:32:19	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf		
29	Bracketing Standard Solution	Unknown	30.00	RA2	Finished	18-11-2018 11:03:37	67_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf		
30	Wash	Unknown	30.00	RA1	Finished	18-11-2018 11:38:45	Wash method _HPLC 67_NewRamithiazide Tablets_RS_Pf		
31	Shut	Unknown	30.00	RA1	Finished	18-11-2018 12:44:02	Shut method _HPLC 67_NewRamithiazide Tablets_RS_Pf		

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Processing Method

Processing Method Name :	Ramithiazide Tablets_RS_PR		
Processing Method Path :	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		
Processing Method Created By :	Swaraj A. Jadhav	Processing Method Last Updated By :	Swaraj A. Jadhav
Processing Method Created On :	17-11-2018 13:03:23	Processing Method Last Updated On :	19-11-2018 19:53:16

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	0.450 [min]	Any	All Channels
4.000	Minimum Width	0.000 [min]	Any	All Channels
7.796	Inhibit Integration	On	Any	All Channels
12.959	Inhibit Integration	Off	Any	All Channels

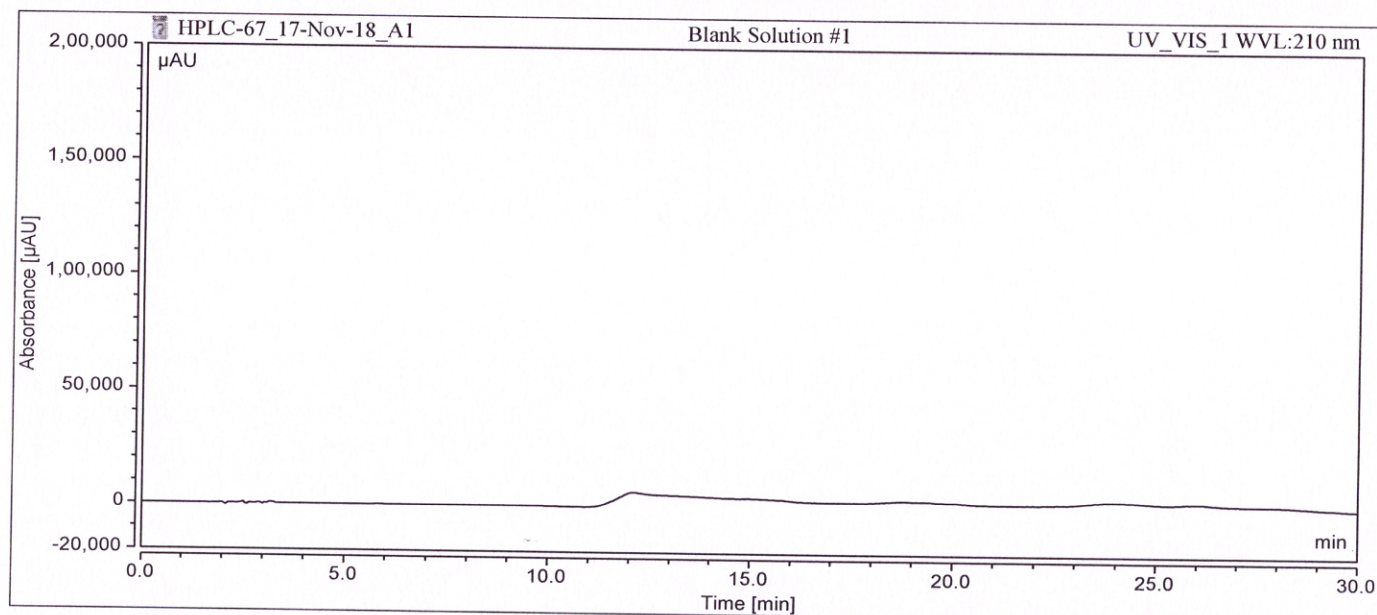
Peak Table

No.	Peak Name	Ret. Time
1	Hydrochlorothiazide	5.147
2	Impurity E	14.100
3	Impurity A	14.643
4	Ramipril	16.123
5	Impurity D	23.927



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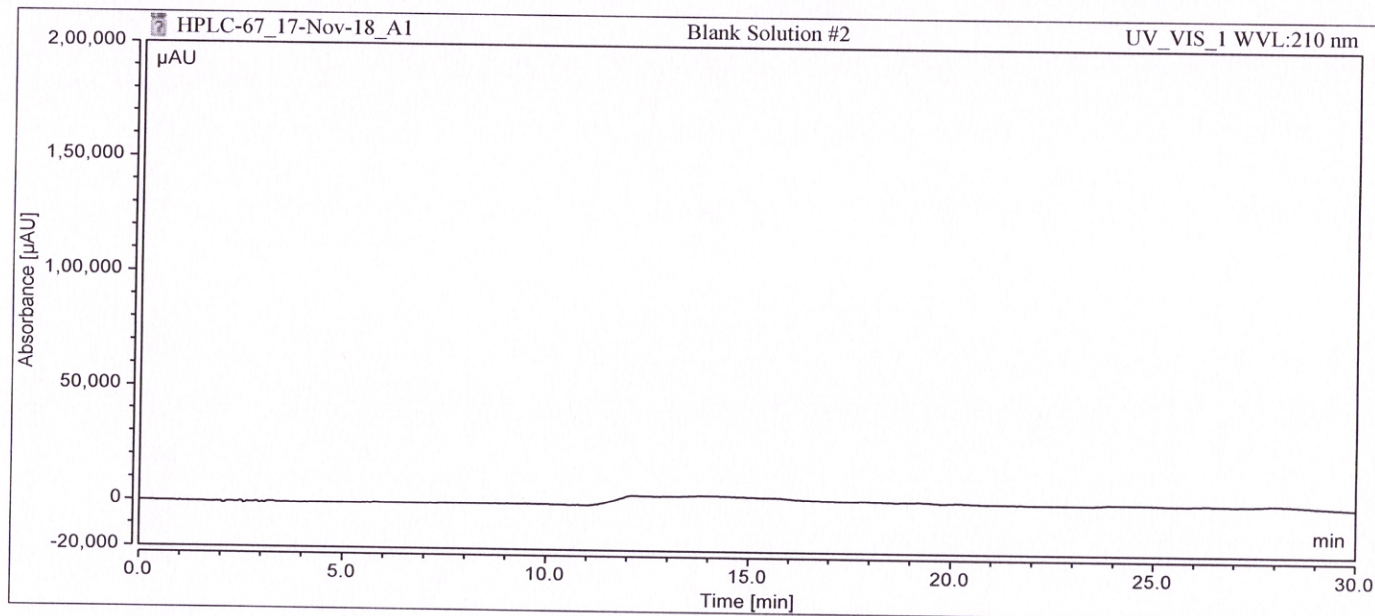
Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	1	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA1	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	17-11-2018 20:28:57	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-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 Tablet	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	2	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA1	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	17-11-2018 21:00:10	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		

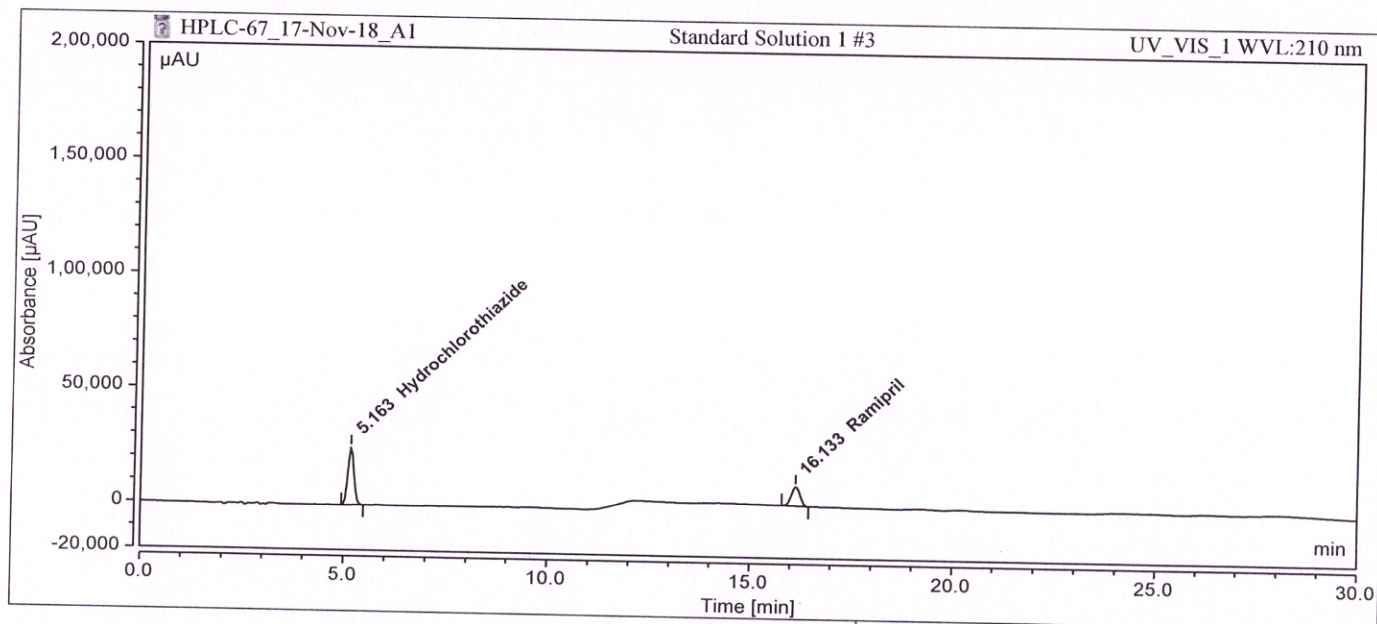


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Standard Solution 1	AR. No. :-	D2404181993
Sample Number :-	3	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA2	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	17-11-2018 21:31:22	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		

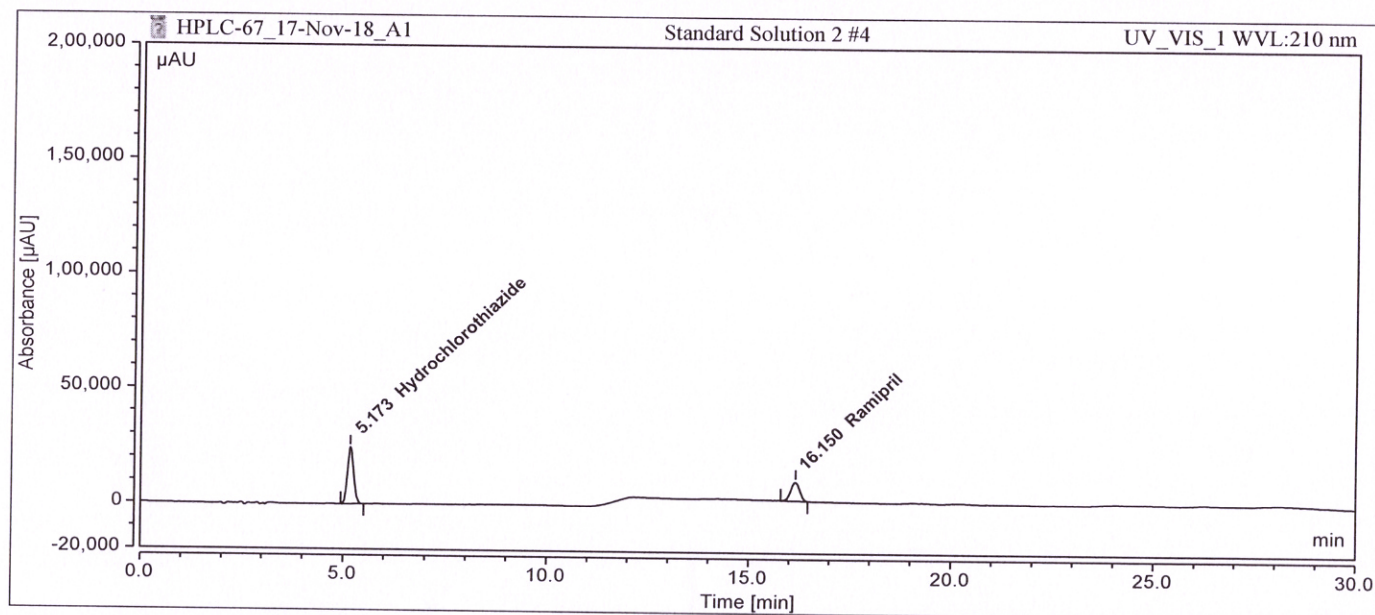


Peak No.	Peak Name	Ref. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.163	4302.226	67.29	1.10	5681	FALSE	n.a.
2	Ramipril	16.133	2091.691	32.71	1.01	26196	FALSE	32.61



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Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Standard Solution 2	AR. No. :-	D2404181993
Sample Number :-	4	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA2	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	17-11-2018 22:02:40	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		

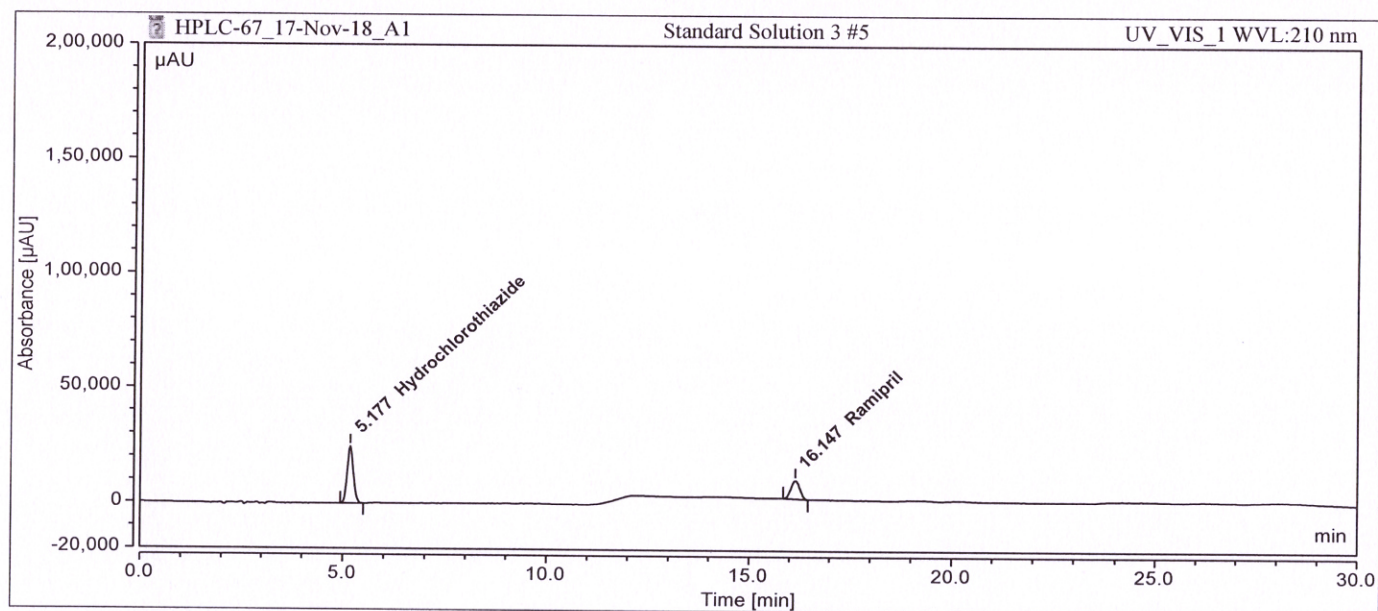


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.173	4297.689	67.31	1.12	5508	FALSE	n.a.
2	Ramipril	16.150	2087.062	32.69	0.99	25509	FALSE	32.13



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Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Standard Solution 3	AR. No. :-	D2404181993
Sample Number :-	5	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA2	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	17-11-2018 22:33:57	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		

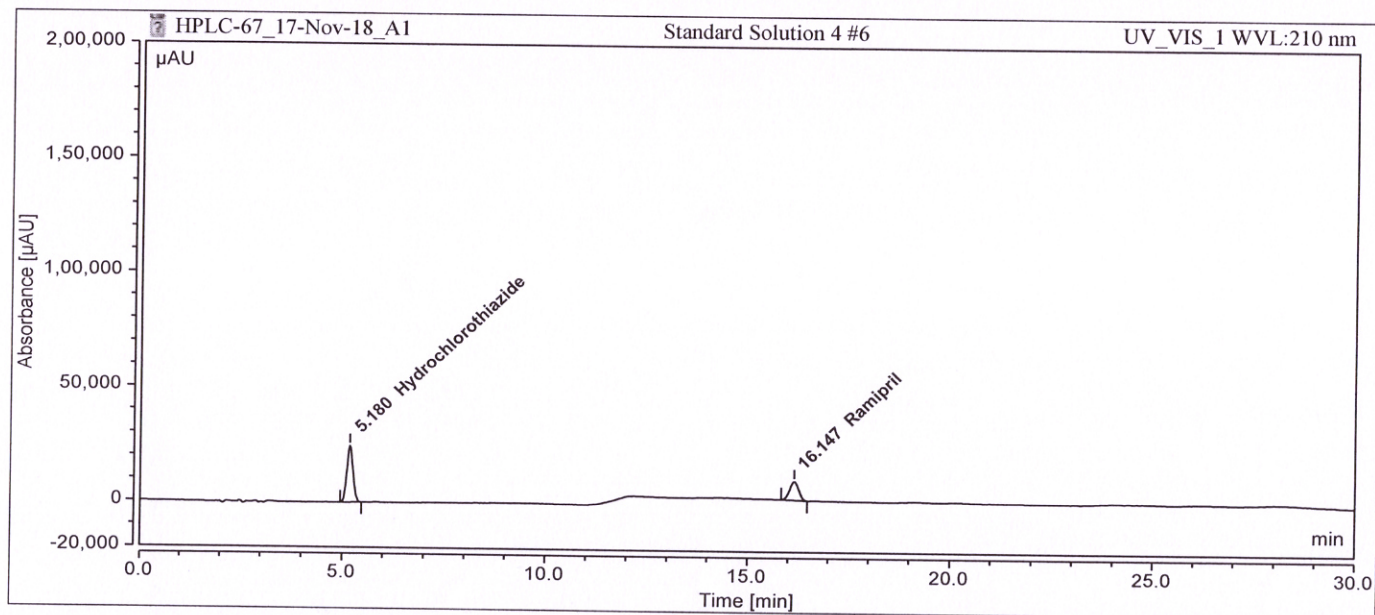


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.177	4308.221	67.66	1.11	5593	FALSE	n.a.
2	Ramipril	16.147	2059.705	32.34	1.02	25396	FALSE	32.16



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Standard Solution 4	AR. No. :-	D2404181993
Sample Number :-	6	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA2	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	17-11-2018 23:05:15	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		

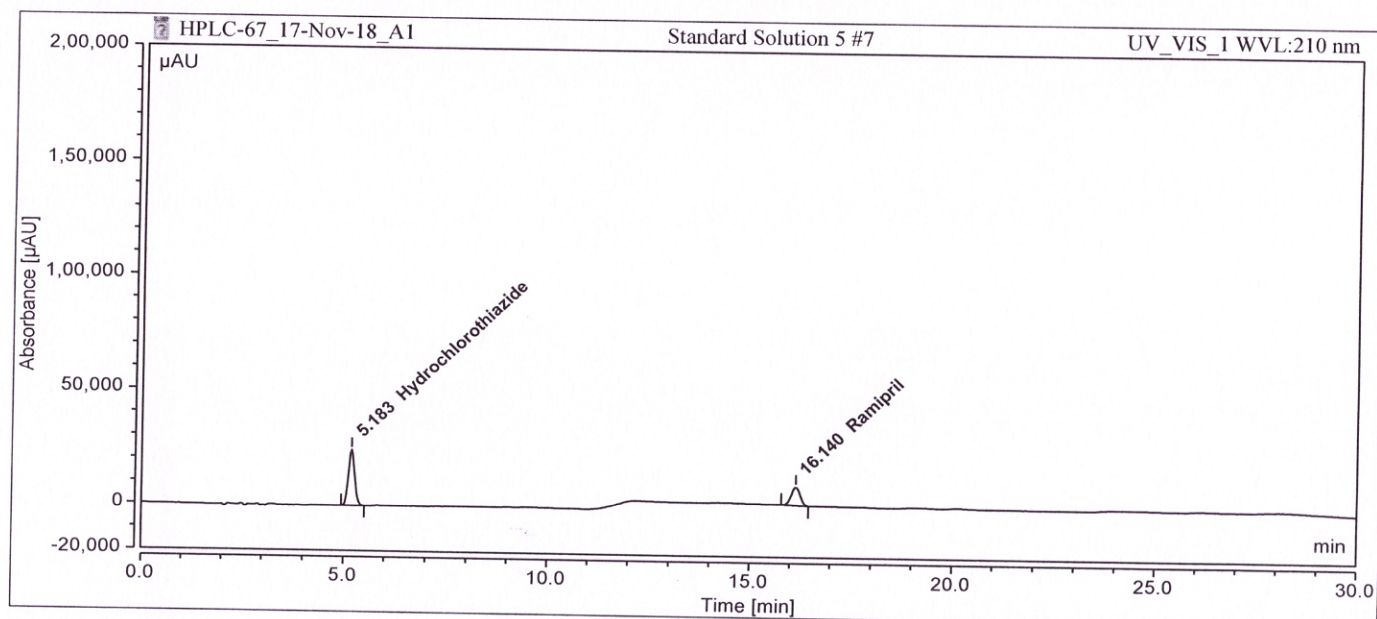


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.180	4292.629	67.39	1.10	5529	FALSE	n.a.
2	Ramipril	16.147	2077.548	32.61	1.00	24898	FALSE	31.88



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Standard Solution 5	AR. No. :-	D2404181993
Sample Number :-	7	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA2	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	17-11-2018 23:36:32	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		

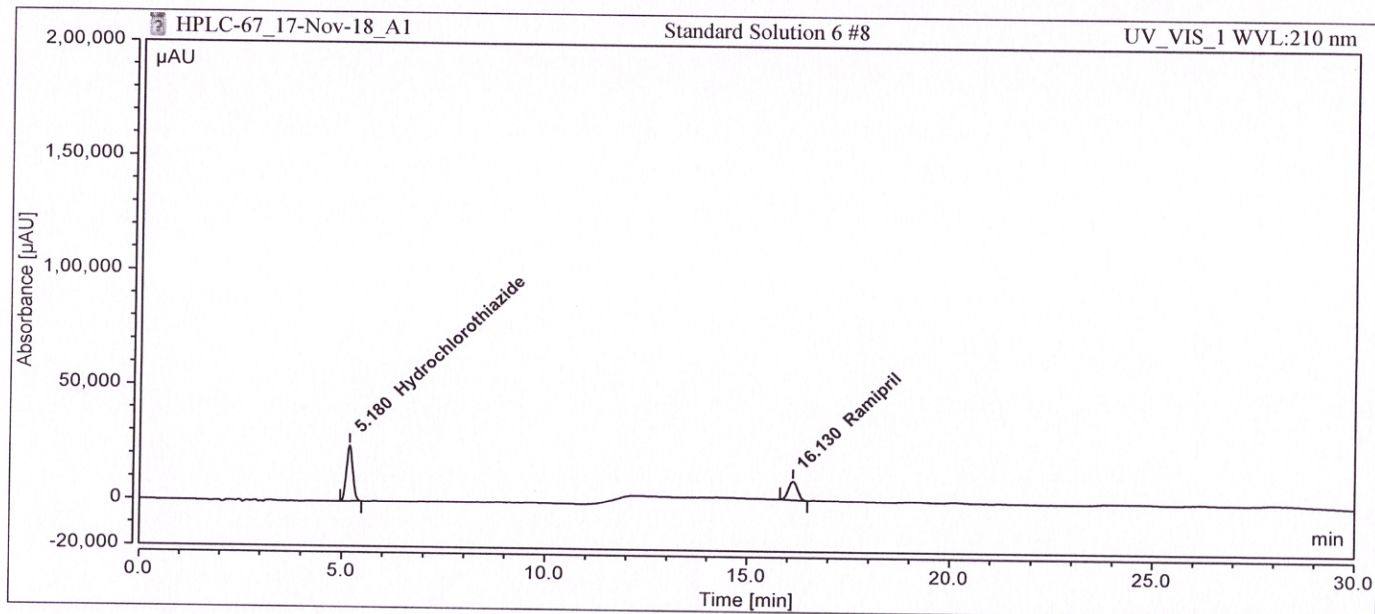


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.183	4306.128	67.33	1.11	5385	FALSE	n.a.
2	Ramipril	16.140	2089.534	32.67	1.00	24025	FALSE	31.35



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Standard Solution 6	AR. No. :-	D2404181993
Sample Number :-	8	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA2	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	18-11-2018 00:07:45	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		

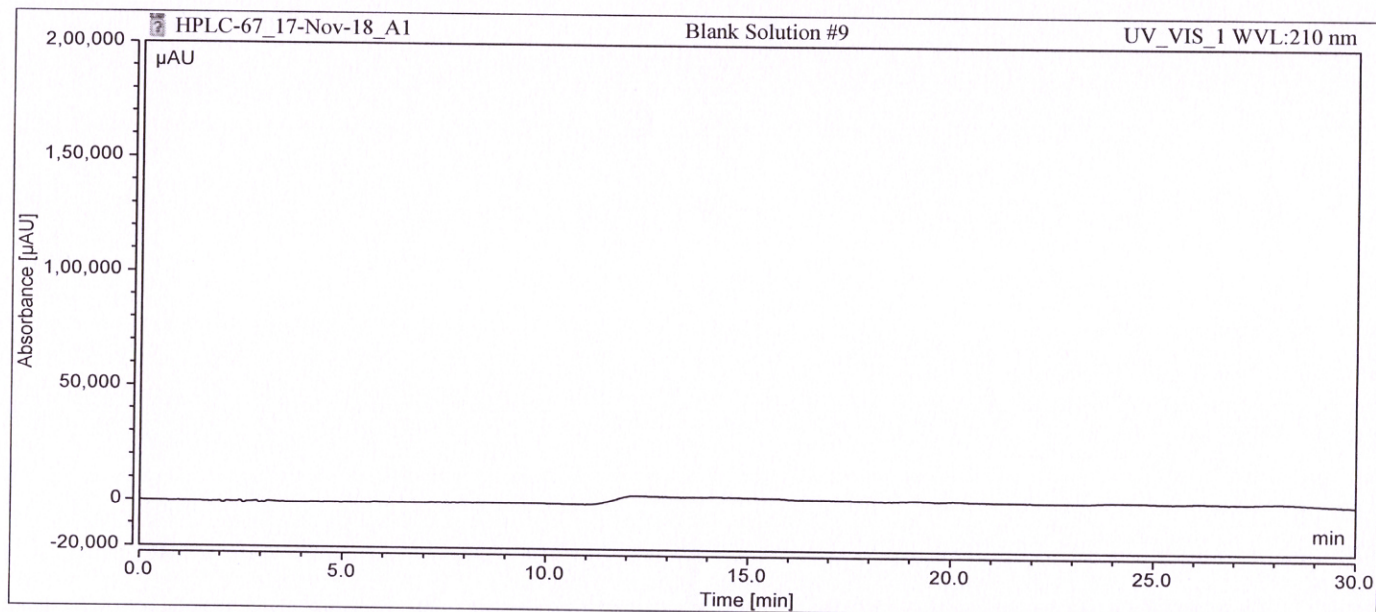


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.180	4289.416	67.38	1.11	5392	FALSE	n.a.
2	Ramipril	16.130	2076.330	32.62	1.02	25262	FALSE	31.83



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	9	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA1	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	18-11-2018 00:39:02	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		

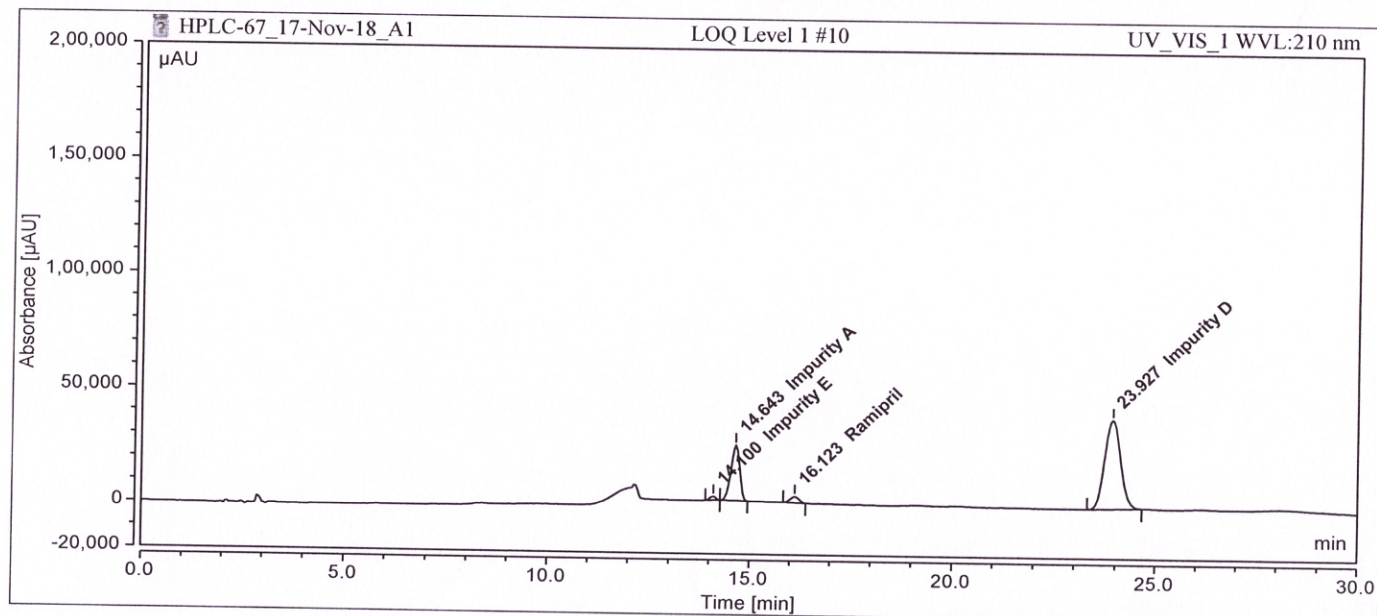


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	LOQ Level I	AR. No. :-	D2404181993
Sample Number :-	10	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA3	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	18-11-2018 01:10:15	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		

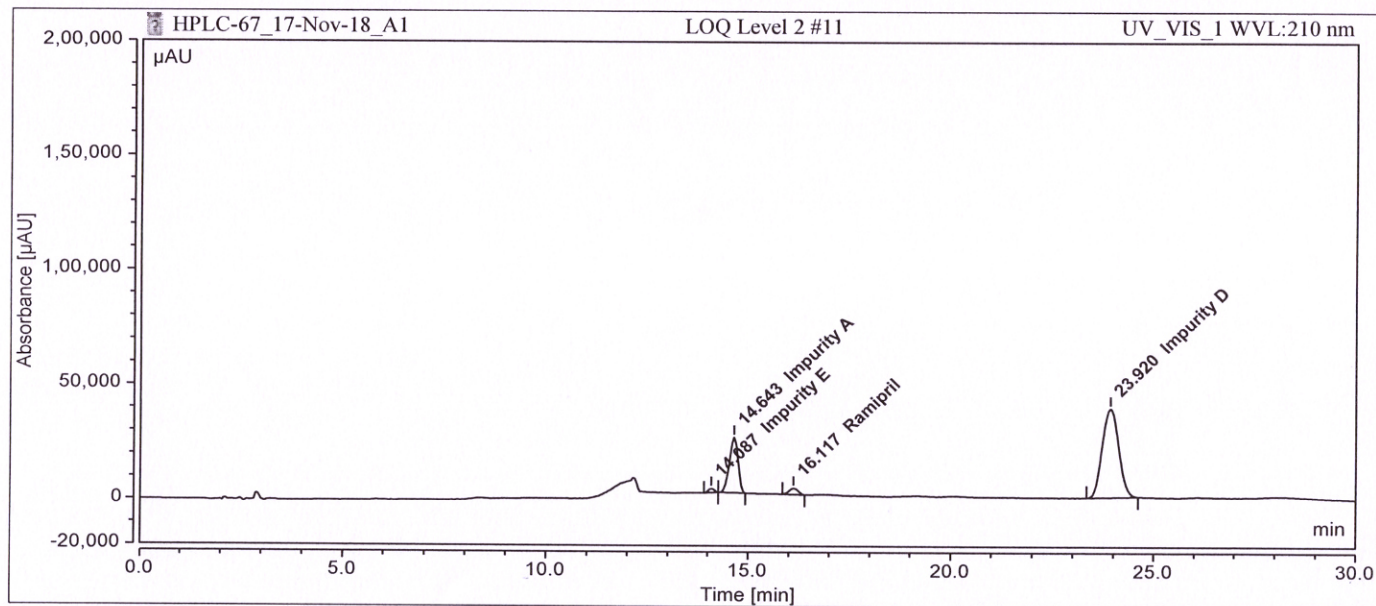


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Impurity E	14.100	294.601	1.17	0.93	30858	FALSE	n.a.
2	Impurity A	14.643	5993.015	23.89	0.91	21484	FALSE	1.51
3	Ramipril	16.123	684.597	2.73	0.97	25483	FALSE	3.68
4	Impurity D	23.927	18113.100	72.21	1.06	16979	FALSE	13.71



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	LOQ Level 2	AR. No. :-	D2404181993
Sample Number :-	11	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA3	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	18-11-2018 01:41:28	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		

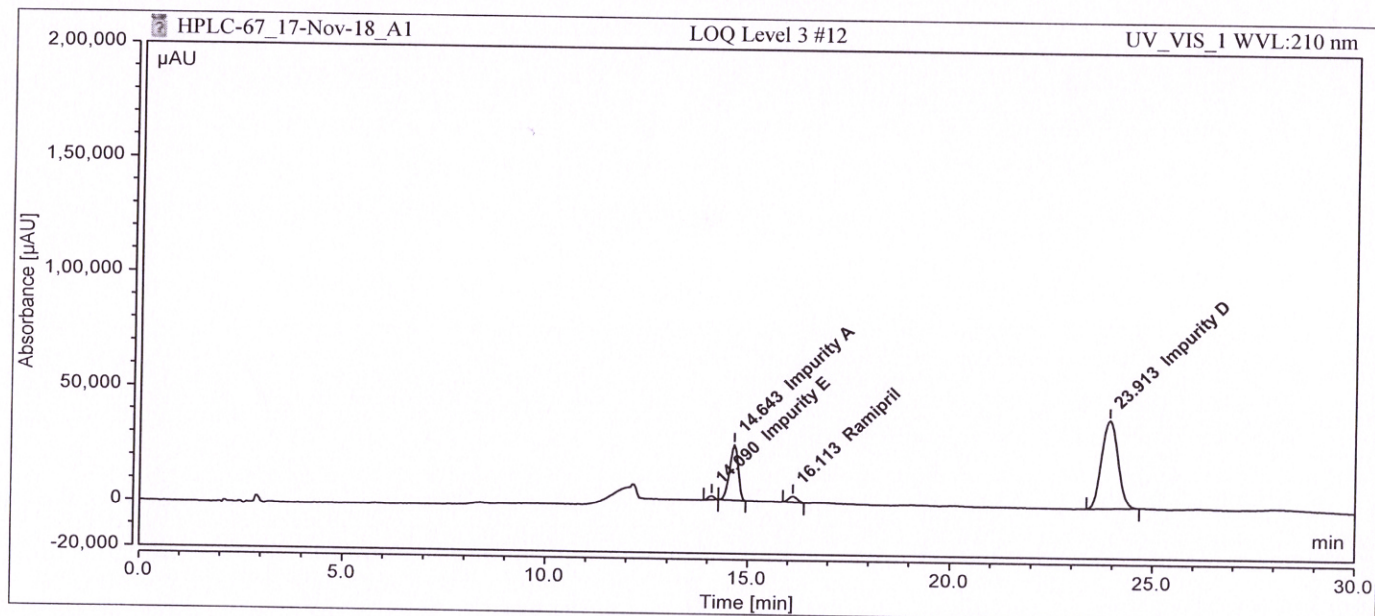


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Impurity E	14.087	300.922	1.20	0.96	41661	FALSE	n.a.
2	Impurity A	14.643	5971.960	23.91	0.91	21689	FALSE	1.65
3	Ramipril	16.117	673.977	2.70	1.00	26435	FALSE	3.71
4	Impurity D	23.920	18029.972	72.19	1.08	17030	FALSE	13.82



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	LOQ Level 3	AR. No. :-	D2404181993
Sample Number :-	12	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA3	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	18-11-2018 02:12:41	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		

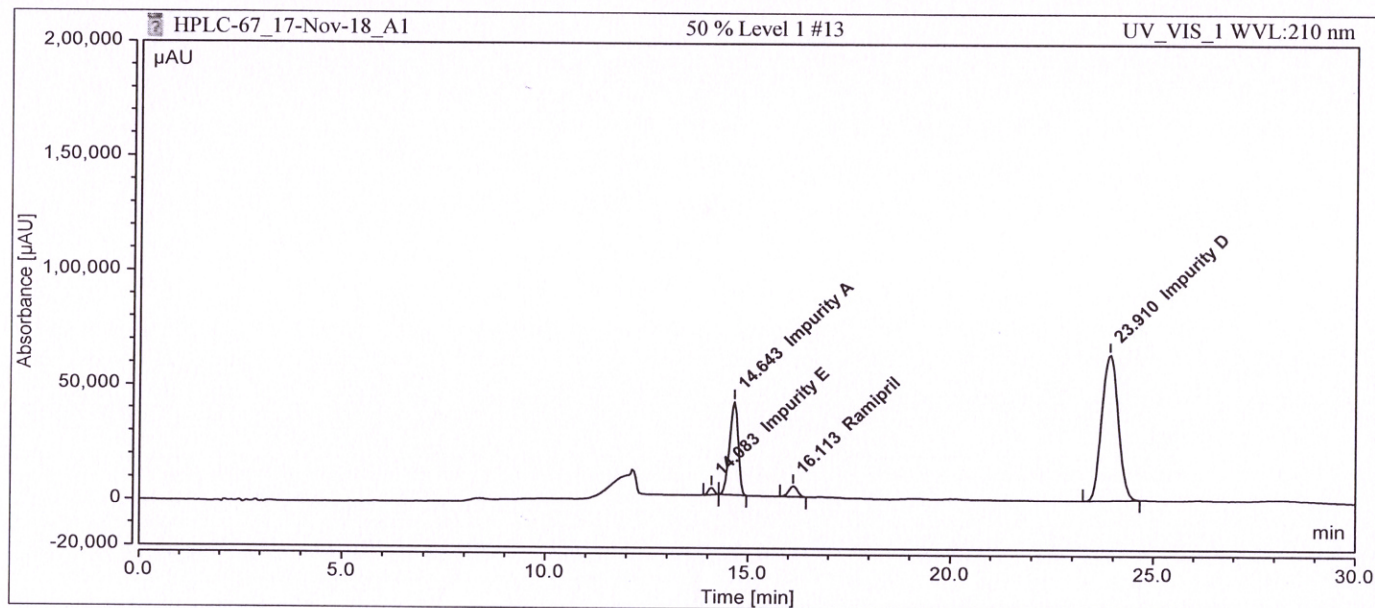


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Impurity E	14.090	301.402	1.20	0.96	41693	FALSE	n.a.
2	Impurity A	14.643	5992.314	23.96	0.90	21607	FALSE	1.64
3	Ramipril	16.113	654.499	2.62	1.05	25939	FALSE	3.68
4	Impurity D	23.913	18064.532	72.22	1.07	16860	FALSE	13.72



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	50 % Level 1	AR. No. :-	D2404181993
Sample Number :-	13	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA4	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	18-11-2018 02:43:54	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		

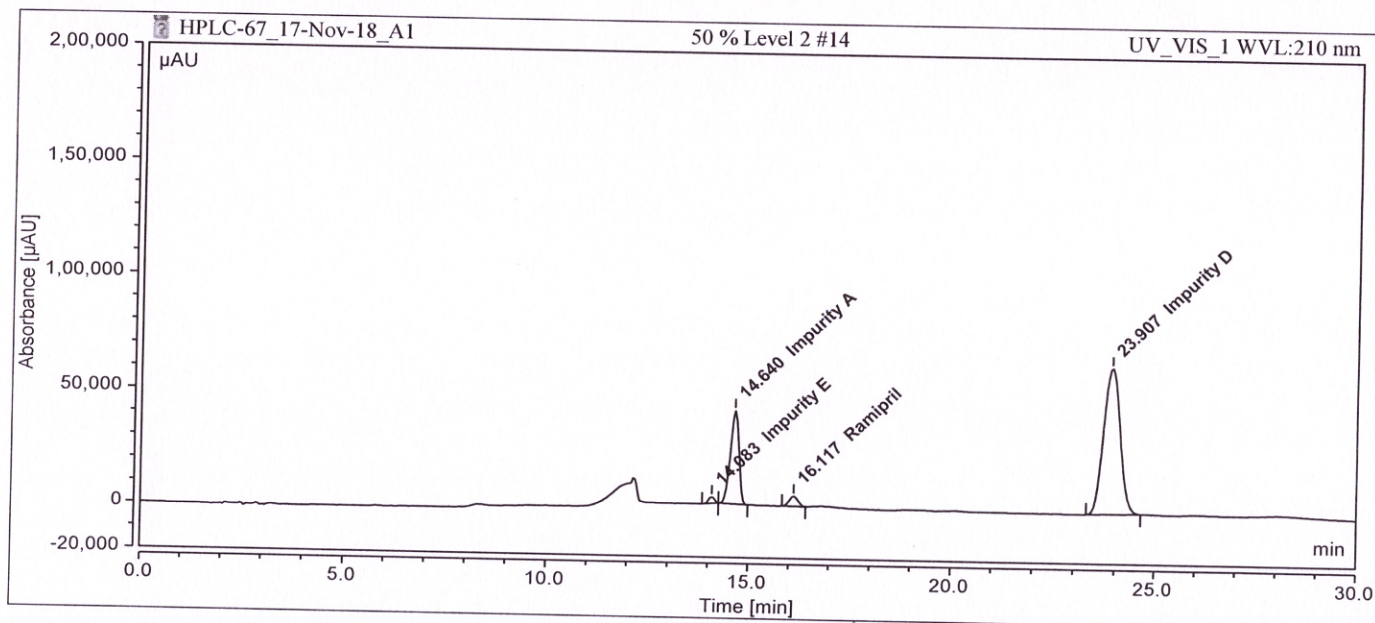


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Impurity E	14.083	520.246	1.25	0.98	43433	FALSE	n.a.
2	Impurity A	14.643	10103.214	24.21	0.90	21531	FALSE	1.67
3	Ramipril	16.113	1181.781	2.83	1.00	23402	FALSE	3.58
4	Impurity D	23.910	29918.477	71.71	1.07	16861	FALSE	13.47



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	50 % Level 2	AR. No. :-	D2404181993
Sample Number :-	14	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA4	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	18-11-2018 03:15:07	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		

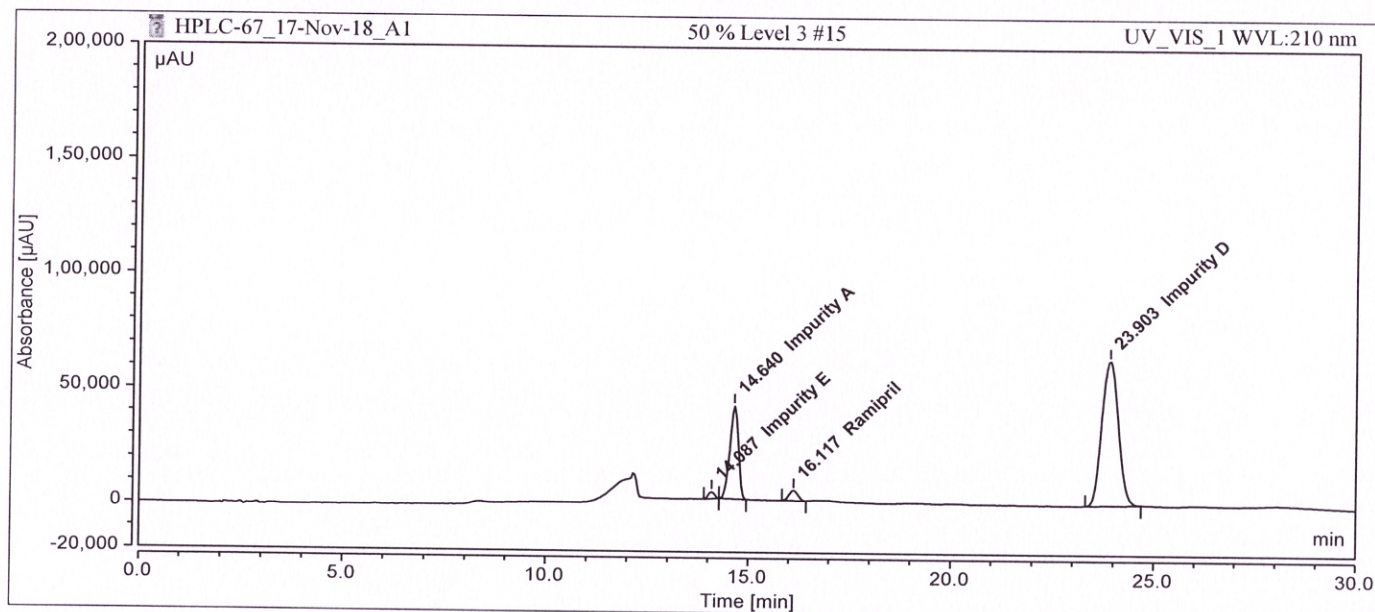


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Impurity E	14.083	514.168	1.23	0.98	42561	FALSE	n.a.
2	Impurity A	14.640	10114.870	24.27	0.91	21464	FALSE	1.65
3	Ramipril	16.117	1134.645	2.72	1.00	25603	FALSE	3.68
4	Impurity D	23.907	29912.041	71.77	1.07	16780	FALSE	13.65



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	50 % Level 3	AR. No. :-	D2404181993
Sample Number :-	15	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA4	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	18-11-2018 03:46:19	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		

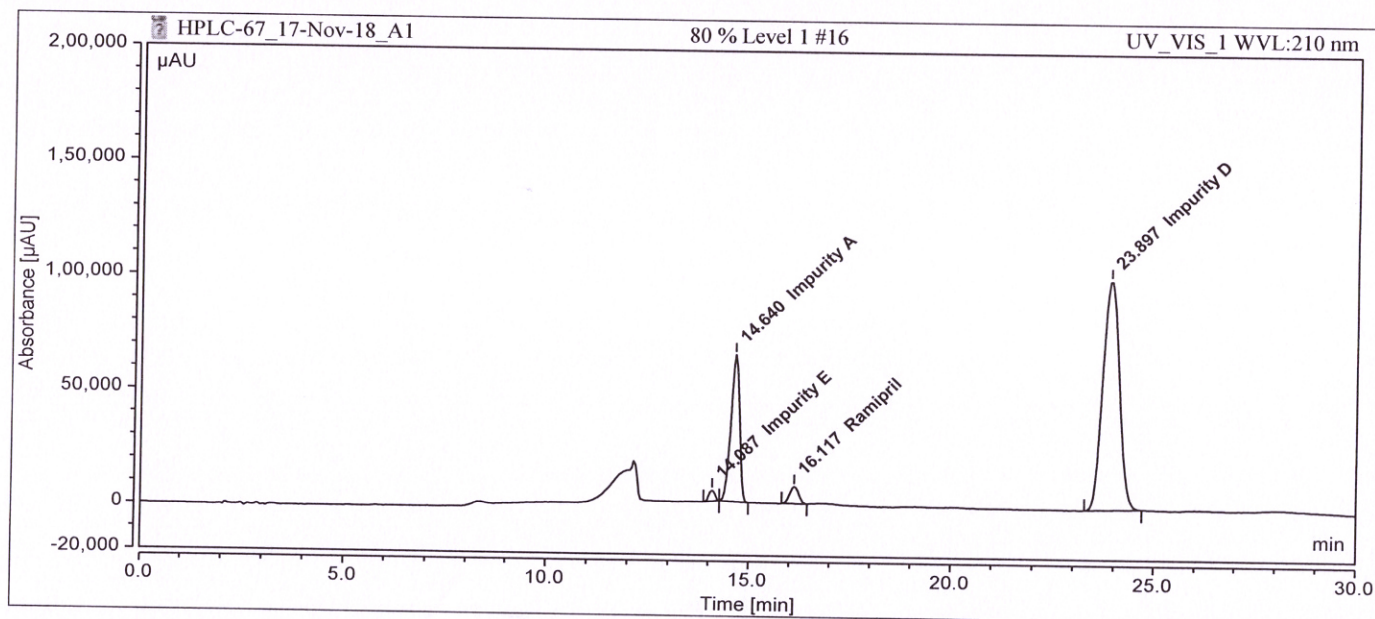


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Impurity E	14.087	520.090	1.25	0.95	42856	FALSE	n.a.
2	Impurity A	14.640	10104.716	24.24	0.91	21477	FALSE	1.65
3	Ramipril	16.117	1139.525	2.73	1.00	25014	FALSE	3.66
4	Impurity D	23.903	29917.663	71.78	1.07	16688	FALSE	13.57



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	80 % Level I	AR. No. :-	D2404181993
Sample Number :-	16	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA5	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	18-11-2018 04:17:32	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		

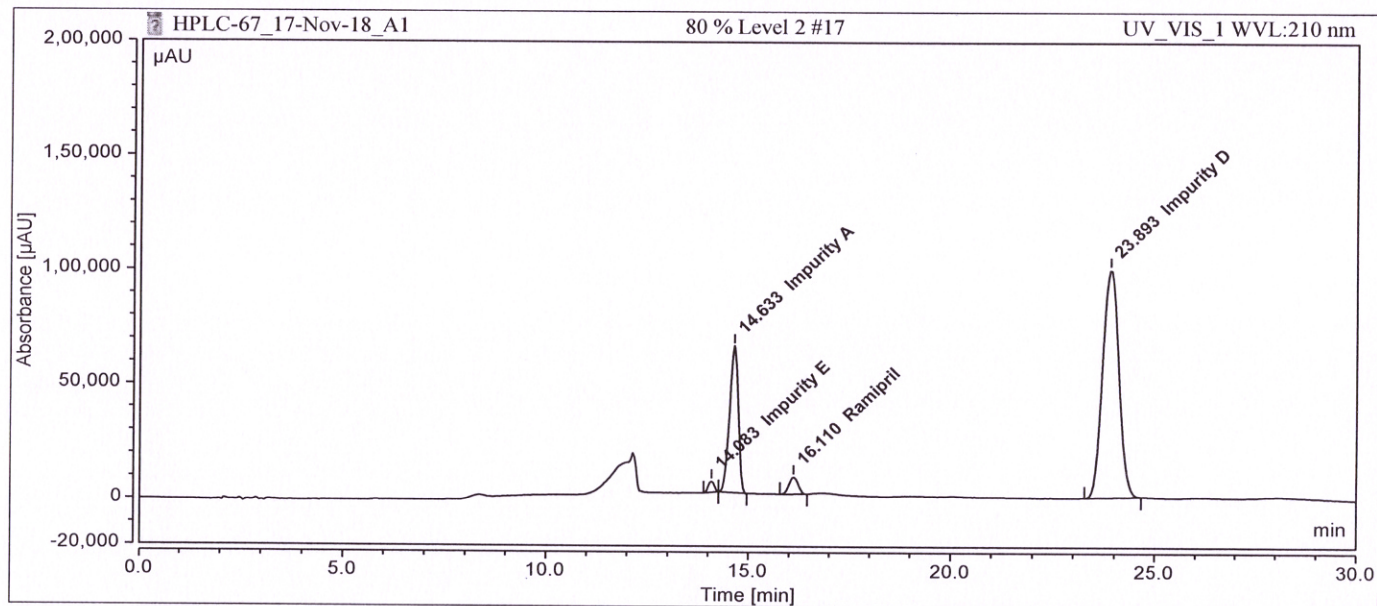


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Impurity E	14.087	836.407	1.27	0.97	40264	FALSE	n.a.
2	Impurity A	14.640	15989.488	24.22	0.92	21544	FALSE	1.63
3	Ramipril	16.117	1918.400	2.91	1.01	25068	FALSE	3.66
4	Impurity D	23.897	47276.501	71.61	1.08	16693	FALSE	13.57



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	80 % Level 2	AR. No. :-	D2404181993
Sample Number :-	17	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA5	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	18-11-2018 04:48:45	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		

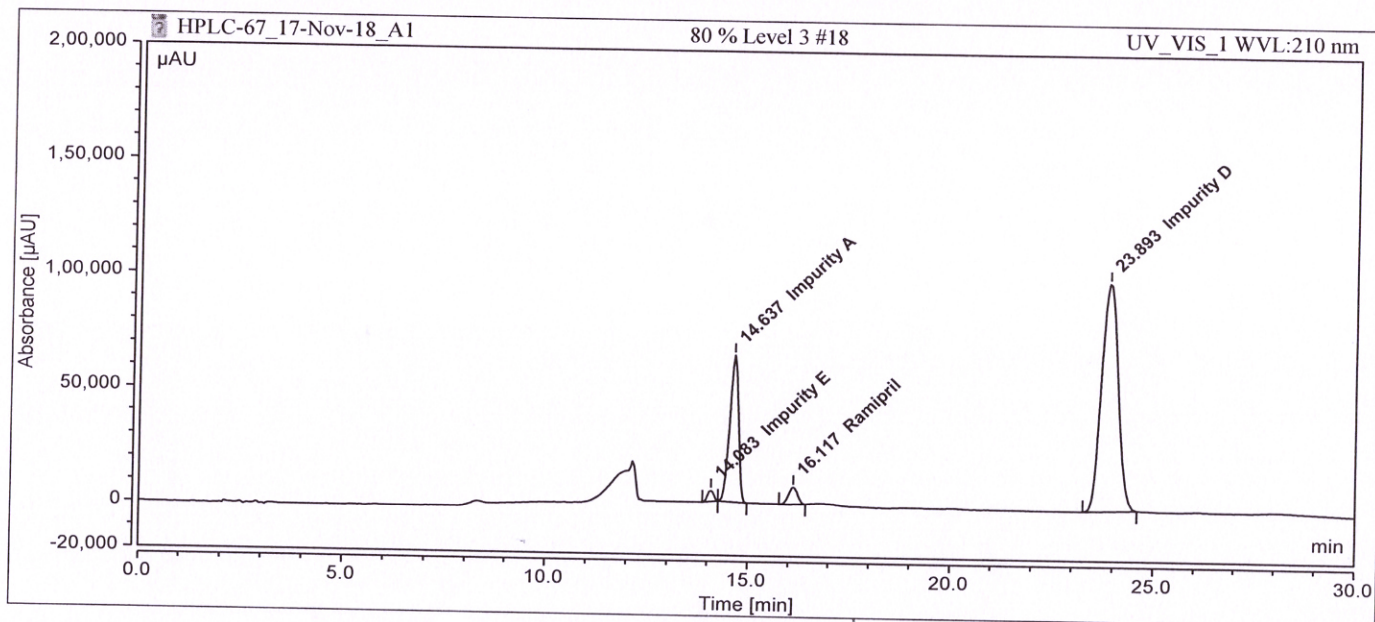


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Impurity E	14.083	839.639	1.27	0.98	41661	FALSE	n.a.
2	Impurity A	14.633	15988.949	24.25	0.92	21412	FALSE	1.63
3	Ramipril	16.110	1890.667	2.87	1.00	24570	FALSE	3.64
4	Impurity D	23.893	47211.271	71.61	1.08	16633	FALSE	13.51



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

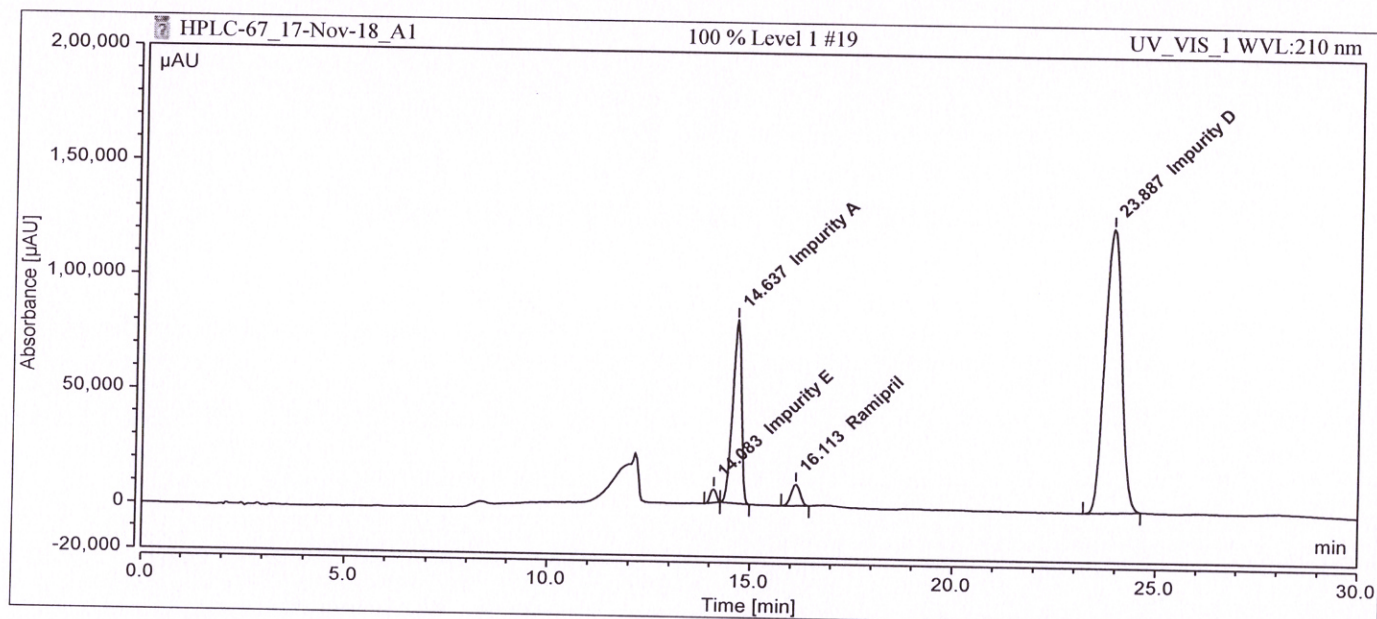
Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	80 % Level 3	AR. No. :-	D2404181993
Sample Number :-	18	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA5	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	18-11-2018 05:19:58	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		



Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Impurity E	14.083	838.133	1.27	0.96	41229	FALSE	n.a.
2	Impurity A	14.637	15988.124	24.26	0.91	21465	FALSE	1.63
3	Ramipril	16.117	1912.607	2.90	0.99	24787	FALSE	3.66
4	Impurity D	23.893	47162.870	71.57	1.07	16537	FALSE	13.49


QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	100 % Level 1	AR. No. :-	D2404181993
Sample Number :-	19	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA6	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	18-11-2018 05:51:11	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		

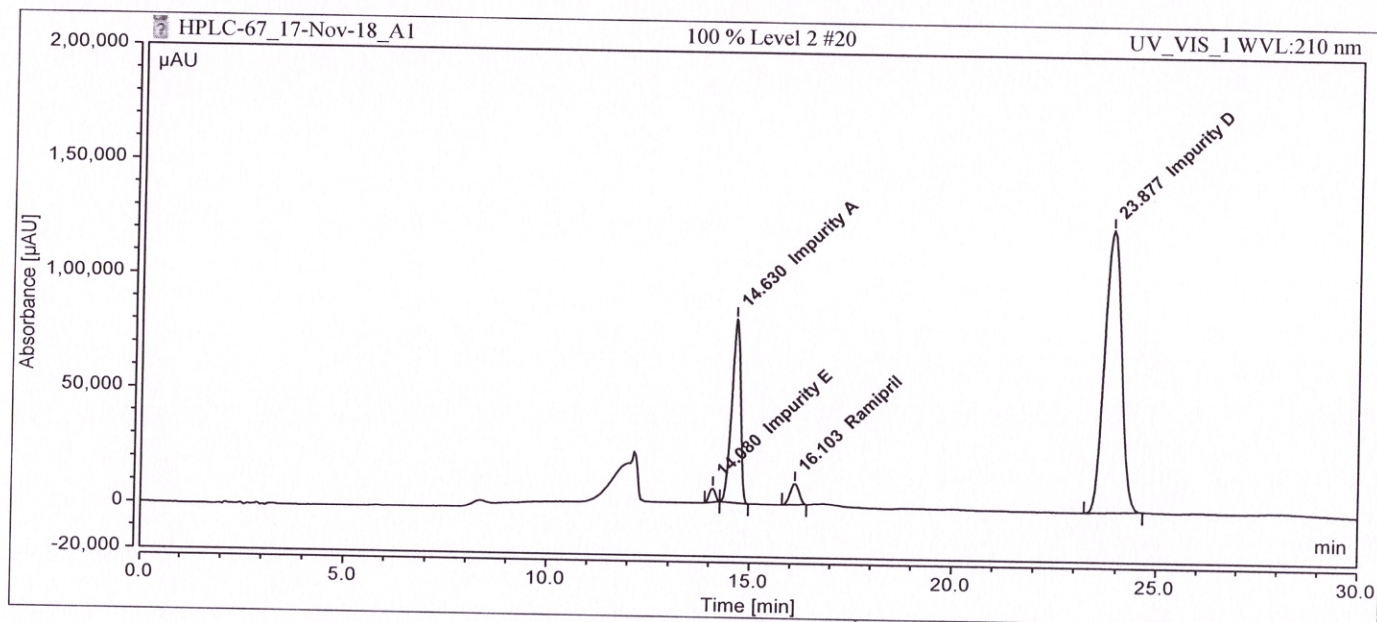


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Impurity E	14.083	1057.842	1.28	0.95	41071	FALSE	n.a.
2	Impurity A	14.637	20077.899	24.35	0.91	21234	FALSE	1.63
3	Ramipril	16.113	2407.134	2.92	1.00	24679	FALSE	3.64
4	Impurity D	23.887	58928.184	71.45	1.07	16542	FALSE	13.48



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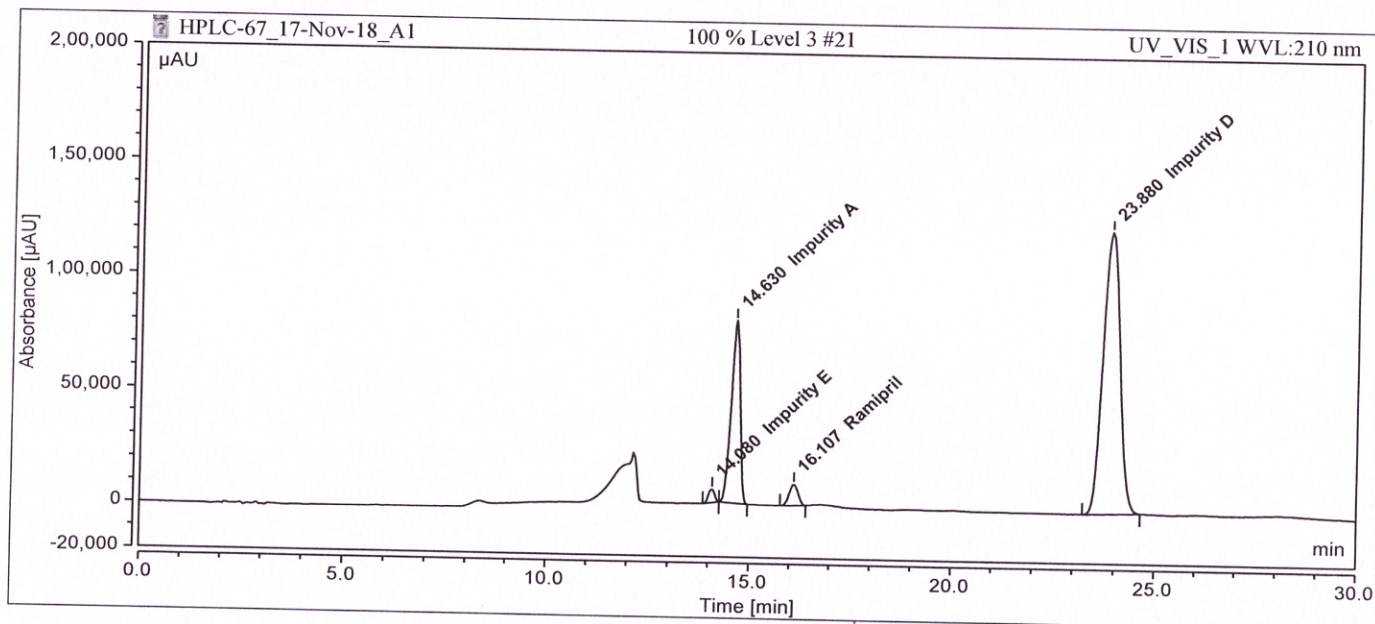
Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	100 % Level 2	AR. No. :-	D2404181993
Sample Number :-	20	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA6	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	18-11-2018 06:22:23	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		



Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Impurity E	14.080	1049.836	1.27	0.94	40620	FALSE	n.a.
2	Impurity A	14.630	20061.336	24.33	0.92	21385	FALSE	1.62
3	Ramipril	16.103	2366.662	2.87	1.01	24730	FALSE	3.64
4	Impurity D	23.877	58983.775	71.53	1.08	16368	FALSE	13.45


QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	100 % Level 3	AR. No. :-	D2404181993
Sample Number :-	21	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA6	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	18-11-2018 06:53:36	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		

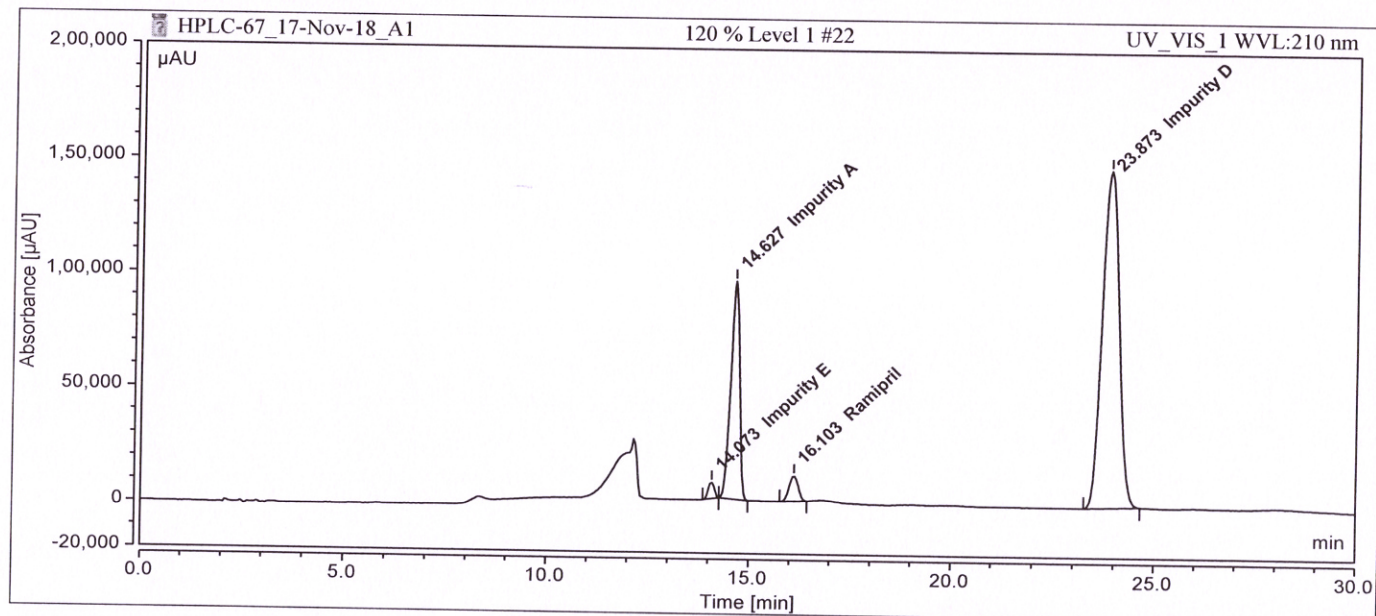


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Impurity E	14.080	1045.242	1.27	0.94	41050	FALSE	n.a.
2	Impurity A	14.630	20019.508	24.30	0.92	21271	FALSE	1.62
3	Ramipril	16.107	2376.389	2.88	0.99	24197	FALSE	3.62
4	Impurity D	23.880	58930.123	71.54	1.07	16254	FALSE	13.36



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	120 % Level 1	AR. No. :-	D2404181993
Sample Number :-	22	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA7	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	18-11-2018 07:24:54	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		

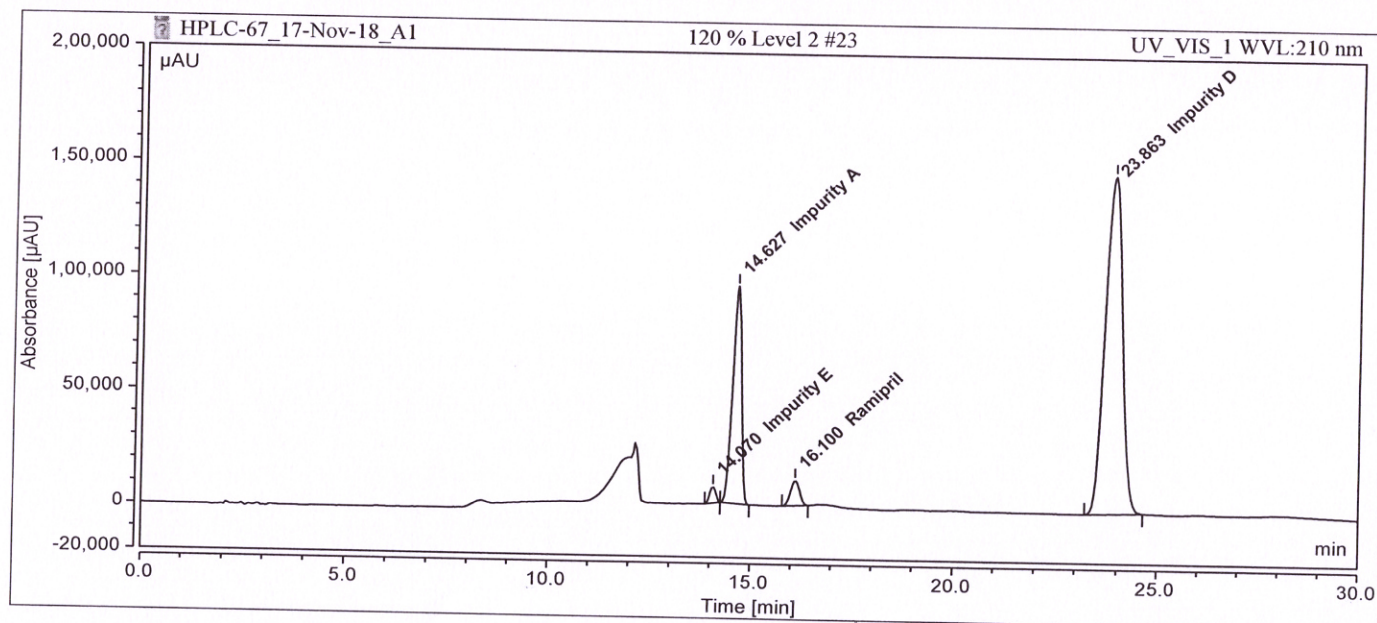


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Impurity E	14.073	1268.187	1.28	0.98	40386	FALSE	n.a.
2	Impurity A	14.627	23979.960	24.22	0.92	21083	FALSE	1.62
3	Ramipril	16.103	2883.472	2.91	0.99	23722	FALSE	3.60
4	Impurity D	23.873	70886.768	71.59	1.07	16152	FALSE	13.29



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	120 % Level 2	AR. No. :-	D2404181993
Sample Number :-	23	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_N
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA7	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	18-11-2018 07:56:06	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		

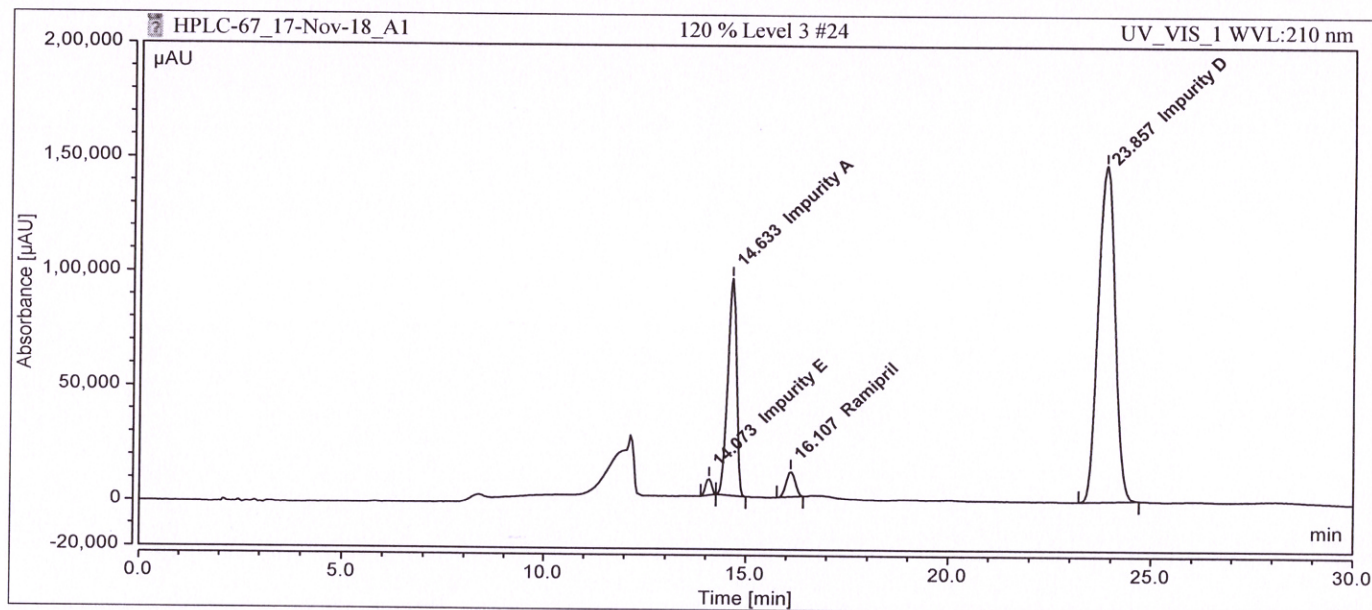


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Impurity E	14.070	1273.170	1.29	0.98	39803	FALSE	n.a.
2	Impurity A	14.627	23997.252	24.23	0.92	21042	FALSE	1.62
3	Ramipril	16.100	2871.566	2.90	1.01	23711	FALSE	3.59
4	Impurity D	23.863	70900.499	71.59	1.07	16194	FALSE	13.29



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	120 % Level 3	AR. No. :-	D2404181993
Sample Number :-	24	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA7	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	18-11-2018 08:27:24	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		

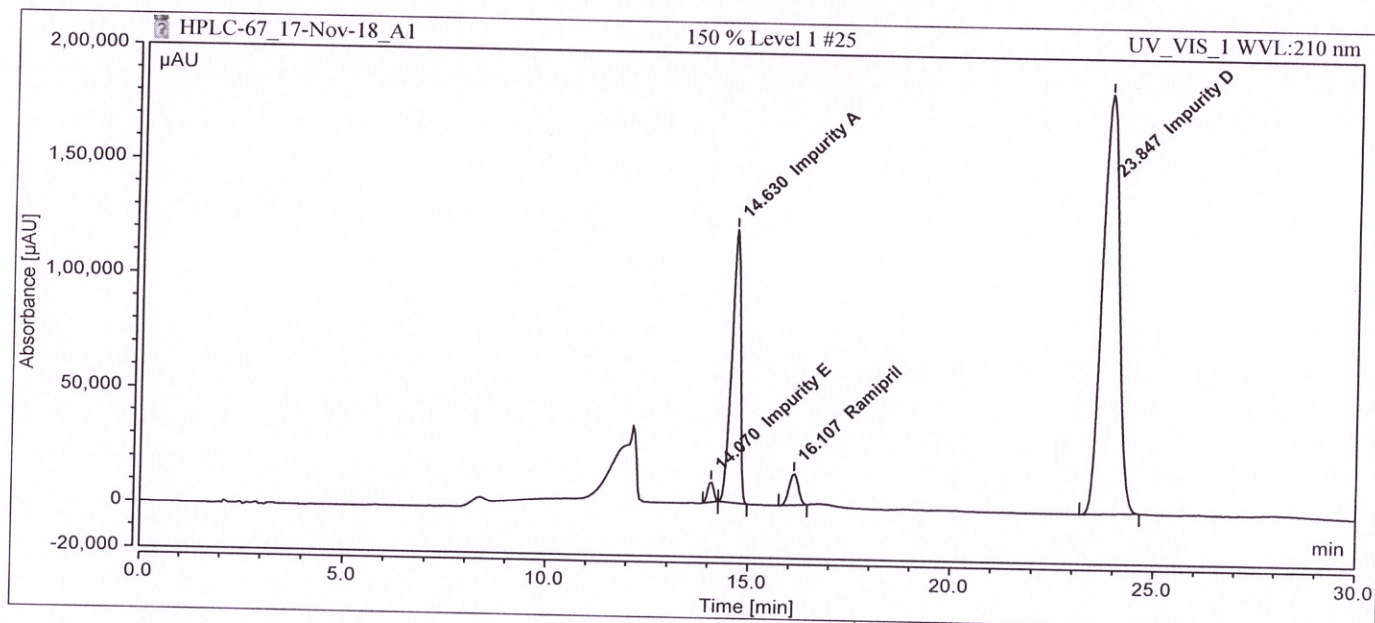


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Impurity E	14.073	1282.744	1.29	0.96	39520	FALSE	n.a.
2	Impurity A	14.633	24010.189	24.23	0.92	20930	FALSE	1.63
3	Ramipril	16.107	2842.489	2.87	1.01	23509	FALSE	3.57
4	Impurity D	23.857	70967.075	71.61	1.08	16049	FALSE	13.21



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	150 % Level 1	AR. No. :-	D2404181993
Sample Number :-	25	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA8	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	18-11-2018 08:58:36	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		

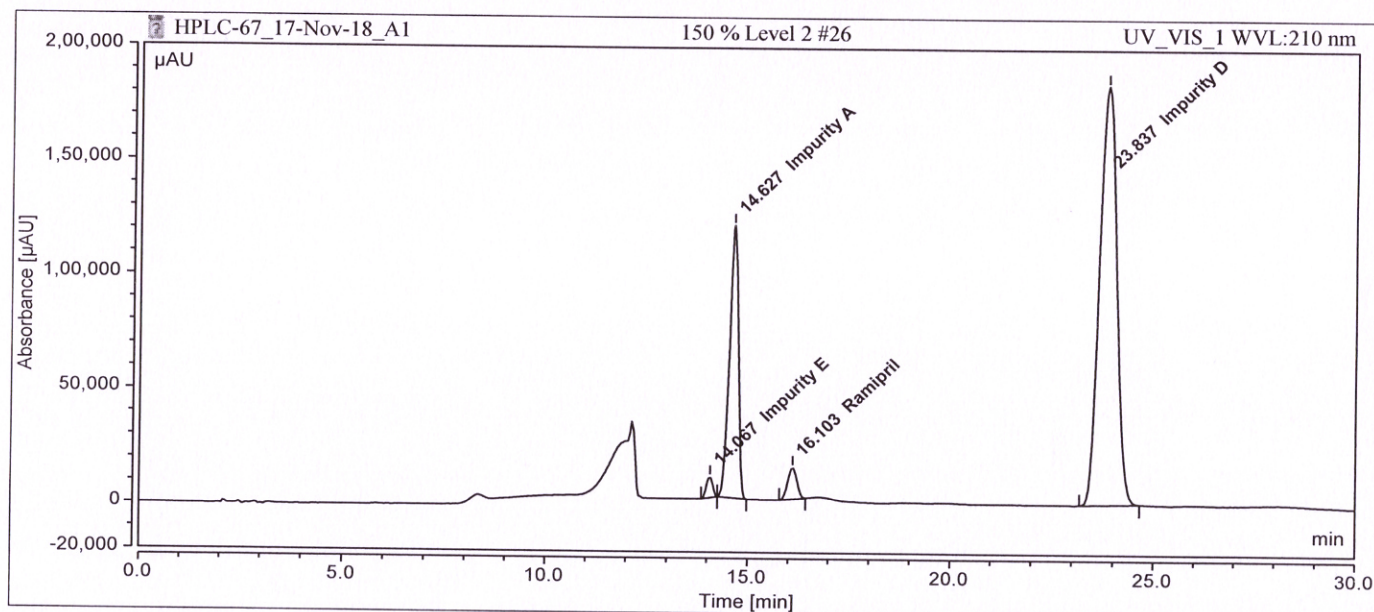


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Impurity E	14.070	1608.814	1.29	0.96	39748	FALSE	n.a.
2	Impurity A	14.630	30264.148	24.34	0.93	20936	FALSE	1.63
3	Ramipril	16.107	3632.981	2.92	1.01	23028	FALSE	3.56
4	Impurity D	23.847	88810.638	71.44	1.07	15935	FALSE	13.12



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	150 % Level 2	AR. No. :-	D2404181993
Sample Number :-	26	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA8	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	18-11-2018 09:29:49	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		

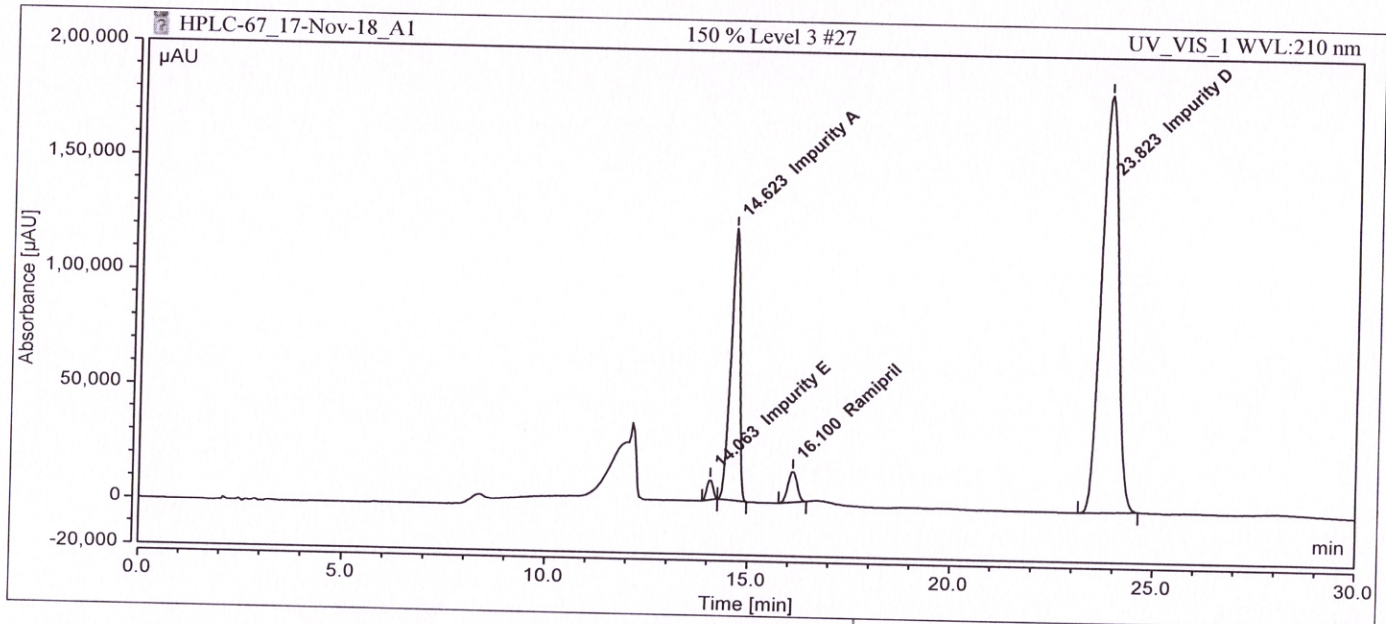


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Impurity E	14.067	1620.526	1.30	0.95	39147	FALSE	n.a.
2	Impurity A	14.627	30290.129	24.33	0.93	20698	FALSE	1.62
3	Ramipril	16.103	3593.575	2.89	1.01	22980	FALSE	3.55
4	Impurity D	23.837	89011.311	71.49	1.07	15817	FALSE	13.07



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	150 % Level 3	AR. No. :-	D2404181993
Sample Number :-	27	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA8	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	18-11-2018 10:01:02	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		

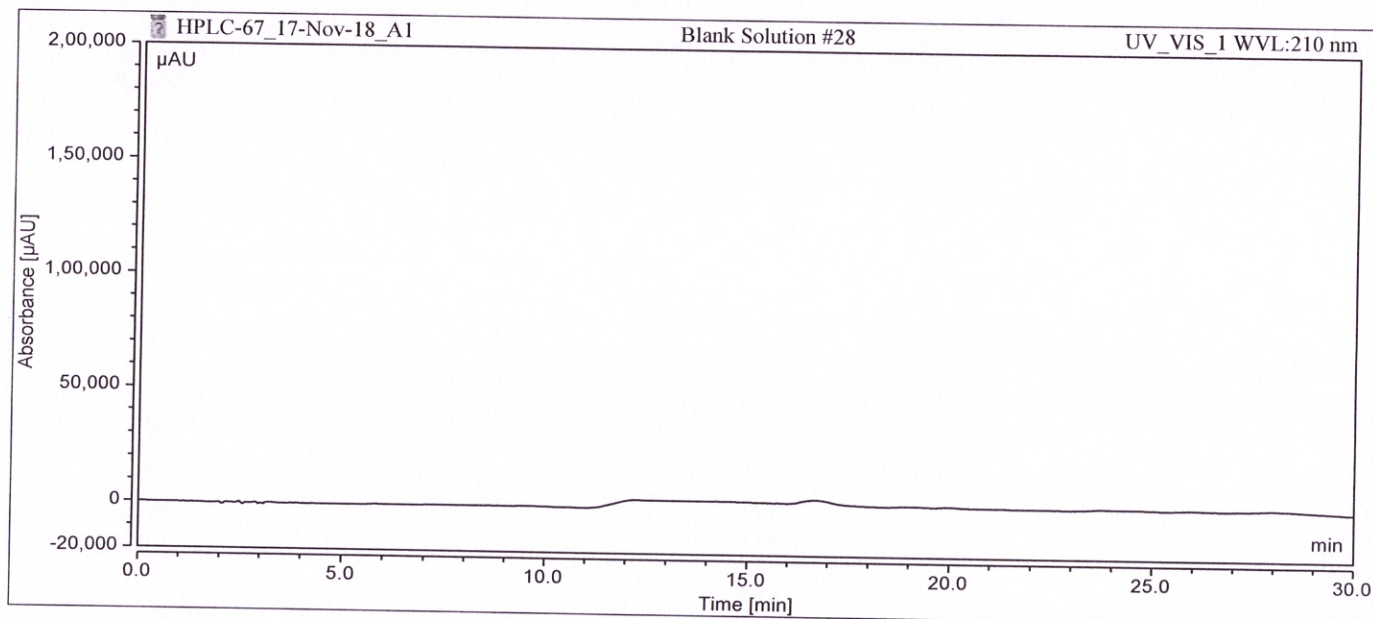


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Impurity E	14.063	1617.725	1.30	0.96	39532	FALSE	n.a.
2	Impurity A	14.623	30300.255	24.34	0.93	20701	FALSE	1.62
3	Ramipril	16.100	3596.265	2.89	1.01	23142	FALSE	3.56
4	Impurity D	23.823	88948.005	71.47	1.08	15774	FALSE	13.07



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Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	28	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA1	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	18-11-2018 10:32:19	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		

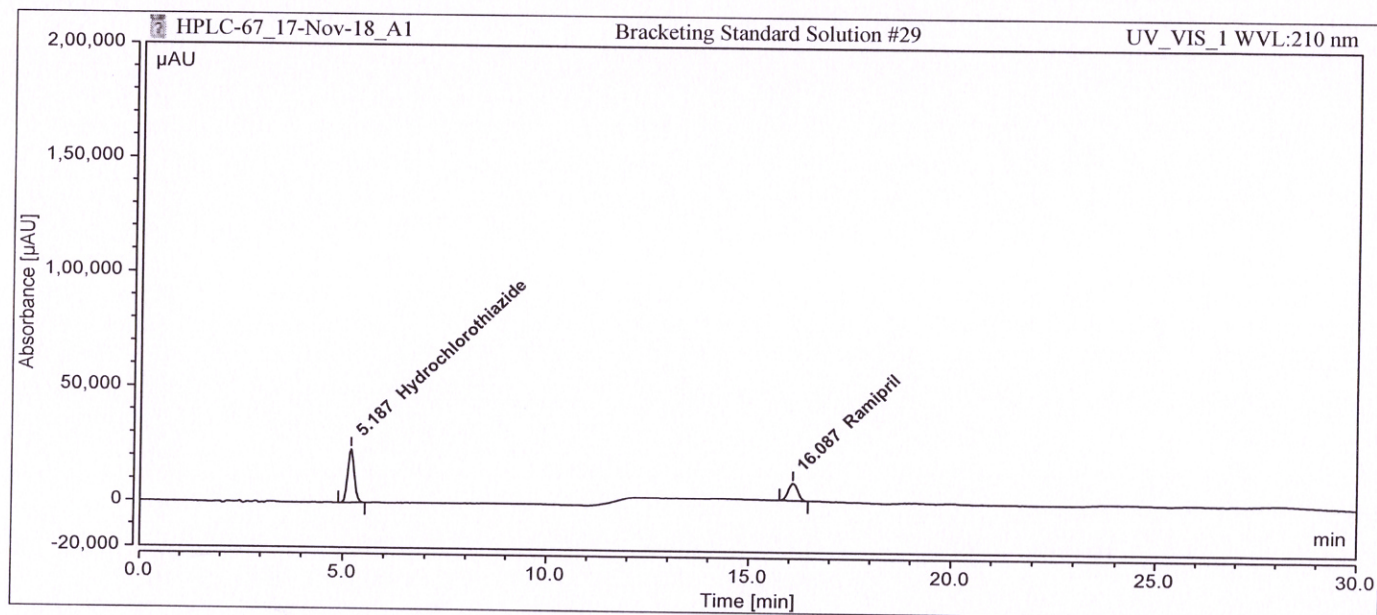


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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Product Name :-	Ramithiazide Tablet	Batch No. :-	N/A
Sample Name :-	Bracketing Standard Solution	AR. No. :-	D2404181993
Sample Number :-	29	Instrument Method :-	HPLC-67_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Gauri Rane
Injection Volume :-	30.00 µL	Instrument Method Created On :-	14-11-2018 16:46:54
Vial Position :-	RA2	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	18-11-2018 11:03:37	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-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	5.187	4340.357	67.67	1.12	4970	FALSE	n.a.
2	Ramipril	16.087	2074.057	32.33	1.02	22079	FALSE	29.97



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Wash method created	Batch No. :-	N/A
Sample Name :-	Wash	AR. No. :-	N/A
Sample Number :-	30	Instrument Method :-	Wash method _HPLC 67_New
Sample Type :-	Unknown	Instrument Method Created By :-	Satish R Dodtale
Injection Volume :-	30.00 µL	Instrument Method Created On :-	11-11-2017 19:41:38
Vial Position :-	RA1	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	18-11-2018 11:38:45	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		

Channel UV_VIS_1 is not available for injection #30 - 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 :-	Shut method	Batch No. :-	N/A
Sample Name :-	Shut	AR. No. :-	N/A
Sample Number :-	31	Instrument Method :-	Shut method _HPLC 67_New-1
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmere
Injection Volume :-	30.00 µL	Instrument Method Created On :-	09-11-2017 20:07:07
Vial Position :-	RA1	Processing Method :-	Ramithiazide Tablets_RS_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Swaraj A. Jadhav
Instrument ID. :-	QbD-INST-HPLC-67	Processing Method Last Updated On :-	19-11-2018 19:53:16
Injection Date & Time :-	18-11-2018 12:44:02	Experiment Name:-	Linearity
Analyst :-	Swaraj Jadhav	Wavelength:-	210. nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-67_17-Nov-18_A1.seq		

Channel UV_VIS_1 is not available for injection #31 - Shut.

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