

CONTENT UNIFORMITY METHOD VALIDATION

Product name :	Ramithiazide tablets 5mg/12.5mg
Lable claim (mg) :	12.5
Content :	Hydrochlorothiazide
B. No. :	GS170401
Parameter :	Intermediate Precision
LNB No./Pg. No.:	419/105

Analysis Date: 24-Jun-17

Name of standard	Standard B. No.	Standard purity(%)	Standard wt (mg)	Dilution details	Conc (ppm)
Hydrochlorothiazide	20140403	99.9	25.43	25 mL, 5 mL -> 100 mL	50.9

Sr.No.	RT	Area	RT	Area
1	2.107	26757.552	3.973	7000.661
2	2.110	26742.164	3.977	7017.555
3	2.107	26729.583	3.974	7006.084
4	2.112	26720.862	3.972	7009.540
5	2.107	26715.221	3.973	7010.196
6	2.112	26708.079	3.972	6990.409
Average	2.109	26728.910	3.974	7005.741
SD	0.00	18.34	0.00	9.33
%RSD	0.12	0.07	0.05	0.13

System suitability results of Hydrochlorothiazide			
% RSD of Area	0.07	NMT 2.0%	
Tailing factor	1.08	NMT 2.0	
Theoretical plates	10583	NLT 2000	

Test Solution :	1	Tablet in	250.0	mL with Diluent
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Sample	Tablets Weight (mg)	Peak Area of Sample	% Content
1	199.98	26738.909	101.7
2	195.70	26777.155	101.8
3	199.17	26455.655	100.6
4	194.89	26811.343	101.9
5	196.42	26641.010	101.3
6	197.84	26754.995	101.7
7	195.91	26962.827	102.5
8	197.34	26777.232	101.8
9	197.05	26783.011	101.8
10	197.94	26719.267	101.6
		Min	100.6
		Max	102.5
		Mean	101.7
		SD	0.49
		% RSD	0.48
		AV Value	1.4

Done by:

Date:

Bhawan
20-Jun-17

Checked by:

Date:

Sant
28-Jun-17

CONTENT UNIFORMITY METHOD VALIDATION

Product name :	Ramithiazide tablets 5mg/12.5mg
Lable claim (mg) :	5
Content :	Ramipril
B. No. :	GS170401
Parameter :	Intermediate Precision
LNB No./Pg. No.:	419/105

Analysis Date: 24-Jun-17

Name of standard	Standard B. No.	Standard purity(%)	Standard wt (mg)	Dilution details	Conc (ppm)
Ramipril	RL-14203	99.8	25.95	25 mL; 2 mL -> 100 mL	20.8

Sr.No.	RT	Area	RT	Area
1	2.107	26757.552	3.973	7000.661
2	2.110	26742.164	3.977	7017.555
3	2.107	26729.583	3.974	7006.084
4	2.112	26720.862	3.972	7009.540
5	2.107	26715.221	3.973	7010.196
6	2.112	26708.079	3.972	6990.409
Average	2.109	26728.910	3.974	7005.741
SD	0.00	18.34	0.00	9.33
%RSD	0.12	0.07	0.05	0.13

System suitability results of Ramipril

% RSD of Area	0.13	NMT 2.0%
Tailing factor	1.03	NMT 2.0
Theoretical plates	11081	NLT 2000

Test Solution :	1	Tablet in	250.0	mL with Diluent
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Sample	Tablets Weight (mg)	Peak Area of Sample	% Content
1	199.98	6811.163	100.7
2	195.70	6536.646	96.7
3	199.17	6440.453	95.2
4	194.89	6638.071	98.2
5	196.42	6489.863	96.0
6	197.84	6595.169	97.5
7	195.91	6659.570	98.5
8	197.34	6602.860	97.6
9	197.05	6587.300	97.4
10	197.94	6578.018	97.3
		Min	95.2
		Max	100.7
		Mean	97.5
		SD	1.49
		% RSD	1.53
		AV Value	4.6

Done by:

Date:

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26-Jun-17

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28-Jun-17

Assay Method Validation

Product name :	Ramithiazide Tablets
Lable claim :	Ramipril 5 mg & Hydrochlorothiazide 12.5 mg
B. No. :	GP170401
Test :	Intermediate Precision
Average wt (mg) :	199.83
LNB No./Pg. No.:	419/052

Analysis Date: 10-Jun-17

Name of standard	Standard purity(%)	Standard wt (mg)	Dilution details	Conc (ppm)
Ramipril	99.8	24.54	25 mL; 2 mL ->100 mL	19.6
Hydrochlorothiazide	99.9	25.16	25 mL; 5 mL ->100 mL	50.3

Injection No.	Hydrochlorothiazide		Ramipril	
	Retention Time	Area of Standard	Retention Time	Area of Standard
1	2.225	29779.744	3.882	6982.083
2	2.225	29910.378	3.883	6990.418
3	2.227	29895.007	3.885	6982.654
4	2.227	29870.134	3.885	6978.374
5	2.225	29937.184	3.883	6982.466
6	2.225	29970.544	3.883	6990.327
Average	2.226	29893.832	3.884	6984.387
SD	0.001	65.75	0.001	4.89
%RSD	0.05	0.22	0.03	0.07

System suitability results		
% RSD of HCTZ	0.22	NMT 2.0%
% RSD of Ramipril	0.07	NMT 2.0%
Theoretical plates of HCTZ	6040	NLT 2000
Theoretical plates of Ramipril	8584	NLT 2000
Tailing factor of HCTZ	1.15	NMT 2.0
Tailing factor of Ramipril	1.06	NMT 2.0

Test Solution :	Sample eq to 25	mg of Ramipril	250.0	mL with diluent
	Further	5	25.0	mL with diluent

Sample No.	Sample Weight (mg)	Area of Sample		% Assay	
		Hydrochlorothiazide	Ramipril	Hydrochlorothiazide	Ramipril
1	995.72	29565.134	7130.849	99.8	100.4
2	994.71	29626.454	7135.219	100.1	100.5
3	995.09	29548.641	7138.142	99.8	100.5
4	995.33	29467.116	7116.769	99.5	100.2
5	995.73	29706.000	7160.037	100.3	100.8
6	995.17	29503.873	7124.497	99.6	100.3
		Mean	99.8	100.5	
		SD	0.29	0.20	
		%RSD	0.29	0.20	

Done by:

Date:

P. M. M.
29-Jun-17

Checked by:

Date:

P. M. M.
29-Jun-17

Assay Method Validation

Product name :	Ramithiazide Tablets
Lable claim :	Ramipril 10 mg & Hydrochlorothiazide 12.5 mg
B. No. :	GP170402
Test :	Intermediate Precision
Average wt (mg) :	198.36
LNB No./Pg. No.:	419/052

Analysis Date: 10-Jun-17

Name of standard	Standard purity(%)	Standard wt (mg)	Dilution details	Cone (ppm)
Ramipril	99.8	24.54	25 mL; 2 mL ->100 mL	19.6
Hydrochlorothiazide	99.9	25.16	25 mL; 2.5 mL ->100 mL	25.2

Injection No.	Hydrochlorothiazide		Ramipril	
	Retention Time	Area of Standard	Retention Time	Area of Standard
1	2.223	15522.964	3.882	7108.906
2	2.225	15529.755	3.882	7106.701
3	2.225	15525.629	3.883	7101.858
4	2.223	15531.716	3.882	7102.031
5	2.223	15526.224	3.882	7098.623
6	2.223	15534.615	3.882	7101.488
Average	2.224	15528.484	3.882	7103.268
SD	0.001	4.32	0.000	3.79
%RSD	0.05	0.03	0.01	0.05

System suitability results		
% RSD of HCTZ	0.03	NMT 2.0%
% RSD of Ramipril	0.05	NMT 2.0%
Theoretical plates of HCTZ	5865	NLT 2000
Theoretical plates of Ramipril	8371	NLT 2000
Tailing factor of of HCTZ	1.13	NMT 2.0
Tailing factor of Ramipril	1.06	NMT 2.0

Test Solution :	Sample eq to 25	mg of Ramipril	250.0	mL with diluent
	Further	5	25.0	mL with diluent

Sample No.	Sample Weight (mg)	Area of Sample		% Assay	
		Hydrochlorothiazide	Ramipril	Hydrochlorothiazide	Ramipril
1	494.49	15452.158	7121.486	100.3	98.5
2	494.59	15470.739	7129.698	100.4	98.6
3	494.95	15490.150	7139.473	100.5	98.7
4	495.81	15432.785	7115.849	99.9	98.2
5	495.66	15588.560	7154.534	101.0	98.7
6	494.95	15574.824	7135.676	101.0	98.6
		Average		100.5	98.5
		SD		0.41	0.20
		%RSD		0.41	0.20

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Assay Method Validation

Product name :	Ramithiazide Tablets
Lable claim :	Ramipril 10 mg & Hydrochlorothiazide 25 mg
B. No. :	GPI70403
Test :	Intermediate Precision
Average wt (mg) :	196.15
LNB No./Pg. No.:	419/052

Analysis Date:	10-Jun-17
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Name of standard	Standard purity(%)	Standard wt (mg)	Dilution details	Conc (ppm)
Ramipril	99.8	24.54	25 mL; 2 mL ->100 mL	19.6
Hydrochlorothiazide	99.9	25.16	25 mL; 5 mL ->100 mL	50.3

Injection No.	Hydrochlorothiazide		Ramipril	
	Retention Time	Area of Standard	Retention Time	Area of Standard
1	2.225	29779.744	3.882	6982.083
2	2.225	29910.378	3.883	6990.418
3	2.227	29895.007	3.885	6982.654
4	2.227	29870.134	3.885	6978.374
5	2.225	29937.184	3.883	6982.466
6	2.225	29970.544	3.883	6990.327
Average	2.226	29893.832	3.884	6984.387
SD	0.001	65.75	0.001	4.89
%RSD	0.05	0.22	0.03	0.07

System suitability results		
% RSD of HCTZ	0.22	NMT 2.0%
% RSD of Ramipril	0.07	NMT 2.0%
Theoretical plates of HCTZ	6040	NLT 2000
Theoretical plates of Ramipril	8584	NLT 2000
Tailing factor of HCTZ	1.15	NMT 2.0
Tailing factor of Ramipril	1.06	NMT 2.0

Test Solution :	Sample eq to 25	mg of Ramipril	250.0	mL with diluent
	Further	5	25.0	mL with diluent

Sample No.	Sample Weight (mg)	Area of Sample		% Assay	
		Hydrochlorothiazide	Ramipril	Hydrochlorothiazide	Ramipril
1	493.22	29503.345	7122.542	98.7	99.3
2	493.35	29483.484	7119.263	98.6	99.3
3	493.63	29462.967	7116.801	98.4	99.2
4	493.27	29499.358	7130.428	98.6	99.4
5	493.44	29512.245	7118.175	98.6	99.2
6	493.83	29534.488	7120.850	98.6	99.2
		Average		98.6	99.3
		SD		0.08	0.10
		%RSD		0.08	0.10

Done by: 
Date: 29-Jun-17

Checked by: 
Date: 29-Jun-17

Assay Method Validation

Product name :	Ramithiazide Tablets
Lable claim :	Ramipril 10 mg & Hydrochlorothiazide 25 mg
B. No. :	GP170403
Test :	Comparision of Method precision and Intermediate precision

Date:	29-Jun-17
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Sample No.	Parameter	% Assay	
		Hydrochlorothiazide	Ramipril
1	Method precision	99.4	100.5
2		100.1	101.2
3		100.3	101.5
4		98.3	99.7
5		100.4	101.6
6		99.4	100.9
1	Intermediate precision	98.7	99.3
2		98.6	99.3
3		98.4	99.2
4		98.6	99.4
5		98.6	99.2
6		98.6	99.2
	Mean	99.1	100.1
	SD	0.76	0.98
	%RSD	0.77	0.98

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Assay Method Validation

Product name :	Ramithiazide Tablets
Lable claim :	Ramipril 10 mg & Hydrochlorothiazide 12.5 mg
B. No. :	GP170402
Test :	Comparision of Method precision and Intermediate precision

Date:	29-Jun-17
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Sample No.	Parameter	% Assay	
		Hydrochlorothiazide	Ramipril
1	Method precision	98.2	101.3
2		98.6	101.6
3		98.5	101.5
4		98.4	101.4
5		98.9	101.5
6		98.5	101.4
1	Intermediate precision	100.3	98.5
2		100.4	98.6
3		100.5	98.7
4		99.9	98.2
5		101.0	98.7
6		101.0	98.6
	Mean	99.6	100.1
	SD	1.11	1.64
	%RSD	1.11	1.64

Done by:
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29-Jun-17

Assay Method Validation

Product name :	Ramithiazide Tablets
Lable claim :	Ramipril 5 mg & Hydrochlorothiazide 12.5 mg
B. No. :	GP170401
Test :	Comparision of Method precision and Intermediate precision

Date:	29-Jun-17
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Sample No.	Parameter	% Assay	
		Hydrochlorothiazide	Ramipril
1	Method precision	100.8	99.5
2		100.0	98.2
3		100.9	100.1
4		101.1	99.4
5		101.7	100.2
6		101.2	99.5
1	Intermediate precision	99.8	100.4
2		100.1	100.5
3		99.8	100.5
4		99.5	100.2
5		100.3	100.8
6		99.6	100.3
	Mean	99.2	101.0
	SD	0.74	0.55
	%RSD	0.74	0.54

Done by:
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29-Jun-17

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29-Jun-17

ASSAY METHOD VALIDATION

Product name :	Ramithiazide
Content :	Ramipril
Parameter :	Robustness comparison
B.No:	GP170401

Date: 28-Jun-17

Robustness parameter	% Assay	% Difference (NMT 2.0 %)
Precision	100.9	NA
Flow Rate 0.9 mL/min	100.9	0.0
Flow Rate 1.1 mL/min	100.8	0.1
Organic content decrease	100.1	0.8
Organic content increase	100.7	0.2
Buffer pH 2.3	100.0	0.9
Buffer pH 2.7	101.7	0.8

Done by: 
Date: 28-Jun-17

Checked by: 
Date: 28-Jun-17

ASSAY METHOD VALIDATION

Product name :	Ramithiazide
Content :	Hydrochlorothiazide
Parameter :	Robustness comparision
B.No:	GP170401

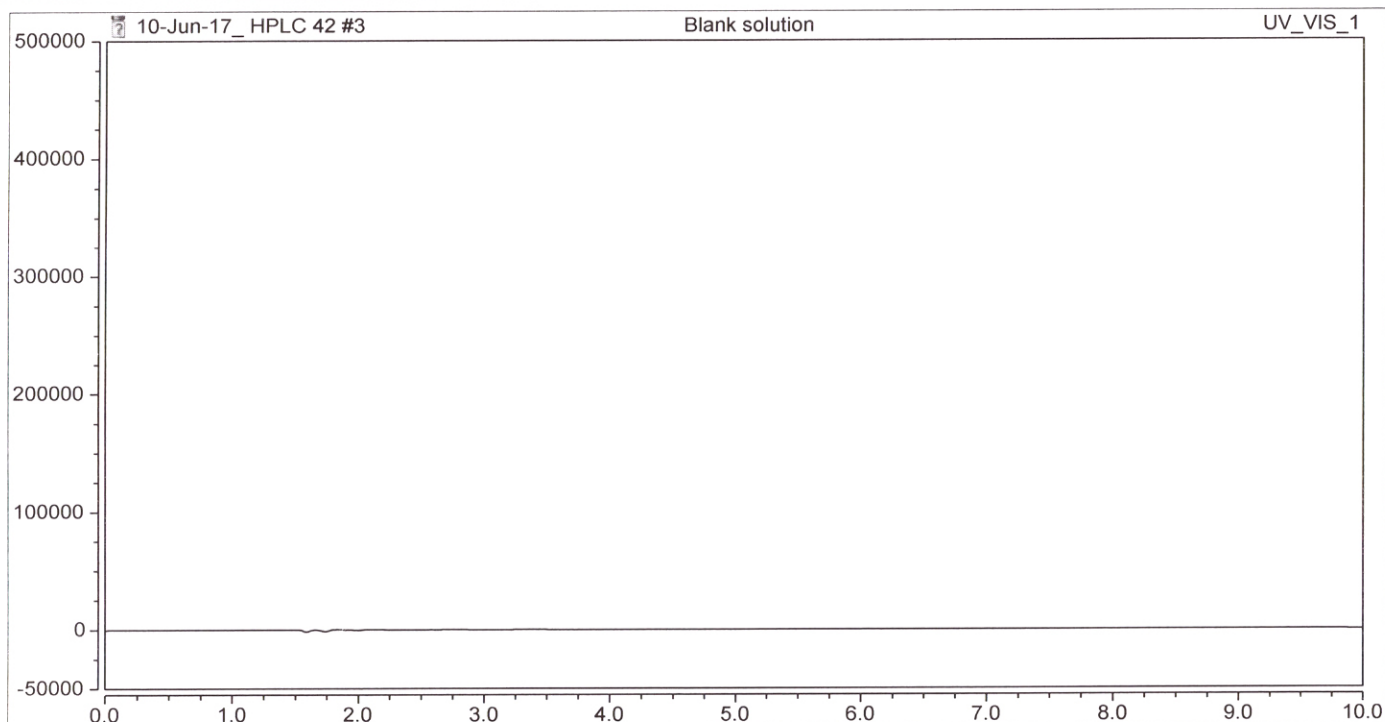
Date: 28-Jun-17

Robustness parameter	% Assay	% Difference (NMT 2.0 %)
Precision	99.6	NA
Flow Rate 0.9 mL/min	100.1	0.5
Flow Rate 1.1 mL/min	99.9	0.3
Organic content decrease	98.9	0.7
Organic content increase	98.4	1.2
Buffer pH 2.3	98.4	1.2
Buffer pH 2.7	98.3	1.3

Done by:
Date:
28 Jun-17Checked by:
Date:
29 Jun-17

QbD Research & Developement Pvt.Ltd.**Injection Details**

Injection Name:	Blank solution	Run Time (min):	10.00
Vial Number:	1_1	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 42	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	10-Jun-17 22:59	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram**Integration Results**

No.	Peak Name	Retention Time min	Area $\mu\text{AU} \cdot \text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
Total:							

Pankaj Gurav
21-Jun-17

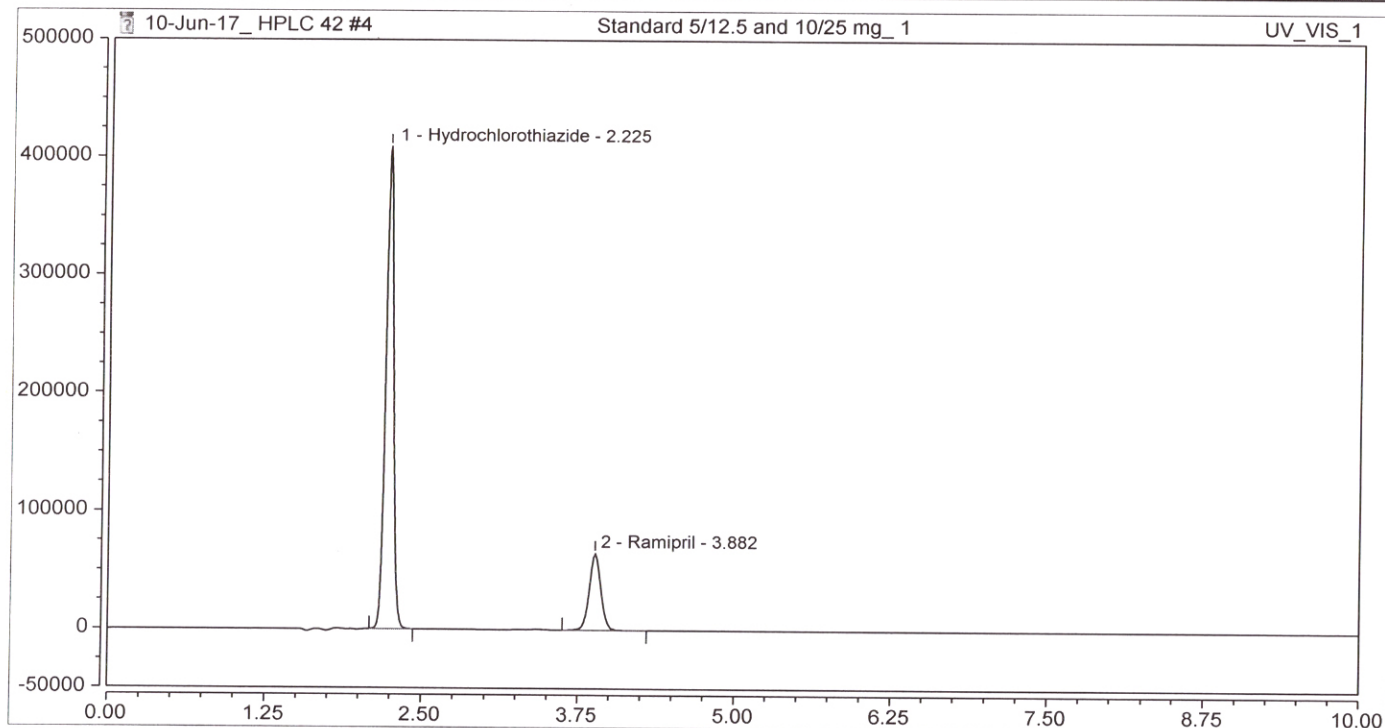
Default/Integration

Pankaj Gurav
22-Jun-17

Chromeleon (c) Dionex
Version 7.2.4.8525

QbD Research & Development Pvt.Ltd.**Injection Details**

Injection Name:	Standard 5/12.5 and 10/25 mg_ 1	Run Time (min):	10.00
Vial Number:	1_2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 42	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	10-Jun-17 23:10	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram**Integration Results**

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.225	29779.744	6040	1.15	11.75	81.01
2	Ramipril	3.882	6982.083	8584	1.06	n.a.	18.99
Total:							

Pankaj
21 Jun-17

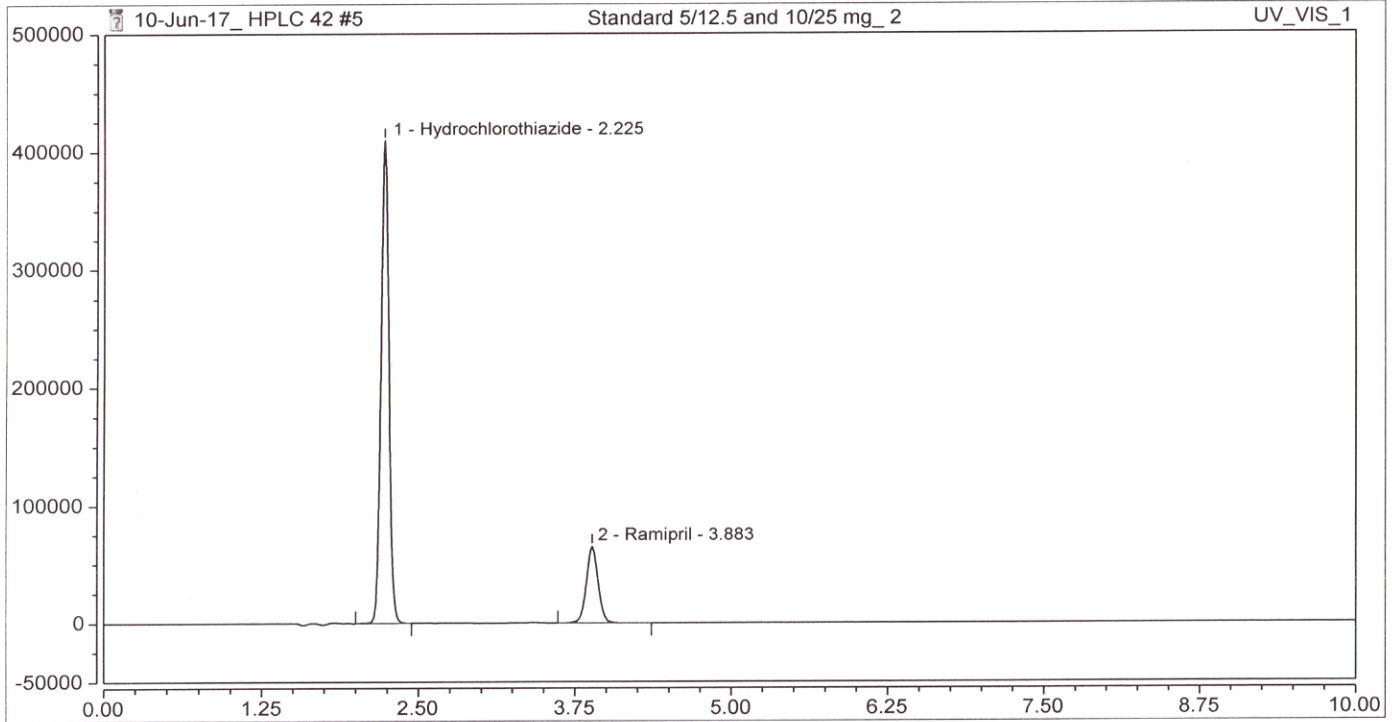
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21 Jun-17

Chromleon (c) Dionex
Version 7.2.4.8525

QbD Research & Developement Pvt.Ltd.**Injection Details**

Injection Name:	Standard 5/12.5 and 10/25 mg_ 2	Run Time (min):	10.00
Vial Number:	1_2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 42	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	10-Jun-17 23:21	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram**Integration Results**

No.	Peak Name	Retention Time min	Area $\mu\text{AU} \cdot \text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.225	29910.378	6028	1.15	11.74	81.06
2	Ramipril	3.883	6990.418	8571	1.06	n.a.	18.94
Total:							

Pankaj Gurav
21-Jun-17

Default/Integration

Pankaj Gurav
21-Jun-17

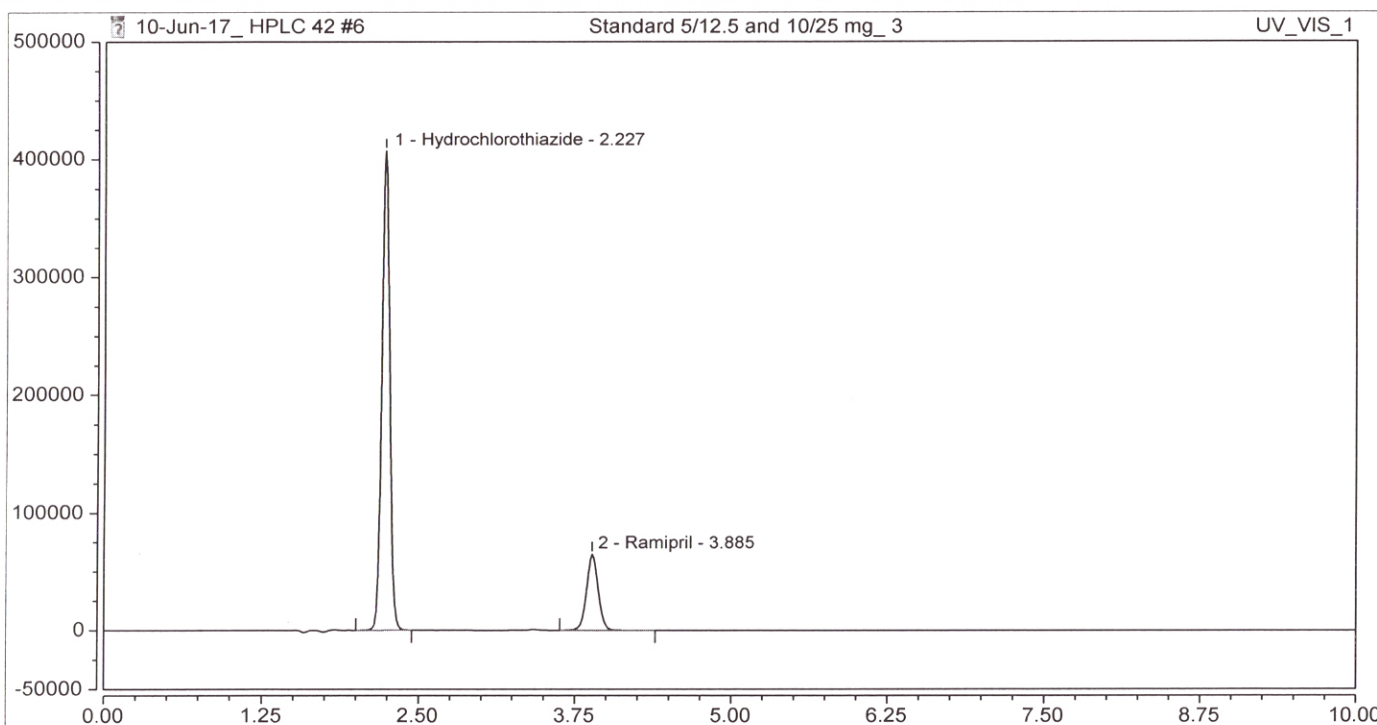
Chromeleon (c) Dionex
Version 7.2.4.8525

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Standard 5/12.5 and 10/25 mg_ 3	Run Time (min):	10.00
Vial Number:	1_2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 42	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	10-Jun-17 23:32	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area $\mu\text{AU} \cdot \text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.227	29895.007	5980	1.16	11.70	81.07
2	Ramipril	3.885	6982.654	8530	1.06	n.a.	18.93
Total:							

21-Jun-17

Default/Integration

21-Jun-17

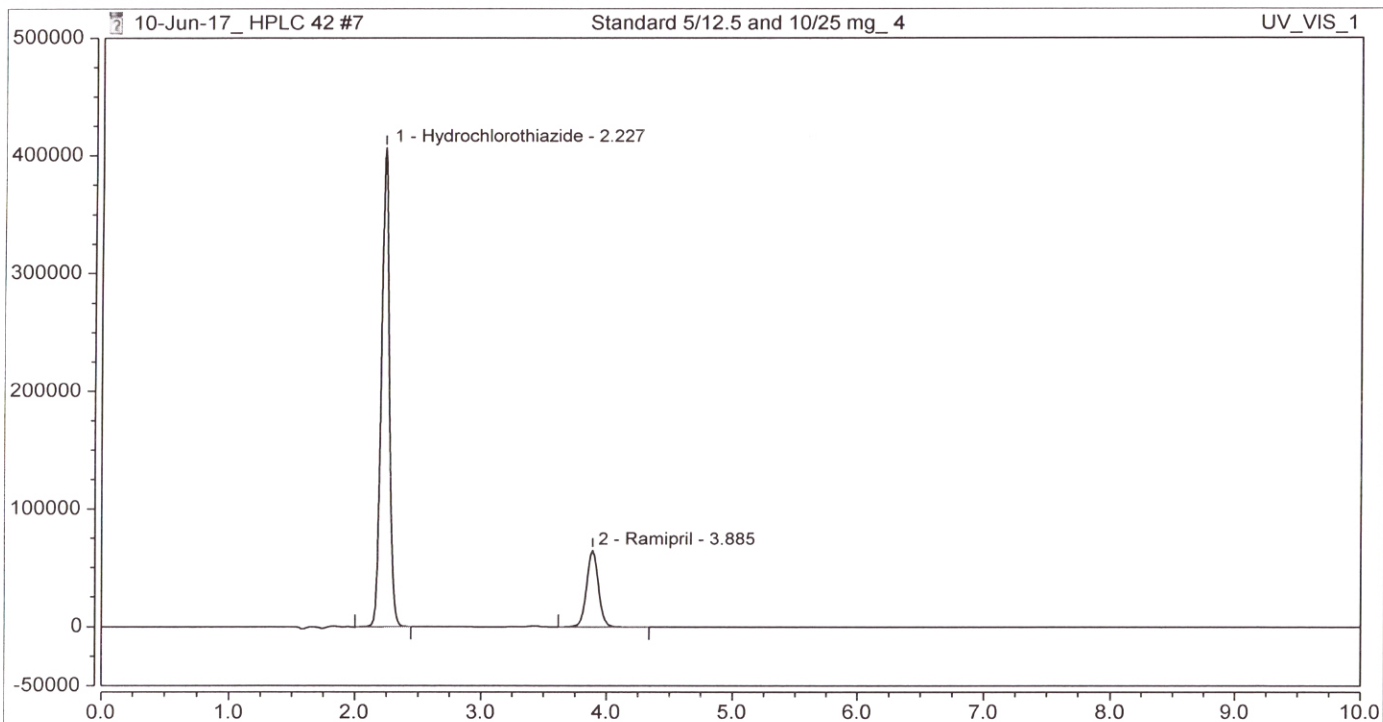
Chromeleon (c) Dionex
Version 7.2.4.8525

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Standard 5/12.5 and 10/25 mg_ 4	Run Time (min):	10.00
Vial Number:	1_2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 42	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	10-Jun-17 23:44	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.227	29870.134	5976	1.14	11.70	81.06
2	Ramipril	3.885	6978.374	8528	1.05	n.a.	18.94
Total:							

Pankaj Gurav
21 Jun 17

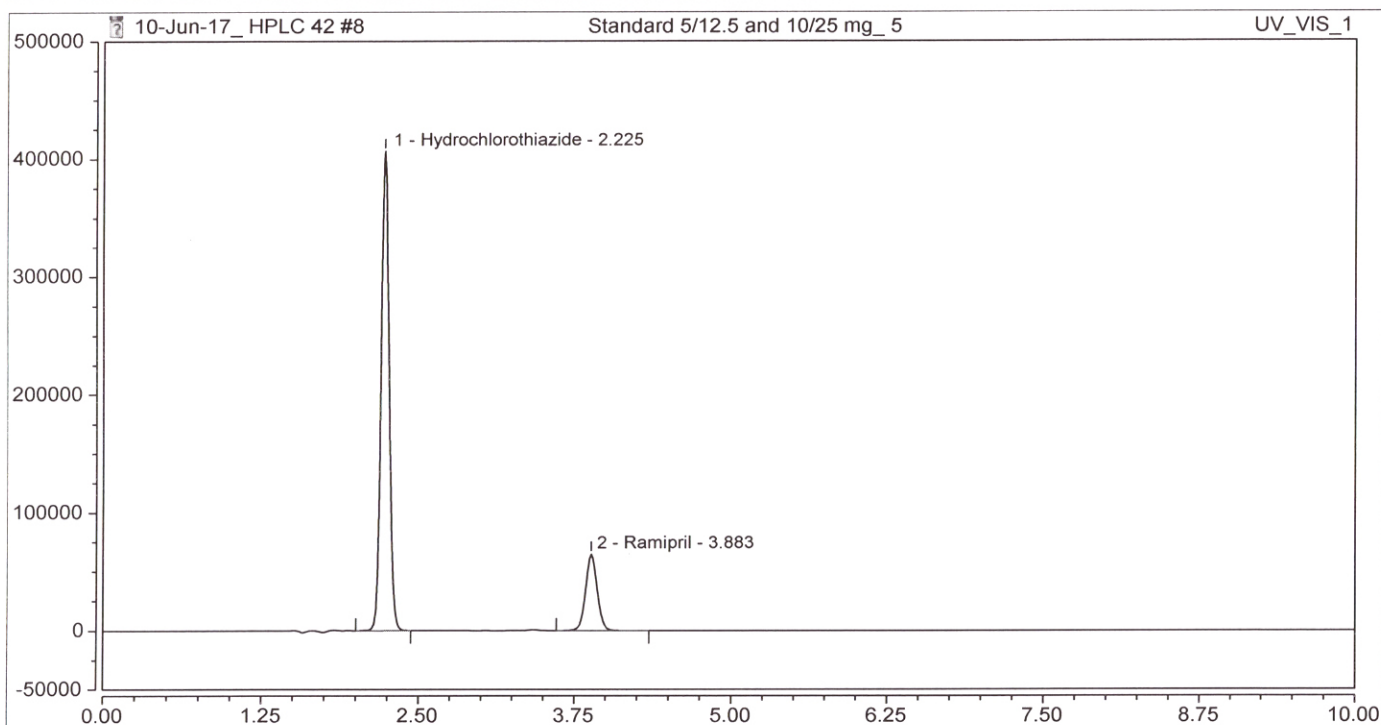
Pankaj Gurav
21 Jun 17

QbD Research & Developement Pvt.Ltd.

Injection Details

Injection Name:	Standard 5/12.5 and 10/25 mg_ 5	Run Time (min):	10.00
Vial Number:	1_2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 42	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	10-Jun-17 23:55	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area $\mu\text{AU} \cdot \text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.225	29937.184	5948	1.16	11.68	81.09
2	Ramipril	3.883	6982.466	8501	1.06	n.a.	18.91
Total:							

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21-Jun-17

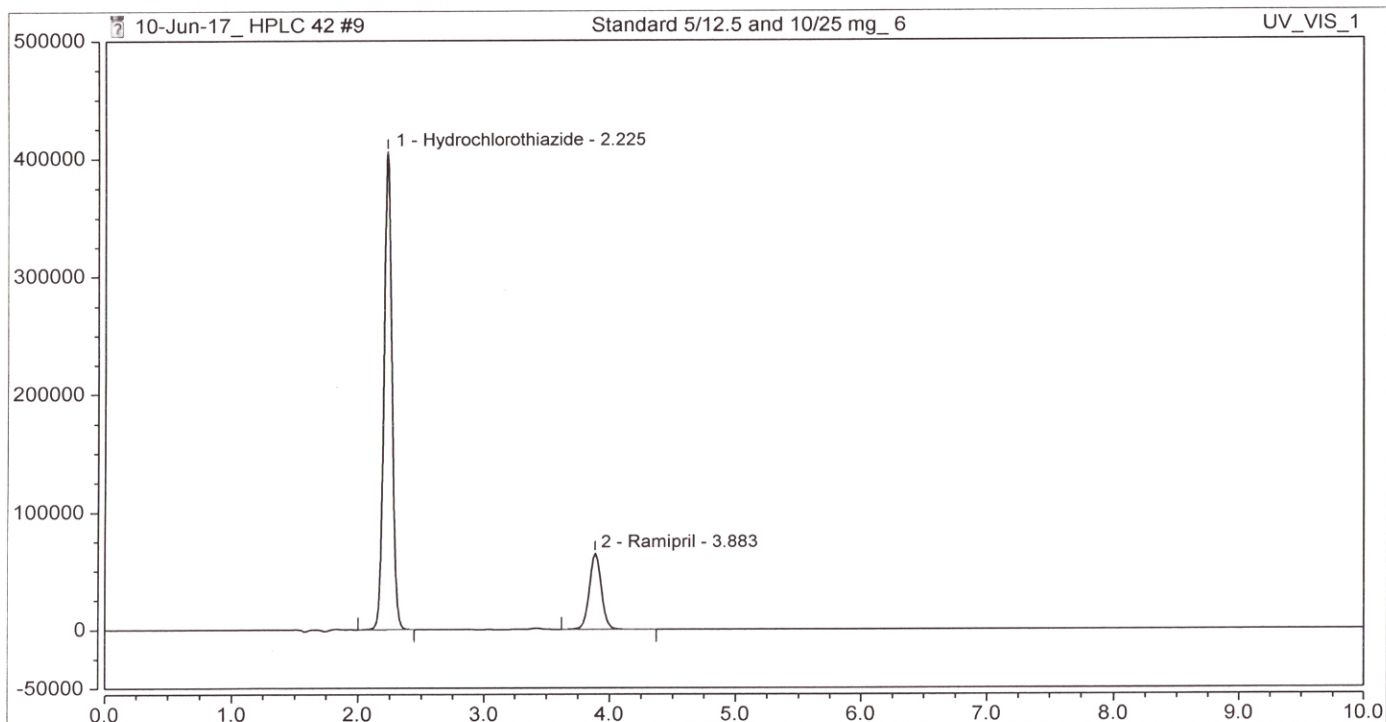
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QbD Research & Developement Pvt.Ltd.

Injection Details

Injection Name:	Standard 5/12.5 and 10/25 mg_ 6	Run Time (min):	10.00
Vial Number:	1_2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 42	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	11-Jun-17 00:06	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area $\mu\text{AU} \cdot \text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.225	29970.544	5917	1.16	11.66	81.09
2	Ramipril	3.883	6990.327	8470	1.07	n.a.	18.91
Total:							

Pankaj
21-Jun-17

Default/Integration

Pankaj
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Chromeleon (c) Dionex
Version 7.2.4.8525

Name	Ramithiazide CU HPLC-05
Data Vault	XVault
Path	chrom://qbd-pc-16/XVault/QbD-INST-HPLC-05/396/24-Jun-17.seq/Ramithiazide CU HPLC-05.instmeth
Comment	Ramithiazide tablets -CU
Description	INSTRUMENT METHOD CREATED
Run time	10.000 [min]
Instrument	QbD-INST-HPLC-05 on qbd-pc-16
Created	24-Jun-17 17:56 +05:30 Sachin Pujari
Last Update	24-Jun-17 17:56 +05:30 Sachin Pujari

B. Pujari
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Property	Value
Settings for module Quat. Pump (G1311C - Pump: PUMP.0)	
Flow	1.000 [mL/min]
Low Pressure Limit	0.00 [bar]
High Pressure Limit	400.00 [bar]
Maximum Flow Gradient	100.000 [mL/min ²]
Primary Channel	Automatic
Section Stroke (StrokeA)	
Automatic Stroke Calculation	Yes
Section Compress (CompressA)	
Compressibility Mode	Compressibility Value Set
Compressibility	100 [10e-6/bar]
Section Stop Time (StopTime)	
Stoptime Mode	Time set
Stoptime	10.00 [min]
Section Post Time (PostTime)	
Posttime Mode	Off
Solvent Composition (SolventComposition)	
0	
Channel	A
Name 1	Mobile Phase
Used	Yes
Percent	100.0 [%]
1	
Channel	B
Name 1	
Used	No
2	
Channel	C
Name 1	
Used	No
3	
Channel	D
Name 1	
Used	No
Timetable (Timetable)	
Settings for module Sampler (G1329B - Sampler: SAMPLER.0)	
Section Auxiliary (Auxiliary)	
Draw Speed	200 [µL/min]
Eject Speed	200 [µL/min]
Draw Position Offset	0.0 [mm]
Section Injection (Injection)	
Injection Mode	Injection with needle wash
Injection Volume	10.00 [µL]

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Section Needle Wash (Injection_NeedleWash)	
Needle Wash Location	Wash Vial
Wash Location	Vial 100
Section High throughput (HighThroughput)	
Section Overlapped Injection (HighThroughput_OverlappedInjection)	
Enable Overlapped Injection	No
Section Stop Time (StopTime)	
Stoptime Mode	As pump/No limit
Section Post Time (PostTime)	
Posttime Mode	Off
Section Timetable (Timetable)	
Timetable (Timetable_TimetableEntry)	
Settings for module Column Comp. (G1316A - Column Comp.: COLCOMP.0)	
Section Left Temperature Control (LeftTemperatureControl)	
Temperature Control Mode	Temperature Set
Temperature	25.00 [°C]
Section Enable Analysis Left Temperature (LeftTemperatureControl_NotReadyLimit)	
Enable Analysis Left Temperature On	Yes
Value	Enable Analysis Left Temperature 0.80 [°C]
Section Right Temperature Control (RightTemperatureControl)	
Right temperature Control Mode	Combined
Section Enable Analysis Right Temperature (RightTemperatureControl_NotReadyLimit)	
Enable Analysis Right Temperature On	Yes
Value	Enable Analysis Right Temperature 0.80 [°C]
Section Stop Time (StopTime)	
Stoptime Mode	As pump/injector
Section Post Time (PostTime)	
Posttime Mode	Off
Section Timetable (Timetable)	
Timetable (Timetable_TimetableEntry)	
Settings for module DAD (G4212B - DAD: DAD.0)	
Peakwidth	> 0.1 min (2 s response time) (2.5 Hz)
UV Lamp Required	Yes

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24-06-17

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```
Section Analog Output 1 (AnalogOutput1)
  Analog 1 Zero Offset          5 [%]
  Analog 1 Attenuation         1000 [mAU]
Section Signals (Signals)
  Signal table (Signals_Signal)
    0
      Use Sig.                  Yes
      Signal                    Signal A
      Wavelength                210.0 [nm]
      Bandwidth                 4.0 [nm]
      Use Ref.                  Yes
      Ref Wavel.                360.0 [nm]
      Ref Bandw.                100.0 [nm]
    1
      Use Sig.                  Yes
      Signal                    Signal B
      Wavelength                254.0 [nm]
      Bandwidth                 4.0 [nm]
      Use Ref.                  Yes
      Ref Wavel.                360.0 [nm]
      Ref Bandw.                100.0 [nm]
    2
      Use Sig.                  Yes
      Signal                    Signal C
      Wavelength                214.0 [nm]
      Bandwidth                 4.0 [nm]
      Use Ref.                  Yes
      Ref Wavel.                360.0 [nm]
      Ref Bandw.                100.0 [nm]
    3
      Use Sig.                  Yes
      Signal                    Signal D
      Wavelength                230.0 [nm]
      Bandwidth                 4.0 [nm]
      Use Ref.                  Yes
      Ref Wavel.                360.0 [nm]
      Ref Bandw.                100.0 [nm]
    4
      Use Sig.                  Yes
      Signal                    Signal E
      Wavelength                260.0 [nm]
      Bandwidth                 4.0 [nm]
      Use Ref.                  Yes
      Ref Wavel.                360.0 [nm]
      Ref Bandw.                100.0 [nm]
    5
      Use Sig.                  No
      Signal                    Signal F
    6
      Use Sig.                  No
```

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Signal	Signal G
7	
Use Sig.	No
Signal	Signal H
Section Prepare Mode (PrepareMode)	
Margin for negative Absorbance	100 [mAU]
Section Autobalance (PrepareAutomation)	
Autobalance Prerun	Yes
Autobalance Postrun	No
Section Spectrum (SpectraAcquisition)	
Spectrum Range WL from	190.0 [nm]
Spectrum Range WL to	400.0 [nm]
Spectrum Step	2.0 [nm]
Spectrum Store	All
Section Stoptime (StopTime)	
Stoptime Mode	As pump/injector
Section Posttime (PostTime)	
Posttime Mode	Off
Section Timetable (Timetable)	
Timetable (Timetable_TimetableEntry)	

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Property	Value
Settings for module Sampler (G1329B - Pretreatment (PretreatmentInstruction)	

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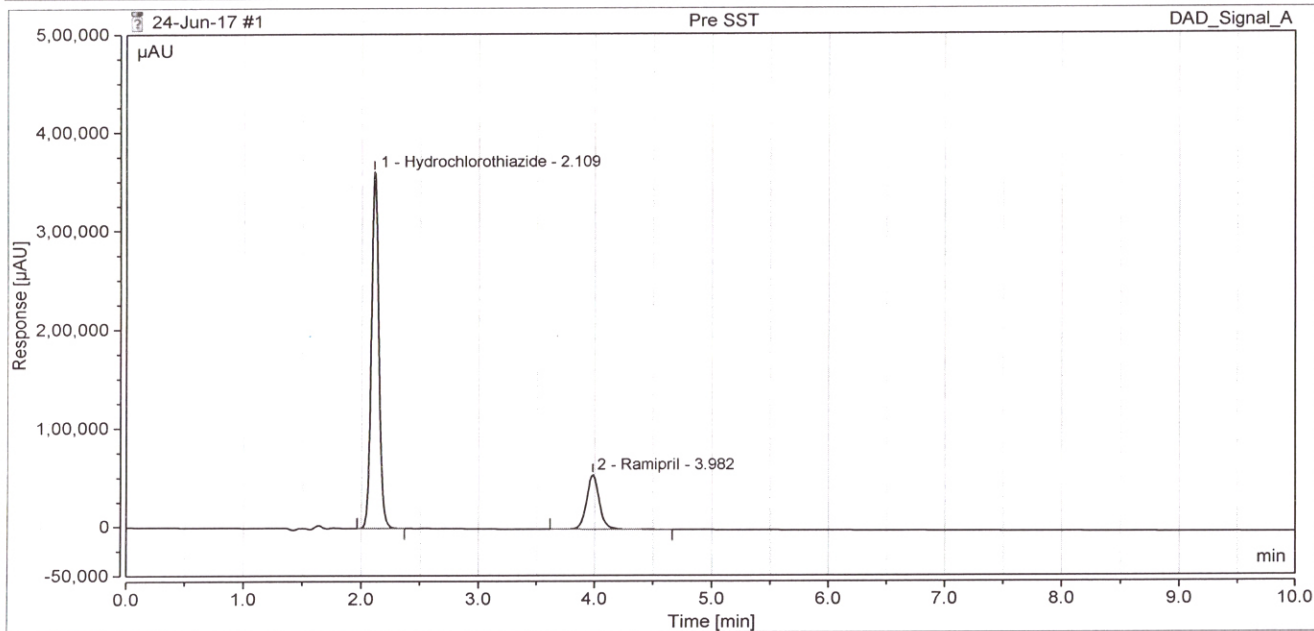
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Injection Details

Injection Name:	Pre SST	Run Time (min):	10.00
Vial Number:	Vial:2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Instrument Method:	Ramithiazide CU HPLC-05	Wavelength:	210
Processing Method:	PR Method_CU_01	Instrument Name:	QbD-INST-HPLC-05
Injection Date/Time:	24-Jun-2017 18:03	Sequence Name:	24-Jun-17
User Name:	Pankaj Gurav		

Chromatogram



Integration Results

No.	Peak Name	Retention (DETECTED) min	Area μAU*min	Rel.Area %	Plates (USP)	Asymmetry (EP)
1	Hydrochlorothiazide	2.109	26853.862	79.21	5396	1.18
2	Ramipril	3.982	7049.794	20.79	6664	1.09
Total:			33903.656			

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24-Jun-17Pankaj Gurav
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D_Signa	Name	Position	Volume [µL]	Instrument Method	Processing Method	Status	Comment
None	Pre SST	Vial:2 ✓	10.00	Ramithiazide CU HPLC-05	PR Method_CU_01	Finished	Intermediate Precision 5/12.5mg
None	Blank Solution	Vial:1 ✓	10.00	Ramithiazide CU HPLC-05	PR Method_CU_01	Idle	Intermediate Precision 5/12.5mg
None	Standard Solution 1	Vial:2 ✓	10.00	Ramithiazide CU HPLC-05	PR Method_CU_01	Idle	Intermediate Precision 5/12.5mg
None	Standard Solution 2	Vial:2 ✓	10.00	Ramithiazide CU HPLC-05	PR Method_CU_01	Idle	Intermediate Precision 5/12.5mg
None	Standard Solution 3	Vial:2 ✓	10.00	Ramithiazide CU HPLC-05	PR Method_CU_01	Idle	Intermediate Precision 5/12.5mg
None	Standard Solution 4	Vial:2 ✓	10.00	Ramithiazide CU HPLC-05	PR Method_CU_01	Idle	Intermediate Precision 5/12.5mg
None	Standard Solution 5	Vial:2 ✓	10.00	Ramithiazide CU HPLC-05	PR Method_CU_01	Idle	Intermediate Precision 5/12.5mg
None	Standard Solution 6	Vial:2 ✓	10.00	Ramithiazide CU HPLC-05	PR Method_CU_01	Idle	Intermediate Precision 5/12.5mg
None	Sample Solution 1	Vial:2 ✓	10.00	Ramithiazide CU HPLC-05	PR Method_CU_01	Idle	Intermediate Precision 5/12.5mg
None	Sample Solution 2	Vial:3 ✓	10.00	Ramithiazide CU HPLC-05	PR Method_CU_01	Idle	Intermediate Precision 5/12.5mg
None	Sample Solution 3	Vial:4 ✓	10.00	Ramithiazide CU HPLC-05	PR Method_CU_01	Idle	Intermediate Precision 5/12.5mg
None	Sample Solution 4	Vial:5 ✓	10.00	Ramithiazide CU HPLC-05	PR Method_CU_01	Idle	Intermediate Precision 5/12.5mg
None	Sample Solution 5	Vial:6 ✓	10.00	Ramithiazide CU HPLC-05	PR Method_CU_01	Idle	Intermediate Precision 5/12.5mg
None	Sample Solution 6	Vial:7 ✓	10.00	Ramithiazide CU HPLC-05	PR Method_CU_01	Idle	Intermediate Precision 5/12.5mg
None	Sample Solution 7	Vial:8 ✓	10.00	Ramithiazide CU HPLC-05	PR Method_CU_01	Idle	Intermediate Precision 5/12.5mg
None	Sample Solution 8	Vial:9 ✓	10.00	Ramithiazide CU HPLC-05	PR Method_CU_01	Idle	Intermediate Precision 5/12.5mg
None	Sample Solution 9	Vial:10 ✓	10.00	Ramithiazide CU HPLC-05	PR Method_CU_01	Idle	Intermediate Precision 5/12.5mg
None	Sample Solution 10	Vial:11 ✓	10.00	Ramithiazide CU HPLC-05	PR Method_CU_01	Idle	Intermediate Precision 5/12.5mg
None	Bracketing Standard Solution	Vial:12 ✓	10.00	Ramithiazide CU HPLC-05	PR Method_CU_01	Idle	Intermediate Precision 5/12.5mg
None	Wash	Vial:1 ✓	10.00	Wash method D_H 05 new	PR Method_CU_01	Idle	Intermediate Precision 5/12.5mg
None	Shut	Vial:1 ✓	10.00	Shut method_HPLC 05 new	PR Method_CU_01	Idle	Intermediate Precision 5/12.5mg

24-Jun-17

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24-06-17 18:47

Inject Time
24-Jun-17 18:03 +05:30

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24-Jun-17

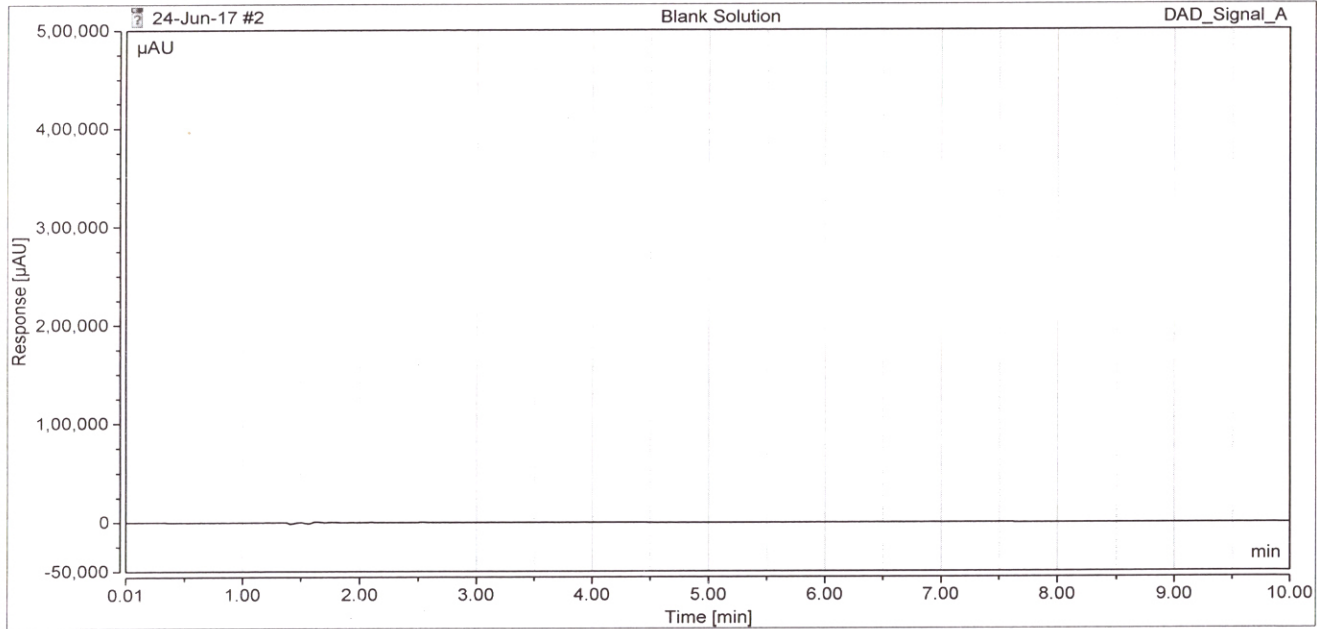
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24-Jun-17

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Injection Details

Injection Name:	Blank Solution	Run Time (min):	9.99
Vial Number:	Vial:1	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Instrument Method:	Ramithiazide CU HPLC-05	Wavelength:	210
Processing Method:	PR Method_CU_01	Instrument Name:	QbD-INST-HPLC-05
Injection Date/Time:	24-Jun-2017 19:07	Sequence Name:	24-Jun-17
User Name:	Pankaj Gurav		

Chromatogram



Integration Results

No.	Peak Name	Retention (DETECTED) min	Area μAU*min	Rel.Area %	Plates (USP)	Asymmetry (EP)
Total:			0.000			

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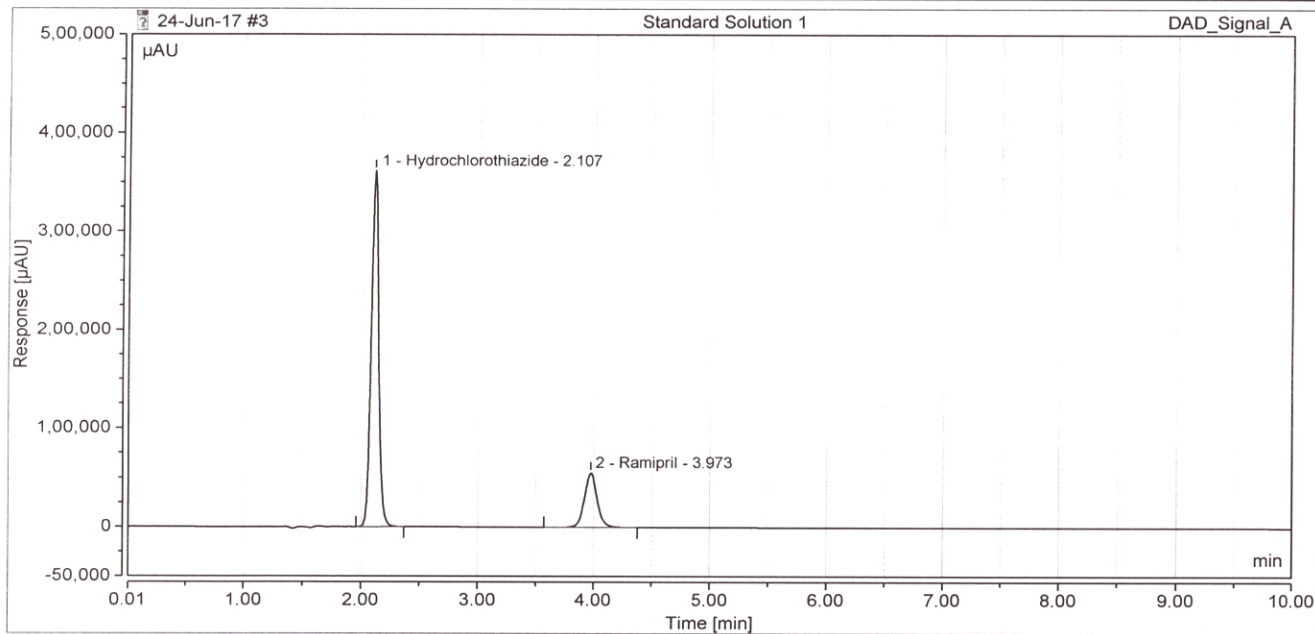
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Injection Details

Injection Name: Standard Solution 1
Vial Number: Vial:2
Injection Type: Unknown
Instrument Method: Ramithiazide CU HPLC-05
Processing Method: PR Method_CU_01
Injection Date/Time: 24-Jun-2017 19:19
User Name: Pankaj Gurav

Run Time (min): 9.99
Injection Volume: 10.00
Channel: DAD_Signal_A
Wavelength: 210
Instrument Name: QbD-INST-HPLC-05
Sequence Name: 24-Jun-17

Chromatogram



Integration Results

No.	Peak Name	Retention (DETECTED) min	Area μAU*min	Rel.Area %	Plates (USP)	Asymmetry (EP)
1	Hydrochlorothiazide	2.107	26757.552	79.26	5426	1.18
2	Ramipril	3.973	7000.661	20.74	6659	1.08
Total:			33758.213			

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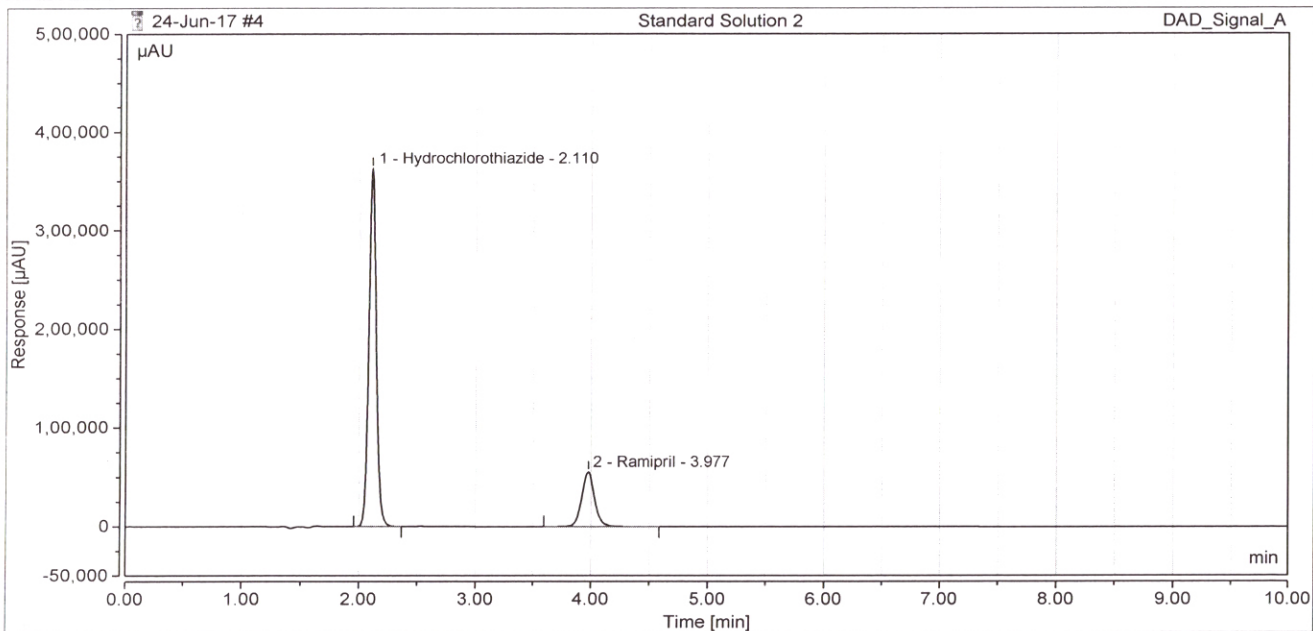
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Injection Details

Injection Name:	Standard Solution 2	Run Time (min):	9.99
Vial Number:	Vial:2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Instrument Method:	Ramithiazide CU HPLC-05	Wavelength:	210
Processing Method:	PR Method_CU_01	Instrument Name:	QbD-INST-HPLC-05
Injection Date/Time:	24-Jun-2017 19:30	Sequence Name:	24-Jun-17
User Name:	Pankaj Gurav		

Chromatogram



Integration Results

No.	Peak Name	Retention (DETECTED) min	Area μAU*min	Rel.Area %	Plates (USP)	Asymmetry (EP)
1	Hydrochlorothiazide	2.110	26742.164	79.21	5420	1.12
2	Ramipril	3.977	7017.555	20.79	6656	1.06
Total:			33759.719			

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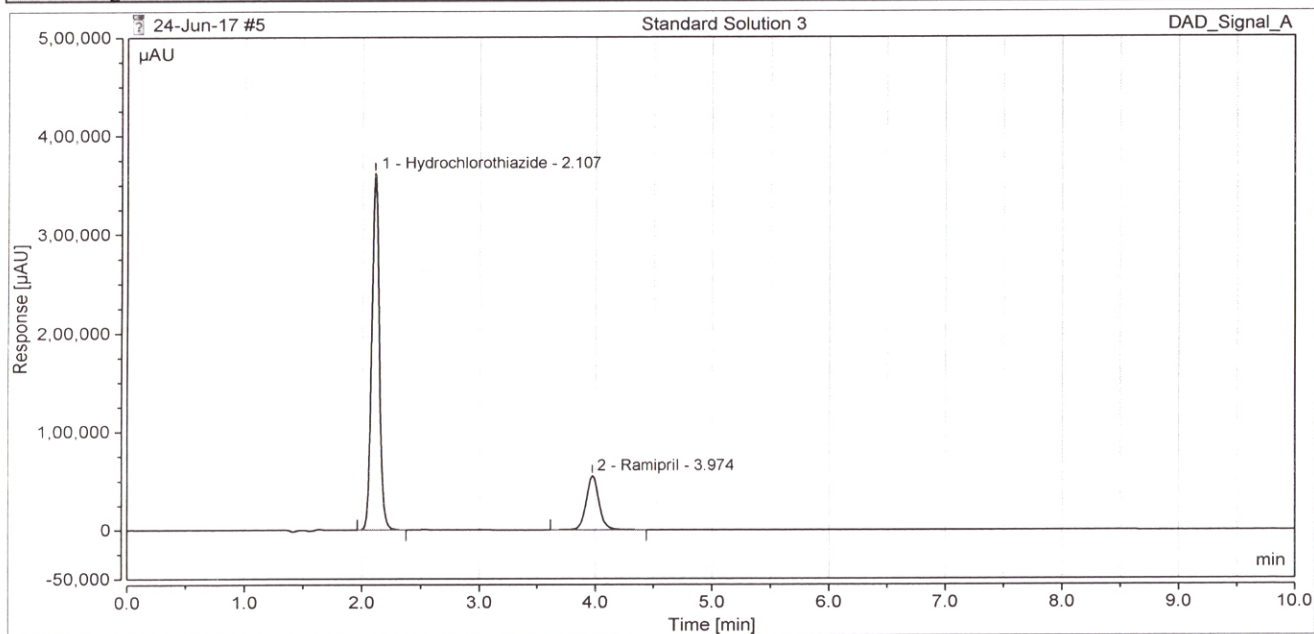
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28-Jun-17

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Injection Details

Injection Name:	Standard Solution 3	Run Time (min):	10.00
Vial Number:	Vial:2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Instrument Method:	Ramithiazide CU HPLC-05	Wavelength:	210
Processing Method:	PR Method_CU_01	Instrument Name:	QbD-INST-HPLC-05
Injection Date/Time:	24-Jun-2017 19:42	Sequence Name:	24-Jun-17
User Name:	Pankaj Gurav		

Chromatogram



Integration Results

No.	Peak Name	Retention (DETECTED) min	Area μAU*min	Rel.Area %	Plates (USP)	Asymmetry (EP)
1	Hydrochlorothiazide	2.107	26729.583	79.23	5444	1.18
2	Ramipril	3.974	7006.084	20.77	6660	1.08
Total:			33735.666			

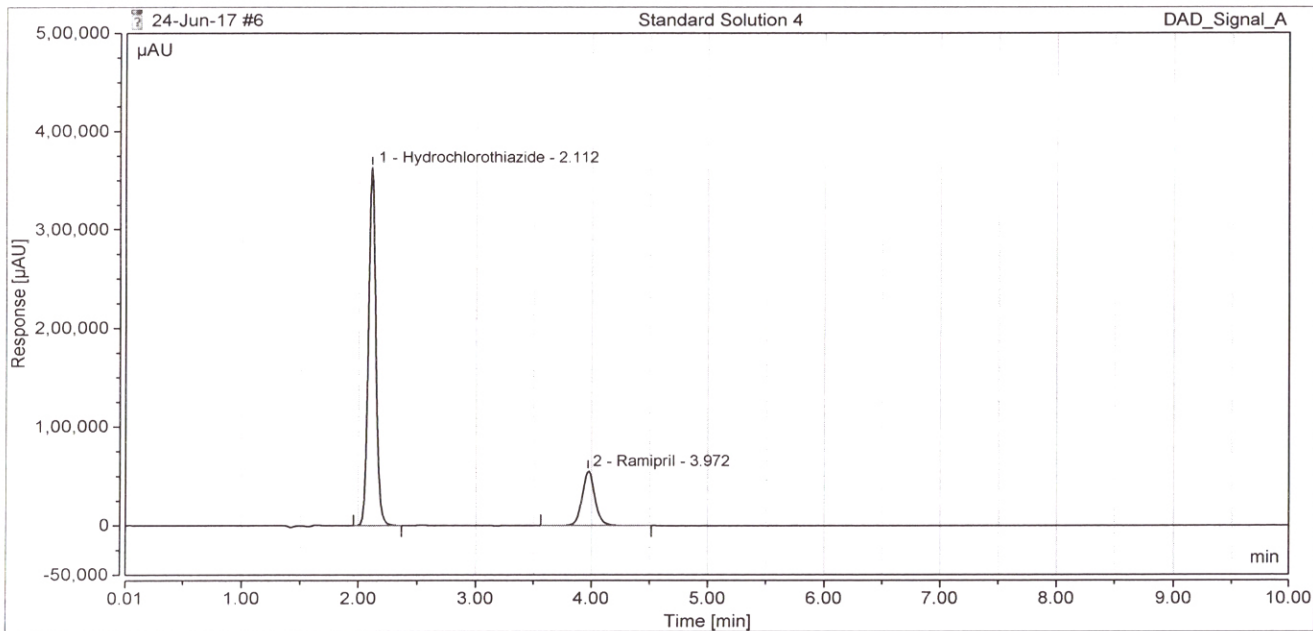
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Injection Details

Injection Name:	Standard Solution 4	Run Time (min):	9.99
Vial Number:	Vial:2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Instrument Method:	Ramithiazide CU HPLC-05	Wavelength:	210
Processing Method:	PR Method_CU_01	Instrument Name:	QbD-INST-HPLC-05
Injection Date/Time:	24-Jun-2017 19:54	Sequence Name:	24-Jun-17
User Name:	Pankaj Gurav		

Chromatogram



Integration Results

No.	Peak Name	Retention (DETECTED) min	Area μAU*min	Rel.Area %	Plates (USP)	Asymmetry (EP)
1	Hydrochlorothiazide	2.112	26720.862	79.22	5483	1.11
2	Ramipril	3.972	7009.540	20.78	6661	1.10
Total:			33730.402			

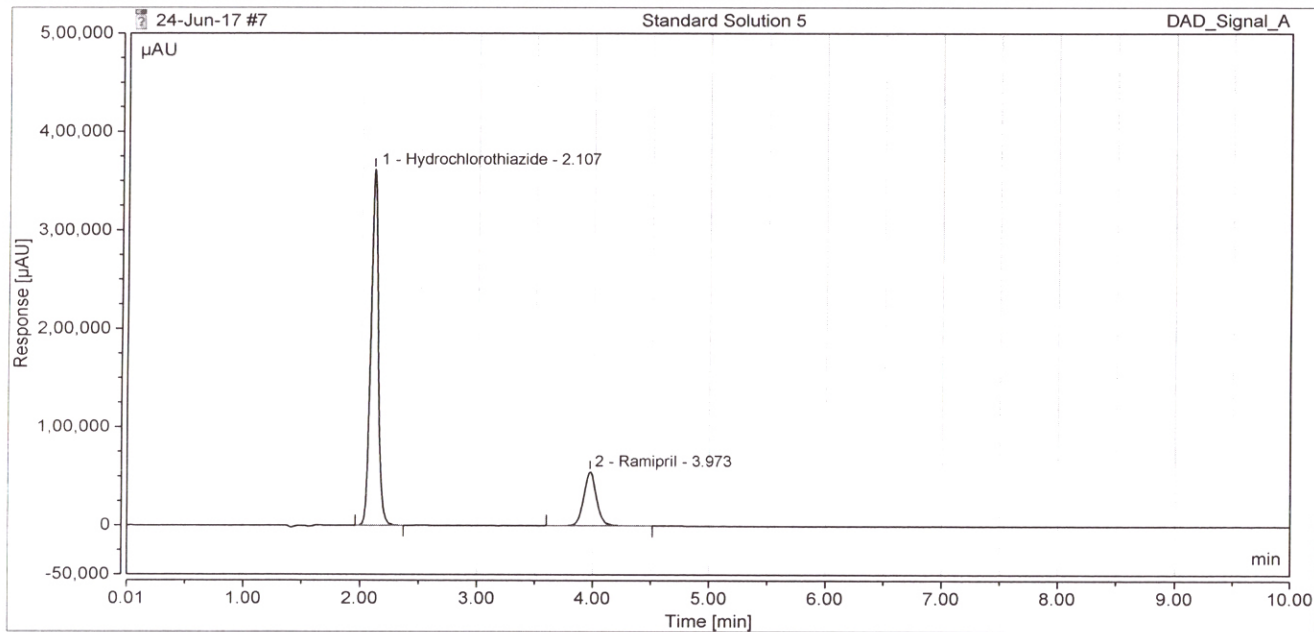
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Injection Details

Injection Name:	Standard Solution 5	Run Time (min):	9.99
Vial Number:	Vial:2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Instrument Method:	Ramithiazide CU HPLC-05	Wavelength:	210
Processing Method:	PR Method_CU_01	Instrument Name:	QbD-INST-HPLC-05
Injection Date/Time:	24-Jun-2017 20:05	Sequence Name:	24-Jun-17
User Name:	Pankaj Gurav		

Chromatogram



Integration Results

No.	Peak Name	Retention (DETECTED) min	Area μAU*min	Rel.Area %	Plates (USP)	Asymmetry (EP)
1	Hydrochlorothiazide	2.107	26715.221	79.21	5455	1.18
2	Ramipril	3.973	7010.196	20.79	6658	1.08
Total:			33725.417			

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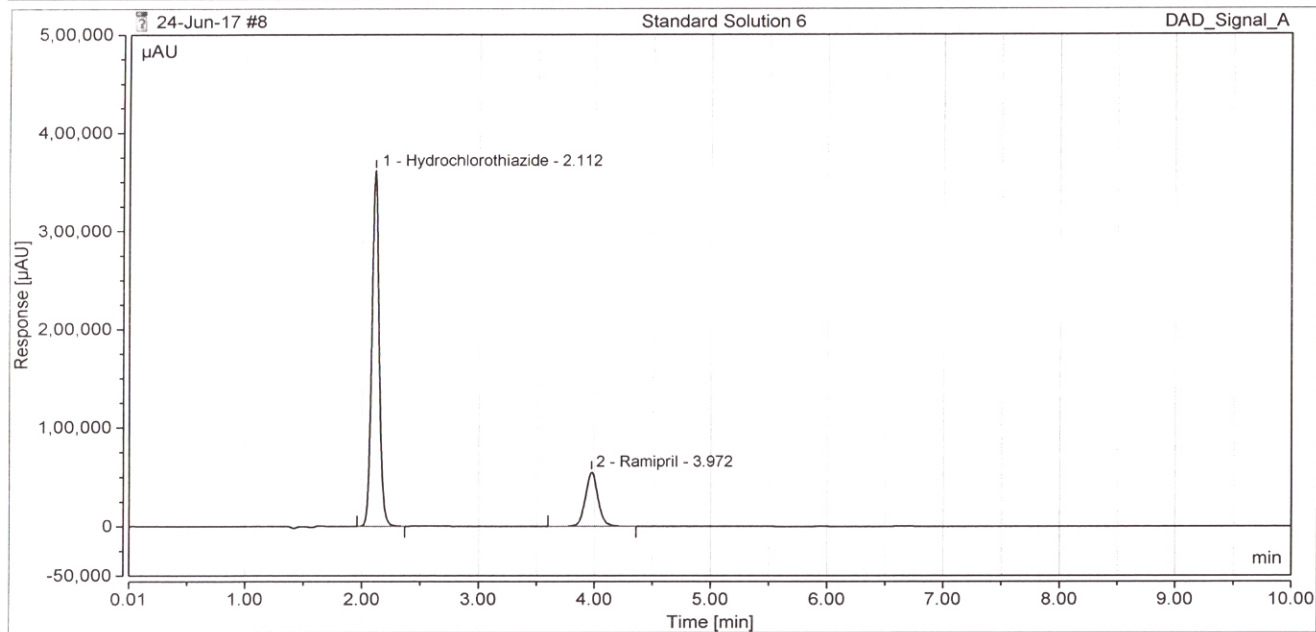
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Injection Details

Injection Name: Standard Solution 6
Vial Number: Vial:2
Injection Type: Unknown
Instrument Method: Ramithiazide CU HPLC-05
Processing Method: PR Method_CU_01
Injection Date/Time: 24-Jun-2017 20:17
User Name: Pankaj Gurav

Run Time (min): 9.99
Injection Volume: 10.00
Channel: DAD_Signal_A
Wavelength: 210
Instrument Name: QbD-INST-HPLC-05
Sequence Name: 24-Jun-17

Chromatogram



Integration Results

No.	Peak Name	Retention (DETECTED) min	Area μAU*min	Rel.Area %	Plates (USP)	Asymmetry (EP)
1	Hydrochlorothiazide	2.112	26708.079	79.26	5486	1.09
2	Ramipril	3.972	6990.409	20.74	6644	1.09
Total:			33698.488			

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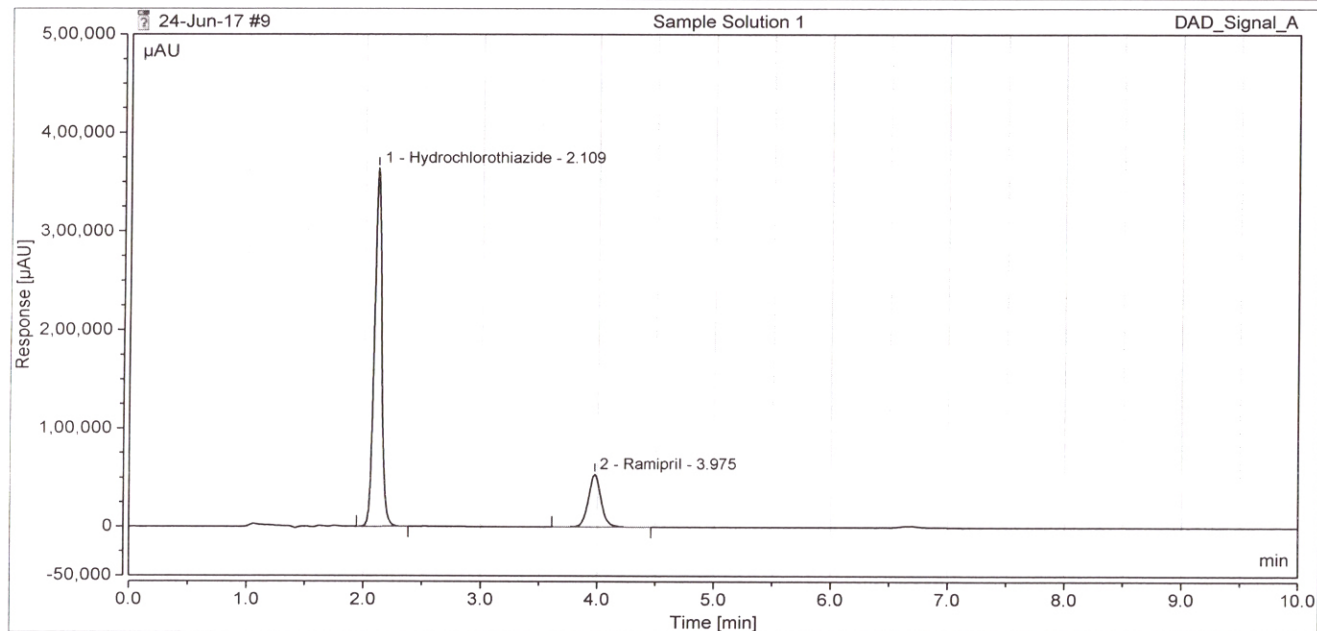
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Injection Details

Injection Name:	Sample Solution 1	Run Time (min):	10.00
Vial Number:	Vial:3	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Instrument Method:	Ramithiazide CU HPLC-05	Wavelength:	210
Processing Method:	PR Method_CU_01	Instrument Name:	QbD-INST-HPLC-05
Injection Date/Time:	24-Jun-2017 20:29	Sequence Name:	24-Jun-17
User Name:	Pankaj Gurav		

Chromatogram



Integration Results

No.	Peak Name	Retention (DETECTED) min	Area μAU*min	Rel.Area %	Plates (USP)	Asymmetry (EP)
1	Hydrochlorothiazide	2.109	26738.909	79.70	5437	1.15
2	Ramipril	3.975	6811.163	20.30	6686	1.06
Total:			33550.071			

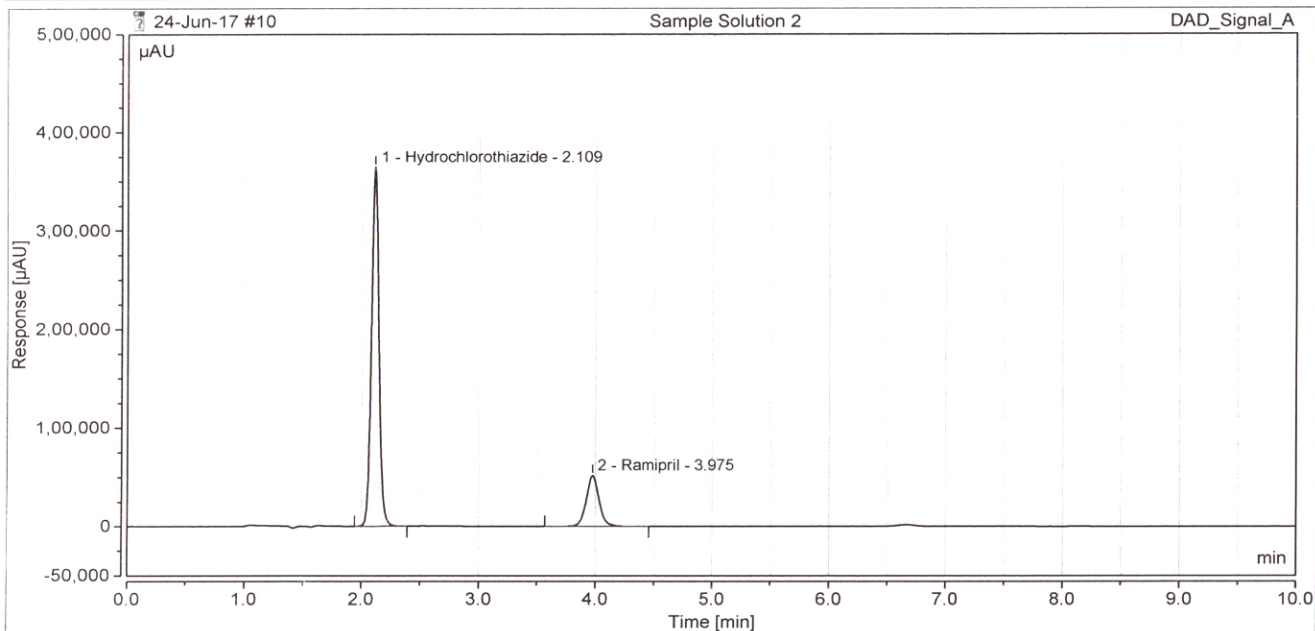
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Injection Details

Injection Name:	Sample Solution 2	Run Time (min):	10.00
Vial Number:	Vial:4	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Instrument Method:	Ramithiazide CU HPLC-05	Wavelength:	210
Processing Method:	PR Method_CU_01	Instrument Name:	QbD-INST-HPLC-05
Injection Date/Time:	24-Jun-2017 20:41	Sequence Name:	24-Jun-17
User Name:	Pankaj Gurav		

Chromatogram



Integration Results

No.	Peak Name	Retention (DETECTED) min	Area μAU*min	Rel.Area %	Plates (USP)	Asymmetry (EP)
1	Hydrochlorothiazide	2.109	26777.155	80.38	5441	1.15
2	Ramipril	3.975	6536.646	19.62	6674	1.06
Total:			33313.801			

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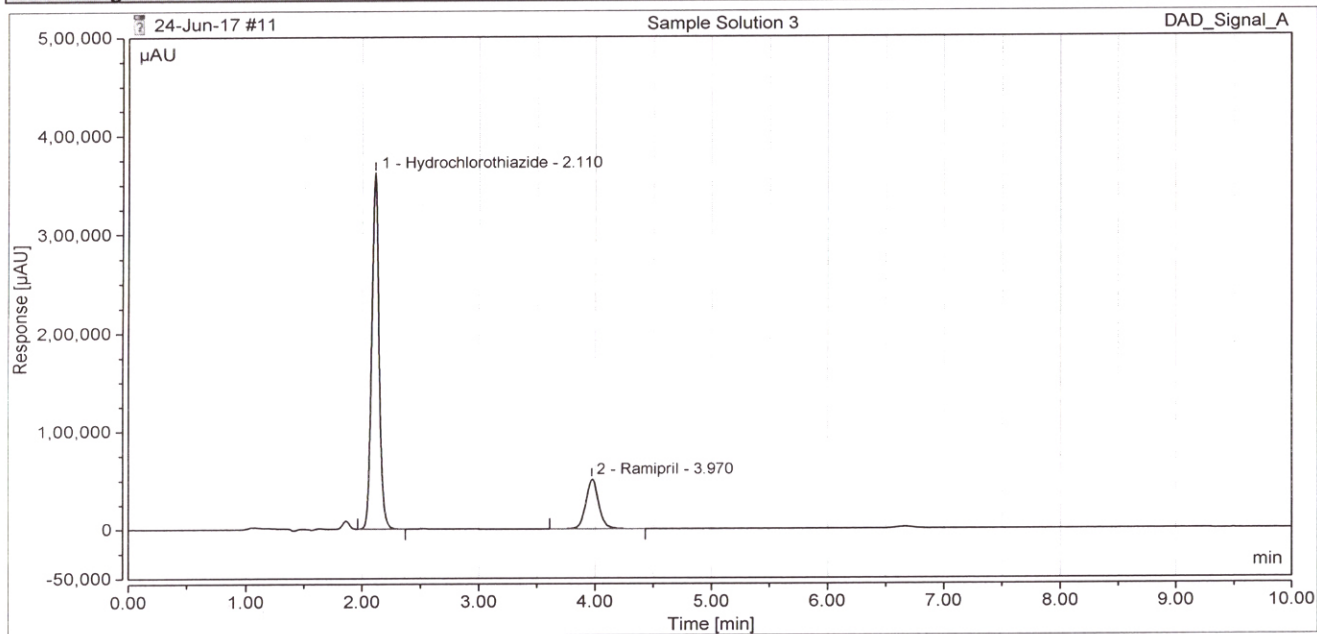
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Injection Details

Injection Name: Sample Solution 3
Vial Number: Vial: 5
Injection Type: Unknown
Instrument Method: Ramithiazide CU HPLC-05
Processing Method: PR Method_CU_01
Injection Date/Time: 24-Jun-2017 20:52
User Name: Pankaj Gurav

Run Time (min): 9.99
Injection Volume: 10.00
Channel: DAD_Signal_A
Wavelength: 210
Instrument Name: QbD-INST-HPLC-05
Sequence Name: 24-Jun-17

Chromatogram



Integration Results

No.	Peak Name	Retention (DETECTED) min	Area μAU*min	Rel.Area %	Plates (USP)	Asymmetry (EP)
1	Hydrochlorothiazide	2.110	26455.655	80.42	5474	1.13
2	Ramipril	3.970	6440.453	19.58	6689	1.10
Total:			32896.109			

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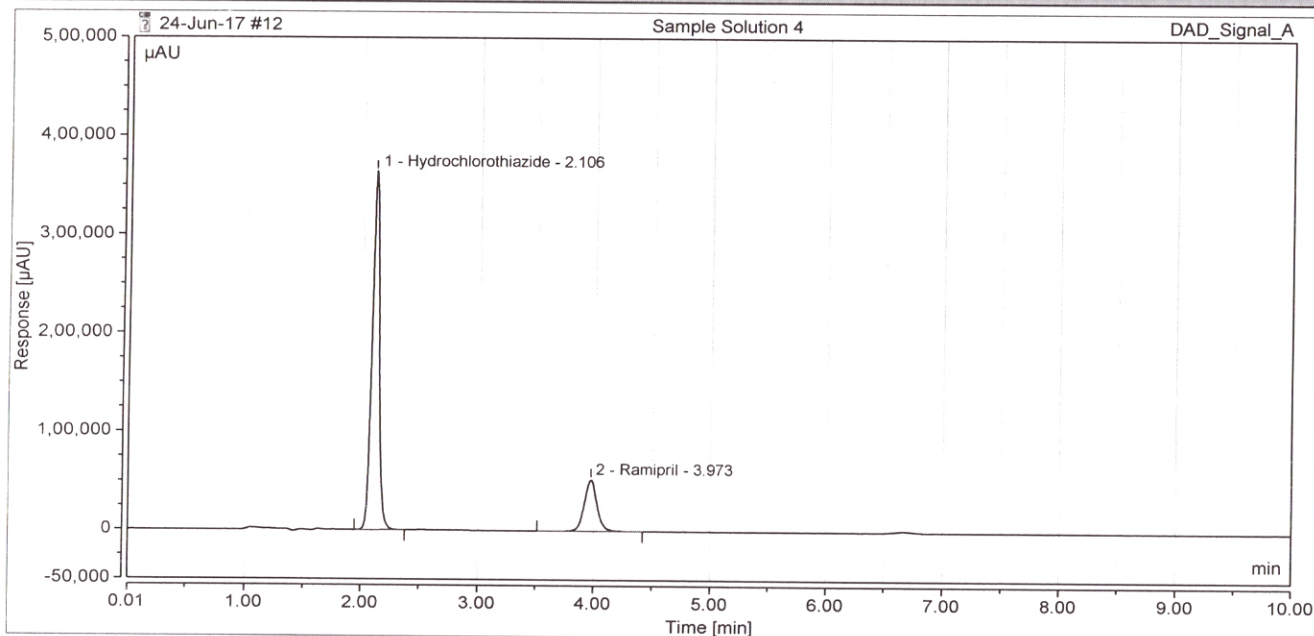
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Injection Details

Injection Name:	Sample Solution 4	Run Time (min):	9.99
Vial Number:	Vial:6	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Instrument Method:	Ramithiazide CU HPLC-05	Wavelength:	210
Processing Method:	PR Method_CU_01	Instrument Name:	QbD-INST-HPLC-05
Injection Date/Time:	24-Jun-2017 21:04	Sequence Name:	24-Jun-17
User Name:	Pankaj Gurav		

Chromatogram



Integration Results

No.	Peak Name	Retention (DETECTED) min	Area μAU*min	Rel.Area %	Plates (USP)	Asymmetry (EP)
1	Hydrochlorothiazide	2.106	26811.343	80.15	5497	1.18
2	Ramipril	3.973	6638.071	19.85	6692	1.07
Total:			33449.413			

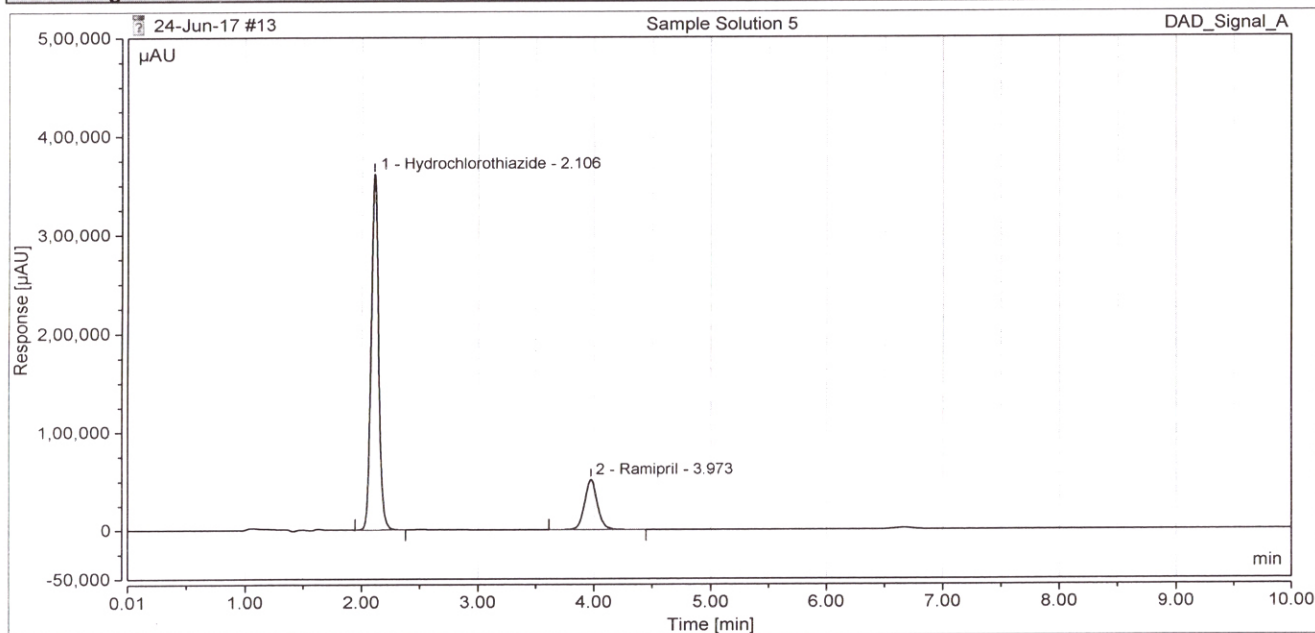
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Injection Details

Injection Name:	Sample Solution 5	Run Time (min):	9.99
Vial Number:	Vial:7	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Instrument Method:	Ramithiazide CU HPLC-05	Wavelength:	210
Processing Method:	PR Method_CU_01	Instrument Name:	QbD-INST-HPLC-05
Injection Date/Time:	24-Jun-2017 21:15	Sequence Name:	24-Jun-17
User Name:	Pankaj Gurav		

Chromatogram



Integration Results

No.	Peak Name	Retention (DETECTED) min	Area μAU*min	Rel.Area %	Plates (USP)	Asymmetry (EP)
1	Hydrochlorothiazide	2.106	26641.010	80.41	5499	1.19
2	Ramipril	3.973	6489.863	19.59	6689	1.07
Total:			33130.873			

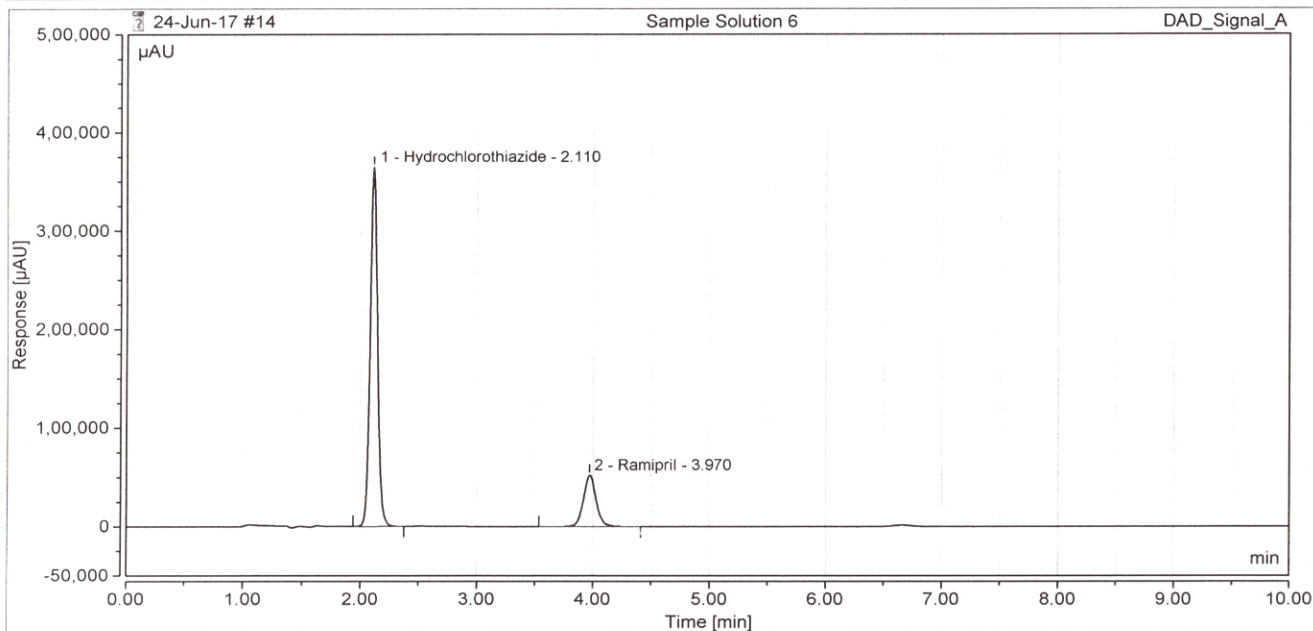
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Injection Details

Injection Name:	Sample Solution 6	Run Time (min):	9.99
Vial Number:	Vial:8	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Instrument Method:	Ramithiazide CU HPLC-05	Wavelength:	210
Processing Method:	PR Method_CU_01	Instrument Name:	QbD-INST-HPLC-05
Injection Date/Time:	24-Jun-2017 21:27	Sequence Name:	24-Jun-17
User Name:	Pankaj Gurav		

Chromatogram



Integration Results

No.	Peak Name	Retention (DETECTED) min	Area μAU*min	Rel.Area %	Plates (USP)	Asymmetry (EP)
1	Hydrochlorothiazide	2.110	26754.995	80.22	5502	1.11
2	Ramipril	3.970	6595.169	19.78	6669	1.09
Total:			33350.164			

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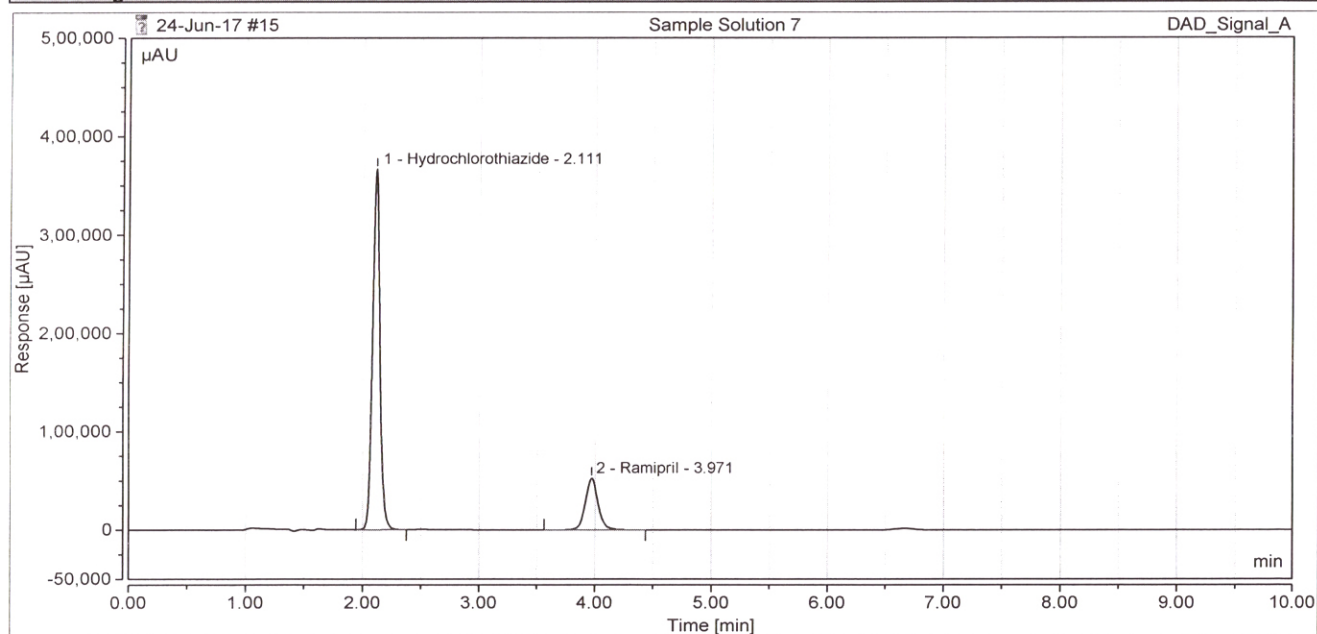
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Injection Details

Injection Name: Sample Solution 7
Vial Number: Vial:9
Injection Type: Unknown
Instrument Method: Ramithiazide CU HPLC-05
Processing Method: PR Method_CU_01
Injection Date/Time: 24-Jun-2017 21:39
User Name: Pankaj Gurav

Run Time (min): 9.99
Injection Volume: 10.00
Channel: DAD_Signal_A
Wavelength: 210
Instrument Name: QbD-INST-HPLC-05
Sequence Name: 24-Jun-17

Chromatogram



Integration Results

No.	Peak Name	Retention (DETECTED) min	Area μAU*min	Rel.Area %	Plates (USP)	Asymmetry (EP)
1	Hydrochlorothiazide	2.111	26962.827	80.19	5529	1.10
2	Ramipril	3.971	6659.570	19.81	6677	1.08
Total:			33622.397			

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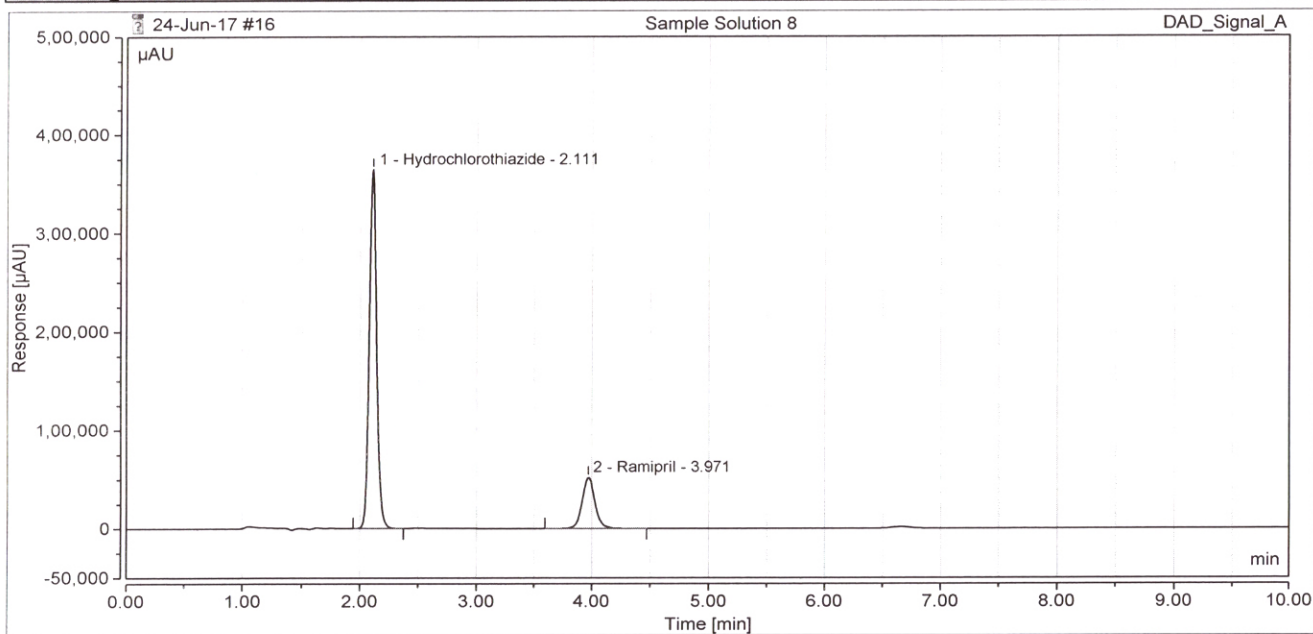
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Injection Details

Injection Name: Sample Solution 8
Vial Number: Vial: 10
Injection Type: Unknown
Instrument Method: Ramithiazide CU HPLC-05
Processing Method: PR Method_CU_01
Injection Date/Time: 24-Jun-2017 21:51
User Name: Pankaj Gurav

Run Time (min): 9.99
Injection Volume: 10.00
Channel: DAD_Signal_A
Wavelength: 210
Instrument Name: QbD-INST-HPLC-05
Sequence Name: 24-Jun-17

Chromatogram



Integration Results

No.	Peak Name	Retention (DETECTED) min	Area μAU*min	Rel.Area %	Plates (USP)	Asymmetry (EP)
1	Hydrochlorothiazide	2.111	26777.232	80.22	5531	1.10
2	Ramipril	3.971	6602.860	19.78	6685	1.08
Total:			33380.092			

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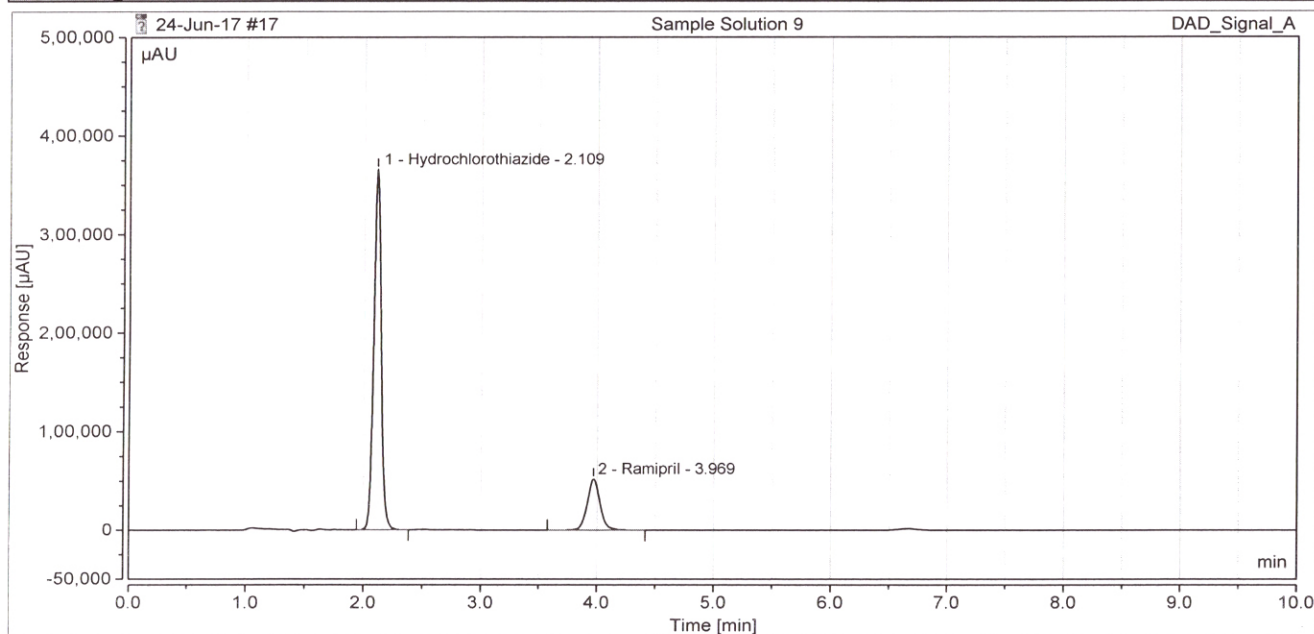
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Injection Details

Injection Name: Sample Solution 9
Vial Number: Vial: 11
Injection Type: Unknown
Instrument Method: Ramithiazide CU HPLC-05
Processing Method: PR Method_CU_01
Injection Date/Time: 24-Jun-2017 22:02
User Name: Pankaj Gurav

Run Time (min): 10.00
Injection Volume: 10.00
Channel: DAD_Signal_A
Wavelength: 210
Instrument Name: QbD-INST-HPLC-05
Sequence Name: 24-Jun-17

Chromatogram



Integration Results

No.	Peak Name	Retention (DETECTED) min	Area μAU*min	Rel.Area %	Plates (USP)	Asymmetry (EP)
1	Hydrochlorothiazide	2.109	26783.011	80.26	5465	1.13
2	Ramipril	3.969	6587.300	19.74	6667	1.09
Total:			33370.311			

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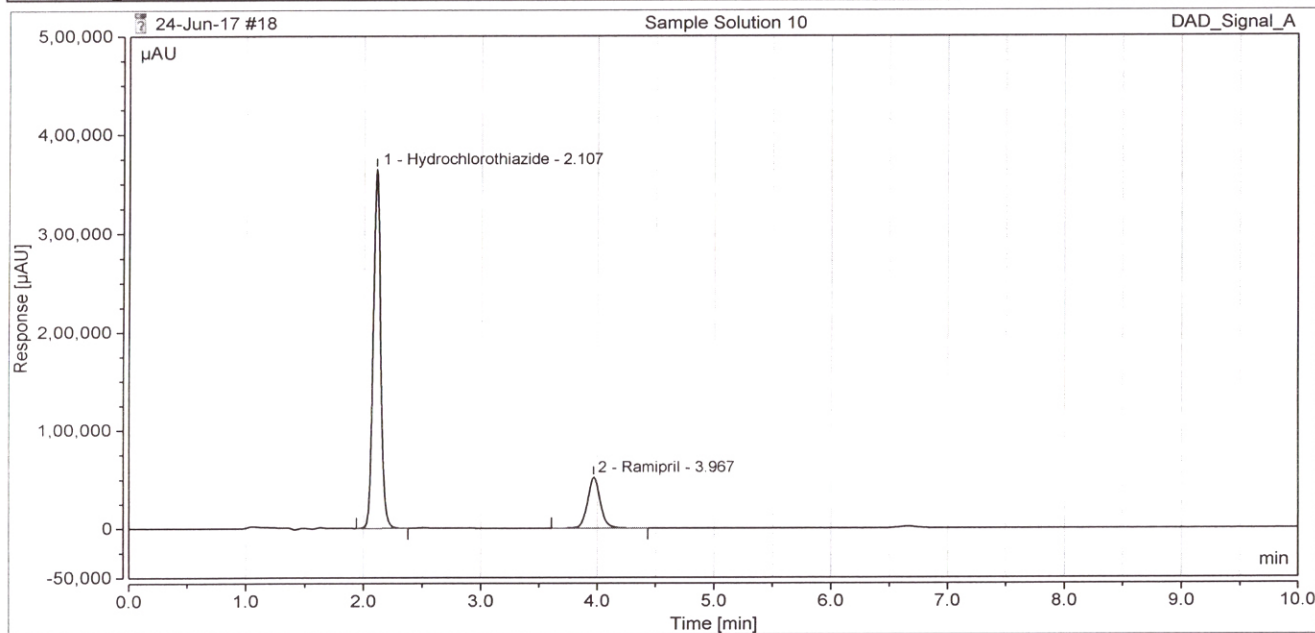
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Injection Details

Injection Name: Sample Solution 10
Vial Number: Vial: 12
Injection Type: Unknown
Instrument Method: Ramithiazide CU HPLC-05
Processing Method: PR Method_CU_01
Injection Date/Time: 24-Jun-2017 22:14
User Name: Pankaj Gurav

Run Time (min): 10.00
Injection Volume: 10.00
Channel: DAD_Signal_A
Wavelength: 210
Instrument Name: QbD-INST-HPLC-05
Sequence Name: 24-Jun-17

Chromatogram



Integration Results

No.	Peak Name	Retention (DETECTED) min	Area μAU*min	Rel.Area %	Plates (USP)	Asymmetry (EP)
1	Hydrochlorothiazide	2.107	26719.267	80.24	5472	1.16
2	Ramipril	3.967	6578.018	19.76	6668	1.10
Total:			33297.285			

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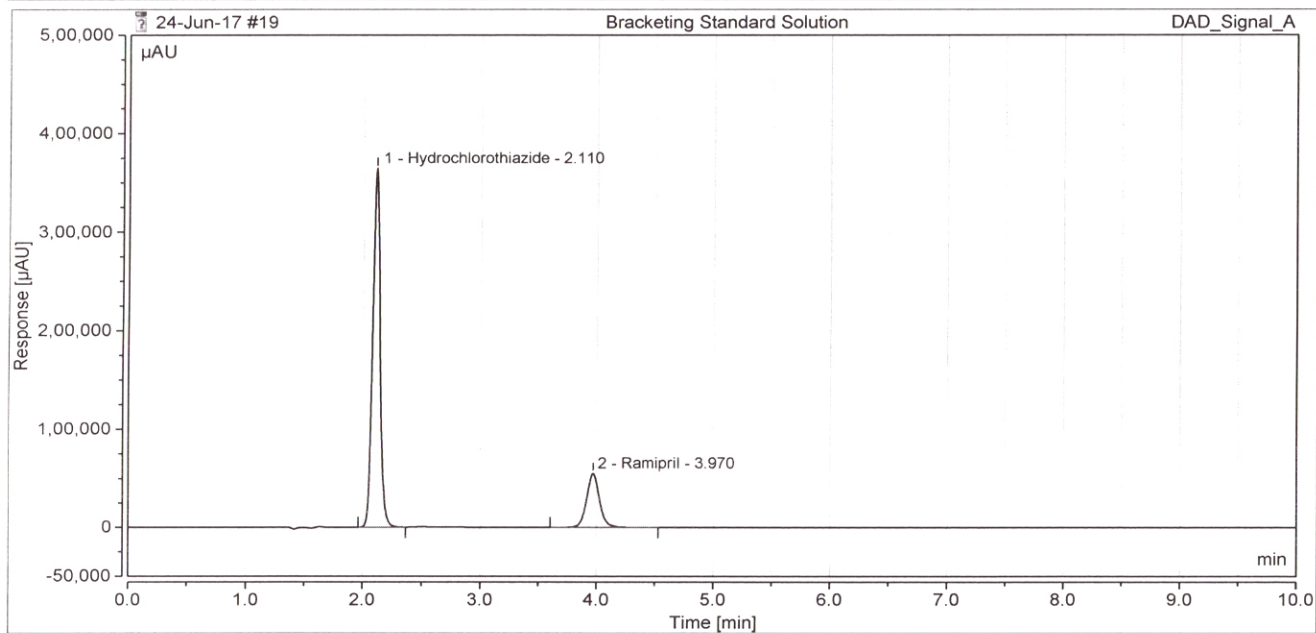
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Injection Details

Injection Name:	Bracketing Standard Solution	Run Time (min):	10.00
Vial Number:	Vial:2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Instrument Method:	Ramithiazide CU HPLC-05	Wavelength:	210
Processing Method:	PR Method_CU_01	Instrument Name:	QbD-INST-HPLC-05
Injection Date/Time:	24-Jun-2017 22:26	Sequence Name:	24-Jun-17
User Name:	Pankaj Gurav		

Chromatogram



Integration Results

No.	Peak Name	Retention (DETECTED) min	Area μAU*min	Rel.Area %	Plates (USP)	Asymmetry (EP)
1	Hydrochlorothiazide	2.110	26727.273	79.22	5508	1.11
2	Ramipril	3.970	7012.288	20.78	6646	1.07
Total:			33739.561			

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