

RAW DATA OF

(PRECISION,
FILTER STUDY
AND
SOLUTION STABILITY)

RELATED SUBSTANCE VALIDATION

Product Name:	Ramithiazide Tablets
Label claim (mg):	10 mg And 25 mg
AR No.:	D2404181193
Batch No.:	GP180301
Parameter:	Filter Study
LNB No./ Page No.:	718/008

Analysis Date: 21-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 (ppm)	Purity (As is Basis)
	25.31	25.0		
	2.0	100.0	2.02	99.64
	2.0	20.0		

Ramipril				
Injection No.	Retention Time	Peak Area	Retention Time	Area of Bkt Standard
1	16.355	2334.829	16.375	2334.470
2	16.365	2488.392	16.295	2376.174
3	16.373	2334.761	16.375	2347.141
4	16.373	2378.015		
5	16.377	2342.541		
6	16.375	2371.960		
Average	16.370	2375.083	16.363	2367.587
SD	0.0083	58.5876	0.0263	48.8469
%RSD	0.05	2.47	0.16	2.06

System Suitability		
%RSD of Area	2.47	NMT 5.0%

Preparation of standard solution for Hydrochlorothiazide	Weight of standard (mg)	Diluted (mL)	Concentration (ppm)	Purity (As is Basis)
	25.35	25.0		
	2.5	100.0	2.54	99.24
	2.0	20.0		

Hydrochlorothiazide				
Injection No.	Retention Time	Peak Area	Retention Time	Area of Bkt Standard
1	5.178	3920.732	5.202	3949.063
2	5.180	3922.535	5.183	3958.714
3	5.187	3926.765	5.193	3963.506
4	5.188	3920.454		
5	5.188	3918.578		
6	5.188	3928.551		
Average	5.185	3922.936	5.187	3934.322
SD	0.0046	3.9080	0.0071	17.7419
%RSD	0.09	0.10	0.14	0.45

System Suitability		
%RSD of Area	0.10	NMT 5.0%

Sample solution :	Eq to 20 mg	diluted to	20.0	mL with Diluent
Average wt. (mg):	195.84			

Sample Details	Sample wt. (mg)	Impurity name	RT	RRT	Area	%Impurity	Reported impurity	Total % Impurity
Centrifuged Sample	391.92	Unknown Impurity	4.208	0.26	95.331	0.01	BQL	5.33
		Unknown Impurity	7.902	0.49	174.140	0.01	BQL	
		Unknown Impurity	10.597	0.66	223.252	0.02	BQL	
		Unknown Impurity	18.083	1.12	542.726	0.05	BQL	
		Unknown Impurity	18.853	1.17	377.108	0.03	BQL	
		Ramipril Impurity E	14.465	0.89	448.952	0.84	0.84	
		Ramipril Impurity D	24.308	1.50	4334.044	4.49	4.49	
		Ramipril	16.168	1.00	713501.276	-	-	
0.45 µ PVDF	391.92	Unknown Impurity	4.210	0.26	98.283	0.01	BQL	5.35
		Unknown Impurity	7.928	0.49	185.555	0.02	BQL	
		Unknown Impurity	10.650	0.66	200.266	0.02	BQL	
		Unknown Impurity	18.117	1.12	500.518	0.04	BQL	
		Unknown Impurity	18.892	1.17	377.395	0.03	BQL	
		Ramipril Impurity E	14.480	0.89	453.134	0.85	0.85	
		Ramipril Impurity D	24.372	1.50	43418.314	4.50	4.50	
		Ramipril	16.202	1.00	716598.677	-	-	
0.45 µ Nylon	391.92	Unknown Impurity	4.212	0.26	98.947	0.01	BQL	5.35
		Unknown Impurity	7.918	0.49	189.123	0.02	BQL	
		Unknown Impurity	10.650	0.66	206.741	0.02	BQL	
		Unknown Impurity	18.087	1.12	521.984	0.04	BQL	
		Unknown Impurity	18.867	1.17	370.984	0.03	BQL	
		Ramipril Impurity E	14.468	0.89	451.164	0.85	0.85	
		Ramipril Impurity D	24.323	1.50	43428.323	4.50	4.50	
		Ramipril	16.177	1.00	714926.014	-	-	
Whatman 41	391.92	Unknown Impurity	4.207	0.26	98.596	0.01	BQL	5.36
		Unknown Impurity	7.913	0.49	181.588	0.02	BQL	
		Unknown Impurity	10.652	0.66	199.714	0.02	BQL	
		Unknown Impurity	18.115	1.12	519.911	0.04	BQL	
		Unknown Impurity	18.890	1.17	387.059	0.03	BQL	
		Ramipril Impurity E	14.480	0.89	453.189	0.85	0.85	
		Ramipril Impurity D	24.368	1.50	43531.180	4.51	4.51	
		Ramipril	16.193	1.00	716936.709	-	-	

Sample	Ramipril Impurity E	Ramipril Impurity D	Total % Impurities
Centrifuged Sample	0.84	4.49	5.33
0.45 µ PVDF	0.85	4.50	5.35
0.45 µ Nylon	0.85	4.50	5.35
Whatman 41	0.85	4.51	5.36
% Difference			
Sample	Ramipril Impurity E	Ramipril Impurity D	Total % Impurities
Centrifuged Sample	0.01	0.01	0.02
0.45 µ PVDF	0.01	0.01	0.02
0.45 µ Nylon	0.01	0.01	0.02
Whatman 41	0.01	0.02	0.03

Done by: *ST*
Date: 23-Nov-18

Checked by: *Chauhan*
Date: 23-Nov-18

RELATED SUBSTANCE VALIDATION

Product Name:	Ramipril Tablets
Label claim (mg):	10 mg And 25 mg
AR No:	D2404181193
Batch No:	GP180301
Parameter:	Method Precision (As Such)
LNB No./ Page No.	718/009

Analysis Date: 21-Nov-18

Name	RRP
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 (nmol)	Purity (As is Basis)
	25.31	25.0		
	2.0	100.0	2.02	99.64
	2.0	20.0		

Ramipril				
Injection No.	Retention Time	Peak Area	Retention Time	Area of Bkt Standard
1	16.155	2334.829	16.375	2334.470
2	16.165	2485.192	16.295	2376.174
3	16.373	2334.761		
4	16.373	2378.015		
5	16.377	2342.541		
6	16.375	2371.060		
Average	16.370	2375.083	16.361	2370.143
SD	0.0083	58.5876	0.0276	51.5722
%RSD	0.05	2.47	0.17	2.18

System Suitability		
%RSD of Area	2.47	NMT 5.0%

Preparation of standard solution for Hydrochlorothiazide	Weight of standard (mg)	Diluted (mL)	Concentration (nmol)	Purity (As is Basis)
	25.35	25.0		
	2.5	100.0	2.54	99.24
	2.0	20.0		

Hydrochlorothiazide				
Injection No.	Retention Time	Peak Area	Retention Time	Area of Bkt Standard
1	5.178	3920.732	5.202	3949.063
2	5.180	3922.535	5.183	3958.714
3	5.187	3926.765		
4	5.188	3920.454		
5	5.188	3918.578		
6	5.188	3928.551		
Average	5.185	3922.936	5.187	3930.674
SD	0.0046	3.9088	0.0073	14.9286
%RSD	0.09	0.10	0.14	0.38

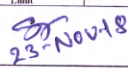
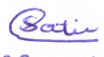
System Suitability		
%RSD of Area	0.10	NMT 5.0%

Sample solution :	Eq to 20 mg	diluted to	20.0	mL with Diluent
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Average wt. (mg)	195.84
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Sample Details	Sample wt. (mg)	Impurity name	RT	RRT	Area	%Impurity	Reported impurity	Total % Impurity
Sample 1	391.92	Unknown Impurity	4.208	0.26	91.111	0.01	BQL	5.30
		Unknown Impurity	7.902	0.49	175.544	0.01	BQL	
		Unknown Impurity	10.598	0.66	208.989	0.02	BQL	
		Unknown Impurity	18.092	1.12	460.949	0.04	BQL	
		Unknown Impurity	18.865	1.17	380.752	0.03	BQL	
		Ramipril Impurity E	14.463	0.89	454.235	0.85	0.85	
		Ramipril Impurity D	24.320	1.50	42936.488	4.45	4.45	
		Ramipril	16.177	1.00	711123.262	-	-	
Sample 2	391.64	Unknown Impurity	4.212	0.26	89.315	0.01	BQL	5.30
		Unknown Impurity	7.895	0.49	183.379	0.02	BQL	
		Unknown Impurity	10.603	0.66	231.313	0.02	BQL	
		Unknown Impurity	18.103	1.12	448.578	0.04	BQL	
		Unknown Impurity	18.867	1.17	379.114	0.03	BQL	
		Ramipril Impurity E	14.468	0.89	454.528	0.85	0.85	
		Ramipril Impurity D	24.338	1.50	42950.770	4.45	4.45	
		Ramipril	16.185	1.00	713836.535	-	-	
Sample 3	391.79	Unknown Impurity	4.210	0.26	95.784	0.01	BQL	5.33
		Unknown Impurity	7.903	0.49	184.530	0.02	BQL	
		Unknown Impurity	10.605	0.66	225.105	0.02	BQL	
		Unknown Impurity	18.095	1.12	462.846	0.04	BQL	
		Unknown Impurity	18.875	1.17	395.959	0.03	BQL	
		Ramipril Impurity E	14.475	0.89	449.074	0.84	0.84	
		Ramipril Impurity D	24.342	1.50	43356.510	4.49	4.49	
		Ramipril	16.190	1.00	717735.838	-	-	
Sample 4	391.28	Unknown Impurity	4.207	0.26	91.211	0.01	BQL	5.29
		Unknown Impurity	7.907	0.49	188.396	0.02	BQL	
		Unknown Impurity	10.627	0.66	205.201	0.02	BQL	
		Unknown Impurity	18.107	1.12	462.493	0.04	BQL	
		Unknown Impurity	18.860	1.17	371.680	0.03	BQL	
		Ramipril Impurity E	14.472	0.89	442.505	0.83	0.83	
		Ramipril Impurity D	24.340	1.50	43027.890	4.46	4.46	
		Ramipril	16.187	1.00	712314.598	-	-	
Sample 5	391.46	Unknown Impurity	4.207	0.26	99.930	0.01	BQL	5.35
		Unknown Impurity	7.915	0.49	171.624	0.01	BQL	
		Unknown Impurity	10.613	0.66	221.065	0.02	BQL	
		Unknown Impurity	18.103	1.12	476.143	0.04	BQL	
		Unknown Impurity	18.873	1.17	380.472	0.03	BQL	
		Ramipril Impurity E	14.475	0.89	453.660	0.85	0.85	
		Ramipril Impurity D	24.340	1.50	43359.429	4.50	4.50	
		Ramipril	16.188	1.00	716873.216	-	-	
Sample 6	391.58	Unknown Impurity	4.212	0.26	91.751	0.01	BQL	5.34
		Unknown Impurity	7.910	0.49	181.242	0.02	BQL	
		Unknown Impurity	10.628	0.66	213.241	0.02	BQL	
		Unknown Impurity	18.108	1.12	455.071	0.04	BQL	
		Unknown Impurity	18.880	1.17	380.378	0.03	BQL	
		Ramipril Impurity E	14.477	0.89	455.028	0.85	0.85	
		Ramipril Impurity D	24.362	1.50	43332.302	4.49	4.49	
		Ramipril	16.197	1.00	715983.534	-	-	

Sample	Ramipril Impurity E	Ramipril Impurity D	% Total Impurities
1	0.85	4.45	5.30
2	0.85	4.45	5.30
3	0.84	4.49	5.33
4	0.83	4.46	5.29
5	0.85	4.50	5.35
6	0.85	4.49	5.34
Average	0.85	4.47	5.32
SD	0.0100	0.0200	0.0200
%RSD	1.18	0.45	0.38
Limit	NMT 15 %		NMT 10 %

Done by: 
Date: 23-Nov-18Checked by: 
Date: 23-Nov-18

RELATED SUBSTANCE VALIDATION

Product Name:	Ramipril Tablets
Label claim (mg):	10 mg And 25 mg
AR No.:	02-60431193
Batch No.:	GP180301
Parameter:	Method Precision (Spiked Sample)
LCH No./Page No.	718/008

Analysis Date: 21-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 (nmol)	Purity (As is Basis)
	25.31	25.0		
	2.0	100.0	2.02	99.64
	2.0	20.0		

Ramipril				
Injection No.	Retention Time	Peak Area	Retention Time	Area of IRI Standard
1	16.355	2334.829	16.375	2334.470
2	16.365	2489.192	16.295	2376.174
3	16.373	2334.561		
4	16.373	2578.015		
5	16.377	2342.541		
6	16.375	2371.560		
Average	16.370	2375.083	16.361	2376.143
SD	0.0083	59.5876	0.0276	51.5722
%RSD	0.05	2.47	0.17	2.18

System Suitability		
%RSD of Area	2.47	NMT 5.0%

Preparation of standard solution for Hydrochlorothiazide	Weight of standard (mg)	Diluted (ml.)	Concentration (nmol)	Purity (As is Basis)
	25.35	25.0		
	2.0	100.0	2.54	99.24
	2.0	20.0		

Hydrochlorothiazide				
Injection No.	Retention Time	Peak Area	Retention Time	Area of IRI Standard
1	5.178	3920.732	5.202	3949.063
2	5.180	3922.535	5.183	3958.714
3	5.187	3926.765		
4	5.188	3920.454		
5	5.188	3918.578		
6	5.188	3928.551		
Average	5.185	3921.836	5.187	3920.674
SD	0.0046	3.5080	0.0072	14.9286
%RSD	0.09	0.10	0.14	0.38

System Suitability		
%RSD of Area	0.10	NMT 5.0%

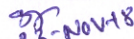
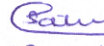
Preparation of Ramipril Impurity A	Batch No.	Weight of standard (mg)	Diluted (ml.)	Concentration (nmol)
	SP-023-164	4.99	20.0	249.50

Sample solution 1	Sp. in 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 1	391.75	Unknown Impurity	4.210	0.26	98.401	0.01	BQL	1.12
		Unknown Impurity	7.912	0.49	182.083	0.02	BQL	
		Unknown Impurity	10.650	0.66	235.107	0.02	BQL	
		Unknown Impurity	18.112	1.12	499.693	0.04	BQL	
		Unknown Impurity	18.883	1.17	371.488	0.03	BQL	
		Ramipril Impurity E	14.483	0.89	470.595	0.88	-	
		Ramipril Impurity A	14.915	0.92	11463.239	1.12	1.12	
		Ramipril Impurity D	24.363	1.50	43485.550	4.51	-	
		Ramipril	16.197	1.00	717600.099	-	-	
		Unknown Impurity	4.212	0.26	103.537	0.01	BQL	
Sample 2	391.93	Unknown Impurity	7.923	0.49	176.130	0.01	BQL	1.11
		Unknown Impurity	10.647	0.66	229.383	0.02	BQL	
		Unknown Impurity	18.113	1.12	492.185	0.04	BQL	
		Unknown Impurity	18.888	1.17	348.429	0.03	BQL	
		Ramipril Impurity E	14.480	0.89	471.283	0.88	-	
		Ramipril Impurity A	14.917	0.92	11387.081	1.11	1.11	
		Ramipril Impurity D	24.363	1.50	43962.193	4.55	-	
		Ramipril	16.197	1.00	718113.082	-	-	
		Unknown Impurity	4.215	0.26	98.186	0.01	BQL	
		Unknown Impurity	7.922	0.49	186.036	0.02	BQL	
Sample 3	391.41	Unknown Impurity	10.650	0.66	227.232	0.02	BQL	1.12
		Unknown Impurity	18.110	1.12	482.521	0.04	BQL	
		Unknown Impurity	18.885	1.17	367.702	0.03	BQL	
		Ramipril Impurity E	14.480	0.89	471.643	0.89	-	
		Ramipril Impurity A	14.913	0.92	11493.367	1.12	1.12	
		Ramipril Impurity D	24.362	1.50	43391.411	4.50	-	
		Ramipril	16.195	1.00	717247.596	-	-	
		Unknown Impurity	4.215	0.26	98.404	0.01	BQL	
		Unknown Impurity	7.912	0.49	181.592	0.02	BQL	
		Unknown Impurity	10.640	0.66	232.774	0.02	BQL	
Sample 4	390.77	Unknown Impurity	18.102	1.12	486.193	0.04	BQL	1.12
		Unknown Impurity	18.888	1.17	371.270	0.03	BQL	
		Ramipril Impurity E	14.478	0.89	470.273	0.88	-	
		Ramipril Impurity A	14.912	0.92	11444.297	1.12	1.12	
		Ramipril Impurity D	24.355	1.50	43574.489	4.53	-	
		Ramipril	16.193	1.00	718985.801	-	-	
		Unknown Impurity	4.213	0.26	98.680	0.01	BQL	
		Unknown Impurity	7.927	0.49	182.113	0.02	BQL	
		Unknown Impurity	10.653	0.66	235.658	0.02	BQL	
		Unknown Impurity	18.108	1.12	500.301	0.04	BQL	
Sample 5	391.03	Unknown Impurity	18.887	1.17	352.182	0.03	BQL	1.11
		Ramipril Impurity E	14.478	0.89	471.604	0.89	-	
		Ramipril Impurity A	14.913	0.92	11385.893	1.11	1.11	
		Ramipril Impurity D	24.357	1.50	43876.560	4.55	-	
		Ramipril	16.195	1.00	718142.805	-	-	
		Unknown Impurity	4.215	0.26	98.698	0.01	BQL	
		Unknown Impurity	7.923	0.49	185.264	0.02	BQL	
		Unknown Impurity	10.650	0.66	222.642	0.02	BQL	
		Unknown Impurity	18.105	1.12	493.310	0.04	BQL	
		Unknown Impurity	18.888	1.17	365.725	0.03	BQL	
Sample 6	392.85	Unknown Impurity	14.478	0.89	477.083	0.89	-	1.12
		Ramipril Impurity E	14.913	0.92	11511.932	1.12	1.12	
		Ramipril Impurity A	24.358	1.50	43477.140	4.49	-	
		Ramipril	16.195	1.00	718072.779	-	-	
		Unknown Impurity	4.215	0.26	98.698	0.01	BQL	
		Unknown Impurity	7.923	0.49	185.264	0.02	BQL	
		Unknown Impurity	10.650	0.66	222.642	0.02	BQL	
		Unknown Impurity	18.105	1.12	493.310	0.04	BQL	
		Unknown Impurity	18.888	1.17	365.725	0.03	BQL	
		Unknown Impurity	14.478	0.89	477.083	0.89	-	

Sample	Ramipril Impurity A	% Total Impurities
1	1.12	1.12
2	1.11	1.11
3	1.12	1.12
4	1.12	1.12
5	1.11	1.11
6	1.12	1.12
Average	1.12	1.12
SD	0.0100	0.0100
%RSD	0.89	0.89
Limit	NMT 10 %	NMT 15 %

Done by: 
Date: 23-Nov-18Checked by: 
Date: 23-Nov-18

RELATED SUBSTANCE VALIDATION

Product Name:	Ramithiazide Tablets
Label claim (mg):	10 mg And 25 mg
AR No:	D2404181193
Batch No.:	GPI80301
Parameter:	Solution Stability For Standard
LNB No./ Page No.	718/008

Analysis Date: 21-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 (ppm)	Purity (As is Basis)
	25.31	25.0		
	2.0	100.0	2.02	99.64
	2.0	20.0		

Ramipril				
Injection No.	Retention Time	Peak Area	Retention Time	Area of Bkt Standard
1	16.355	2334.829	16.375	2334.470
2	16.365	2488.392	16.295	2376.174
3	16.373	2334.761	16.350	2377.441
4	16.373	2378.015	16.375	2347.141
5	16.377	2342.541	16.365	2348.814
6	16.375	2371.960	16.325	2396.538
			16.337	2369.408
Average	16.370	2375.083	16.359	2369.256
SD	0.0083	58.5876	0.0251	43.0036
%RSD	0.05	2.47	0.15	1.82

System Suitability		
%RSD of Area	2.47	NMT 5.0%

Preparation of standard solution for Hydrochlorothiazide	Weight of standard (mg)	Diluted (mL)	Concentration (ppm)	Purity (As is Basis)
	25.35	25.0		
	2.5	100.0	2.54	99.24
	2.0	20.0		

Hydrochlorothiazide				
Injection No.	Retention Time	Peak Area	Retention Time	Area of Bkt Standard
1	5.178	3920.732	5.202	3949.063
2	5.180	3922.535	5.183	3958.714
3	5.187	3926.765	5.193	3957.677
4	5.188	3920.454	5.193	3963.506
5	5.188	3918.578	5.197	3963.714
6	5.188	3928.551	5.178	3972.408
			5.183	3974.737
Average	5.185	3922.936	5.188	3941.891
SD	0.0046	3.9080	0.0075	20.6498
%RSD	0.09	0.10	0.14	0.52

System Suitability		
%RSD of Area	0.10	NMT 5.0%

Standard Details (Time Intervals)	Area
Standard (Initial)	2353.728
Standard (10 Hrs)	2396.874
Standard (16 Hrs)	2355.192
Standard (21 Hrs)	2348.193
Standard (27 Hrs)	2338.447
Average	2358.487
SD	22.4423
%RSD	0.95

Done by: *SP*
Date: 23-Nov-18

Checked by: *Ram*
Date: 23-Nov-18

RELATED SUBSTANCE VALIDATION

Product Name:	Ramipril Tablets
Label claim (mg):	10 mg And 25 mg
Alt. No.:	10440181193
Batch No.:	GP180381
Parameter:	Solution Stability For Sample (Spiked)
LNB No./ Page No.:	718/008

Analysis Date: 21-Nov-18

Name	RRP
Ramipril Impurity A	1.15
Ramipril Impurity D	1.12
Ramipril Impurity E	22.09

Preparation of standard solution for Ramipril	Weight of standard (mg)	Diluted (ml.)	Concentration (nm)	Purity (As is Basis)
	25.31	25.0		
	2.0	100.0	2.02	99.64
	2.0	20.0		

Ramipril				
Injection No.	Retention Time	Peak Area	Retention Time	Area of Bkt Standard
1	16.355	2134.829	16.375	2134.470
2	16.365	2448.192	16.395	2176.174
3	16.371	2134.761	16.359	2177.441
4	16.371	2178.015	16.375	2147.141
5	16.377	2142.541	16.365	2148.814
6	16.375	2171.560	16.325	2196.518
			16.337	2169.408
Average	16.370	2175.883	16.359	2169.256
SD	0.0083	58.5876	0.0251	43.8836
%RSD	0.05	2.47	0.15	1.81

System Suitability		
%RSD of Area	2.47	NMT 5.0%

Preparation of standard solution for Hydrochlorothiazide	Weight of standard (mg)	Diluted (ml.)	Concentration (nm)	Purity (As is Basis)
	25.35	25.0		
	2.5	100.0	2.54	99.24
	2.0	20.0		

Hydrochlorothiazide				
Injection No.	Retention Time	Peak Area	Retention Time	Area of Bkt Standard
1	5.178	3920.772	5.202	3949.063
2	5.180	3922.535	5.183	3958.714
3	5.187	3926.765	5.193	3957.677
4	5.188	3920.454	5.193	3963.506
5	5.188	3918.578	5.197	3963.714
6	5.188	3928.551	5.178	3972.408
			5.183	3974.777
Average	5.185	3922.936	5.188	3941.891
SD	0.0046	3.9889	0.0075	20.6498
%RSD	0.09	0.10	0.14	0.52

System Suitability		
%RSD of Area	0.10	NMT 5.0%

Preparation of Ramipril Impurity A	Batch No.	Weight of standard	Diluted (ml.)	Concentration (nm)
	SP-423-164	4.99	20.0	249.50

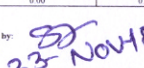
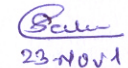
Sample solution :	Eq to 20 mg	diluted to	20.0	ml. with Diluent
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Average wt. (mg):	195.84
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Sample Details	Sample wt. (mg)	Impurity name	RT	RRT	Area	%Impurity	Reported impurity	Total % Impurity
Sample (Initial)	391.75	Unknown Impurity	4.213	0.26	98.637	0.01	BQL	1.12
		Unknown Impurity	7.917	0.49	186.984	0.02	BQL	
		Unknown Impurity	10.652	0.66	231.570	0.02	BQL	
		Unknown Impurity	18.117	1.12	480.247	0.04	BQL	
		Unknown Impurity	18.890	1.17	361.525	0.03	BQL	
		Ramipril Impurity E	14.487	0.89	468.186	0.88	-	
		Ramipril Impurity A	14.925	0.92	11447.837	1.12	1.12	
		Ramipril Impurity D	24.370	1.50	43469.981	4.50	-	
		Ramipril	16.203	1.00	716923.065	-	-	
		Unknown Impurity	4.210	0.26	89.998	0.01	BQL	
Sample (10 Hrs)	391.75	Unknown Impurity	7.912	0.49	179.541	0.02	BQL	1.12
		Unknown Impurity	10.618	0.66	240.524	0.02	BQL	
		Unknown Impurity	18.063	1.12	526.411	0.04	BQL	
		Unknown Impurity	18.843	1.17	371.617	0.03	BQL	
		Ramipril Impurity E	14.453	0.89	472.507	0.89	-	
		Ramipril Impurity A	14.893	0.92	11424.548	1.12	1.12	
		Ramipril Impurity D	24.295	1.51	43520.373	4.51	-	
		Ramipril	16.168	1.00	716519.485	-	-	
		Unknown Impurity	4.207	0.26	100.234	0.01	BQL	
		Unknown Impurity	7.918	0.49	184.669	0.02	BQL	
Sample (16 Hrs)	391.75	Unknown Impurity	10.645	0.66	239.338	0.02	BQL	1.12
		Unknown Impurity	18.120	1.12	579.831	0.05	BQL	
		Unknown Impurity	18.891	1.17	371.017	0.03	BQL	
		Ramipril Impurity E	14.487	0.90	472.356	0.89	-	
		Ramipril Impurity A	14.908	0.92	11476.367	1.12	1.12	
		Ramipril Impurity D	24.365	1.50	43791.544	4.54	-	
		Ramipril	16.188	1.00	718545.967	-	-	
		Unknown Impurity	4.205	0.26	87.873	0.01	BQL	
		Unknown Impurity	7.892	0.49	183.311	0.02	BQL	
		Unknown Impurity	10.595	0.66	247.352	0.02	BQL	
Sample (21 Hrs)	391.75	Unknown Impurity	18.085	1.12	593.104	0.05	BQL	1.12
		Unknown Impurity	18.853	1.17	383.802	0.03	BQL	
		Ramipril Impurity E	14.463	0.90	481.009	0.90	-	
		Ramipril Impurity A	14.885	0.92	11566.385	1.12	1.12	
		Ramipril Impurity D	24.302	1.51	43681.592	4.52	-	
		Ramipril	16.152	1.00	716067.012	-	-	
		Unknown Impurity	4.195	0.26	99.519	0.01	BQL	
		Unknown Impurity	7.893	0.49	182.506	0.02	BQL	
		Unknown Impurity	10.608	0.66	262.086	0.02	BQL	
		Unknown Impurity	18.108	1.12	593.069	0.05	BQL	
Sample (27 Hrs)	391.75	Unknown Impurity	18.877	1.17	361.139	0.03	BQL	1.12
		Ramipril Impurity E	14.475	0.90	466.717	0.88	-	
		Ramipril Impurity A	14.892	0.92	11477.971	1.12	1.12	
		Ramipril Impurity D	24.333	1.51	43793.780	4.54	-	
		Ramipril	16.158	1.00	712172.223	-	-	
		Unknown Impurity	4.195	0.26	99.519	0.01	BQL	
		Unknown Impurity	7.893	0.49	182.506	0.02	BQL	
		Unknown Impurity	10.608	0.66	262.086	0.02	BQL	
		Unknown Impurity	18.108	1.12	593.069	0.05	BQL	
		Unknown Impurity	18.877	1.17	361.139	0.03	BQL	

Sample	Ramipril Impurity E	Ramipril Impurity A	Ramipril Impurity D
Initial	0.88	1.12	4.50
10 Hrs	0.89	1.12	4.51
16 Hrs	0.89	1.12	4.54
21 Hrs	0.90	1.12	4.52
27 Hrs	0.88	1.12	4.54

% Difference			
Sample	Ramipril Impurity E	Ramipril Impurity A	Ramipril Impurity D
Initial	-	-	-
10 Hrs	0.01	0.00	0.01
16 Hrs	0.01	0.00	0.04
21 Hrs	0.02	0.00	0.02
27 Hrs	0.00	0.00	0.04

Done by: 
Date: 23-Nov-18Checked by: 
Date: 23-Nov-18



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Instrument ID : Qbd-INST-HPLC-42

Sequence Name :

HPLC-42_21-Nov-18_A1

Data Vault :

Qbd_2018

Sequence Path :

Method Validation\Generic Healthcare\Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq

Seq. Created By : Swaraj A. Jadhav

Seq. Last Updated By :

Seq. Created On : 21-11-2018 15:28:00

Seq. Last Updated On

21-11-2018 17:53:38

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	42_Ramithiazide 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	42_Ramithiazide 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	42_Ramithiazide 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	42_Ramithiazide 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	42_Ramithiazide 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	42_Ramithiazide 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	42_Ramithiazide 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	42_Ramithiazide 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	42_Ramithiazide Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
10	Placebo Solution	Unknown	30.00	1_3	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	42_Ramithiazide Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
11	Standard Solution 1 (Initial)	Unknown	30.00	1_2	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	42_Ramithiazide Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
12	Spiked Sample Solution 1 (Initial)	Unknown	30.00	1_10	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	42_Ramithiazide 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	42_Ramithiazide Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
14	Sample Solution 1	Unknown	30.00	1_4	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	42_Ramithiazide Tablets_RS_Pf		D2404181993	GP180301	QbD/LC/COL/128
15	Sample Solution 2	Unknown	30.00	1_5	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	42_Ramithiazide Tablets_RS_Pf		D2404181993	GP180301	QbD/LC/COL/128
16	Sample Solution 3	Unknown	30.00	1_6	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	42_Ramithiazide Tablets_RS_Pf		D2404181993	GP180301	QbD/LC/COL/128
17	Sample Solution 4	Unknown	30.00	1_7	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	42_Ramithiazide Tablets_RS_Pf		D2404181993	GP180301	QbD/LC/COL/128
18	Sample Solution 5	Unknown	30.00	1_8	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	42_Ramithiazide Tablets_RS_Pf		D2404181993	GP180301	QbD/LC/COL/128
19	Sample Solution 6	Unknown	30.00	1_9	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	42_Ramithiazide Tablets_RS_Pf		D2404181993	GP180301	QbD/LC/COL/128
20	Blank Solution	Unknown	30.00	1_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	42_Ramithiazide Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
21	Bracketing Standard Solution	Unknown	30.00	1_2	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	42_Ramithiazide Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
22	Spiked Sample Solution 1	Unknown	30.00	1_10	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	42_Ramithiazide Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
23	Spiked Sample Solution 2	Unknown	30.00	1_11	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	42_Ramithiazide Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
24	Spiked Sample Solution 3	Unknown	30.00	1_12	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	42_Ramithiazide Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
25	Spiked Sample Solution 4	Unknown	30.00	1_13	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	42_Ramithiazide Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
26	Spiked Sample Solution 5	Unknown	30.00	1_14	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	42_Ramithiazide Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
27	Spiked Sample Solution 6	Unknown	30.00	1_15	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	42_Ramithiazide Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128
28	Blank Solution	Unknown	30.00	1_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	42_Ramithiazide Tablets_RS_Pf		D2404181993	N/A	QbD/LC/COL/128

QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Instrument ID : QBD-INST-HPLC-42
Sequence Name : HPLC-42_21-Nov-18_A1
Data Vault : QBD_2018
Sequence Path : Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq

Seq. Created By : Swaraj A. Jadhav
Seq. Created On : 21-11-2018 15:28:00
Seq. Last Updated By : Swaraj A. Jadhav
Seq. Last Updated On : 21-11-2018 17:53:38

29	Bracketing Standard Solution	Unknown	30.00	1_2	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
30	Standard Solution 1 (Stability Inter)	Unknown	30.00	1_2	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
31	Spiked Sample Solution 1 (Stability Inter)	Unknown	30.00	1_10	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
32	Blank Solution	Unknown	30.00	1_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
33	Bracketing Standard Solution	Unknown	30.00	1_2	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
34	Blank Solution	Unknown	30.00	1_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
35	Centrifuged Sample Solution	Unknown	30.00	1_16	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	GP180301	QbD/LC/COL/128
36	Sample Solution 0.45 µ PVDF Filter	Unknown	30.00	1_17	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	GP180301	QbD/LC/COL/128
37	Sample Solution 0.45 µ Nylon Filter	Unknown	30.00	1_18	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	GP180301	QbD/LC/COL/128
38	Sample Solution Whatman 41 Filter	Unknown	30.00	1_19	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	GP180301	QbD/LC/COL/128
39	Blank Solution	Unknown	30.00	1_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
40	Bracketing Standard Solution	Unknown	30.00	1_2	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
41	Blank Solution	Unknown	30.00	1_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
42	Standard Solution 1 (Stability Inter)	Unknown	30.00	1_2	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
43	Spiked Sample Solution 1 (Stability Inter)	Unknown	30.00	1_10	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
44	Blank Solution	Unknown	30.00	1_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
45	Bracketing Standard Solution	Unknown	30.00	1_2	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
46	Blank Solution (Saturation)	Unknown	30.00	1_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
47	Blank Solution	Unknown	30.00	1_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
48	Blank Solution	Unknown	30.00	1_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
49	Standard Solution 1 (Stability Inter)	Unknown	30.00	1_2	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
50	Spiked Sample Solution 1 (Stability Inter)	Unknown	30.00	1_10	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
51	Blank Solution	Unknown	30.00	1_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
52	Bracketing Standard Solution	Unknown	30.00	1_2	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
53	Blank Solution (Saturation)	Unknown	30.00	1_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
54	Blank Solution	Unknown	30.00	1_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
55	Blank Solution	Unknown	30.00	1_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
56	Standard Solution 1 (Stability Inter)	Unknown	30.00	1_2	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
57	Spiked Sample Solution 1 (Stability Inter)	Unknown	30.00	1_10	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
58	Blank Solution	Unknown	30.00	1_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
59	Bracketing Standard Solution	Unknown	30.00	1_2	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128

21-Nov-18

QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Instrument ID :		QbD-INST-HPLC-42				Seq. Created By : Swaraj A. Jadhav		Seq. Last Updated By : Swaraj A. Jadhav		
Sequence Name :		HPLC-42_21-Nov-18_A1				Seq. Created On : 21-11-2018 15:28:00		Seq. Last Updated On 21-11-2018 17:53:38		
Data Vault :		QbD_2018								
Sequence Path :		Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq								
60	Wash	Unknown	30.00	1_1	Idle	n.a.	Wash method _HPLC 42	Ramithiazide Tablets_RS_Pf	N/A	QbD/LC/COL/128
61	Shut	Unknown	30.00	1_1	Idle	n.a.	Shut method _HPLC 42	Ramithiazide Tablets_RS_Pf	N/A	QbD/LC/COL/128



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Instrument ID :	QbD-INST-HPLC-42	Seq. Created By :	Swaraj A. Jadhav	Seq. Last Updated By :	Swaraj A. Jadhav
Sequence Name :	HPLC-42_21-Nov-18_A	Seq. Created On :	21-11-2018 15:28:00	Seq. Last Updated On	21-11-2018 17:22:12
Data Vault :	QbD_2018				
Sequence Path :	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A.seq				

Inj No.	Injection Name	Injection Type	Volume μL	Vial No.	Status	Injection Time	Instrument Method	Processing Method	Level	AR_NO	BATCH_NO	COLUMN_NO
1	Blank Solution	Unknown	30.00	1_1 ✓	Idle	n.a	42_Ramthiazide Tablet_Ramthiazide Tablets_RS_PL			D2404181993	N/A	QbD/LC/COL/128
2	Blank Solution	Unknown	30.00	1_1 ✓	Idle	n.a	42_Ramthiazide Tablet_Ramthiazide Tablets_RS_PL			D2404181993	N/A	QbD/LC/COL/128
3	Standard Solution 1	Unknown	30.00	1_2 ✗	Idle	n.a	42_Ramthiazide Tablet_Ramthiazide Tablets_RS_PL			D2404181993	N/A	QbD/LC/COL/128
4	Standard Solution 2	Unknown	30.00	1_2 ✓	Idle	n.a	42_Ramthiazide Tablet_Ramthiazide Tablets_RS_PL			D2404181993	N/A	QbD/LC/COL/128
5	Standard Solution 3	Unknown	30.00	1_2 ✓	Idle	n.a	42_Ramthiazide Tablet_Ramthiazide Tablets_RS_PL			D2404181993	N/A	QbD/LC/COL/128
6	Standard Solution 4	Unknown	30.00	1_2 ✓	Idle	n.a	42_Ramthiazide Tablet_Ramthiazide Tablets_RS_PL			D2404181993	N/A	QbD/LC/COL/128
7	Standard Solution 5	Unknown	30.00	1_2 ✓	Idle	n.a	42_Ramthiazide Tablet_Ramthiazide Tablets_RS_PL			D2404181993	N/A	QbD/LC/COL/128
8	Standard Solution 6	Unknown	30.00	1_2 ✓	Idle	n.a	42_Ramthiazide Tablet_Ramthiazide Tablets_RS_PL			D2404181993	N/A	QbD/LC/COL/128
9	Blank Solution	Unknown	30.00	1_1 ✓	Idle	n.a	42_Ramthiazide Tablet_Ramthiazide Tablets_RS_PL			D2404181993	N/A	QbD/LC/COL/128
10	Placebo Solution	Unknown	30.00	1_3 ✗	Idle	n.a	42_Ramthiazide Tablet_Ramthiazide Tablets_RS_PL			D2404181993	N/A	QbD/LC/COL/128
11	Standard Solution 1 (Initial)	Unknown	30.00	1_2 ✓	Idle	n.a	42_Ramthiazide Tablet_Ramthiazide Tablets_RS_PL			D2404181993	N/A	QbD/LC/COL/128
12	Spiked Sample Solution 1 (Initial)	Unknown	30.00	1_10 ✗	Idle	n.a	42_Ramthiazide Tablet_Ramthiazide Tablets_RS_PL			D2404181993	N/A	QbD/LC/COL/128
13	Blank Solution	Unknown	30.00	1_1 ✓	Idle	n.a	42_Ramthiazide Tablet_Ramthiazide Tablets_RS_PL			D2404181993	N/A	QbD/LC/COL/128
14	Sample Solution 1	Unknown	30.00	1_4 ✗	Idle	n.a	42_Ramthiazide Tablet_Ramthiazide Tablets_RS_PL			D2404181993	GP180301	QbD/LC/COL/128
15	Sample Solution 2	Unknown	30.00	1_5 ✗	Idle	n.a	42_Ramthiazide Tablet_Ramthiazide Tablets_RS_PL			D2404181993	GP180301	QbD/LC/COL/128
16	Sample Solution 3	Unknown	30.00	1_6 ✗	Idle	n.a	42_Ramthiazide Tablet_Ramthiazide Tablets_RS_PL			D2404181993	GP180301	QbD/LC/COL/128
17	Sample Solution 4	Unknown	30.00	1_7 ✗	Idle	n.a	42_Ramthiazide Tablet_Ramthiazide Tablets_RS_PL			D2404181993	GP180301	QbD/LC/COL/128
18	Sample Solution 5	Unknown	30.00	1_8 ✗	Idle	n.a	42_Ramthiazide Tablet_Ramthiazide Tablets_RS_PL			D2404181993	GP180301	QbD/LC/COL/128
19	Sample Solution 6	Unknown	30.00	1_9 ✗	Idle	n.a	42_Ramthiazide Tablet_Ramthiazide Tablets_RS_PL			D2404181993	GP180301	QbD/LC/COL/128
20	Blank Solution	Unknown	30.00	1_1 ✓	Idle	n.a	42_Ramthiazide Tablet_Ramthiazide Tablets_RS_PL			D2404181993	N/A	QbD/LC/COL/128
21	Bracketing Standard Solution	Unknown	30.00	1_2 ✓	Idle	n.a	42_Ramthiazide Tablet_Ramthiazide Tablets_RS_PL			D2404181993	N/A	QbD/LC/COL/128
22	Spiked Sample Solution 1	Unknown	30.00	1_10 ✗	Idle	n.a	42_Ramthiazide Tablet_Ramthiazide Tablets_RS_PL			D2404181993	N/A	QbD/LC/COL/128
23	Spiked Sample Solution 2	Unknown	30.00	1_11 ✗	Idle	n.a	42_Ramthiazide Tablet_Ramthiazide Tablets_RS_PL			D2404181993	N/A	QbD/LC/COL/128
24	Spiked Sample Solution 3	Unknown	30.00	1_12 ✗	Idle	n.a	42_Ramthiazide Tablet_Ramthiazide Tablets_RS_PL			D2404181993	N/A	QbD/LC/COL/128
25	Spiked Sample Solution 4	Unknown	30.00	1_13 ✗	Idle	n.a	42_Ramthiazide Tablet_Ramthiazide Tablets_RS_PL			D2404181993	N/A	QbD/LC/COL/128
26	Spiked Sample Solution 5	Unknown	30.00	1_14 ✗	Idle	n.a	42_Ramthiazide Tablet_Ramthiazide Tablets_RS_PL			D2404181993	N/A	QbD/LC/COL/128
27	Spiked Sample Solution 6	Unknown	30.00	1_15 ✗	Idle	n.a	42_Ramthiazide Tablet_Ramthiazide Tablets_RS_PL			D2404181993	N/A	QbD/LC/COL/128
28	Blank Solution	Unknown	30.00	1_1	Idle	n.a	42_Ramthiazide Tablet_Ramthiazide Tablets_RS_PL			D2404181993	N/A	QbD/LC/COL/128

QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Instrument ID : QBD-INST-HPLC-42

Sequence Name :

HPLC-42_21-Nov-18_A

Data Vault :

Qbd_2018

Seq. Created By : Swaraj A. Jadhav

Seq. Last Updated By : Swaraj A. Jadhav

Seq. Created On : 21-11-2018 15:28:00

Seq. Last Updated On : 21-11-2018 17:22:12

Sequence Path : Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A.seq

29	Bracketing Standard Solution	Unknown	30.00	1_2_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
30	Standard Solution 1 (Stability Interv)	Unknown	30.00	1_2_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
31	Spiked Sample Solution 1 (Stability Interv)	Unknown	30.00	1_10_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
32	Blank Solution	Unknown	30.00	1_1_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
33	Bracketing Standard Solution	Unknown	30.00	1_2_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
34	Blank Solution	Unknown	30.00	1_1_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
35	Centrifuged Sample Solution	Unknown	30.00	1_16_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	GP180301	QbD/LC/COL/128
36	Sample Solution 0.45 µ PVDF Filter	Unknown	30.00	1_17_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	GP180301	QbD/LC/COL/128
37	Sample Solution 0.45 µ Nylon Filter	Unknown	30.00	1_18_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	GP180301	QbD/LC/COL/128
38	Sample Solution Whatman 41 Filter	Unknown	30.00	1_19_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	GP180301	QbD/LC/COL/128
39	Blank Solution	Unknown	30.00	1_1_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
40	Bracketing Standard Solution	Unknown	30.00	1_2_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
41	Blank Solution	Unknown	30.00	1_1_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
42	Standard Solution 1 (Stability Interv)	Unknown	30.00	1_2_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
43	Spiked Sample Solution 1 (Stability Interv)	Unknown	30.00	1_10_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
44	Blank Solution	Unknown	30.00	1_1_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
45	Bracketing Standard Solution	Unknown	30.00	1_2_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
46	Blank Solution (Saturation)	Unknown	30.00	1_1_1	Idle	n.a.	42_Ramithiazide Tablet_RS_Saturation	D2404181993	N/A	QbD/LC/COL/128
47	Blank Solution	Unknown	30.00	1_1_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
48	Blank Solution	Unknown	30.00	1_1_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
49	Standard Solution 1 (Stability Interv)	Unknown	30.00	1_2_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
50	Spiked Sample Solution 1 (Stability Interv)	Unknown	30.00	1_10_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
51	Blank Solution	Unknown	30.00	1_1_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
52	Bracketing Standard Solution	Unknown	30.00	1_2_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
53	Blank Solution (Saturation)	Unknown	30.00	1_1_1	Idle	n.a.	42_Ramithiazide Tablet_RS_Saturation	D2404181993	N/A	QbD/LC/COL/128
54	Blank Solution	Unknown	30.00	1_1_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
55	Blank Solution	Unknown	30.00	1_1_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
56	Standard Solution 1 (Stability Interv)	Unknown	30.00	1_2_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
57	Spiked Sample Solution 1 (Stability Interv)	Unknown	30.00	1_10_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
58	Blank Solution	Unknown	30.00	1_1_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128
59	Bracketing Standard Solution	Unknown	30.00	1_2_1	Idle	n.a.	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_Pf	D2404181993	N/A	QbD/LC/COL/128

n.a.

Page No. 2 of 3 Printed Time 21-Nov-2018 17:22

Electronically Signed Document

21-Nov-18 21-Nov-18
 * Refer AR NO :- D2404181193 instead of AR NO :- D2404181993

n.a.

QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Instrument ID : QbD-INST-HPLC-42

Sequence Name : HPLC-42_21-Nov-18_A

Data Vault : QbD_2018

Sequence Path : Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A.seq

Seq. Created By : Swaraj A. Jadhav

Seq. Created On : 21-11-2018 15:28:00

Seq. Last Updated By :

21-11-2018 17:22:12

Seq. Last Updated On

60	Wash	Unknown	30.00	1_1	Idle	n.a.	Wash method_HPLC 42	Ramithiazide Tablets_RS_Pt	N/A	N/A	QbD/LC/COL/128
61	Shut	Unknown	30.00	1_1	Idle	n.a.	Shut method_HPLC 42	Ramithiazide Tablets_RS_Pt	N/A	N/A	QbD/LC/COL/128

21-Nov-18

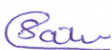
n.a.

21-Nov-18

n.a.

Name	HPLC-42_Ramithiazide Tablet_RS_Met
Data Vault	XVault
Path	chrom://qbd-pc-03/XVault/QbD-INST-HPLC-42/1306/HPLC-42_21-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


21-Nov-18


21-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	0.000		Duration =	
			30.000 [min] ✓	
	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	30.0 [%] ✓	
		Pump.%C.Value	0.0 [%]	
		Pump.%D.Value	0.0 [%]	
	25.000	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		

21-Nov-18

Satu
21-Nov-18

Name	HPLC-42_Ramithiazide Tablet_RS_Saturation_Met
Data Vault	XVault
Path	chrom://qbd-pc-03/XVault/QbD-INST-HPLC-42/1306/HPLC-42_21-Nov-18_A.seq/HPLC-42_Ramithiazide Tablet_RS_Saturation_Met.instmeth
Comment	Ramithiazide Tablets
Description	Ramithiazide Tablets-Related Substance
Run time	120.000 [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 16:08:43 +05:30 Santosh Padmure

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21-Nov-18

Satu
21-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	0.000		Duration = 120.000 [min]	
		Pump.Flow	0.200 [ml/min]	
		Pump.%B.Value	30.0 [%]	
		Pump.%C.Value	0.0 [%]	
	120.000	Pump.%D.Value	0.0 [%]	
		Pump.Flow	0.200 [ml/min]	
		Pump.%B.Value	30.0 [%]	
		Pump.%C.Value	0.0 [%]	
Stop Run	120.000	Pump.%D.Value	0.0 [%]	
		UV.UV_VIS_1.AcqOff		
End				

SD
21 Nov 18

Sadhu
21 Nov 18



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Instrument ID : QbD-INST-HPLC-42

Sequence Name : HPLC-42_21-Nov-18_AI

Data Vault : QbD_2018

Sequence Path : Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_AI.seq

Seq. Created By : Swaraj A. Jadhav
 Seq. Created On : 21-11-2018 15:28:00
 Seq. Last Updated By : Swaraj A. Jadhav
 Seq. Last Updated On : 23-11-2018 19:16:47

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	21-11-2018 18:15:12	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbD/LC/COL/128
2	Blank Solution	Unknown	30.00	1_1	Finished	21-11-2018 18:46:22	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbD/LC/COL/128
3	Standard Solution 1	Unknown	30.00	1_2	Finished	21-11-2018 19:17:30	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbD/LC/COL/128
4	Standard Solution 2	Unknown	30.00	1_2	Finished	21-11-2018 19:48:40	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbD/LC/COL/128
5	Standard Solution 3	Unknown	30.00	1_2	Finished	21-11-2018 20:19:48	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbD/LC/COL/128
6	Standard Solution 4	Unknown	30.00	1_2	Finished	21-11-2018 20:50:58	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbD/LC/COL/128
7	Standard Solution 5	Unknown	30.00	1_2	Finished	21-11-2018 21:22:08	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbD/LC/COL/128
8	Standard Solution 6	Unknown	30.00	1_2	Finished	21-11-2018 21:53:16	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbD/LC/COL/128
9	Blank Solution	Unknown	30.00	1_1	Finished	21-11-2018 22:24:24	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbD/LC/COL/128
10	Placebo Solution	Unknown	30.00	1_3	Finished	21-11-2018 22:55:32	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbD/LC/COL/128
11	Standard Solution 1 (Initial)	Unknown	30.00	1_2	Finished	21-11-2018 23:26:43	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbD/LC/COL/128
12	Spiked Sample Solution 1 (Initial)	Unknown	30.00	1_10	Finished	21-11-2018 23:57:54	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbD/LC/COL/128
13	Blank Solution	Unknown	30.00	1_1	Finished	22-11-2018 00:29:02	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbD/LC/COL/128
14	Sample Solution 1	Unknown	30.00	1_4	Finished	22-11-2018 01:00:11	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	GP180301	QbD/LC/COL/128
15	Sample Solution 2	Unknown	30.00	1_5	Finished	22-11-2018 01:31:19	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	GP180301	QbD/LC/COL/128
16	Sample Solution 3	Unknown	30.00	1_6	Finished	22-11-2018 02:02:29	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	GP180301	QbD/LC/COL/128
17	Sample Solution 4	Unknown	30.00	1_7	Finished	22-11-2018 02:33:38	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	GP180301	QbD/LC/COL/128
18	Sample Solution 5	Unknown	30.00	1_8	Finished	22-11-2018 03:04:47	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	GP180301	QbD/LC/COL/128
19	Sample Solution 6	Unknown	30.00	1_9	Finished	22-11-2018 03:35:58	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	GP180301	QbD/LC/COL/128
20	Blank Solution	Unknown	30.00	1_1	Finished	22-11-2018 04:07:04	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbD/LC/COL/128
21	Bracketing Standard Solution	Unknown	30.00	1_2	Finished	22-11-2018 04:38:14	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbD/LC/COL/128
22	Spiked Sample Solution 1	Unknown	30.00	1_10	Finished	22-11-2018 05:09:25	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbD/LC/COL/128
23	Spiked Sample Solution 2	Unknown	30.00	1_11	Finished	22-11-2018 05:40:33	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbD/LC/COL/128
24	Spiked Sample Solution 3	Unknown	30.00	1_12	Finished	22-11-2018 06:11:41	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbD/LC/COL/128
25	Spiked Sample Solution 4	Unknown	30.00	1_13	Finished	22-11-2018 06:42:48	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbD/LC/COL/128
26	Spiked Sample Solution 5	Unknown	30.00	1_14	Finished	22-11-2018 07:13:57	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbD/LC/COL/128
27	Spiked Sample Solution 6	Unknown	30.00	1_15	Finished	22-11-2018 07:45:06	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbD/LC/COL/128
28	Blank Solution	Unknown	30.00	1_1	Finished	22-11-2018 08:16:13	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbD/LC/COL/128

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

28-Nov-18

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Instrument ID : QbD-INST-HPLC-42															
Sequence Name : HPLC-42_21-Nov-18_AI															
Data Vault : QbD_2018															
Sequence Path : Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_AI.seq															
29	Bracketing Standard Solution	Unknown	30.00	1_2	Finished	22-11-2018 08:47:22	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbDILC/COL/128			
30	Standard Solution 1 (Stability Inten	Unknown	30.00	1_2	Finished	22-11-2018 09:18:31	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbDILC/COL/128			
31	Spiked Sample Solution 1 (Stability	Unknown	30.00	1_10	Finished	22-11-2018 09:49:42	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbDILC/COL/128			
32	Blank Solution	Unknown	30.00	1_1	Finished	22-11-2018 10:20:48	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbDILC/COL/128			
33	Bracketing Standard Solution	Unknown	30.00	1_2	Finished	22-11-2018 10:51:59	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbDILC/COL/128			
34	Blank Solution	Unknown	30.00	1_1	Finished	22-11-2018 11:23:06	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbDILC/COL/128			
35	Centrifuged Sample Solution	Unknown	30.00	1_16	Finished	22-11-2018 11:54:16	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	GP180301	QbDILC/COL/128			
36	Sample Solution 0.45 µ PVDF Filter	Unknown	30.00	1_17	Finished	22-11-2018 12:25:26	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	GP180301	QbDILC/COL/128			
37	Sample Solution 0.45 µ Nylon Filter	Unknown	30.00	1_18	Finished	22-11-2018 12:56:35	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	GP180301	QbDILC/COL/128			
38	Sample Solution Whatman 41 Filter	Unknown	30.00	1_19	Finished	22-11-2018 13:27:45	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	GP180301	QbDILC/COL/128			
39	Blank Solution	Unknown	30.00	1_1	Finished	22-11-2018 13:58:52	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbDILC/COL/128			
40	Bracketing Standard Solution	Unknown	30.00	1_2	Finished	22-11-2018 14:29:58	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbDILC/COL/128			
41	Blank Solution	Unknown	30.00	1_1	Finished	22-11-2018 15:01:06	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbDILC/COL/128			
42	Standard Solution 1 (Stability Interv	Unknown	30.00	1_2	Finished	22-11-2018 15:32:14	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbDILC/COL/128			
43	Spiked Sample Solution 1 (Stability	Unknown	30.00	1_10	Finished	22-11-2018 16:03:25	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbDILC/COL/128			
44	Blank Solution	Unknown	30.00	1_1	Finished	22-11-2018 16:34:32	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbDILC/COL/128			
45	Bracketing Standard Solution	Unknown	30.00	1_2	Finished	22-11-2018 17:05:40	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbDILC/COL/128			
46	Blank Solution (Saturation)	Unknown	30.00	1_1	Finished	22-11-2018 17:36:53	amithiazide Tablet_RS_Sapamithiazide Tablets_RS_PR			D2404181993	N/A	QbDILC/COL/128			
47	Blank Solution	Unknown	30.00	1_1	Finished	22-11-2018 19:38:02	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbDILC/COL/128			
48	Blank Solution	Unknown	30.00	1_1	Finished	22-11-2018 20:09:10	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbDILC/COL/128			
49	Standard Solution 1 (Stability Interv	Unknown	30.00	1_2	Finished	22-11-2018 20:40:18	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbDILC/COL/128			
50	Spiked Sample Solution 1 (Stability	Unknown	30.00	1_10	Finished	22-11-2018 21:11:28	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbDILC/COL/128			
51	Blank Solution	Unknown	30.00	1_1	Finished	22-11-2018 21:42:34	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbDILC/COL/128			
52	Bracketing Standard Solution	Unknown	30.00	1_2	Finished	22-11-2018 22:13:42	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbDILC/COL/128			
53	Blank Solution (Saturation)	Unknown	30.00	1_1	Finished	22-11-2018 22:44:55	amithiazide Tablet_RS_Sapamithiazide Tablets_RS_PR			D2404181993	N/A	QbDILC/COL/128			
54	Blank Solution	Unknown	30.00	1_1	Finished	23-11-2018 00:46:05	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbDILC/COL/128			
55	Blank Solution	Unknown	30.00	1_1	Finished	23-11-2018 01:17:13	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbDILC/COL/128			
56	Standard Solution 1 (Stability Interv	Unknown	30.00	1_2	Finished	23-11-2018 01:48:21	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbDILC/COL/128			
57	Spiked Sample Solution 1 (Stability	Unknown	30.00	1_10	Finished	23-11-2018 02:19:31	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbDILC/COL/128			
58	Blank Solution	Unknown	30.00	1_1	Finished	23-11-2018 02:50:39	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbDILC/COL/128			
59	Bracketing Standard Solution	Unknown	30.00	1_2	Finished	23-11-2018 03:21:46	42_Ramithiazide Tablet_Ramithiazide Tablets_RS_PR			D2404181993	N/A	QbDILC/COL/128			

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

28-Nov-18

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Instrument ID :		QbD-INST-HPLC-42									
Sequence Name :		HPLC-42_21-Nov-18_A1									
Data Vault :		QbD_2018									
Sequence Path :		Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq									
60	Wash	Unknown	30.00	1_1	Finished	23-11-2018 03:52:32	Wash method _HPLC 42	Ramithiazide Tablets_RS_Pf		N/A	QbD/LC/COL/128
61	Shut	Unknown	30.00	1_1	Finished	23-11-2018 04:53:08	Shut method _HPLC 42	Ramithiazide Tablets_RS_Pf		N/A	QbD/LC/COL/128



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Processing Method

Processing Method Name :	Ramithiazide Tablets_RS_PR_1		
Processing Method Path :	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		
Processing Method Created By :	Swaraj A. Jadhav	Processing Method Last Updated By :	Swaraj A. Jadhav
Processing Method Created On :	21-11-2018 16:02:02	Processing Method Last Updated On :	23-11-2018 09:42:00

Detection Algorithm	Chromeleon 6	Version	2
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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	0.600 [min]	Any	All Channels
4.009	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
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	1500.000 [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	4.133
2	Placebo	4.667
3	Hydrochlorothiazide	5.207
4	Unknown	7.963
5	Unknown	10.598
6	Placebo	11.197
7	Impurity E	14.463
8	Impurity A	14.915
9	Ramipril	16.197
10	Unknown	18.092
11	Unknown	18.865
12	Impurity D	24.363

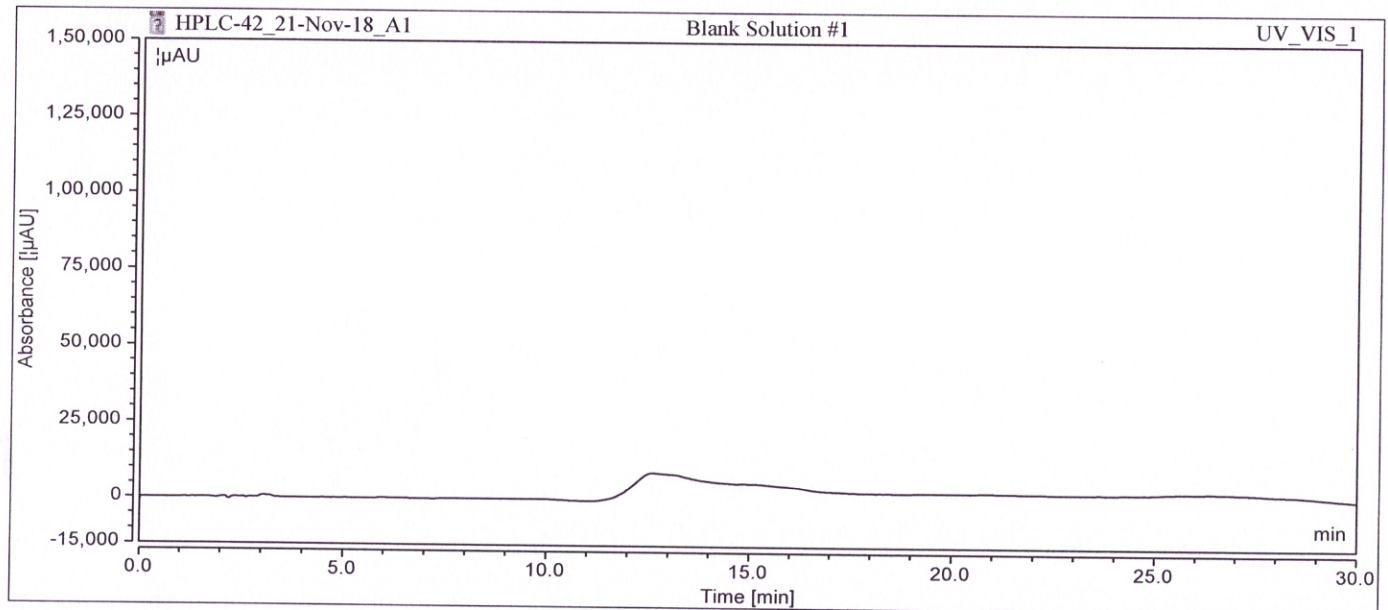
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Processing Method



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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	1	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	21-11-2018 18:15:12	Experiment Name:-	Precision, Solution Stability & Filter S
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

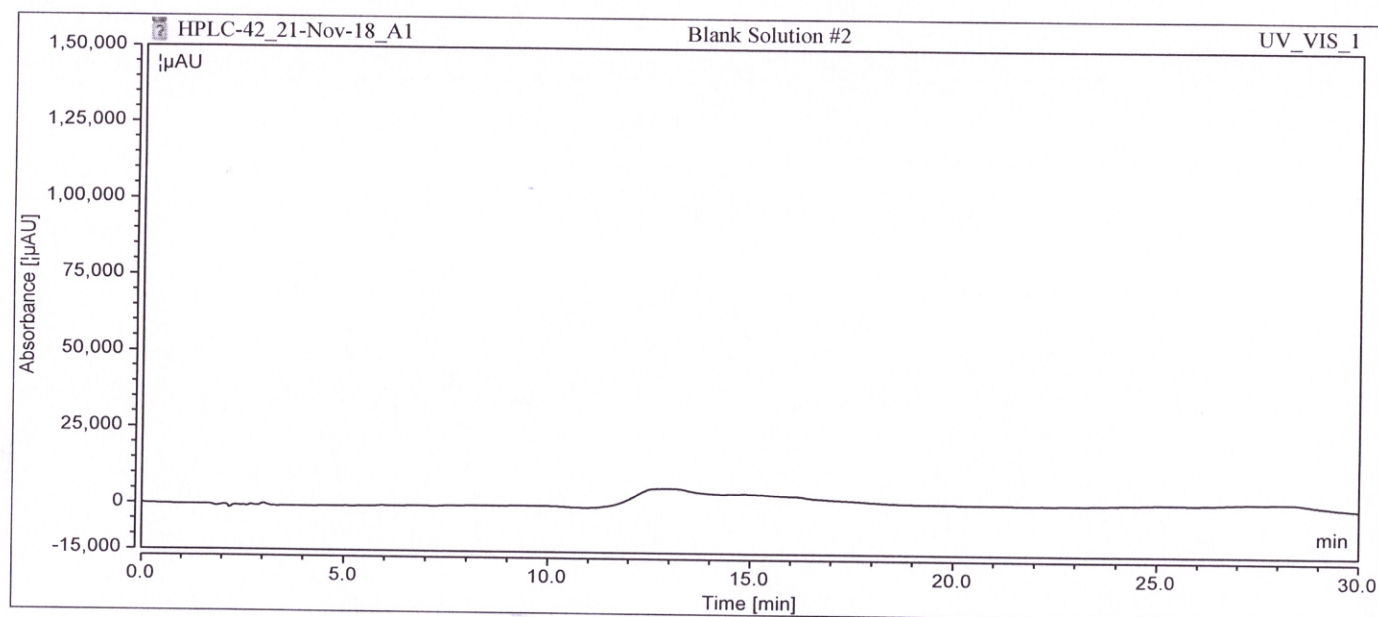


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	2	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	21-11-2018 18:46:22	Experiment Name:-	Precision, Solution Stability & Filter S
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

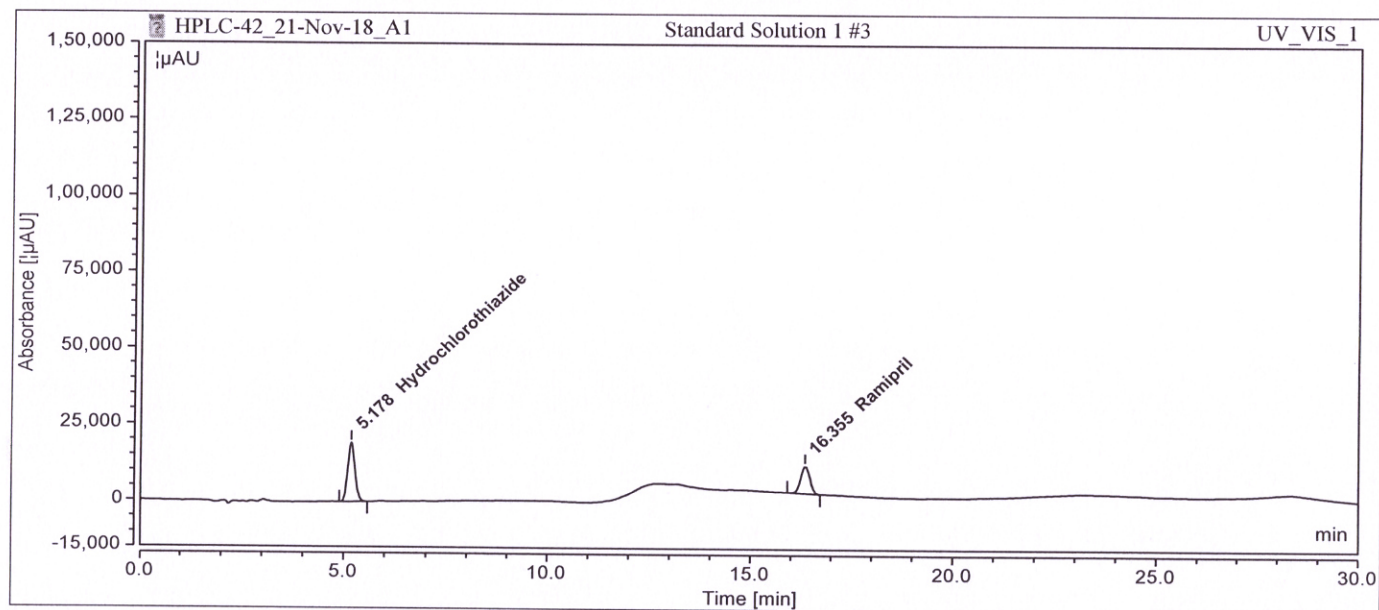


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Standard Solution 1	AR. No. :-	D2404181993
Sample Number :-	3	Instrument 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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	21-11-2018 19:17:30	Experiment Name:-	Precision, Solution Stability & Filter S
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

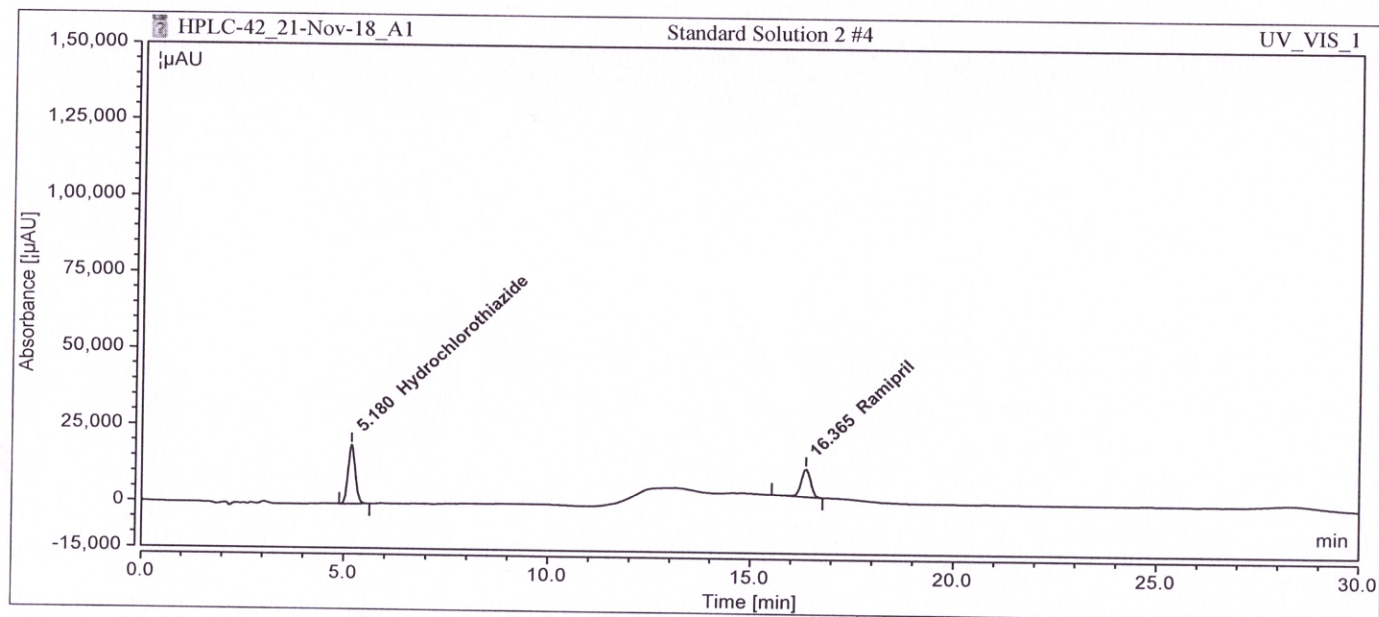


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.178	3920.732	62.68	1.14	4043	FALSE	n.a.
2	Ramipril	16.355	2334.829	37.32	1.01	24595	FALSE	30.09



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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_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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	21-11-2018 19:48:40	Experiment Name:-	Precision,Solution Stability & Filter S
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

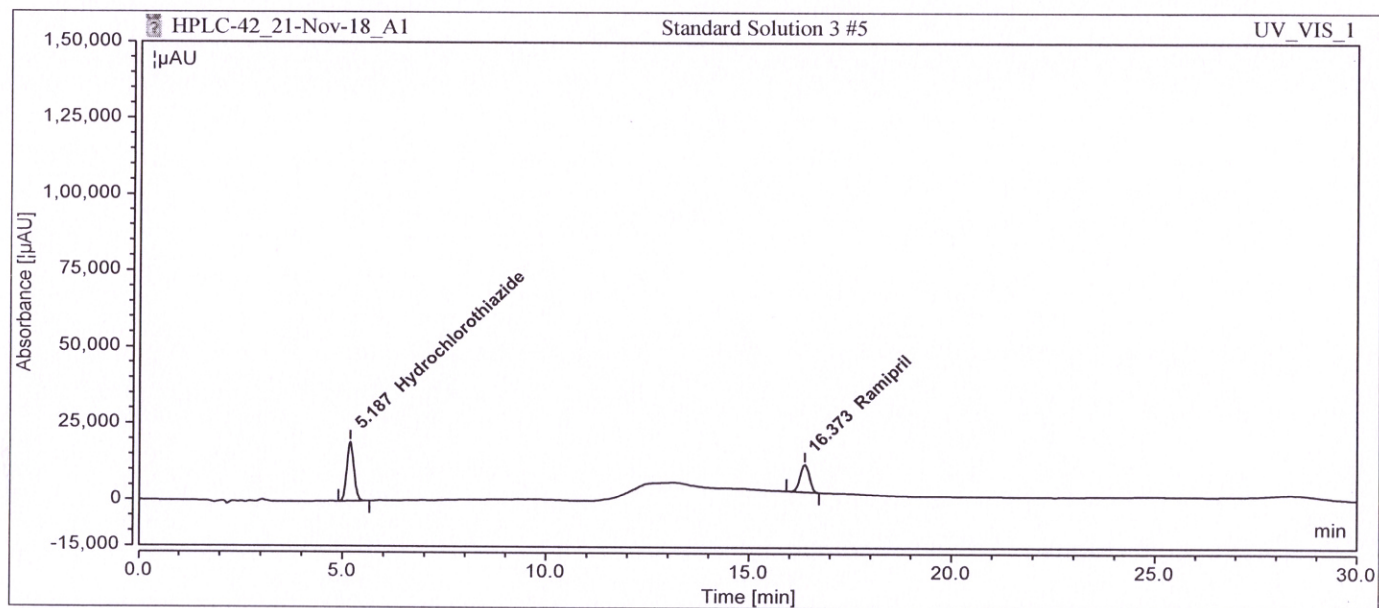


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.180	3922.535	61.19	1.13	4063	FALSE	n.a.
2	Ramipril	16.365	2488.392	38.81	0.97	24025	FALSE	29.93



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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_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_2	Processing Method :-	Ramithiazide Tablets_RS_PR_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	21-11-2018 20:19:48	Experiment Name:-	Precision, Solution Stability & Filter S
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

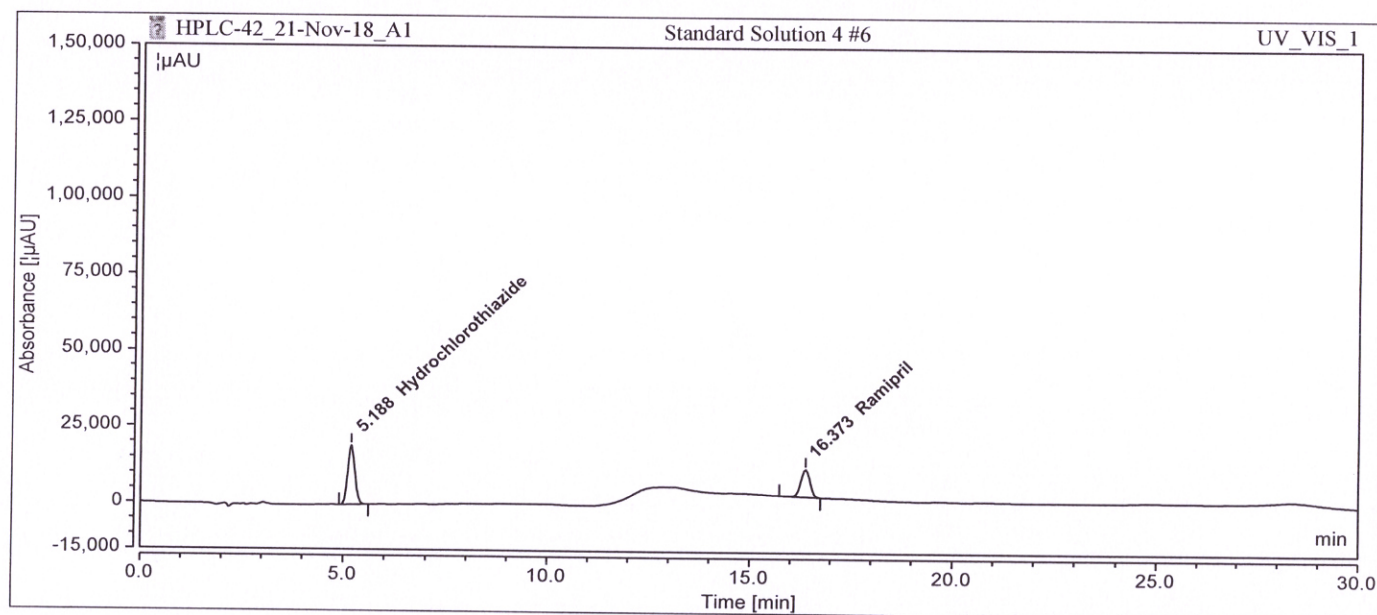


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.187	3926.765	62.71	1.13	4073	FALSE	n.a.
2	Ramipril	16.373	2334.761	37.29	1.01	24893	FALSE	30.23



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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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	21-11-2018 20:50:58	Experiment Name:-	Precision, Solution Stability & Filter S
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

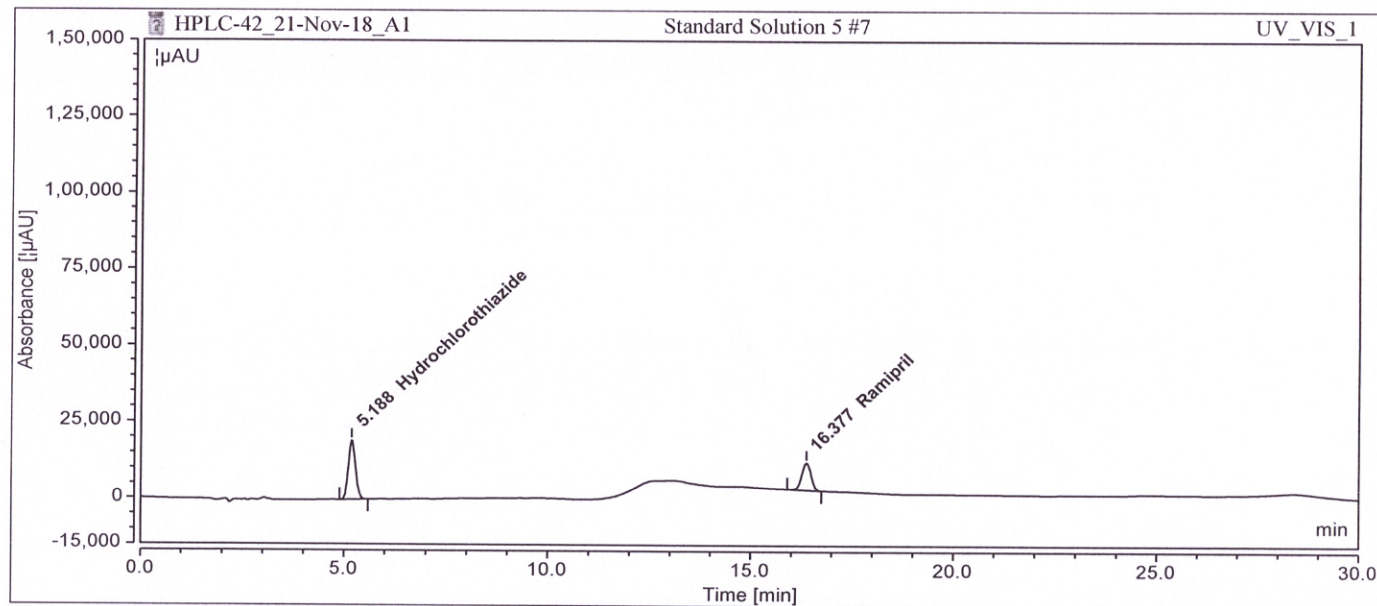


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.188	3920.454	62.24	1.13	4094	FALSE	n.a.
2	Ramipril	16.373	2378.015	37.76	0.99	24620	FALSE	30.16



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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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	21-11-2018 21:22:08	Experiment Name:-	Precision,Solution Stability & Filter S
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

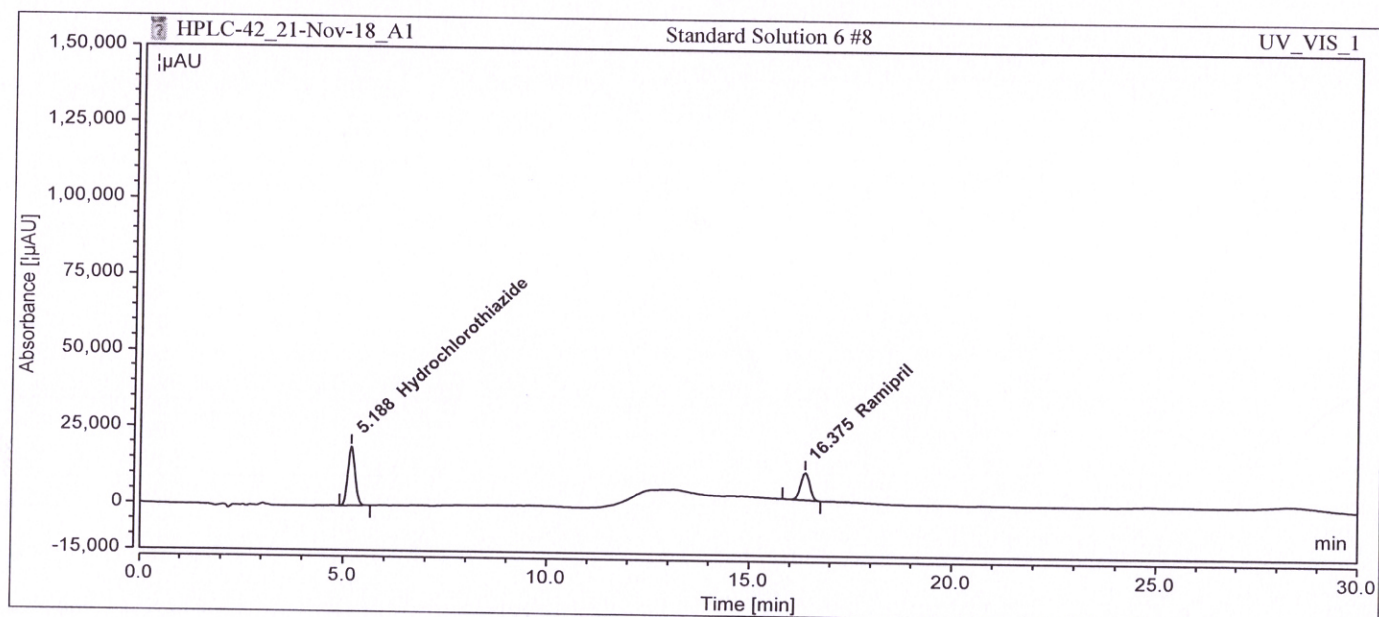


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.188	3918.578	62.59	1.14	4070	FALSE	n.a.
2	Ramipril	16.377	2342.541	37.41	1.01	24698	FALSE	30.15



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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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	21-11-2018 21:53:16	Experiment Name:-	Precision, Solution Stability & Filter S
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

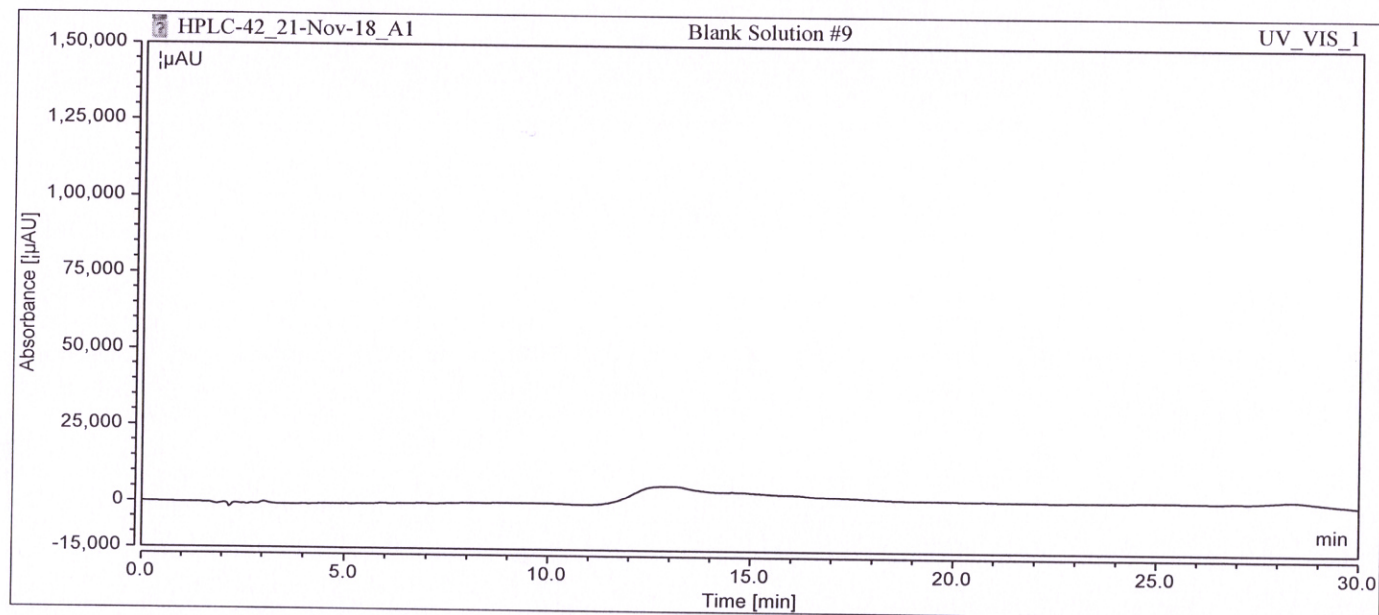


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.188	3928.551	62.35	1.13	4042	FALSE	n.a.
2	Ramipril	16.375	2371.960	37.65	1.00	24632	FALSE	30.08



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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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	21-11-2018 22:24:24	Experiment Name:-	Precision,Solution Stability & Filter S
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-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_PR		
Processing Method Path :	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		
Processing Method Created By :	Swaraj A. Jadhav	Processing Method Last Updated By :	Swaraj A. Jadhav
Processing Method Created On :	21-11-2018 16:02:02	Processing Method Last Updated On :	23-11-2018 19:16:47

Detection Alogrithm	Chromeleon 6	Version	6
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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	0.600 [min]	Any	All Channels
4.009	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	4.133
2	Placebo	4.667
3	Hydrochlorothiazide	5.207
4	Unknown	7.963
5	Unknown	10.598
6	Placebo	11.197
7	Impurity E	14.463
8	Impurity A	14.915
9	Ramipril	16.197
10	Unknown	18.092
11	Unknown	18.865
12	Impurity D	24.363

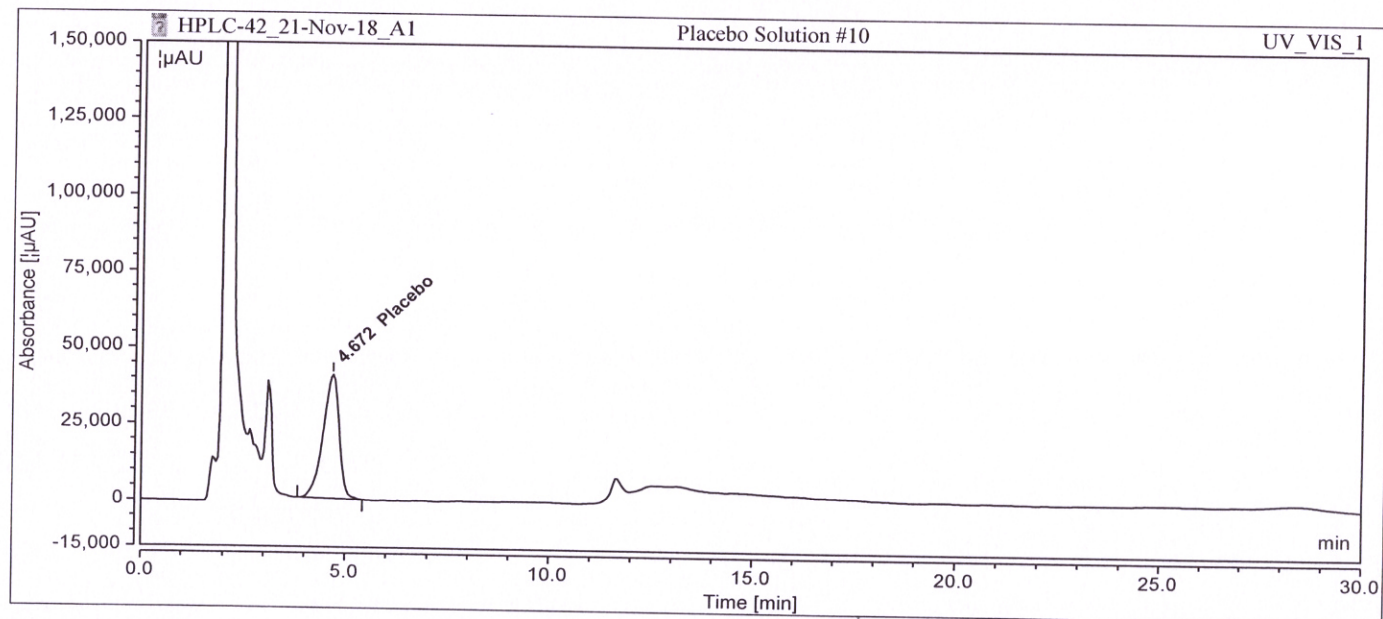
QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Processing Method



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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Placebo Solution	AR. No. :-	D2404181993
Sample Number :-	10	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_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 :-	23-11-2018 19:16:47
Injection Date & Time :-	21-11-2018 22:55:32	Experiment Name:-	Precision, Solution Stability & Filter S
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

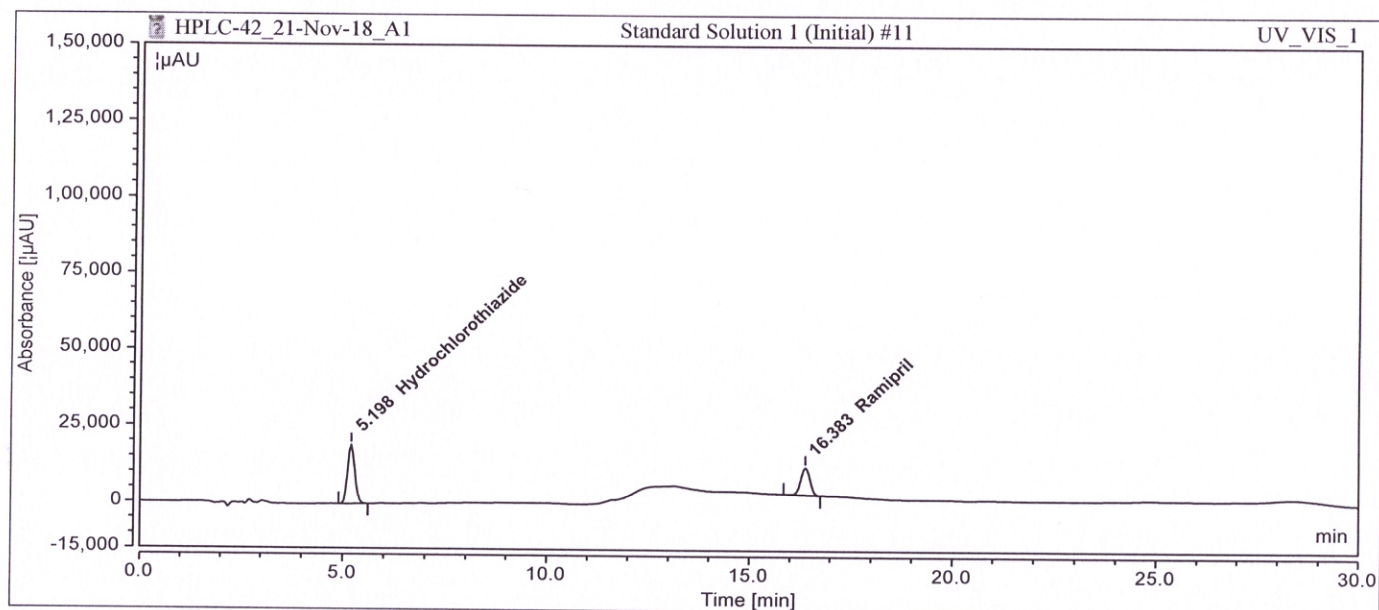


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Placebo	4.672	18567.699	100.00	0.83	675	FALSE	n.a.



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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Standard Solution I (Initial)	AR. No. :-	D2404181993
Sample Number :-	11	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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	21-11-2018 23:26:43	Experiment Name:-	Solution Stability
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

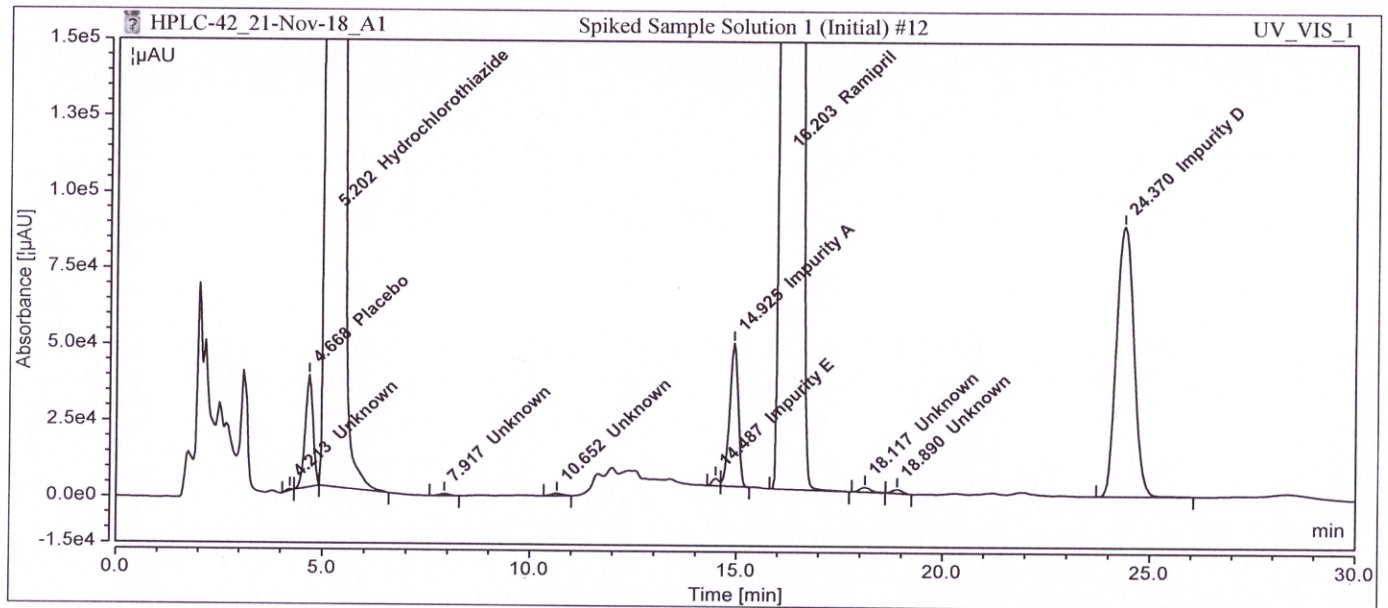


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.198	3924.989	62.51	1.13	4058	FALSE	n.a.
2	Ramipril	16.383	2353.728	37.49	1.01	24680	FALSE	30.08



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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Spiked Sample Solution 1 (Initial)	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_10	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 :-	23-11-2018 19:16:47
Injection Date & Time :-	21-11-2018 23:57:54	Experiment Name:-	Solution Stability
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

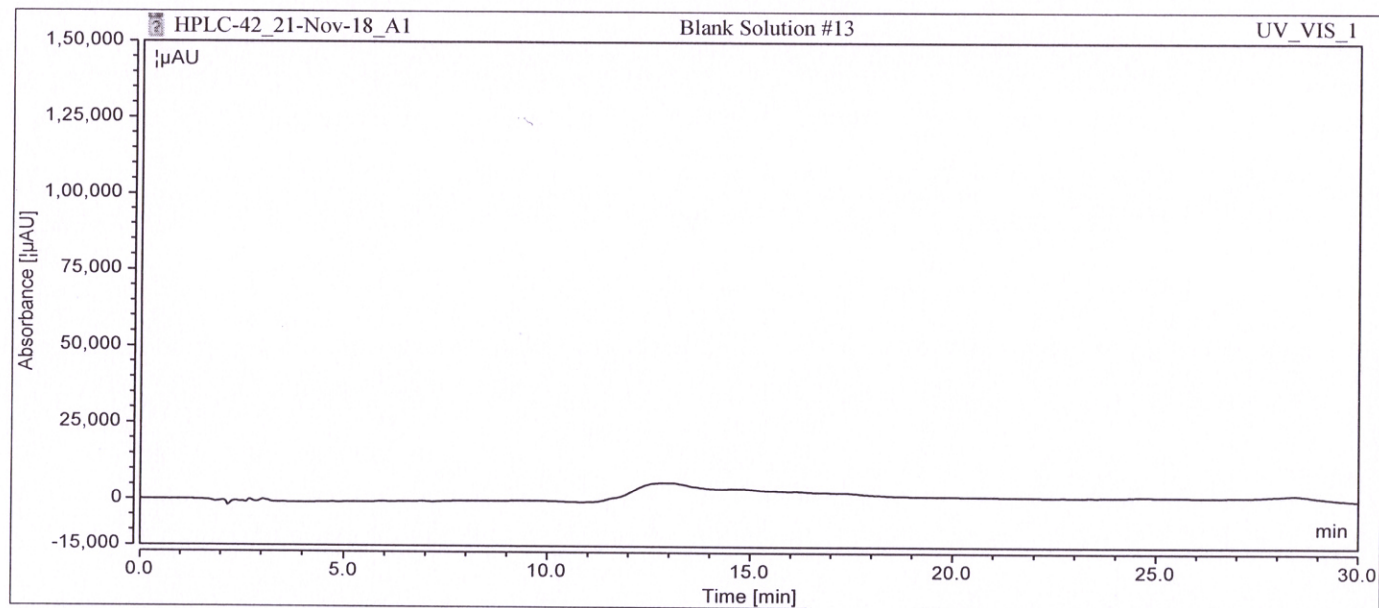


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Unknown	4.213	98.637	0.01	0.79	5487	FALSE	n.a.
2	Placebo	4.668	7888.793	0.45	0.95	2962	FALSE	1.59
3	Hydrochlorothiazide	5.202	969424.691	55.36	1.23	2189	FALSE	1.35
4	Unknown	7.917	186.984	0.01	1.08	4790	FALSE	6.02
5	Unknown	10.652	231.570	0.01	1.03	6678	FALSE	5.59
6	Impurity E	14.487	468.186	0.03	n.a.	30295	FALSE	8.98
7	Impurity A	14.925	11487.837	0.66	0.91	23268	FALSE	1.21
8	Ramipril	16.203	716923.065	40.94	1.39	13000	FALSE	2.66
9	Unknown	18.117	480.287	0.03	1.30	24150	FALSE	3.70
10	Unknown	18.890	363.525	0.02	1.11	27013	FALSE	1.67
11	Impurity D	24.370	43469.983	2.48	1.12	16757	FALSE	9.04



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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_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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	22-11-2018 00:29:02	Experiment Name:-	Precision
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

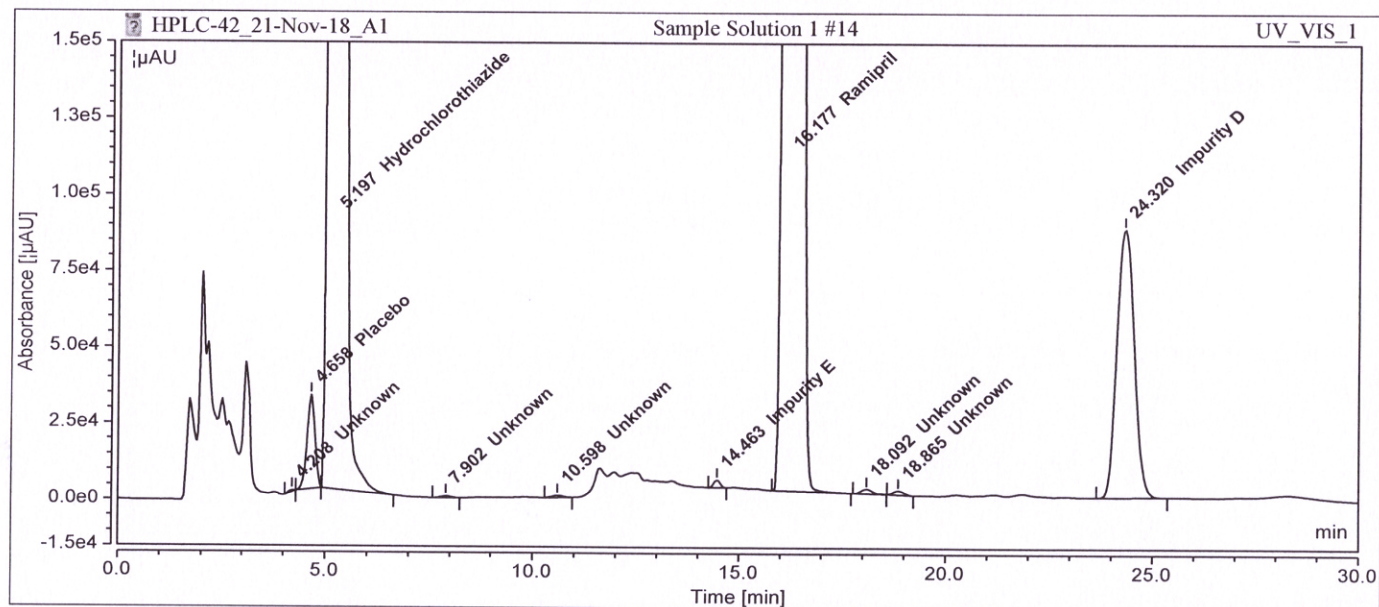


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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Product Name :-	Ramithiazide Tablets	Batch No. :-	GP180301
Sample Name :-	Sample Solution 1	AR. No. :-	D2404181993
Sample Number :-	14	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_4	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 :-	23-11-2018 19:16:47
Injection Date & Time :-	22-11-2018 01:00:11	Experiment Name:-	Precision
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

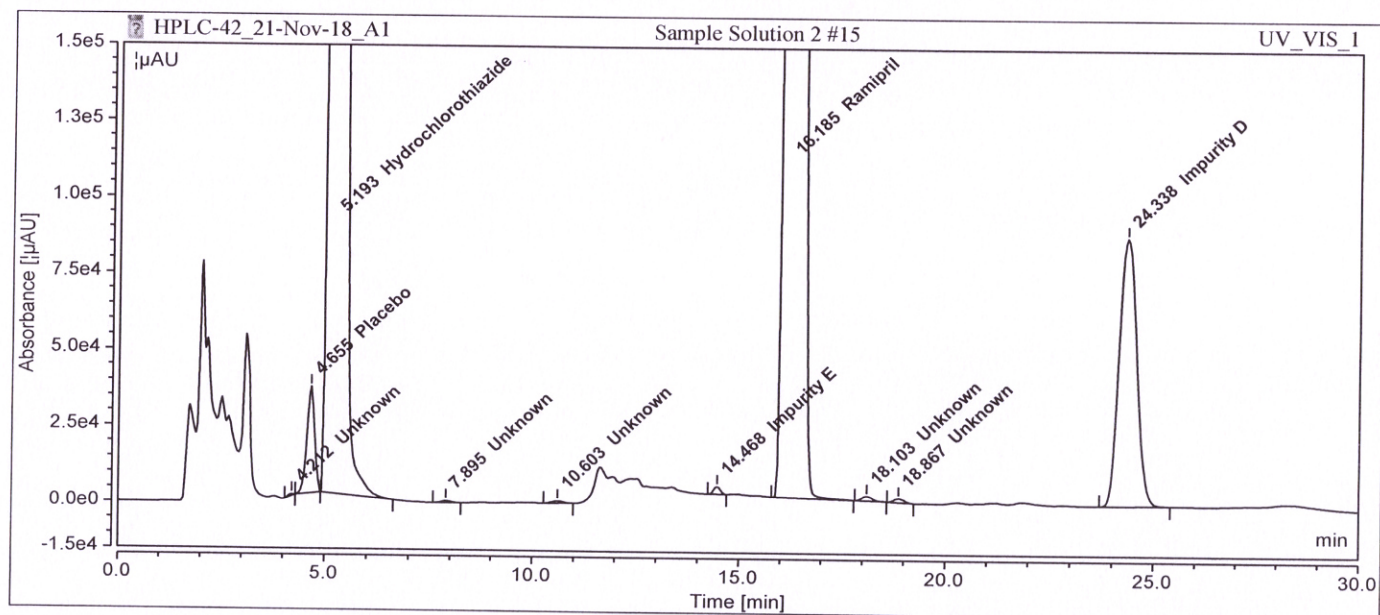


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Unknown	4.208	91.111	0.01	0.77	5528	FALSE	n.a.
2	Placebo	4.658	6688.556	0.39	0.94	2870	FALSE	1.57
3	Hydrochlorothiazide	5.197	971232.409	56.02	1.20	2173	FALSE	1.36
4	Unknown	7.902	175.544	0.01	1.05	5150	FALSE	6.10
5	Unknown	10.598	208.989	0.01	1.06	7671	FALSE	5.83
6	Impurity E	14.463	454.235	0.03	1.04	37975	FALSE	9.90
7	Ramipril	16.177	711123.262	41.02	1.39	13146	FALSE	3.98
8	Unknown	18.092	460.949	0.03	1.31	24094	FALSE	3.72
9	Unknown	18.865	380.752	0.02	1.11	26280	FALSE	1.66
10	Impurity D	24.320	42936.488	2.48	1.13	16734	FALSE	8.96



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Product Name :-	Ramithiazide Tablets	Batch No. :-	GP180301
Sample Name :-	Sample Solution 2	AR. No. :-	D2404181993
Sample Number :-	15	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_5	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 :-	23-11-2018 19:16:47
Injection Date & Time :-	22-11-2018 01:31:19	Experiment Name:-	Precision
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

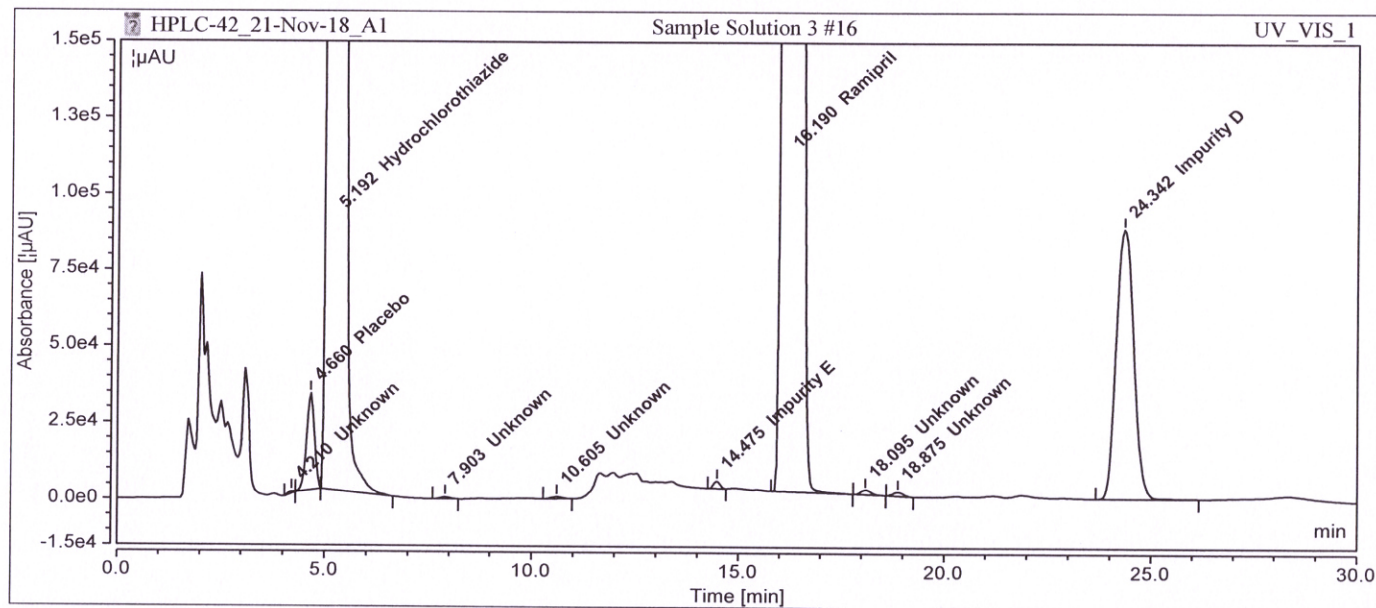


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Unknown	4.212	89.315	0.01	0.73	5516	FALSE	n.a.
2	Placebo	4.655	7454.447	0.43	0.95	2962	FALSE	1.56
3	Hydrochlorothiazide	5.193	973852.625	55.97	1.20	2159	FALSE	1.36
4	Unknown	7.895	183.379	0.01	1.09	5094	FALSE	6.07
5	Unknown	10.603	231.313	0.01	1.06	5551	FALSE	5.35
6	Impurity E	14.468	454.528	0.03	1.03	38253	FALSE	8.93
7	Ramipril	16.185	713836.535	41.03	1.40	13072	FALSE	3.98
8	Unknown	18.103	448.578	0.03	1.31	25971	FALSE	3.78
9	Unknown	18.867	379.114	0.02	1.17	26542	FALSE	1.67
10	Impurity D	24.338	42950.770	2.47	1.13	16739	FALSE	9.00



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Product Name :-	Ramithiazide Tablets	Batch No. :-	GP180301
Sample Name :-	Sample Solution 3	AR. No. :-	D2404181993
Sample Number :-	16	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_6	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 :-	23-11-2018 19:16:47
Injection Date & Time :-	22-11-2018 02:02:29	Experiment Name:-	Precision
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

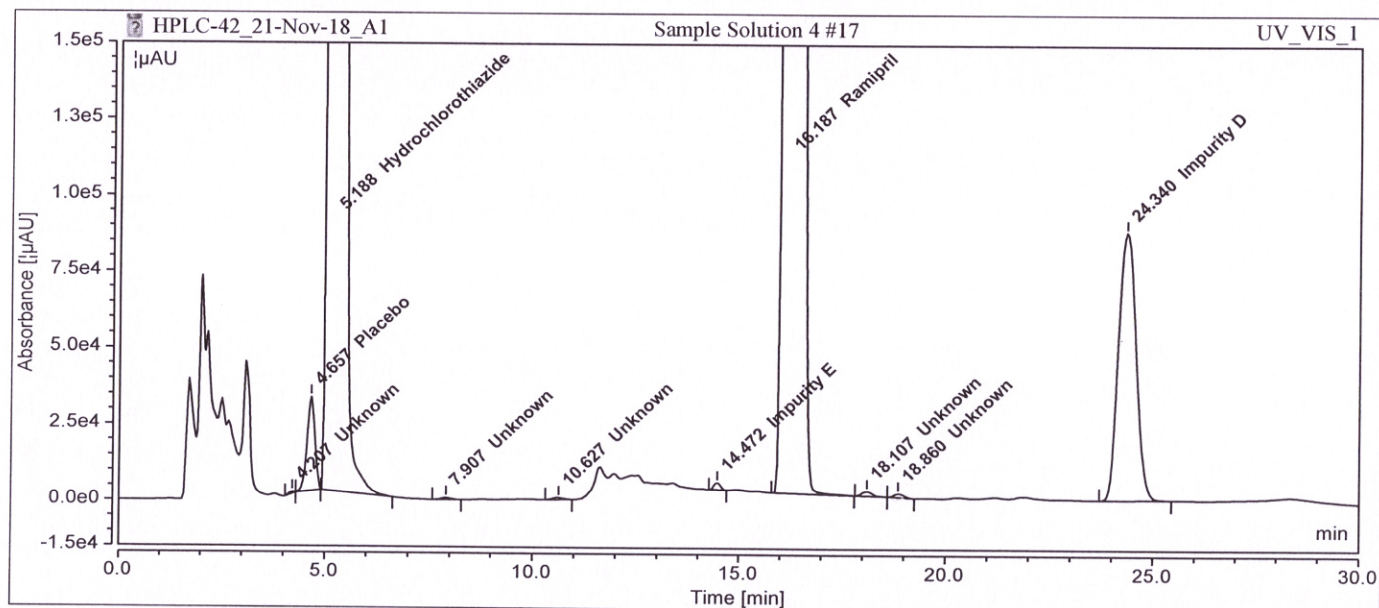


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Unknown	4.210	95.784	0.01	0.78	5368	FALSE	n.a.
2	Placebo	4.660	6886.617	0.40	0.95	2865	FALSE	1.56
3	Hydrochlorothiazide	5.192	972124.034	55.81	1.24	2169	FALSE	1.34
4	Unknown	7.903	184.530	0.01	1.04	5307	FALSE	6.16
5	Unknown	10.605	225.105	0.01	1.08	6269	FALSE	5.57
6	Impurity E	14.475	449.074	0.03	1.02	38080	FALSE	9.30
7	Ramipril	16.190	717735.838	41.20	1.39	12906	FALSE	3.96
8	Unknown	18.095	462.846	0.03	1.35	24506	FALSE	3.69
9	Unknown	18.875	395.959	0.02	1.14	26579	FALSE	1.69
10	Impurity D	24.342	43356.510	2.49	1.13	16675	FALSE	8.98



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	GP180301
Sample Name :-	Sample Solution 4	AR. No. :-	D2404181993
Sample Number :-	17	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_7	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 :-	23-11-2018 19:16:47
Injection Date & Time :-	22-11-2018 02:33:38	Experiment Name:-	Precision
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

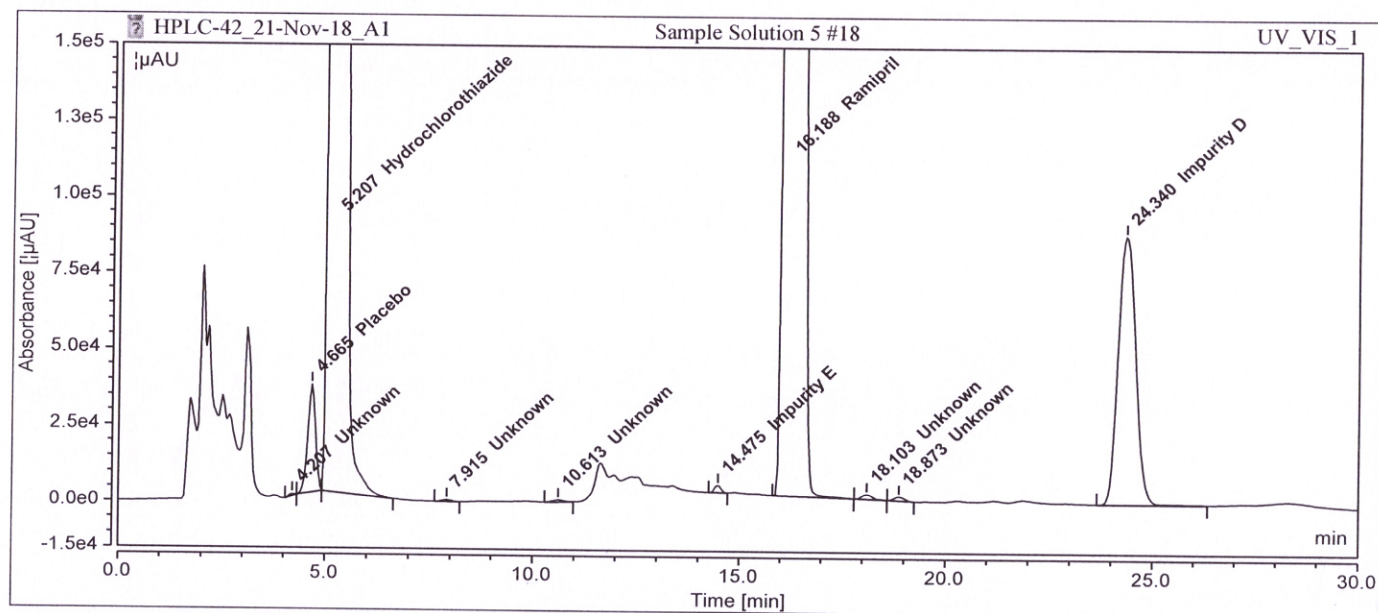


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Unknown	4.207	91.211	0.01	0.77	5859	FALSE	n.a.
2	Placebo	4.657	6721.497	0.39	0.95	2864	FALSE	1.58
3	Hydrochlorothiazide	5.188	970451.331	55.96	1.24	2170	FALSE	1.34
4	Unknown	7.907	188.396	0.01	1.07	4403	FALSE	5.90
5	Unknown	10.627	205.201	0.01	0.99	6380	FALSE	5.39
6	Impurity E	14.472	442.505	0.03	1.03	38486	FALSE	9.30
7	Ramipril	16.187	712314.598	41.07	1.40	13113	FALSE	3.99
8	Unknown	18.107	462.493	0.03	1.28	24883	FALSE	3.75
9	Unknown	18.860	371.680	0.02	1.19	27133	FALSE	1.64
10	Impurity D	24.340	43027.890	2.48	1.13	16648	FALSE	9.04



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Product Name :-	Ramithiazide Tablets	Batch No. :-	GP180301
Sample Name :-	Sample Solution 5	AR. No. :-	D2404181993
Sample Number :-	18	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_8	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 :-	23-11-2018 19:16:47
Injection Date & Time :-	22-11-2018 03:04:47	Experiment Name:-	Precision
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

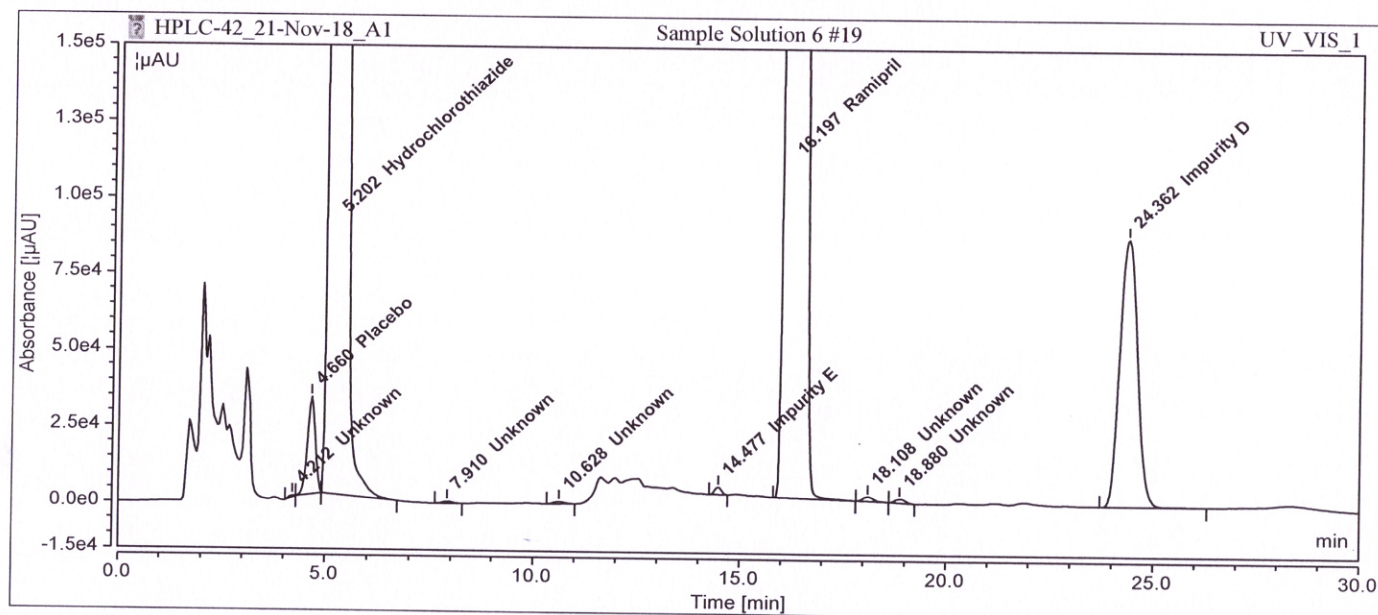


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Unknown	4.207	99.930	0.01	0.83	5330	FALSE	n.a.
2	Placebo	4.665	7568.471	0.44	0.96	2971	FALSE	1.60
3	Hydrochlorothiazide	5.207	969002.676	55.73	1.18	2196	FALSE	1.38
4	Unknown	7.915	171.624	0.01	1.03	5338	FALSE	6.17
5	Unknown	10.613	221.065	0.01	1.07	6427	FALSE	5.60
6	Impurity E	14.475	453.660	0.03	1.01	37948	FALSE	9.34
7	Ramipril	16.188	716873.216	41.23	1.40	12981	FALSE	3.96
8	Unknown	18.103	476.143	0.03	1.35	23557	FALSE	3.68
9	Unknown	18.873	380.472	0.02	1.16	26522	FALSE	1.65
10	Impurity D	24.340	43359.429	2.49	1.14	16615	FALSE	8.97



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Product Name :-	Ramithiazide Tablets	Batch No. :-	GP180301
Sample Name :-	Sample Solution 6	AR. No. :-	D2404181993
Sample Number :-	19	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_9	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 :-	23-11-2018 19:16:47
Injection Date & Time :-	22-11-2018 03:35:58	Experiment Name:-	Precision
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

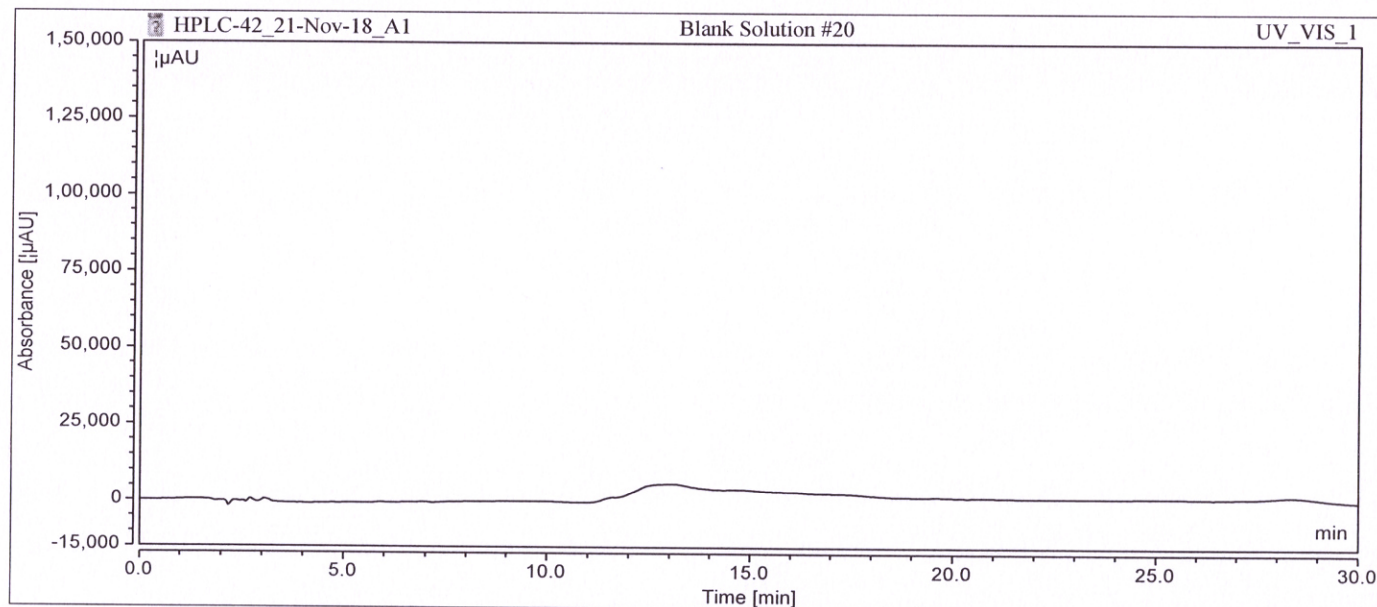


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Unknown	4.212	91.751	0.01	0.75	5593	FALSE	n.a.
2	Placebo	4.660	6935.286	0.40	0.95	2873	FALSE	1.56
3	Hydrochlorothiazide	5.202	973009.271	55.89	1.20	2172	FALSE	1.36
4	Unknown	7.910	181.242	0.01	1.08	4730	FALSE	5.98
5	Unknown	10.628	213.241	0.01	1.08	6694	FALSE	5.55
6	Impurity E	14.477	455.028	0.03	1.03	37598	FALSE	9.41
7	Ramipril	16.197	715983.534	41.12	1.39	13002	FALSE	3.97
8	Unknown	18.108	455.071	0.03	1.33	25339	FALSE	3.74
9	Unknown	18.880	380.378	0.02	1.17	26506	FALSE	1.68
10	Impurity D	24.362	43332.302	2.49	1.14	16526	FALSE	8.97



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	20	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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	22-11-2018 04:07:04	Experiment Name:-	Precision,Solution Stability & Filter S
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

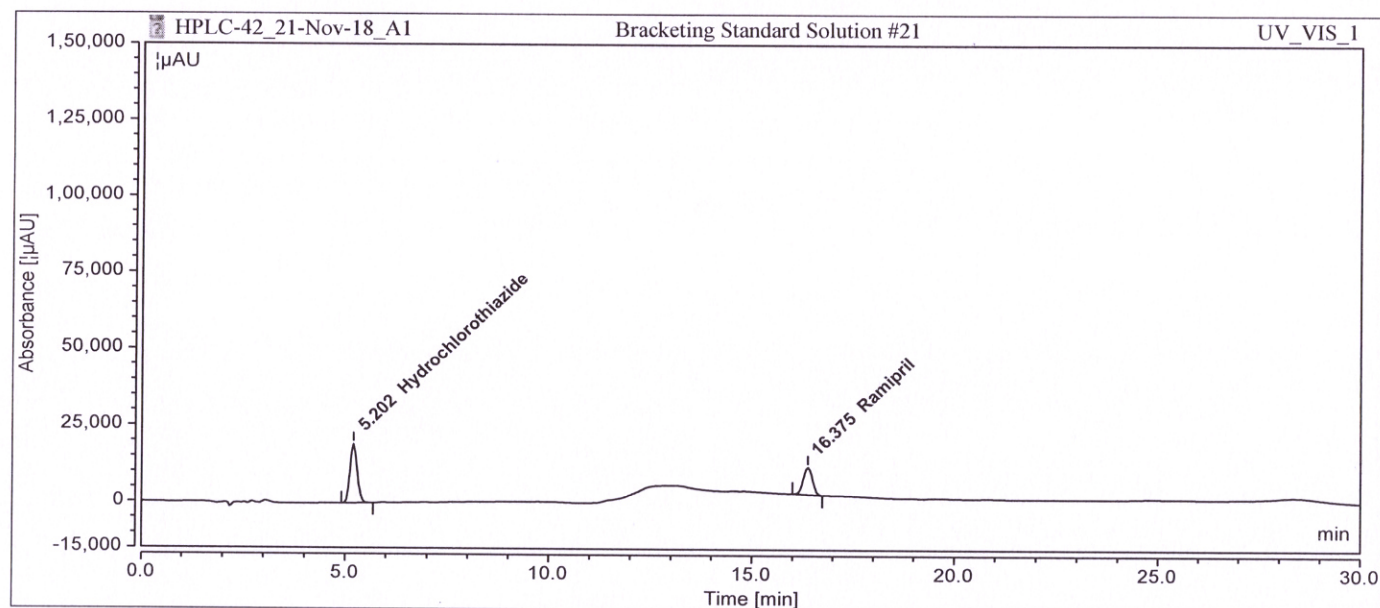


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Bracketing Standard Solution	AR. No. :-	D2404181993
Sample Number :-	21	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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	22-11-2018 04:38:14	Experiment Name:-	Precision,Solution Stability & Filter S
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

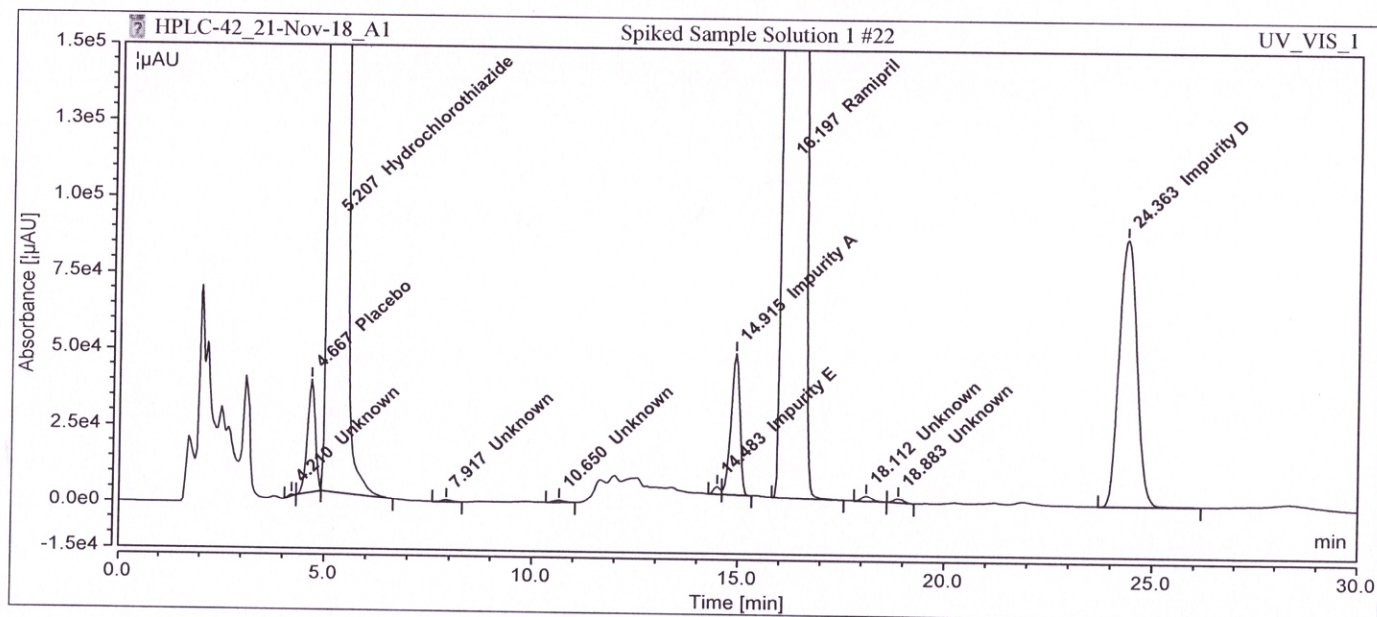


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.202	3949.063	62.85	1.14	4042	FALSE	n.a.
2	Ramipril	16.375	2334.470	37.15	1.02	24333	FALSE	29.91



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Spiked Sample Solution 1	AR. No. :-	D2404181993
Sample Number :-	22	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_10	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 :-	23-11-2018 19:16:47
Injection Date & Time :-	22-11-2018 05:09:25	Experiment Name:-	Precision
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

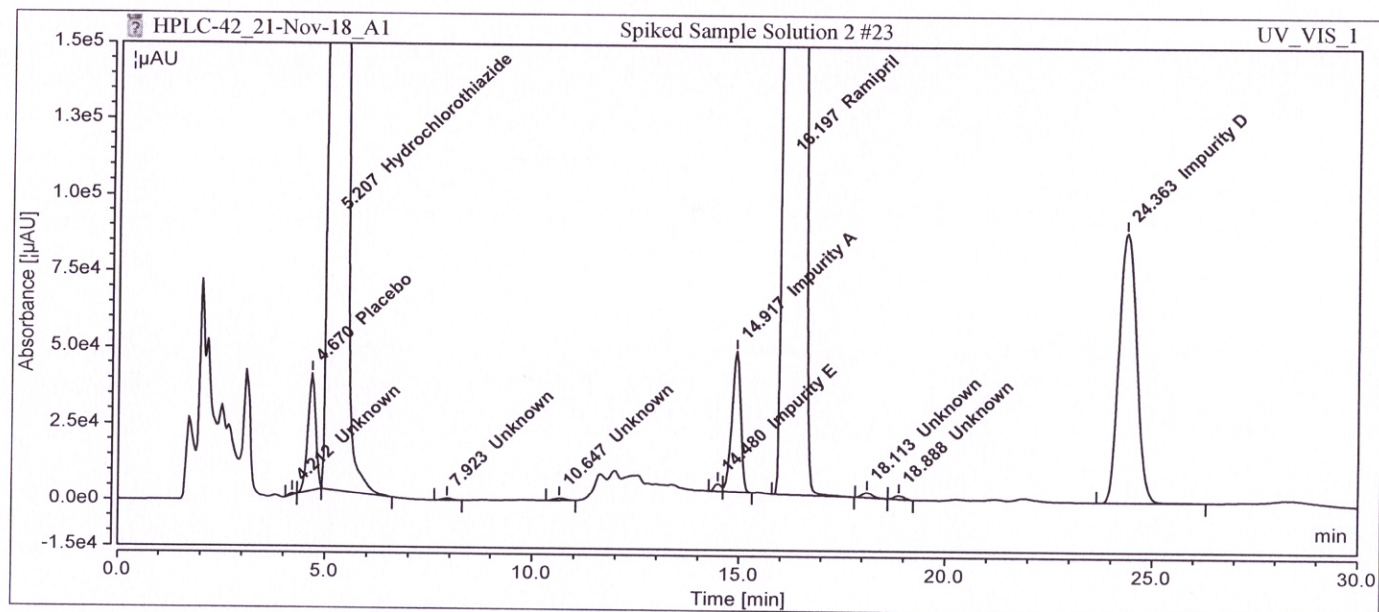


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Unknown	4.210	98.401	0.01	0.81	5348	FALSE	n.a.
2	Placebo	4.667	7950.621	0.45	0.95	2944	FALSE	1.59
3	Hydrochlorothiazide	5.207	972694.350	55.43	1.20	2178	FALSE	1.37
4	Unknown	7.917	182.683	0.01	1.10	5207	FALSE	6.12
5	Unknown	10.650	235.107	0.01	1.08	6652	FALSE	5.69
6	Impurity E	14.483	470.595	0.03	n.a.	28103	FALSE	8.83
7	Impurity A	14.915	11463.239	0.65	0.92	22782	FALSE	1.17
8	Ramipril	16.197	717490.039	40.88	1.39	12955	FALSE	2.66
9	Unknown	18.112	499.693	0.03	1.31	24330	FALSE	3.71
10	Unknown	18.883	371.488	0.02	1.16	26487	FALSE	1.66
11	Impurity D	24.363	43485.550	2.48	1.15	16410	FALSE	8.95



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Spiked Sample Solution 2	AR. No. :-	D2404181993
Sample Number :-	23	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_11	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 :-	23-11-2018 19:16:47
Injection Date & Time :-	22-11-2018 05:40:33	Experiment Name:-	Precision
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

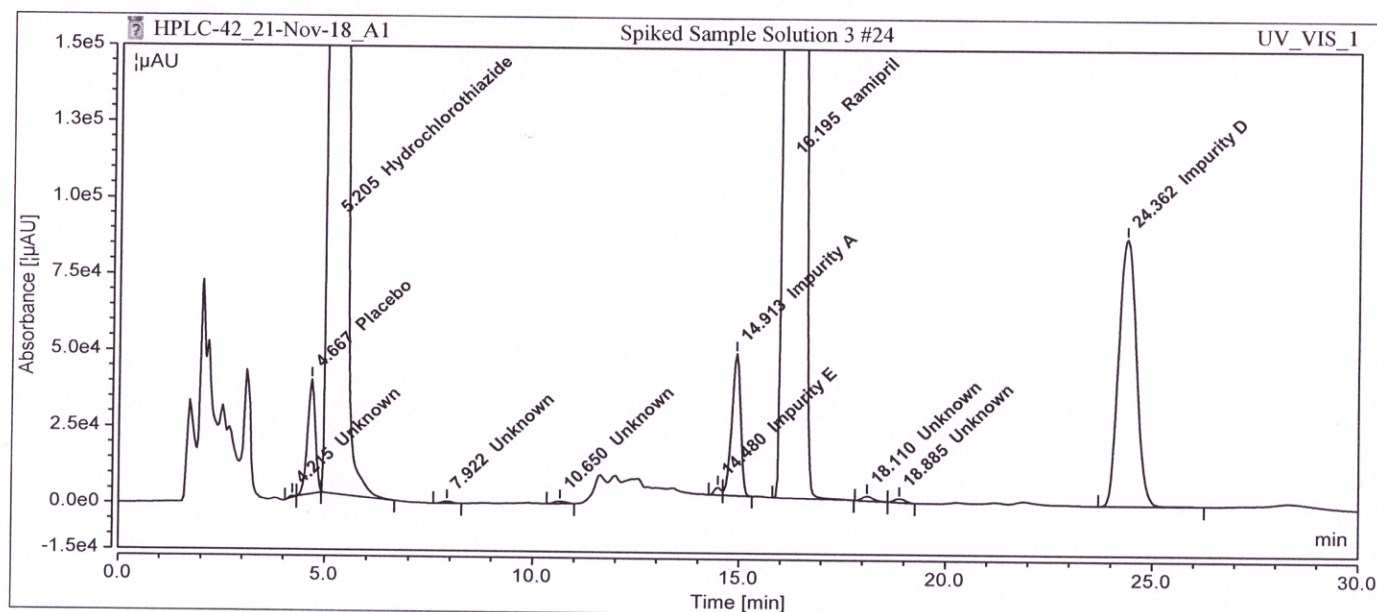


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Unknown	4.212	103.537	0.01	0.83	4238	FALSE	n.a.
2	Placebo	4.670	8249.764	0.47	0.96	2965	FALSE	1.52
3	Hydrochlorothiazide	5.207	972919.009	55.39	1.21	2176	FALSE	1.36
4	Unknown	7.923	176.130	0.01	1.06	4748	FALSE	5.99
5	Unknown	10.647	229.383	0.01	1.07	7064	FALSE	5.63
6	Impurity E	14.480	471.283	0.03	n.a.	28260	FALSE	9.01
7	Impurity A	14.917	11387.081	0.65	0.91	22758	FALSE	1.18
8	Ramipril	16.197	718113.082	40.89	1.39	12943	FALSE	2.65
9	Unknown	18.113	492.185	0.03	1.32	24898	FALSE	3.73
10	Unknown	18.888	348.429	0.02	1.14	26867	FALSE	1.68
11	Impurity D	24.363	43902.193	2.50	1.15	16394	FALSE	8.96



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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Spiked Sample Solution 3	AR. No. :-	D2404181993
Sample Number :-	24	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_12	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 :-	23-11-2018 19:16:47
Injection Date & Time :-	22-11-2018 06:11:41	Experiment Name:-	Precision
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

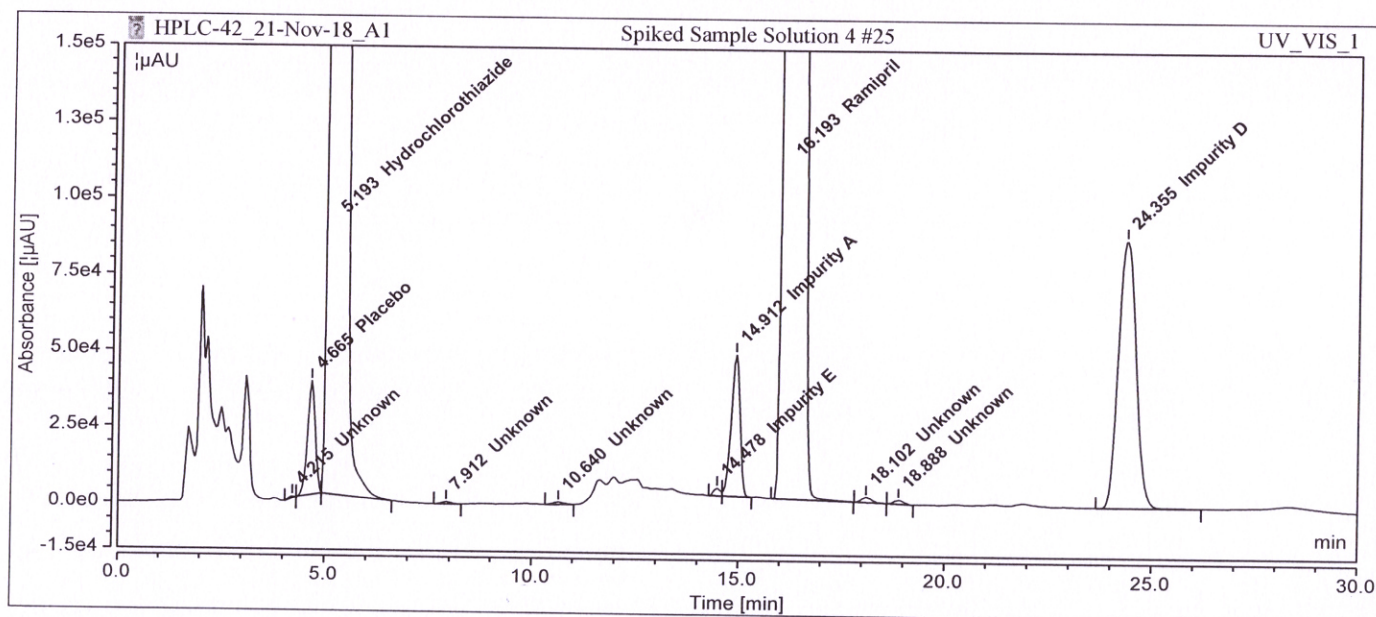


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Unknown	4.215	98.186	0.01	0.78	5308	FALSE	n.a.
2	Placebo	4.667	8072.584	0.46	0.95	2948	FALSE	1.57
3	Hydrochlorothiazide	5.205	975997.662	55.52	1.21	2160	FALSE	1.36
4	Unknown	7.922	186.036	0.01	1.05	5217	FALSE	6.13
5	Unknown	10.650	227.222	0.01	1.04	6976	FALSE	5.75
6	Impurity E	14.480	471.643	0.03	n.a.	28802	FALSE	9.00
7	Impurity A	14.913	11492.367	0.65	0.92	22742	FALSE	1.18
8	Ramipril	16.195	717247.596	40.80	1.39	12973	FALSE	2.66
9	Unknown	18.110	482.521	0.03	1.31	24432	FALSE	3.71
10	Unknown	18.885	367.702	0.02	1.13	26118	FALSE	1.67
11	Impurity D	24.362	43393.431	2.47	1.15	16409	FALSE	8.92



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Spiked Sample Solution 4	AR. No. :-	D2404181993
Sample Number :-	25	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_13	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 :-	23-11-2018 19:16:47
Injection Date & Time :-	22-11-2018 06:42:48	Experiment Name:-	Precision
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

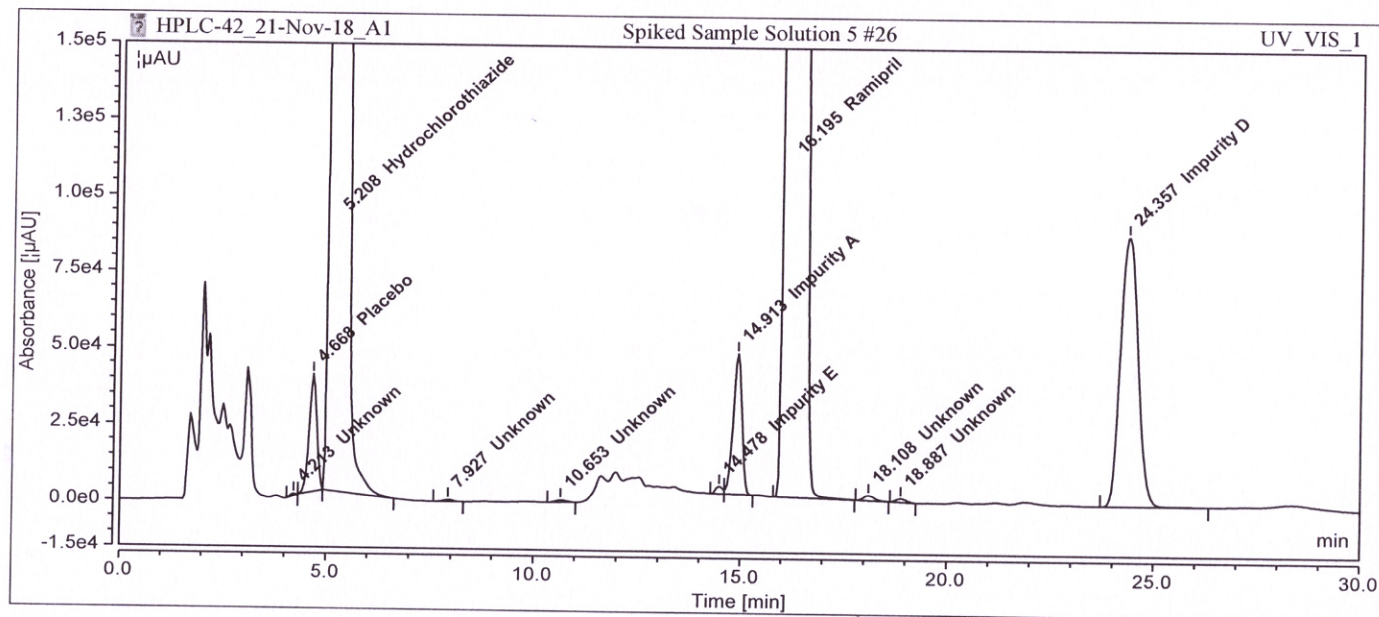


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Unknown	4.215	98.404	0.01	0.78	5462	FALSE	n.a.
2	Placebo	4.665	8025.624	0.46	0.95	2949	FALSE	1.57
3	Hydrochlorothiazide	5.193	974075.700	55.41	1.27	2162	FALSE	1.34
4	Unknown	7.912	181.592	0.01	1.11	5311	FALSE	6.17
5	Unknown	10.640	232.774	0.01	1.08	6513	FALSE	5.67
6	Impurity E	14.478	470.273	0.03	n.a.	27515	FALSE	8.76
7	Impurity A	14.912	11484.297	0.65	0.92	22768	FALSE	1.16
8	Ramipril	16.193	718985.801	40.90	1.39	12904	FALSE	2.65
9	Unknown	18.102	486.193	0.03	1.34	23929	FALSE	3.68
10	Unknown	18.888	371.270	0.02	1.12	25817	FALSE	1.68
11	Impurity D	24.355	43574.489	2.48	1.15	16321	FALSE	8.87



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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Spiked Sample Solution 5	AR. No. :-	D2404181993
Sample Number :-	26	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_14	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 :-	23-11-2018 19:16:47
Injection Date & Time :-	22-11-2018 07:13:57	Experiment Name:-	Precision
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

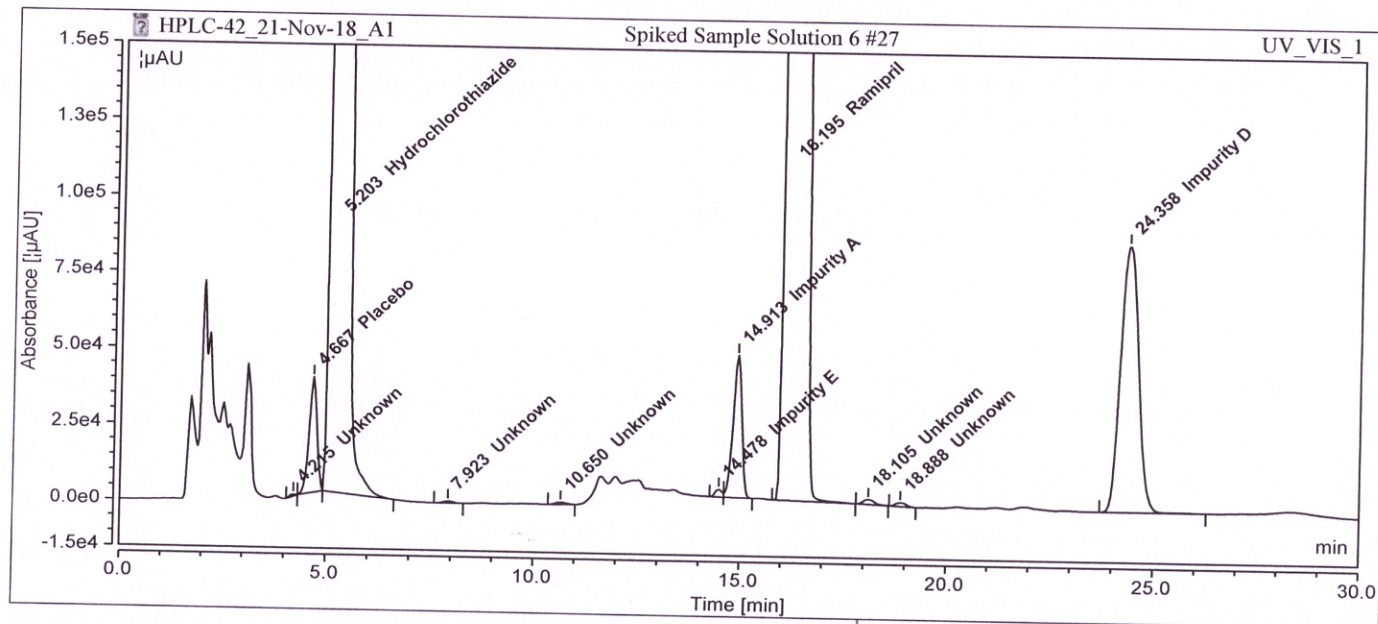


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Unknown	4.213	98.680	0.01	0.80	5009	FALSE	n.a.
2	Placebo	4.668	8283.957	0.47	0.95	2953	FALSE	1.56
3	Hydrochlorothiazide	5.208	974419.324	55.43	1.20	2172	FALSE	1.37
4	Unknown	7.927	182.113	0.01	1.08	4913	FALSE	6.04
5	Unknown	10.653	235.658	0.01	1.06	6220	FALSE	5.49
6	Impurity E	14.478	471.604	0.03	n.a.	27836	FALSE	8.62
7	Impurity A	14.913	11385.893	0.65	0.92	22681	FALSE	1.17
8	Ramipril	16.195	718142.805	40.85	1.39	12936	FALSE	2.65
9	Unknown	18.108	500.301	0.03	1.30	24202	FALSE	3.70
10	Unknown	18.887	352.182	0.02	1.14	26961	FALSE	1.68
11	Impurity D	24.357	43876.560	2.50	1.15	16332	FALSE	8.95



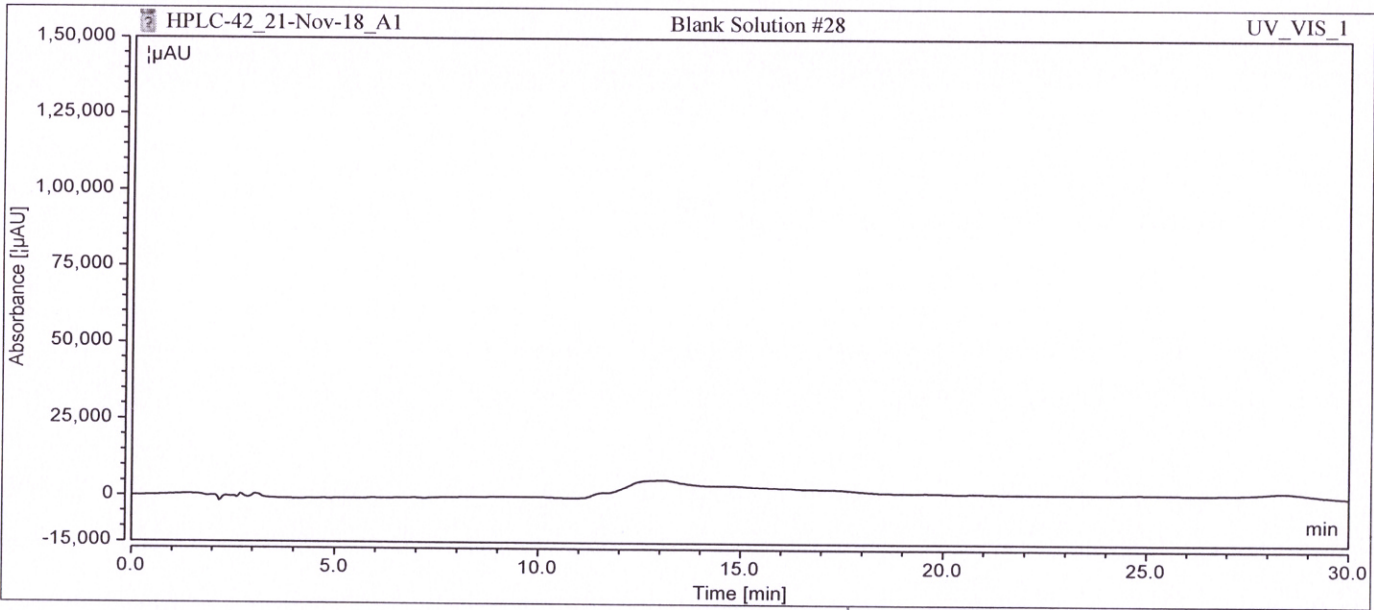
QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Spiked Sample Solution 6	AR. No. :-	D2404181993
Sample Number :-	27	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_15	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 :-	23-11-2018 19:16:47
Injection Date & Time :-	22-11-2018 07:45:06	Experiment Name:-	Precision
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_AI.seq		



Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Unknown	4.215	98.698	0.01	0.78	5405	FALSE	n.a.
2	Placebo	4.667	8124.689	0.46	0.96	2957	FALSE	1.58
3	Hydrochlorothiazide	5.203	975162.794	55.46	1.22	2163	FALSE	1.36
4	Unknown	7.923	185.264	0.01	1.07	5013	FALSE	6.08
5	Unknown	10.650	222.642	0.01	1.06	5871	FALSE	5.43
6	Impurity E	14.478	477.083	0.03	n.a.	27367	FALSE	8.45
7	Impurity A	14.913	11511.932	0.65	0.92	22728	FALSE	1.17
8	Ramipril	16.195	718072.779	40.84	1.39	12944	FALSE	2.66
9	Unknown	18.105	493.310	0.03	1.35	24852	FALSE	3.71
10	Unknown	18.888	363.732	0.02	1.14	25645	FALSE	1.68
11	Impurity D	24.358	43477.140	2.47	1.15	16309	FALSE	8.86

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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	28	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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	22-11-2018 08:16:13	Experiment Name:-	Precision,Solution Stability & Filter S
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

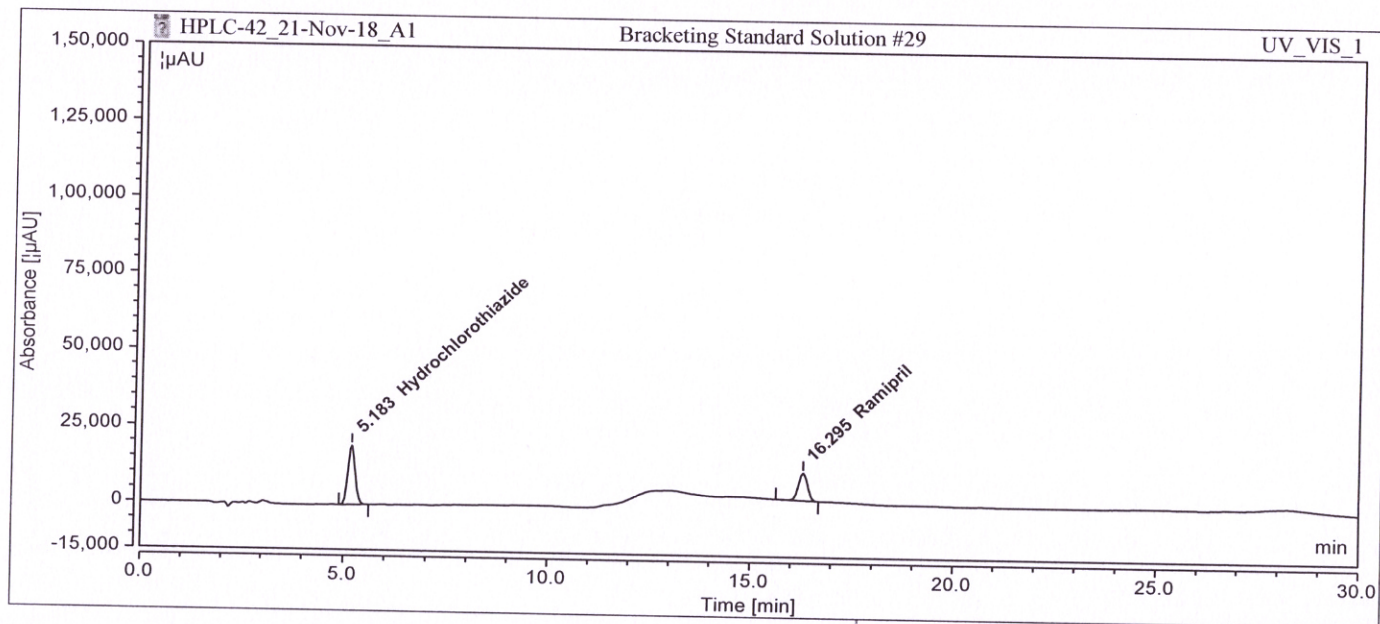


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Bracketing Standard Solution	AR. No. :-	D2404181993
Sample Number :-	29	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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	22-11-2018 08:47:22	Experiment Name:-	Precision, Solution Stability & Filter S
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

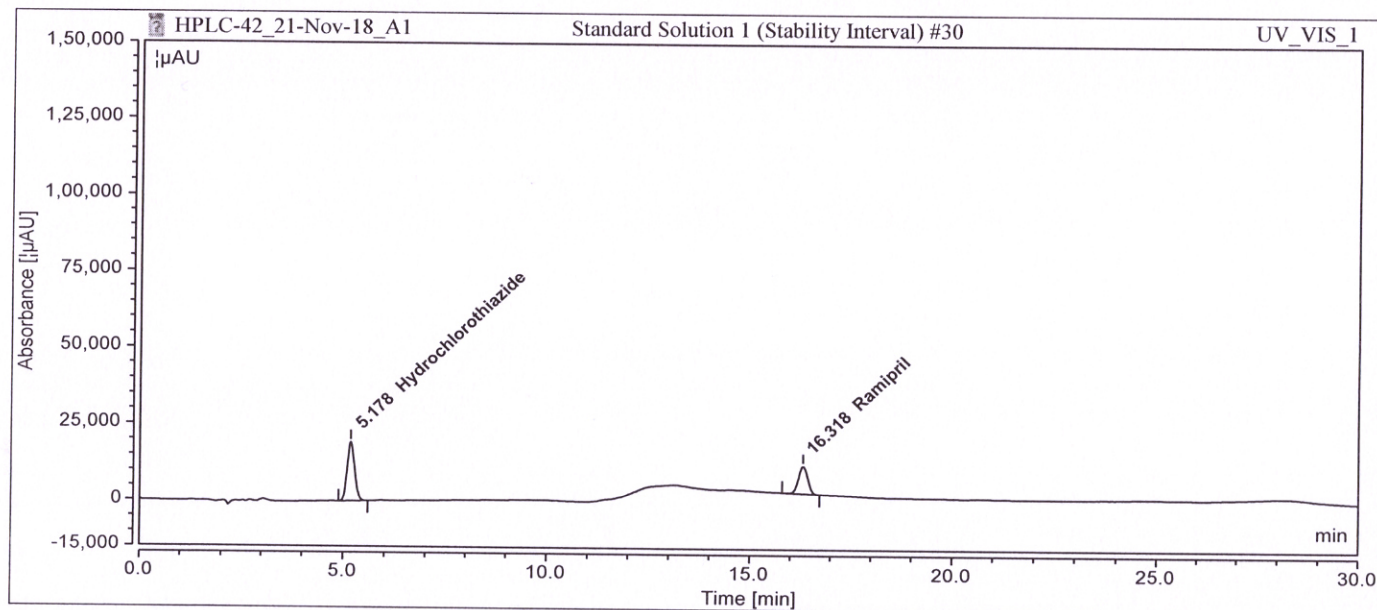


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.183	3958.714	62.49	1.14	3973	FALSE	n.a.
2	Ramipril	16.295	2376.174	37.51	1.01	24318	FALSE	29.75



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Standard Solution 1 (Stability Interval)	AR. No. :-	D2404181993
Sample Number :-	30	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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	22-11-2018 09:18:31	Experiment Name:-	Solution Stability
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

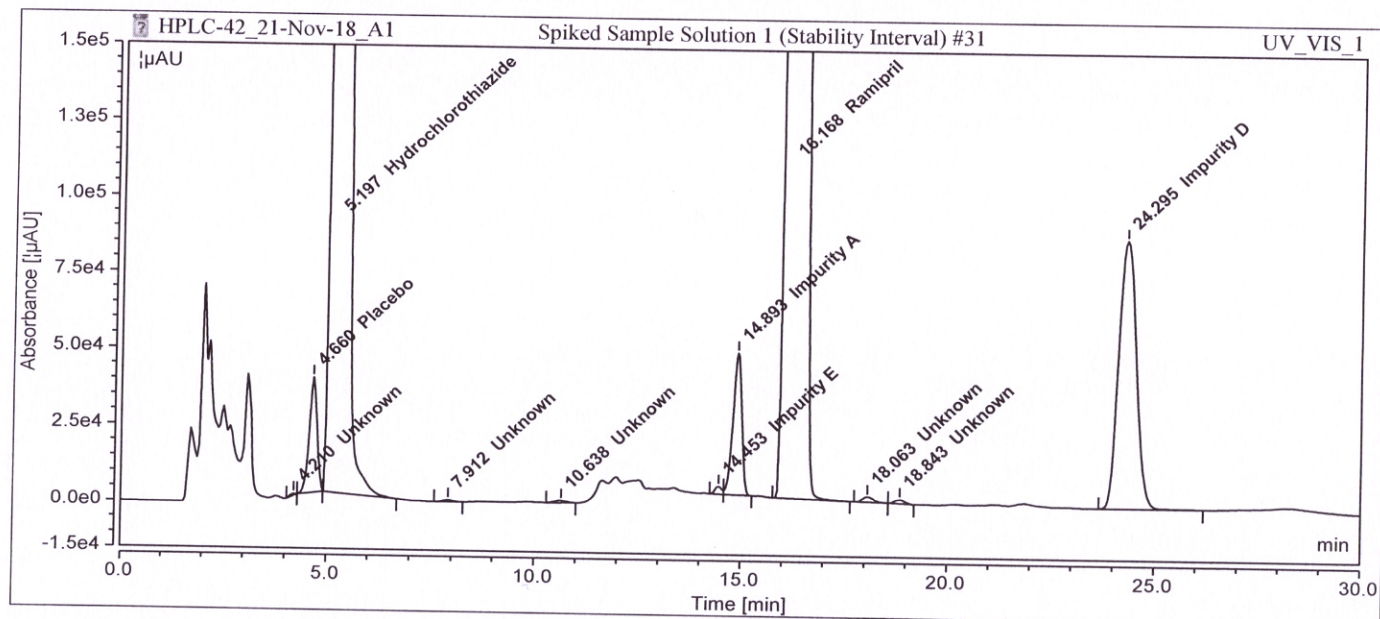


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.178	3961.051	62.30	1.15	3958	FALSE	n.a.
2	Ramipril	16.318	2396.874	37.70	1.01	23763	FALSE	29.60



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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Spiked Sample Solution 1 (Stability Interval)	AR. No. :-	D2404181993
Sample Number :-	31	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_10	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 :-	23-11-2018 19:16:47
Injection Date & Time :-	22-11-2018 09:49:42	Experiment Name:-	Solution Stability
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

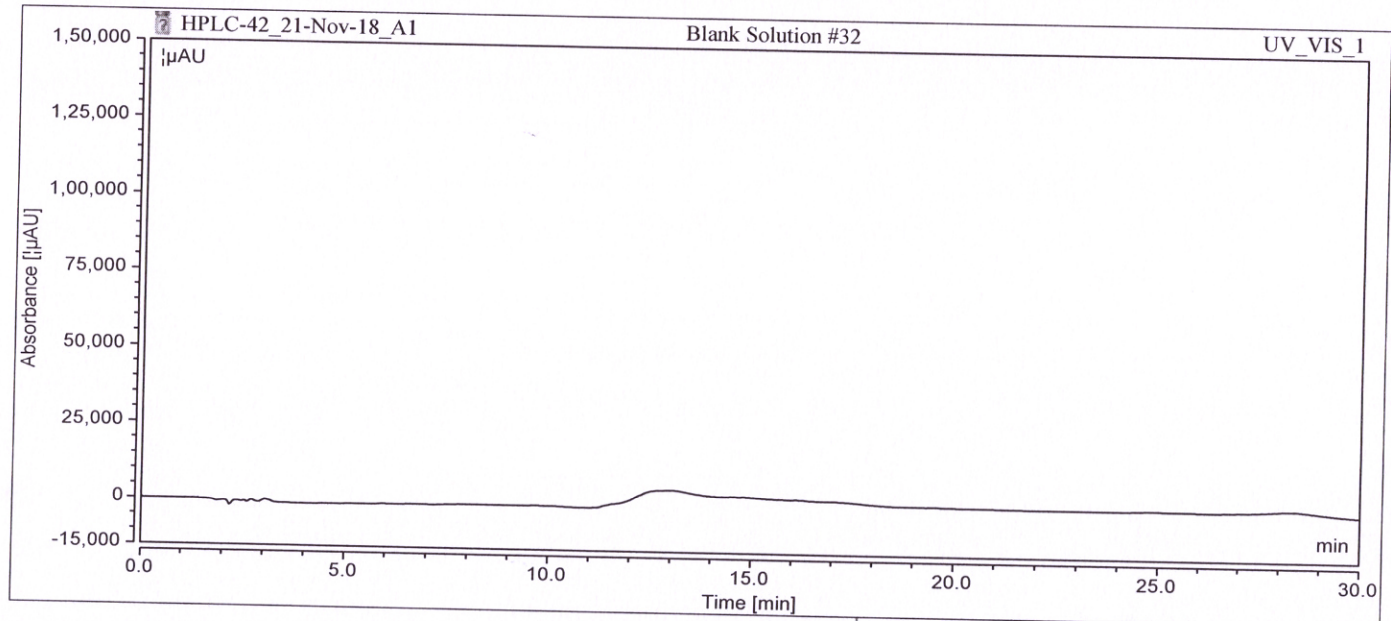


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Unknown	4.210	89.998	0.01	0.75	5800	FALSE	n.a.
2	Placebo	4.660	8103.816	0.46	0.94	2947	FALSE	1.59
3	Hydrochlorothiazide	5.197	974191.004	55.49	1.22	2162	FALSE	1.36
4	Unknown	7.912	179.541	0.01	1.04	5041	FALSE	6.08
5	Unknown	10.638	240.524	0.01	1.00	6339	FALSE	5.56
6	Impurity E	14.453	472.507	0.03	n.a.	29223	FALSE	8.74
7	Impurity A	14.893	11424.548	0.65	0.92	22754	FALSE	1.20
8	Ramipril	16.168	716519.485	40.81	1.38	12951	FALSE	2.65
9	Unknown	18.063	526.411	0.03	1.33	24329	FALSE	3.67
10	Unknown	18.843	371.637	0.02	1.14	25214	FALSE	1.66
11	Impurity D	24.295	43520.373	2.48	1.16	16318	FALSE	8.83



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	32	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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	22-11-2018 10:20:48	Experiment Name:-	Solution Stability & Filter Study
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

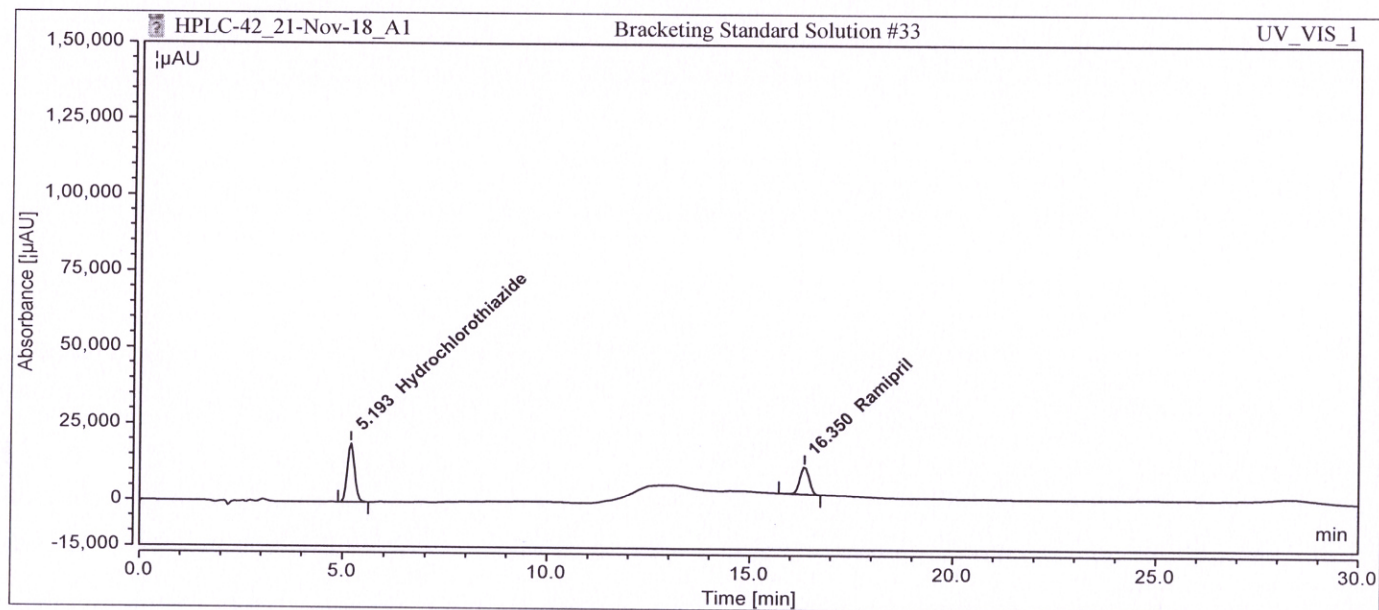


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Bracketing Standard Solution	AR. No. :-	D2404181993
Sample Number :-	33	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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	22-11-2018 10:51:59	Experiment Name:-	Solution Stability & Filter Study
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

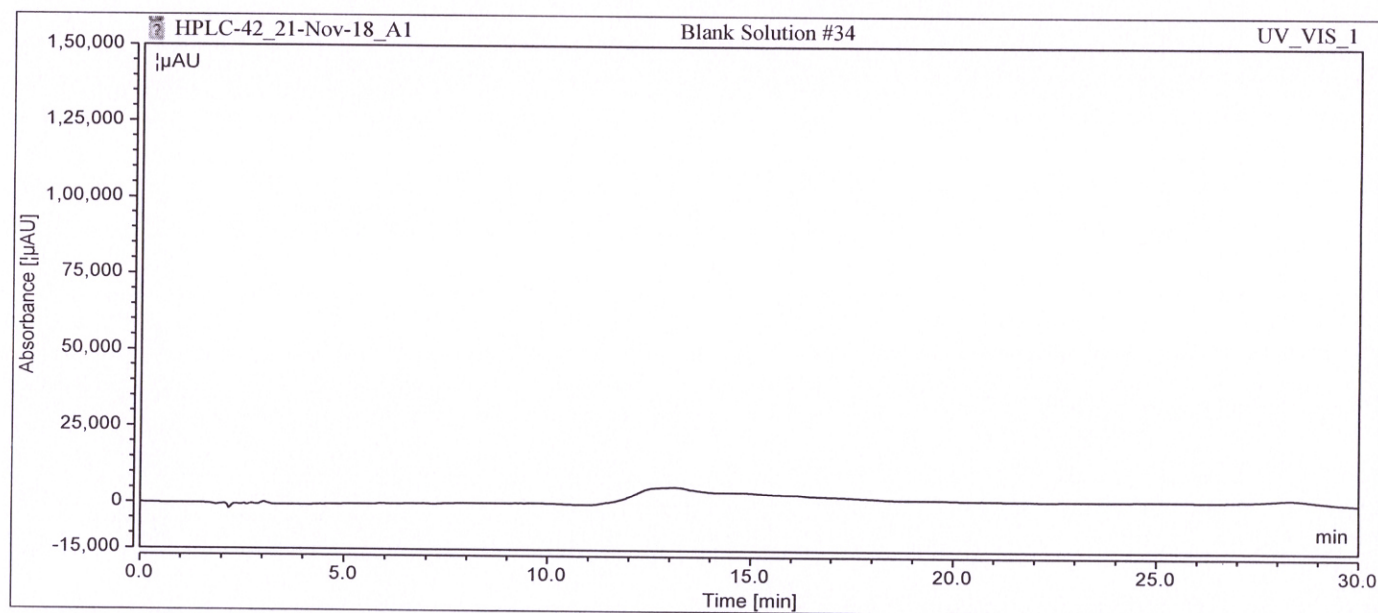


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.193	3957.677	62.47	1.14	3979	FALSE	n.a.
2	Ramipril	16.350	2377.441	37.53	1.01	23792	FALSE	29.62



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	34	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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	22-11-2018 11:23:06	Experiment Name:-	Solution Stability & Filter Study
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

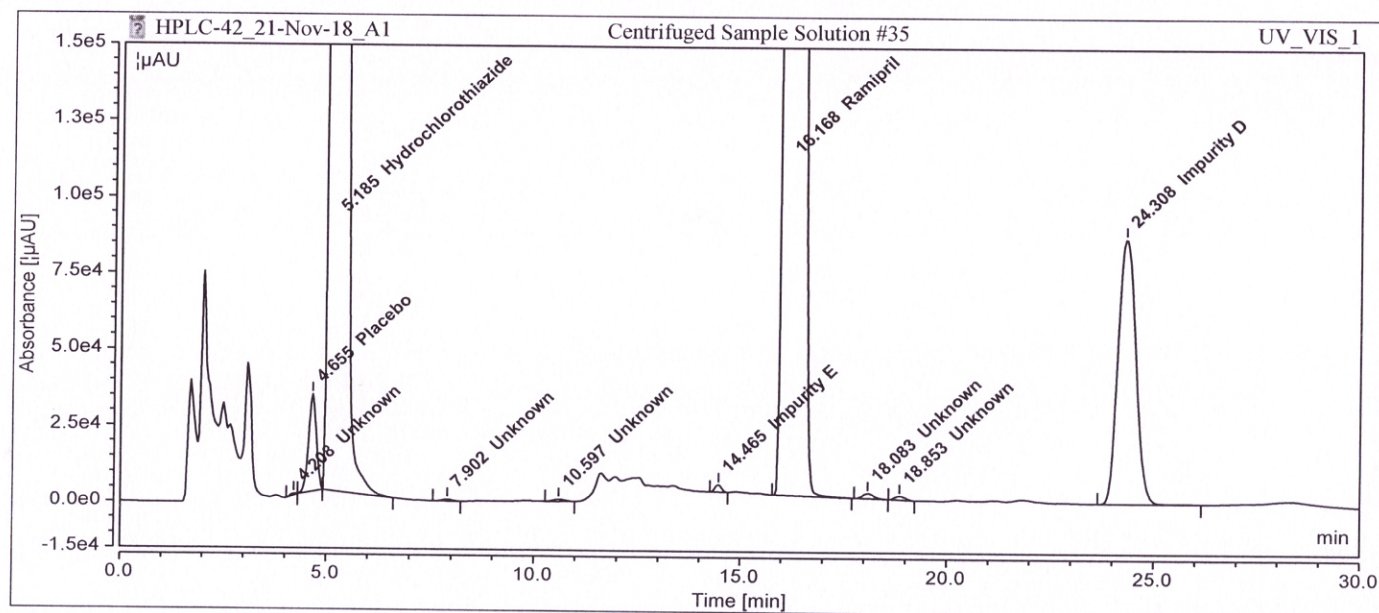


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	GP180301
Sample Name :-	Centrifuged Sample Solution	AR. No. :-	D2404181993
Sample Number :-	35	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_16	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 :-	23-11-2018 19:16:47
Injection Date & Time :-	22-11-2018 11:54:16	Experiment Name:-	Filter Study
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

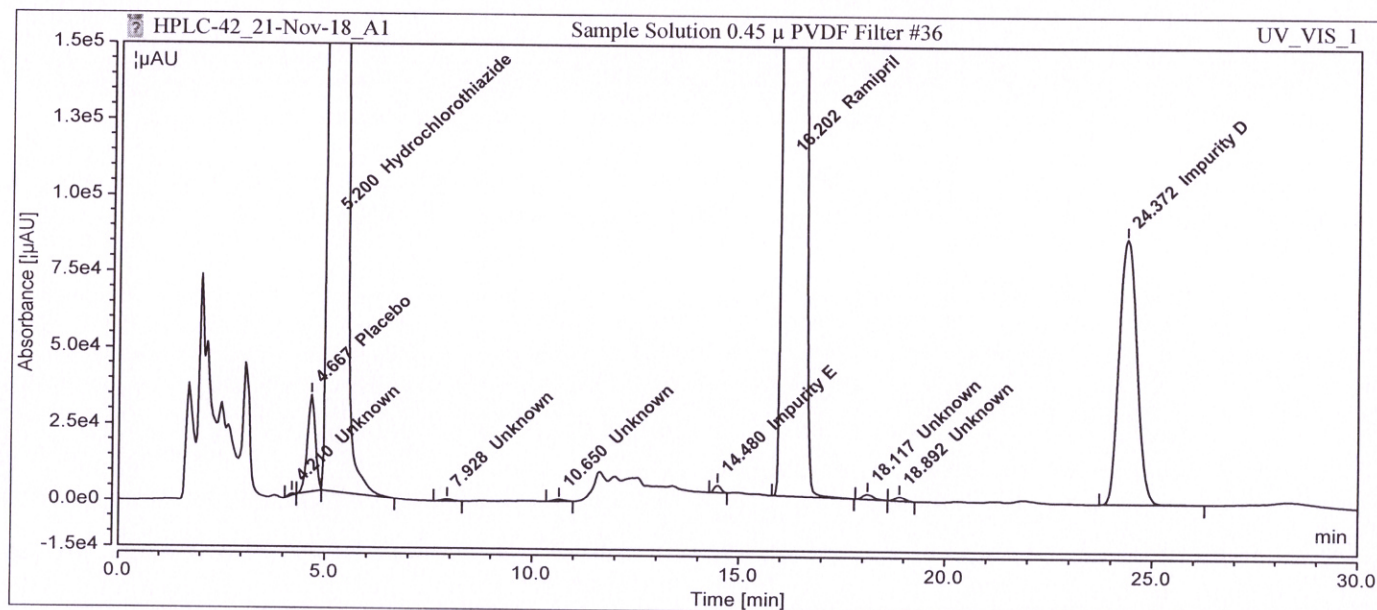


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Unknown	4.208	95.331	0.01	0.77	5461	FALSE	n.a.
2	Placebo	4.655	6952.117	0.40	0.96	2840	FALSE	1.55
3	Hydrochlorothiazide	5.185	974272.166	56.00	1.26	2148	FALSE	1.33
4	Unknown	7.902	174.140	0.01	1.02	5344	FALSE	6.17
5	Unknown	10.597	223.252	0.01	1.08	6328	FALSE	5.58
6	Impurity E	14.465	448.952	0.03	1.03	38208	FALSE	9.33
7	Ramipril	16.168	713501.276	41.01	1.39	13027	FALSE	3.95
8	Unknown	18.083	542.726	0.03	1.34	22382	FALSE	3.65
9	Unknown	18.853	377.108	0.02	1.16	26286	FALSE	1.62
10	Impurity D	24.308	43334.044	2.49	1.16	16226	FALSE	8.88



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	GP180301
Sample Name :-	Sample Solution 0.45 µ PVDF Filter	AR. No. :-	D2404181993
Sample Number :-	36	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_17	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 :-	23-11-2018 19:16:47
Injection Date & Time :-	22-11-2018 12:25:26	Experiment Name:-	Filter Study
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

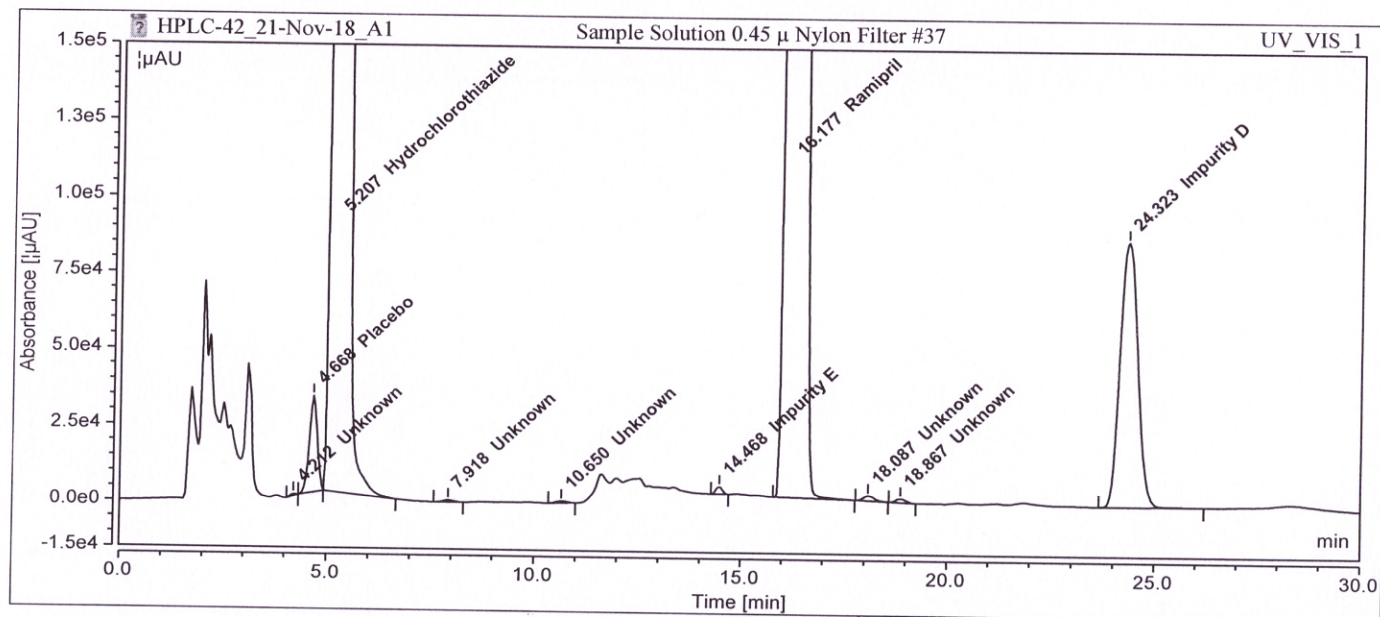


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Unknown	4.210	98.283	0.01	0.82	4918	FALSE	n.a.
2	Placebo	4.667	6912.338	0.40	0.96	2847	FALSE	1.55
3	Hydrochlorothiazide	5.200	976034.018	55.94	1.25	2152	FALSE	1.34
4	Unknown	7.928	185.555	0.01	1.06	3624	FALSE	5.60
5	Unknown	10.650	200.266	0.01	1.04	6888	FALSE	5.23
6	Impurity E	14.480	453.134	0.03	1.05	37785	FALSE	9.44
7	Ramipril	16.202	716598.677	41.07	1.38	12945	FALSE	3.97
8	Unknown	18.117	500.518	0.03	1.32	23974	FALSE	3.69
9	Unknown	18.892	377.395	0.02	1.17	24799	FALSE	1.64
10	Impurity D	24.372	43418.314	2.49	1.16	16175	FALSE	8.79



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	GP180301
Sample Name :-	Sample Solution 0.45 µ Nylon Filter	AR. No. :-	D2404181993
Sample Number :-	37	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_18	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 :-	23-11-2018 19:16:47
Injection Date & Time :-	22-11-2018 12:56:35	Experiment Name:-	Filter Study
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

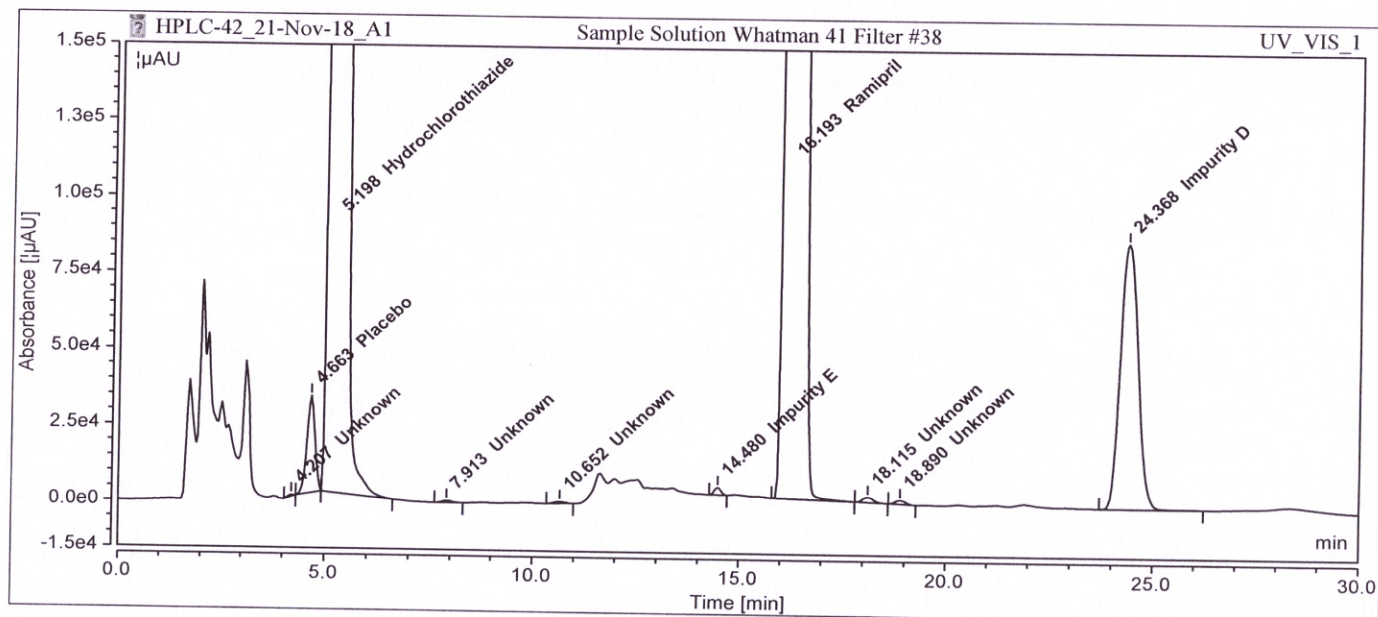


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Unknown	4.212	98.947	0.01	0.84	5333	FALSE	n.a.
2	Placebo	4.668	6899.800	0.40	0.96	2861	FALSE	1.58
3	Hydrochlorothiazide	5.207	976372.460	56.00	1.22	2156	FALSE	1.35
4	Unknown	7.918	189.123	0.01	1.08	4857	FALSE	6.01
5	Unknown	10.650	206.741	0.01	1.04	6780	FALSE	5.62
6	Impurity E	14.468	451.164	0.03	1.04	37875	FALSE	9.37
7	Ramipril	16.177	714926.014	41.01	1.39	13002	FALSE	3.95
8	Unknown	18.087	521.984	0.03	1.37	23626	FALSE	3.68
9	Unknown	18.867	370.984	0.02	1.16	26470	FALSE	1.67
10	Impurity D	24.323	43428.323	2.49	1.17	16166	FALSE	8.88



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	GP180301
Sample Name :-	Sample Solution Whatman 41 Filter	AR. No. :-	D2404181993
Sample Number :-	38	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_19	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 :-	23-11-2018 19:16:47
Injection Date & Time :-	22-11-2018 13:27:45	Experiment Name:-	Filter Study
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

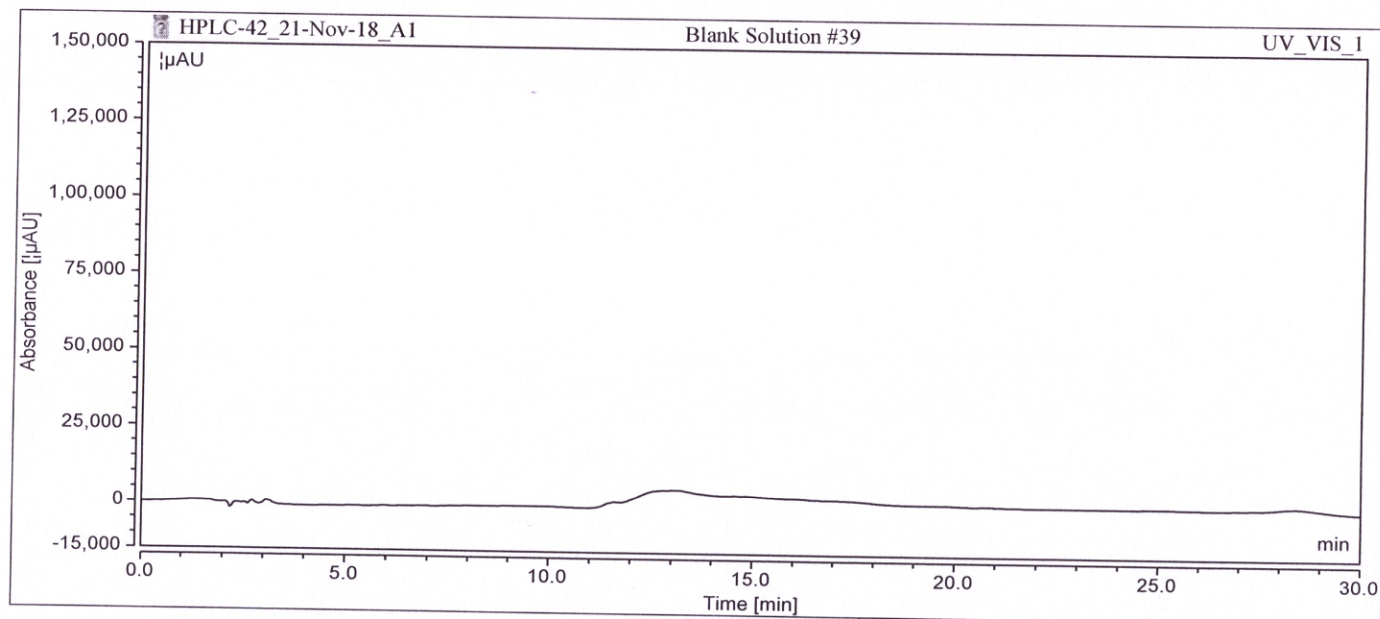


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Unknown	4.207	98.596	0.01	0.83	4691	FALSE	n.a.
2	Placebo	4.663	6931.359	0.40	0.96	2858	FALSE	1.54
3	Hydrochlorothiazide	5.198	977399.953	55.96	1.24	2146	FALSE	1.34
4	Unknown	7.913	181.588	0.01	1.13	5263	FALSE	6.13
5	Unknown	10.652	199.714	0.01	1.01	6758	FALSE	5.74
6	Impurity E	14.480	453.189	0.03	1.04	38350	FALSE	9.41
7	Ramipril	16.193	716936.709	41.05	1.39	12946	FALSE	3.96
8	Unknown	18.115	519.911	0.03	1.31	23749	FALSE	3.70
9	Unknown	18.890	387.059	0.02	1.16	25727	FALSE	1.65
10	Impurity D	24.368	43531.180	2.49	1.17	16166	FALSE	8.85



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	39	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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	22-11-2018 13:58:52	Experiment Name:-	Solution Stability & Filter Study
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

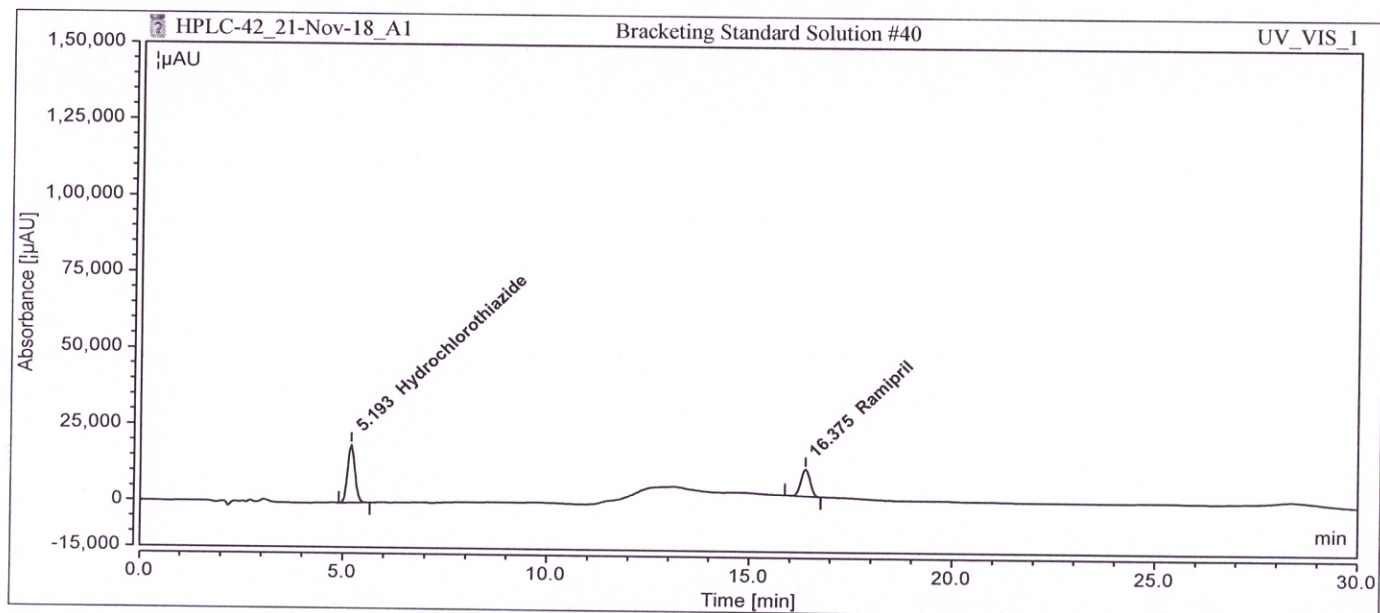


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Bracketing Standard Solution	AR. No. :-	D2404181993
Sample Number :-	40	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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	22-11-2018 14:29:58	Experiment Name:-	Solution Stability & Filter Study
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

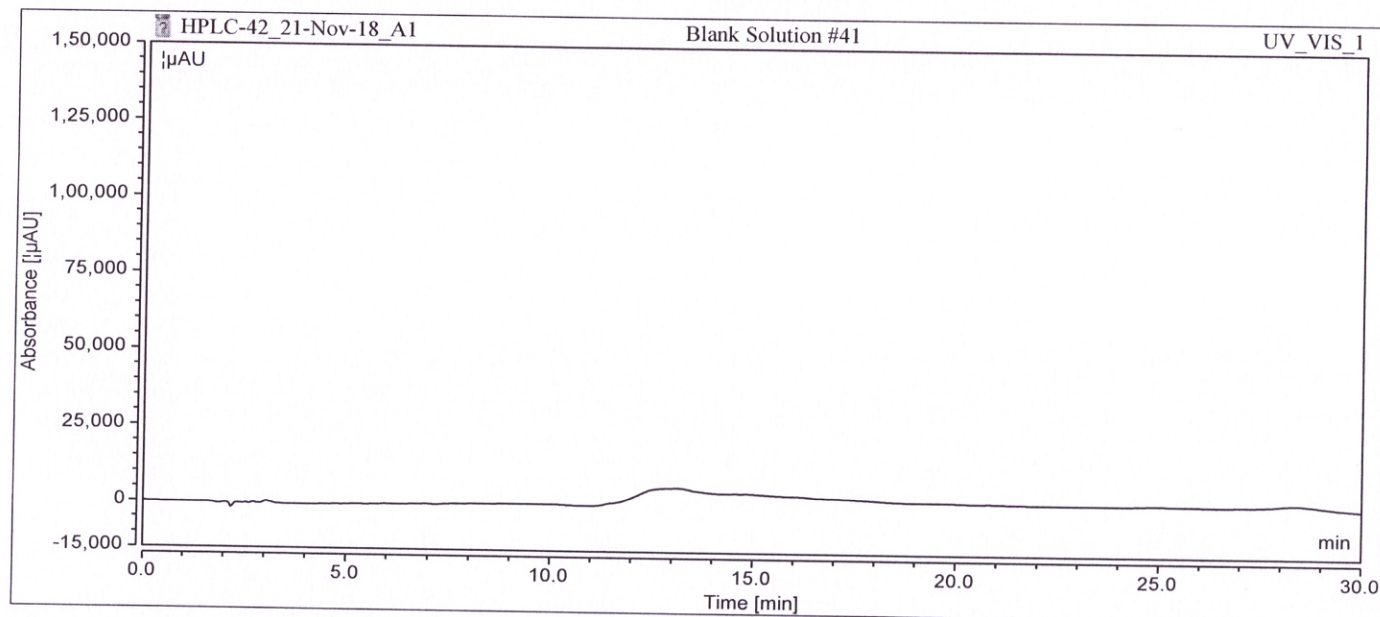


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.193	3963.506	62.81	1.15	3917	FALSE	n.a.
2	Ramipril	16.375	2347.141	37.19	1.02	24027	FALSE	29.64



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	41	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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	22-11-2018 15:01:06	Experiment Name:-	Solution Stability
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

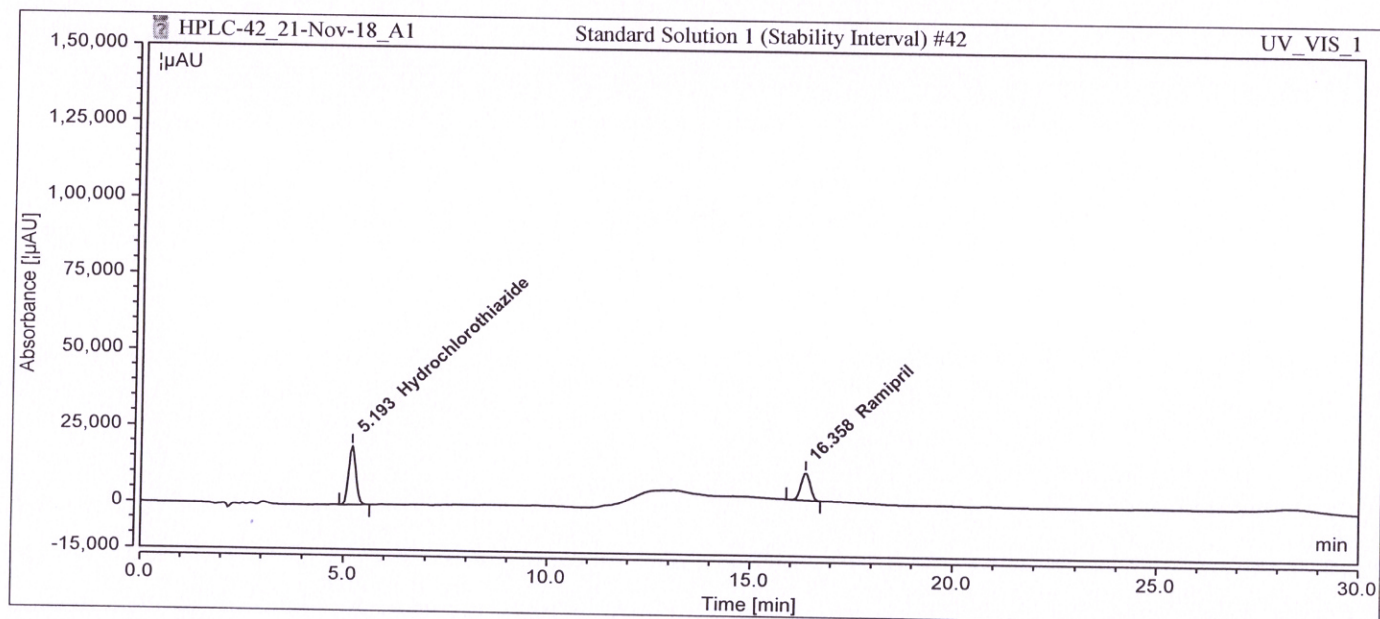


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Standard Solution 1 (Stability Interval)	AR. No. :-	D2404181993
Sample Number :-	42	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_2	Processing Method :-	Ramithiazide Tablets_RS_PR_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	22-11-2018 15:32:14	Experiment Name:-	Solution Stability
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

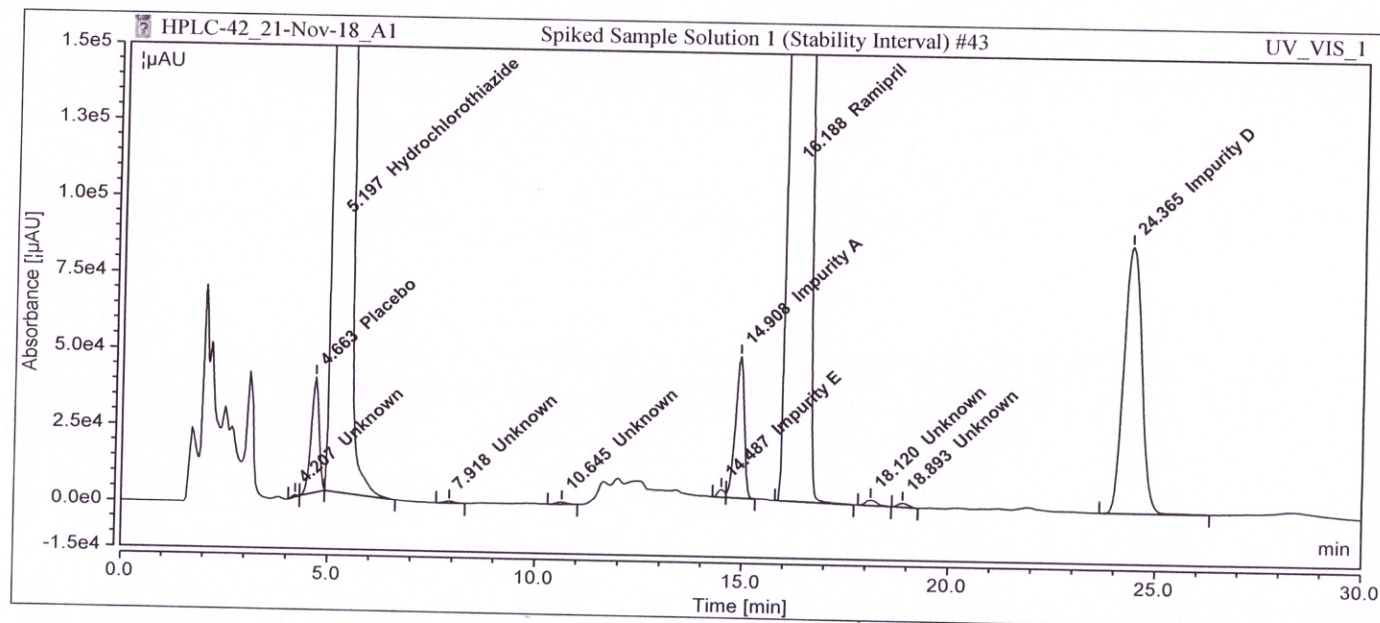


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.193	3962.498	62.72	1.14	3999	FALSE	n.a.
2	Ramipril	16.358	2355.192	37.28	1.02	24024	FALSE	29.75



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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Spiked Sample Solution 1 (Stability Interval)	AR. No. :-	D2404181993
Sample Number :-	43	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_10	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 :-	23-11-2018 19:16:47
Injection Date & Time :-	22-11-2018 16:03:25	Experiment Name:-	Solution Stability
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

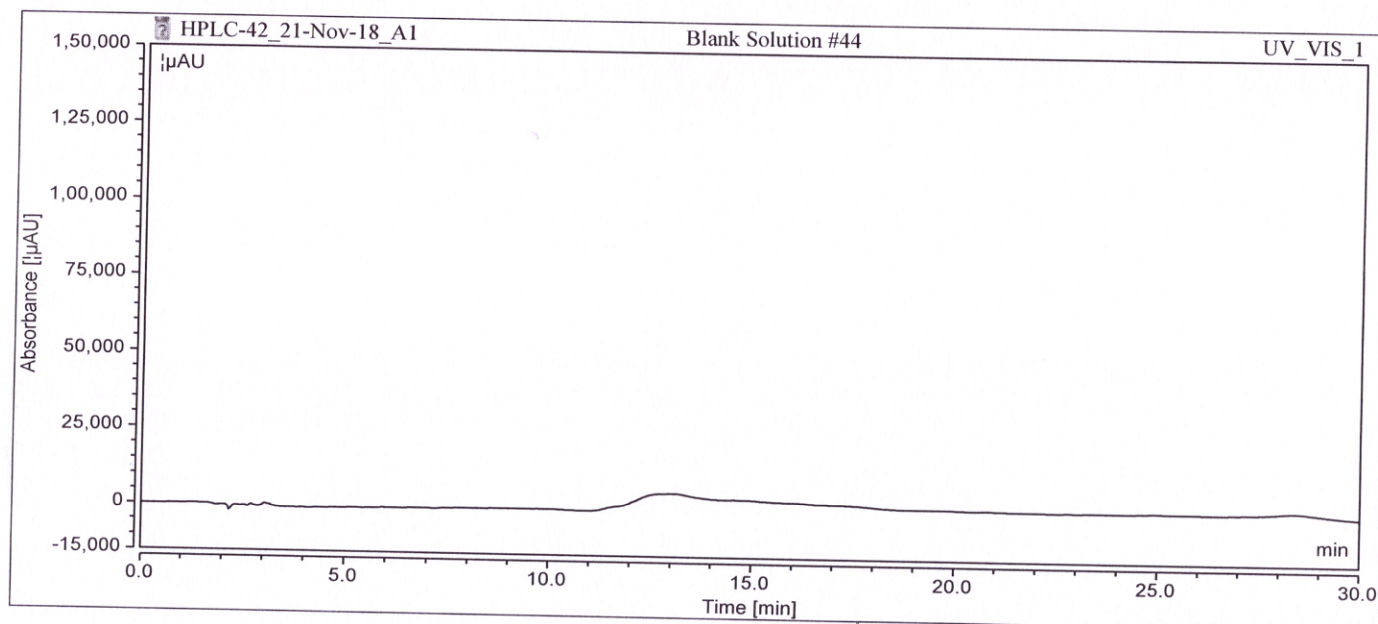


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Unknown	4.207	100.234	0.01	0.83	5244	FALSE	n.a.
2	Placebo	4.663	8121.316	0.46	0.96	2957	FALSE	1.59
3	Hydrochlorothiazide	5.197	976977.566	55.48	1.24	2147	FALSE	1.35
4	Unknown	7.918	184.669	0.01	1.11	4742	FALSE	5.99
5	Unknown	10.645	239.338	0.01	1.05	6427	FALSE	5.50
6	Impurity E	14.487	472.356	0.03	n.a.	25711	FALSE	8.61
7	Impurity A	14.908	11476.367	0.65	0.92	22705	FALSE	1.11
8	Ramipril	16.188	718545.967	40.81	1.40	12923	FALSE	2.65
9	Unknown	18.120	573.831	0.03	1.35	22768	FALSE	3.68
10	Unknown	18.893	371.017	0.02	1.19	25349	FALSE	1.62
11	Impurity D	24.365	43791.544	2.49	1.18	16192	FALSE	8.82



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	44	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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	22-11-2018 16:34:32	Experiment Name:-	Solution Stability
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

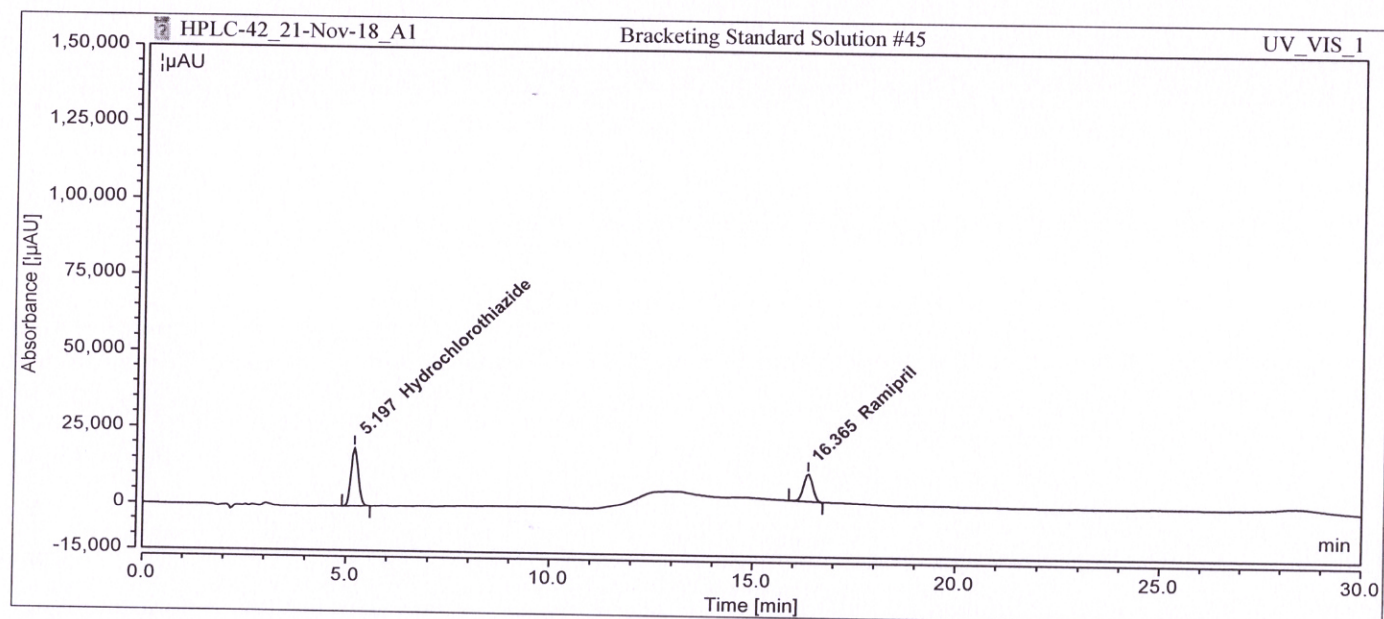


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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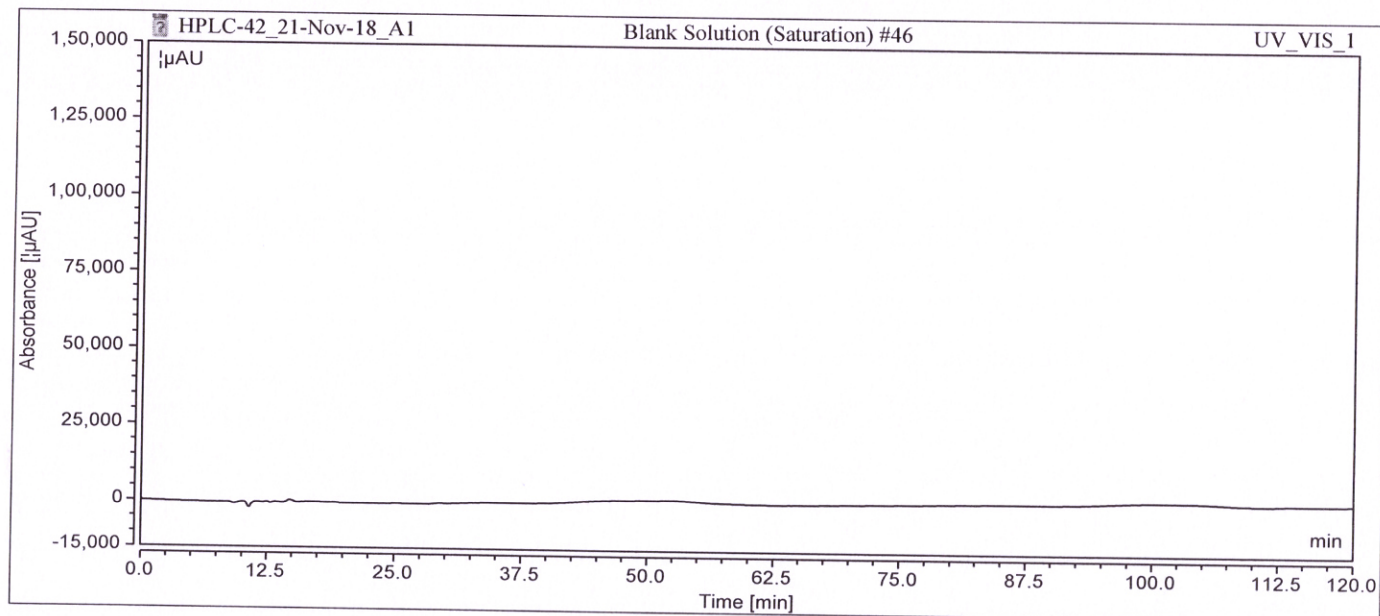
Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Bracketing Standard Solution	AR. No. :-	D2404181993
Sample Number :-	45	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	21-11-2018 15:24:45
Vial Position :-	1_2	Processing Method :-	Ramithiazide Tablets_RS_PR_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	22-11-2018 17:05:40	Experiment Name:-	Solution Stability
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-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	3963.714	62.79	1.15	3941	FALSE	n.a.
2	Ramipril	16.365	2348.814	37.21	1.03	24011	FALSE	29.64


QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Blank Solution (Saturation)	AR. No. :-	D2404181993
Sample Number :-	46	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_S
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	21-11-2018 16:08:44
Vial Position :-	1_1	Processing Method :-	Ramithiazide Tablets_RS_PR_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	22-11-2018 17:36:53	Experiment Name:-	Solution Stability
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

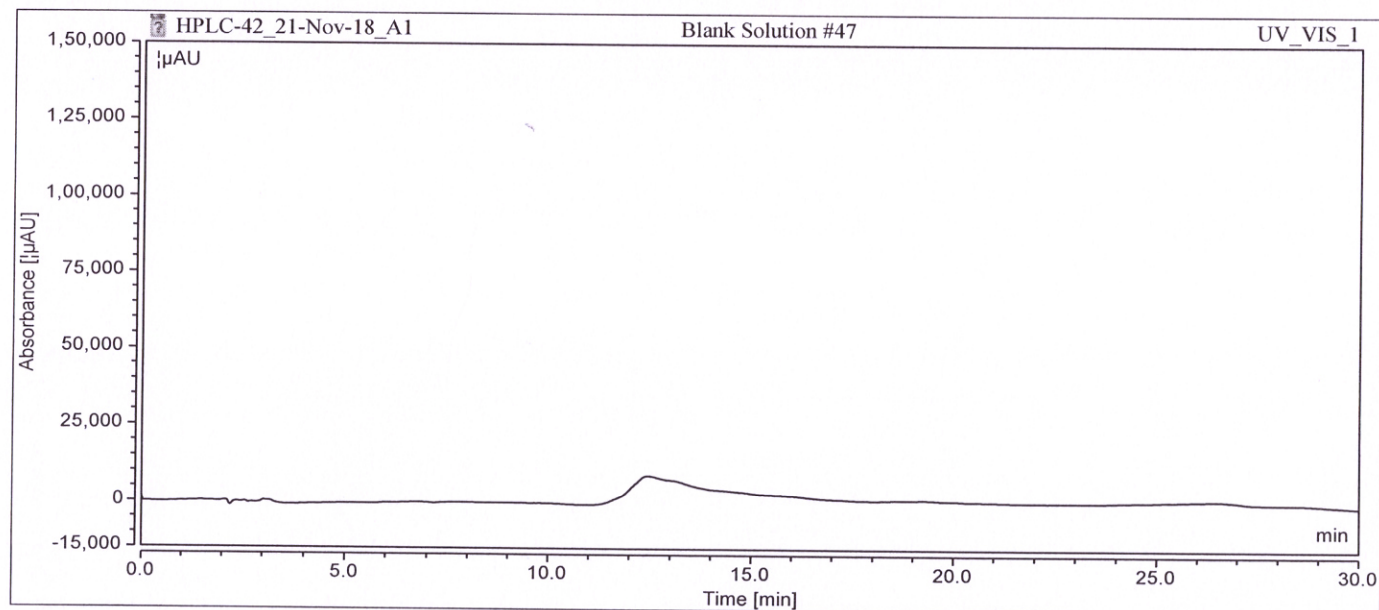


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	47	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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	22-11-2018 19:38:02	Experiment Name:-	Solution Stability
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

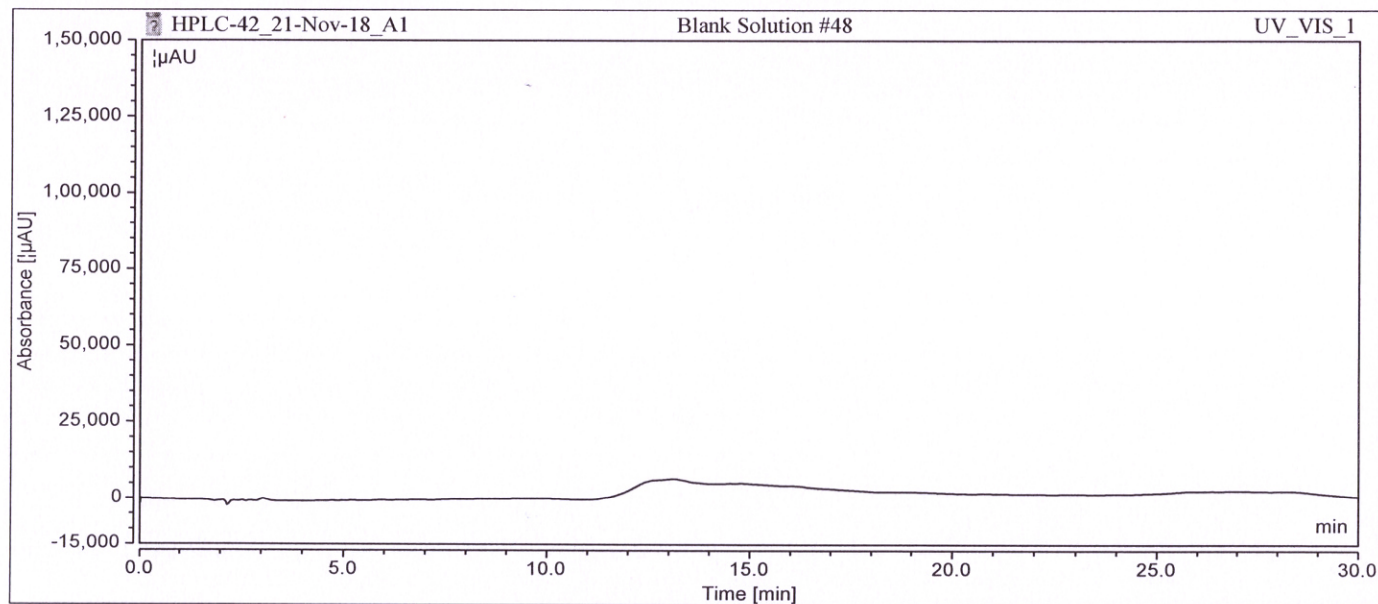


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	48	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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	22-11-2018 20:09:10	Experiment Name:-	Solution Stability
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

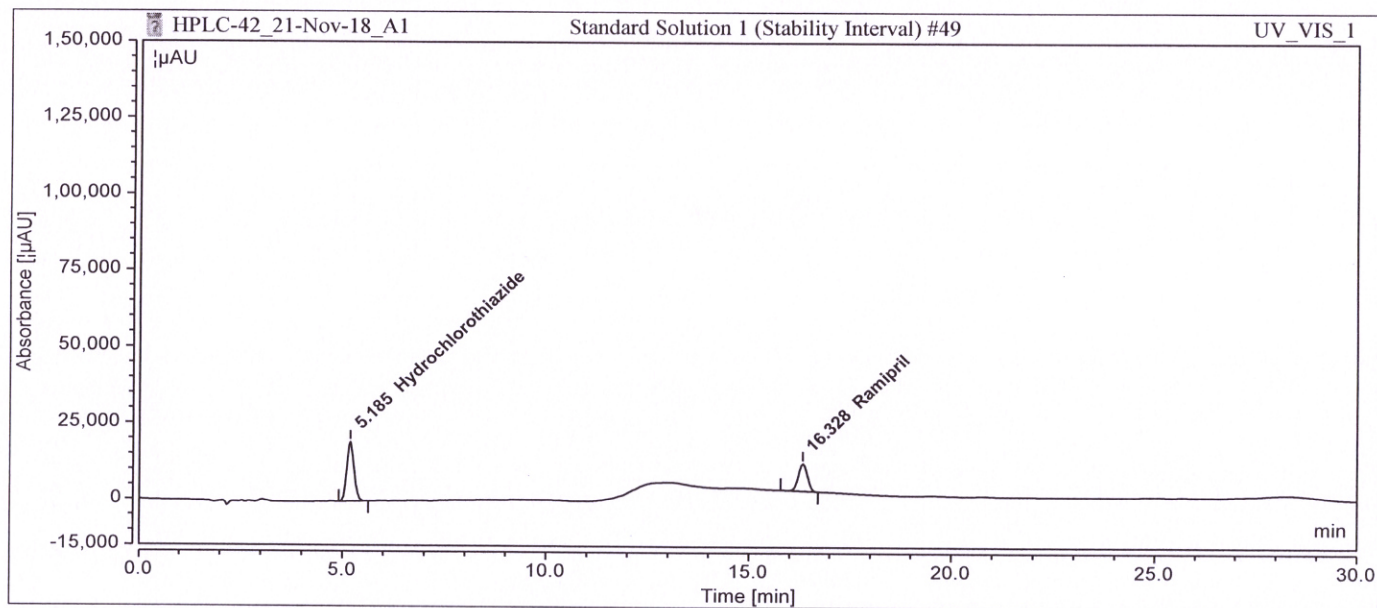


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Standard Solution 1 (Stability Interval)	AR. No. :-	D2404181993
Sample Number :-	49	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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	22-11-2018 20:40:18	Experiment Name:-	Solution Stability
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

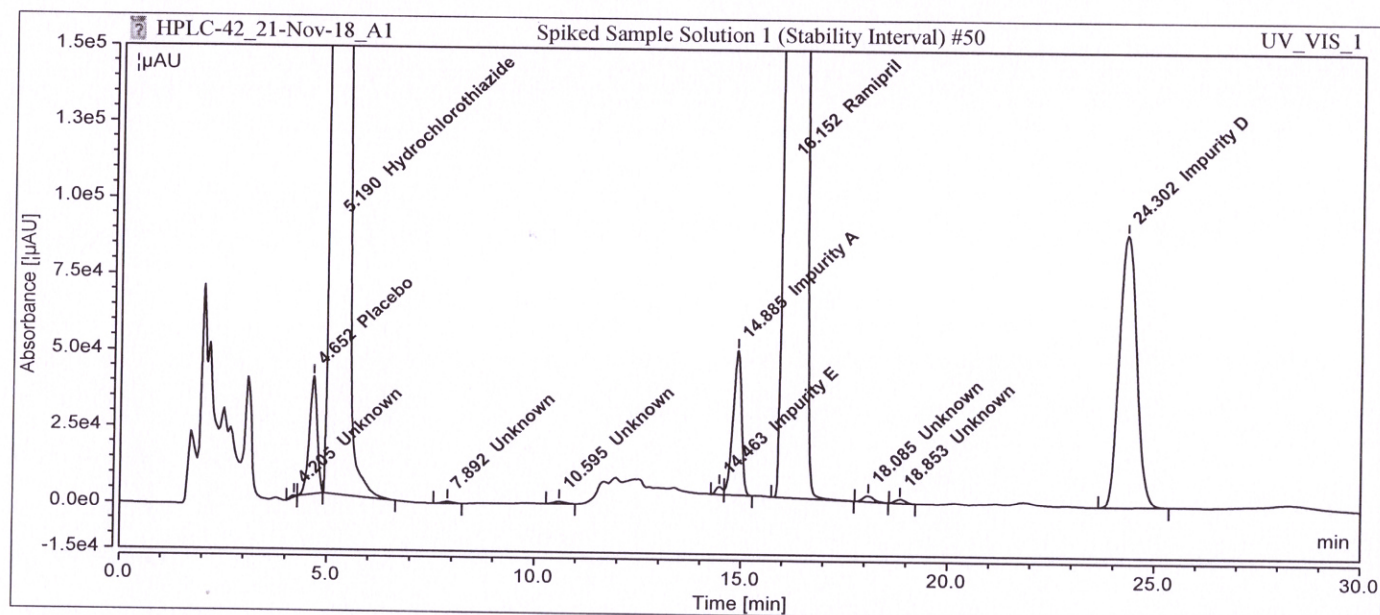


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.185	3970.600	62.84	1.15	4040	FALSE	n.a.
2	Ramipril	16.328	2348.193	37.16	1.02	24729	FALSE	30.05



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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Spiked Sample Solution 1 (Stability Interval)	AR. No. :-	D2404181993
Sample Number :-	50	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_10	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 :-	23-11-2018 19:16:47
Injection Date & Time :-	22-11-2018 21:11:28	Experiment Name:-	Solution Stability
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

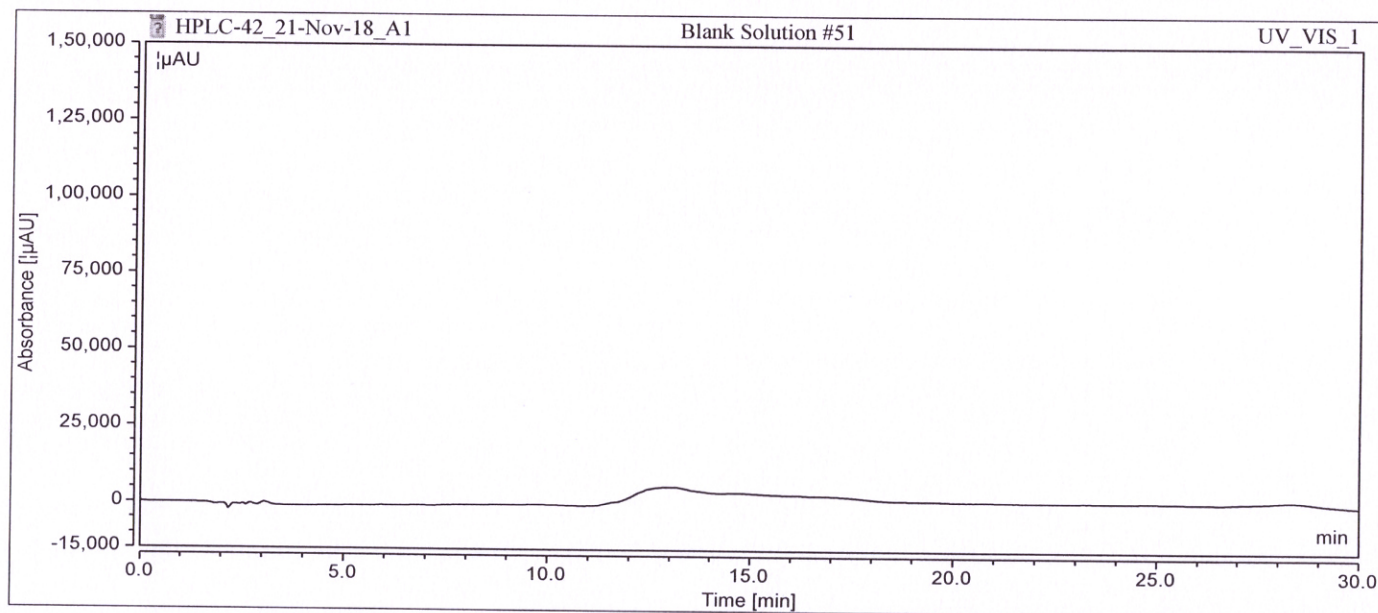


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Unknown	4.205	87.873	0.01	0.73	5834	FALSE	n.a.
2	Placebo	4.652	8267.342	0.47	0.95	2992	FALSE	1.59
3	Hydrochlorothiazide	5.190	969821.317	55.38	1.23	2170	FALSE	1.37
4	Unknown	7.892	183.311	0.01	1.04	5686	FALSE	6.25
5	Unknown	10.595	247.352	0.01	1.10	6660	FALSE	5.76
6	Impurity E	14.463	481.009	0.03	n.a.	27290	FALSE	8.90
7	Impurity A	14.885	11506.385	0.66	0.91	23522	FALSE	1.14
8	Ramipril	16.152	716007.012	40.89	1.43	12947	FALSE	2.65
9	Unknown	18.085	593.104	0.03	1.28	23960	FALSE	3.74
10	Unknown	18.853	385.802	0.02	1.16	27127	FALSE	1.66
11	Impurity D	24.302	43641.592	2.49	1.17	16679	FALSE	9.00



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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	51	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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	22-11-2018 21:42:34	Experiment Name:-	Solution Stability
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

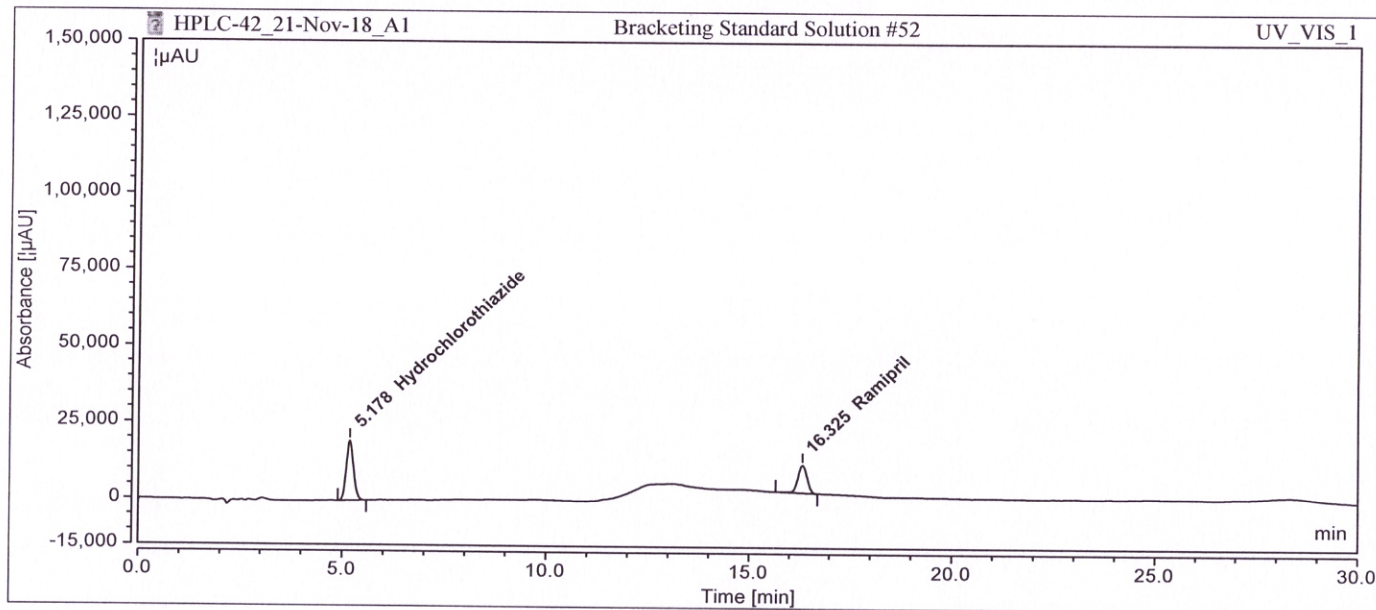


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Bracketing Standard Solution	AR. No. :-	D2404181993
Sample Number :-	52	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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	22-11-2018 22:13:42	Experiment Name:-	Solution Stability
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

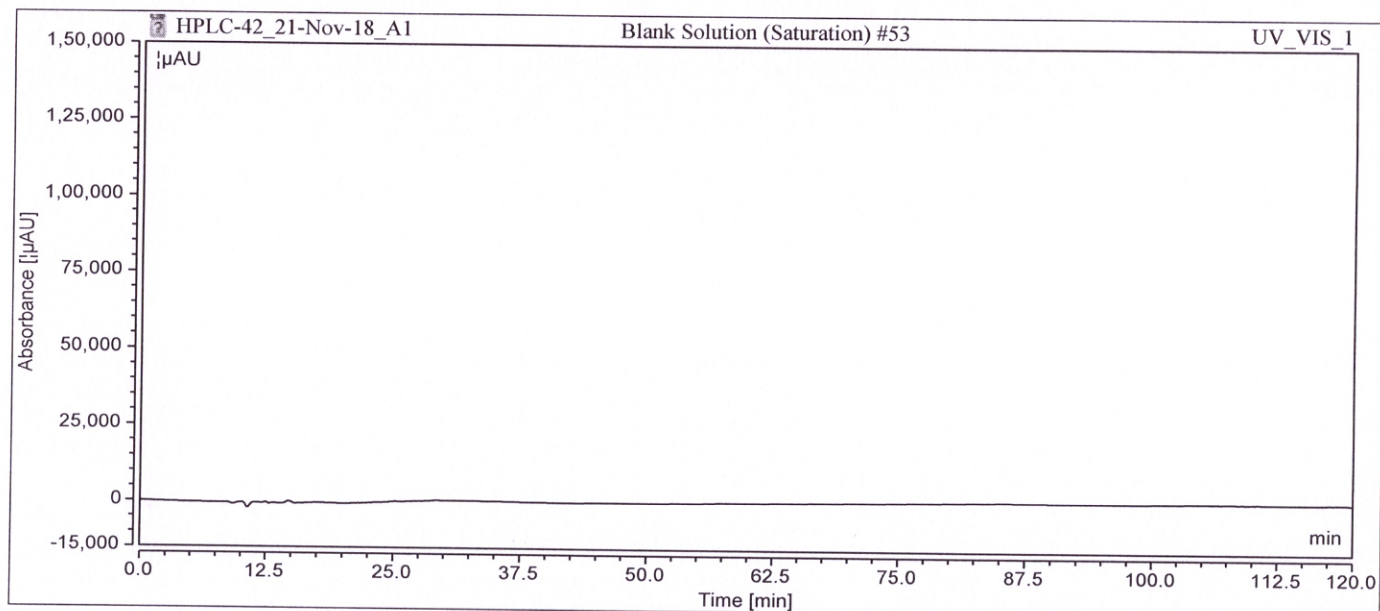


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.178	3972.408	62.37	1.15	4039	FALSE	n.a.
2	Ramipril	16.325	2396.538	37.63	1.01	24663	FALSE	30.06



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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Blank Solution (Saturation)	AR. No. :-	D2404181993
Sample Number :-	53	Instrument Method :-	HPLC-42_Ramithiazide Tablet_RS_S
Sample Type :-	Unknown	Instrument Method Created By :-	Mahesh M Nikam
Injection Volume :-	30.00 µL	Instrument Method Created On :-	21-11-2018 16:08:44
Vial Position :-	1_1	Processing Method :-	Ramithiazide Tablets_RS_PR_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	22-11-2018 22:44:55	Experiment Name:-	Solution Stability
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

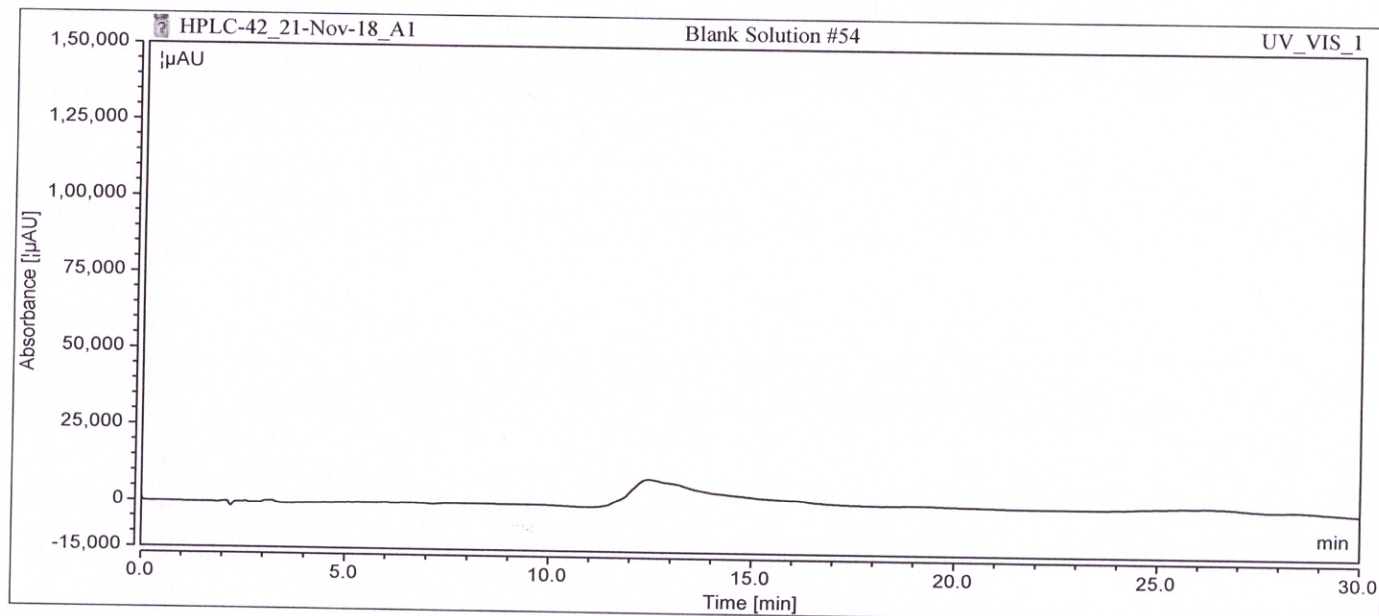


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	54	Instrument 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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	23-11-2018 00:46:05	Experiment Name:-	Solution Stability
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

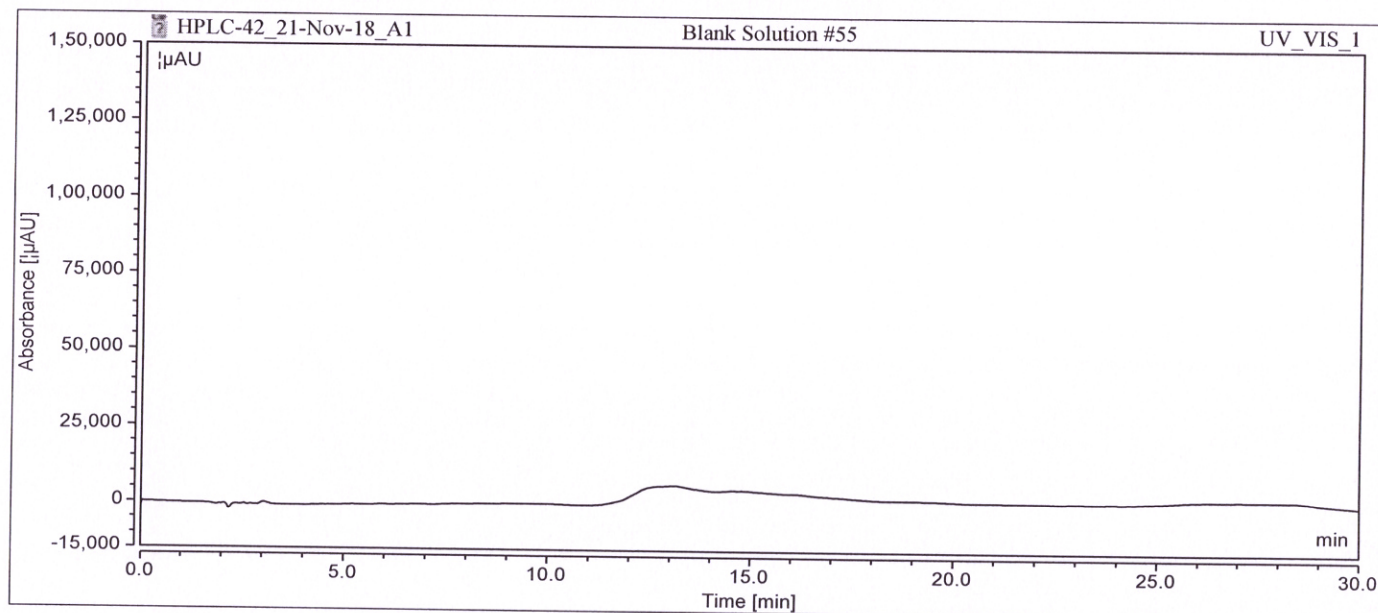


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	55	Instrument 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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	23-11-2018 01:17:13	Experiment Name:-	Solution Stability
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

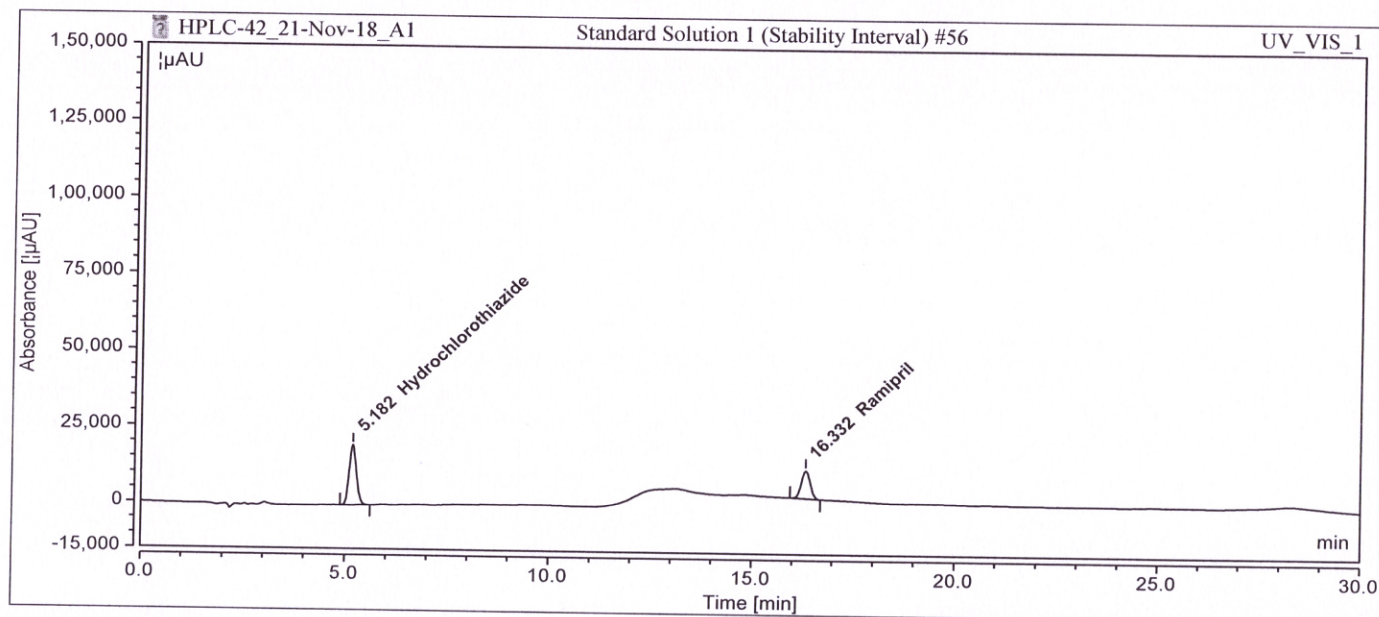


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Standard Solution 1 (Stability Interval)	AR. No. :-	D2404181993
Sample Number :-	56	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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	23-11-2018 01:48:21	Experiment Name:-	Solution Stability
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

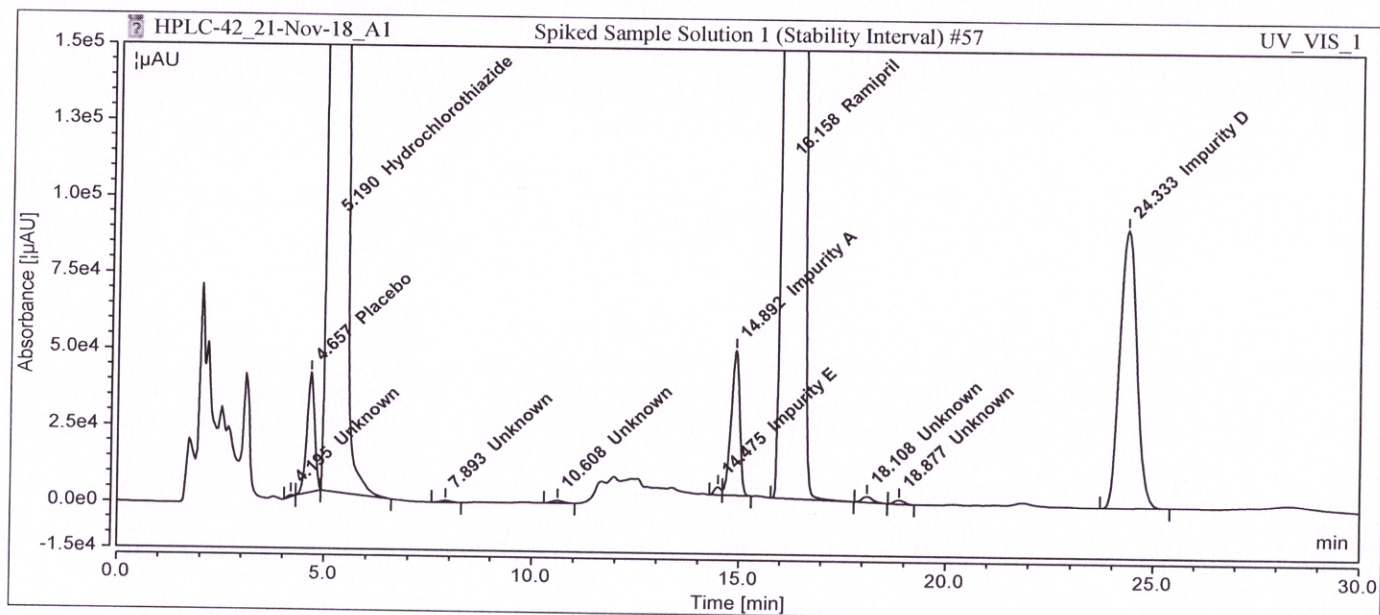


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	5.182	3972.311	62.95	1.16	4127	FALSE	n.a.
2	Ramipril	16.332	2338.447	37.05	1.02	25585	FALSE	30.50



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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Spiked Sample Solution 1 (Stability Interval)	AR. No. :-	D2404181993
Sample Number :-	57	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_10	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 :-	23-11-2018 19:16:47
Injection Date & Time :-	23-11-2018 02:19:31	Experiment Name:-	Solution Stability
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_AI.seq		

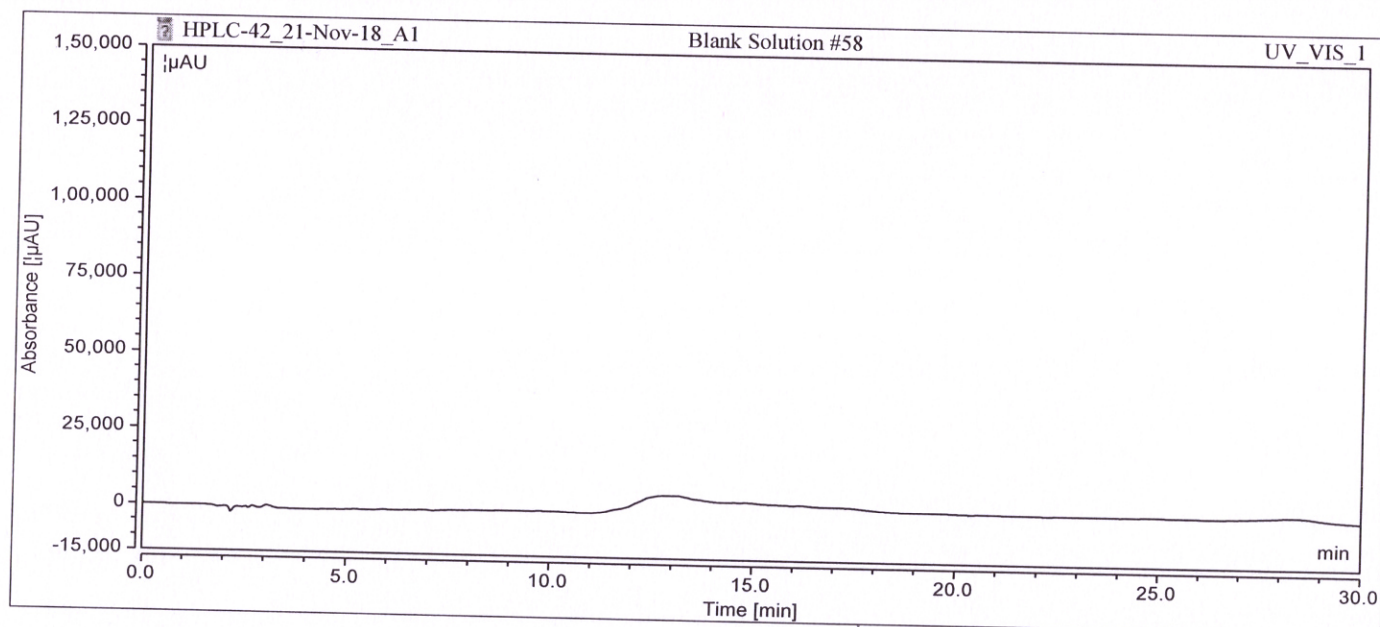


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Unknown	4.195	99.519	0.01	0.85	5351	FALSE	n.a.
2	Placebo	4.657	8303.264	0.48	0.96	3051	FALSE	1.63
3	Hydrochlorothiazide	5.190	969601.021	55.48	1.23	2164	FALSE	1.36
4	Unknown	7.893	182.506	0.01	1.08	5339	FALSE	6.16
5	Unknown	10.608	262.086	0.01	1.07	5974	FALSE	5.53
6	Impurity E	14.475	466.737	0.03	n.a.	29135	FALSE	8.71
7	Impurity A	14.892	11477.971	0.66	0.91	23852	FALSE	1.15
8	Ramipril	16.158	712372.223	40.76	1.42	13176	FALSE	2.67
9	Unknown	18.108	593.069	0.03	1.34	24471	FALSE	3.80
10	Unknown	18.877	361.139	0.02	1.14	28377	FALSE	1.69
11	Impurity D	24.333	43793.780	2.51	1.17	17217	FALSE	9.17



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Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Blank Solution	AR. No. :-	D2404181993
Sample Number :-	58	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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	23-11-2018 02:50:39	Experiment Name:-	Solution Stability
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

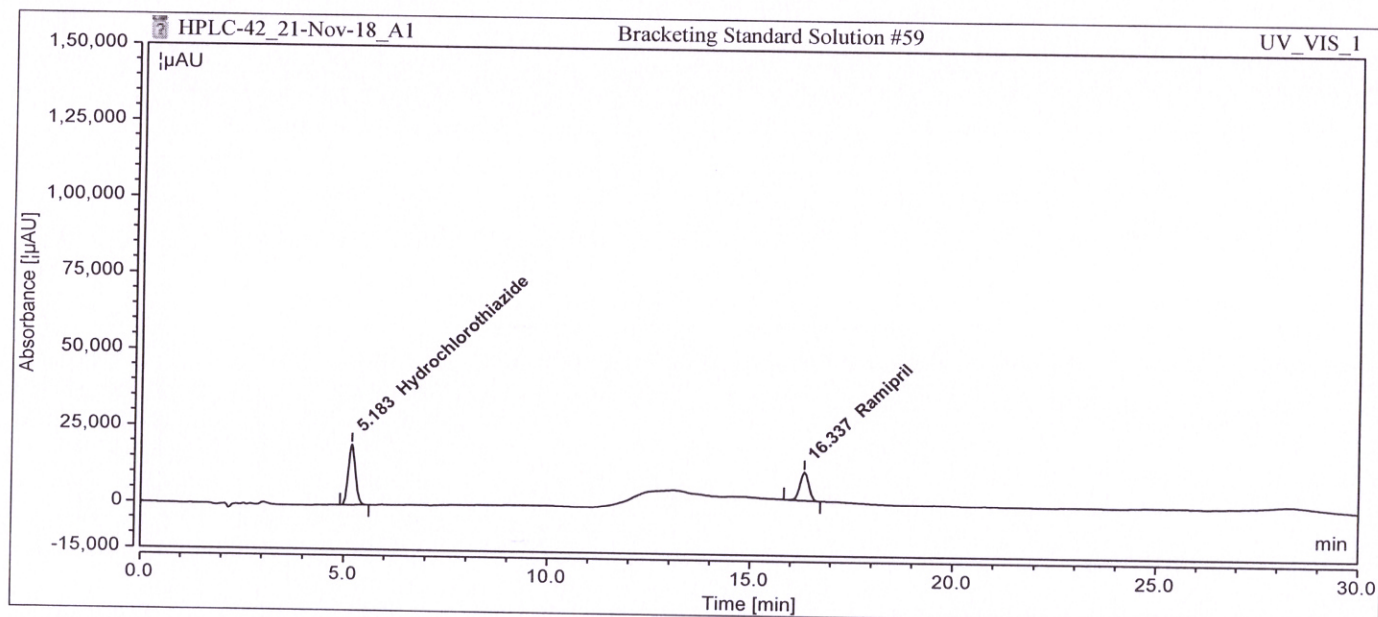


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablets	Batch No. :-	N/A
Sample Name :-	Bracketing Standard Solution	AR. No. :-	D2404181993
Sample Number :-	59	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_1
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 :-	23-11-2018 09:42:00
Injection Date & Time :-	23-11-2018 03:21:46	Experiment Name:-	Solution Stability
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-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	3974.737	62.65	1.15	4102	FALSE	n.a.
2	Ramipril	16.337	2369.408	37.35	1.02	25328	FALSE	30.38



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	metod created	Batch No. :-	N/A
Sample Name :-	Wash	AR. No. :-	N/A
Sample Number :-	60	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_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 :-	23-11-2018 19:16:47
Injection Date & Time :-	23-11-2018 03:52:32	Experiment Name:-	Solution Stability
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

Channel UV_VIS_1 is not available for injection #60 - Wash.

Peak No.	Peak Name	Ret. Time min	Area n.a.	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
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Product Name :-	metod created	Batch No. :-	N/A
Sample Name :-	Shut	AR. No. :-	N/A
Sample Number :-	61	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_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 :-	23-11-2018 19:16:47
Injection Date & Time :-	23-11-2018 04:53:08	Experiment Name:-	Solution Stability
Analyst :-	Swaraj Jadhav	Wavelength:-	210 nm
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-42_21-Nov-18_A1.seq		

Channel UV_VIS_1 is not available for injection #61 - Shut.

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