

DISSOLUTION METHOD VALIDATION

Product name:	Ramithiazide Tablets 10mg/25mg
Label claim (mg):	25
Content:	Hydrochlorothiazide
B. No.:	GP170403
Parameter:	Flow Rate Decrease
LNB No./Pg. No.:	421/009
Dissolution Medium:	0.1N HCl

Analysis Date: 11-Jun-17

Name of Standard	Standard Purity(%)	Standard Wt (mg)	Dilution Details	Conc (ppm)
Hydrochlorothiazide	99.9	30.0	250 mL, 6 mL → 25 mL	14.4

Sr.No.	RT	Area
1	2.340	17566.916
2	2.340	17761.238
3	2.340	17812.386
4	2.340	17708.996
5	2.340	17830.016
Bkt Std	2.340	17844.272
Average	2.340	17753.971
SD	0.000	104.32
%RSD	0.00	0.59
System Suitability Results		
% RSD of Area	0.59	NMT 2.0%
Tailing Factor	1.31	NMT 2.0%
Theoretical Plates	6038	NLT 2000

Test Solution :	1	capsule in	750.0	mL with Disso media
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Sample No.	Capsule Weight (mg)	Area of Sample	% Release
1	201.2	20785.953	101.1
2	200.4	21534.941	104.7
3	195.8	21259.473	103.4
4	199.2	20955.135	101.9
5	193.6	20459.248	99.5
6	194.5	20623.819	100.3
		Average	101.8
		SD	1.9580
		%RSD	1.92

Done by: (H)
Date: 16-Jun-17

Checked by: 
Date: 

DISSOLUTION METHOD VALIDATION

Product name :	Ramithiazide Tablets 10mg/25mg
Lable claim (mg) :	10
Content :	Ramipril
B. No. :	GP170403
Parameter :	Flow Rate Decrease
LNB No./Pg. No. :	421/009
Dissolution Medium:	0.1N HCl

Analysis Date: 11-Jun-17

Name of Standard	Standard Purity(%)	Standard Wt (mg)	Dilution Details	Conc (ppm)
Ramipril	99.8	25.2	250 mL; 3 mL -> 25 mL	12.1

Sr.No.	RT	Area
1	4.320	4707.854
2	4.320	4723.778
3	4.320	4770.437
4	4.320	4727.686
5	4.320	4773.285
Average	4.320	4740.608
SD	0.000	29.50
%RSD	0.00	0.62

System Suitability Results

% RSD of Area	0.62	NMT 2.0%
Tailing factor	1.18	NMT 2.0%
Theoretical plates	6473	NLT 2000

Test Solution :	1	capsule in	750.0	mL with Disso media
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Sample No.	Capsule Weight (mg)	Area of Sample	% Release
1	201.2	5210.217	99.5
2	200.4	5289.433	101.0
3	195.8	5012.056	95.7
4	199.2	5793.806	110.7
5	193.6	5153.679	98.4
6	194.5	5047.462	96.4
		Average	100.3
		SD	5.4407
		%RSD	5.43

Done by: F He
Date: 16-Jun-17

Checked by: [Signature]
Date: 16-Jun-17

DISSOLUTION METHOD VALIDATION

Product name :	Ramithiazide Tablets 10mg/25mg
Lable claim (mg) :	25
Content :	Hydrochlorothiazide
B. No. :	GP170403
Parameter :	Flow Rate Increase
LNB No./Pg. No.:	421/009
Dissolution Medium:	0.1N HCl

Analysis Date: 11-Jun-17

Name of Standard	Standard Purity(%)	Standard Wt (mg)	Dilution Details	Conc (ppm)
Hydrochlorothiazide	99.9	30.0	250 mL; 6 mL -> 25 mL	14.4

Sr.No.	RT	Area
1	1.920	14409.197
2	1.920	14546.271
3	1.920	14573.800
4	1.920	14536.461
5	1.920	14587.097
Average	1.920	14530.565
SD	0.000	70.85
%RSD	0.00	0.49
System Suitability Results		
% RSD of Area	0.49	NMT 2.0%
Tailing Factor	1.28	NMT 2.0%
Theoretical Plates	5428	NLT 2000

Test Solution :	1	capsule in	750.0	mL with Dissomedia
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Sample No.	Capsule Weight (mg)	Area of Sample	% Release
1	201.2	17101.767	101.6
2	200.4	17587.600	104.5
3	195.8	17415.607	103.5
4	199.2	17162.485	101.9
5	193.6	16736.493	99.4
6	194.5	16921.581	100.5
		Average	101.9
		SD	1.8550
		%RSD	1.82

Done by:
Date:B37
15-Jun-17Checked by:
Date:B37
16-Jun-17

DISSOLUTION METHOD VALIDATION

Product name :	Ramithiazide Tablets 10mg/25mg
Lable claim (mg) :	10
Content :	Ramipril
B. No. :	GP170403
Parameter :	Flow Rate Increase
LNB No./Pg. No.:	421/009
Dissolution Medium:	0.1N HCl

Analysis Date: 11-Jun-17

Name of Standard	Standard Purity(%)	Standard Wt (mg)	Dilution Details	Conc (ppm)
Ramipril	99.8	25.2	250 mL, 3 mL -> 25 mL	12.1

Sr.No.	RT	Area
1	3.547	3840.955
2	3.547	3871.573
3	3.550	3890.064
4	3.547	3880.312
5	3.547	3896.581
Average	3.548	3875.897
SD	0.001	21.72
%RSD	0.04	0.56

System Suitability Results

% RSD of Area	0.56	NMT 2.0%
Tailing Factor	1.15	NMT 2.0
Theoretical Plates	5983	NLT 2000

Test Solution :	1	capsule in	750.0	mL with Dissomedia
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Sample No.	Capsule Weight (mg)	Area of Sample	% Release
1	201.2	4282.835	100.0
2	200.4	4337.566	101.3
3	195.8	4076.178	95.2
4	199.2	4763.683	111.3
5	193.6	4190.655	97.9
6	194.5	4147.267	96.9
		Average	100.4
		SD	5.7417
		%RSD	5.72

Done by: 
Date: 15-Jun-17

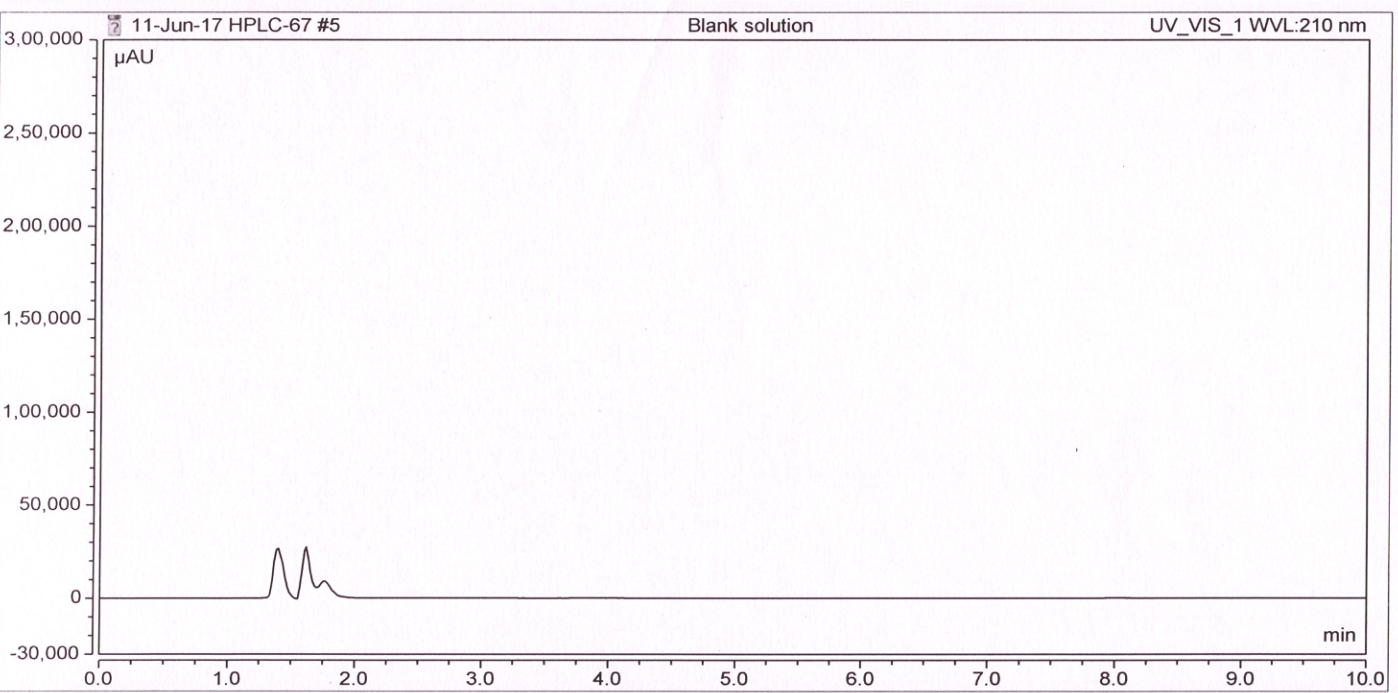
Checked by: 
Date: 16-Jun-17

QbD Research & Developement Pvt.Ltd.

Injection Details

Injection Name:	Blank solution	Run Time (min):	10.00
Vial Number:	RA1	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Dissolution	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution PR	Dilution Factor:	1.0000
Injection Date/Time:	11-Jun-17 19:43	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

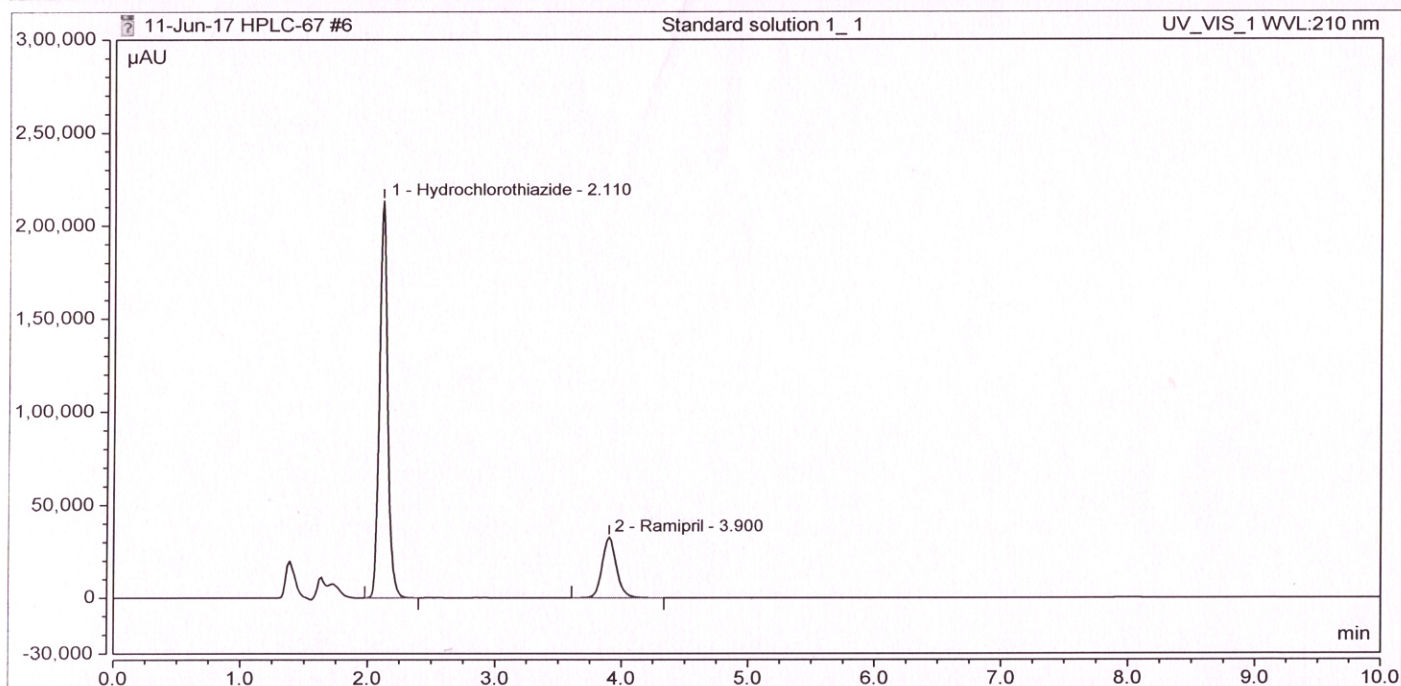
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
Total:							

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Standard solution 1_1	Run Time (min):	10.00
Vial Number:	RA2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Dissolution	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution PR	Dilution Factor:	1.0000
Injection Date/Time:	11-Jun-17 19:54	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

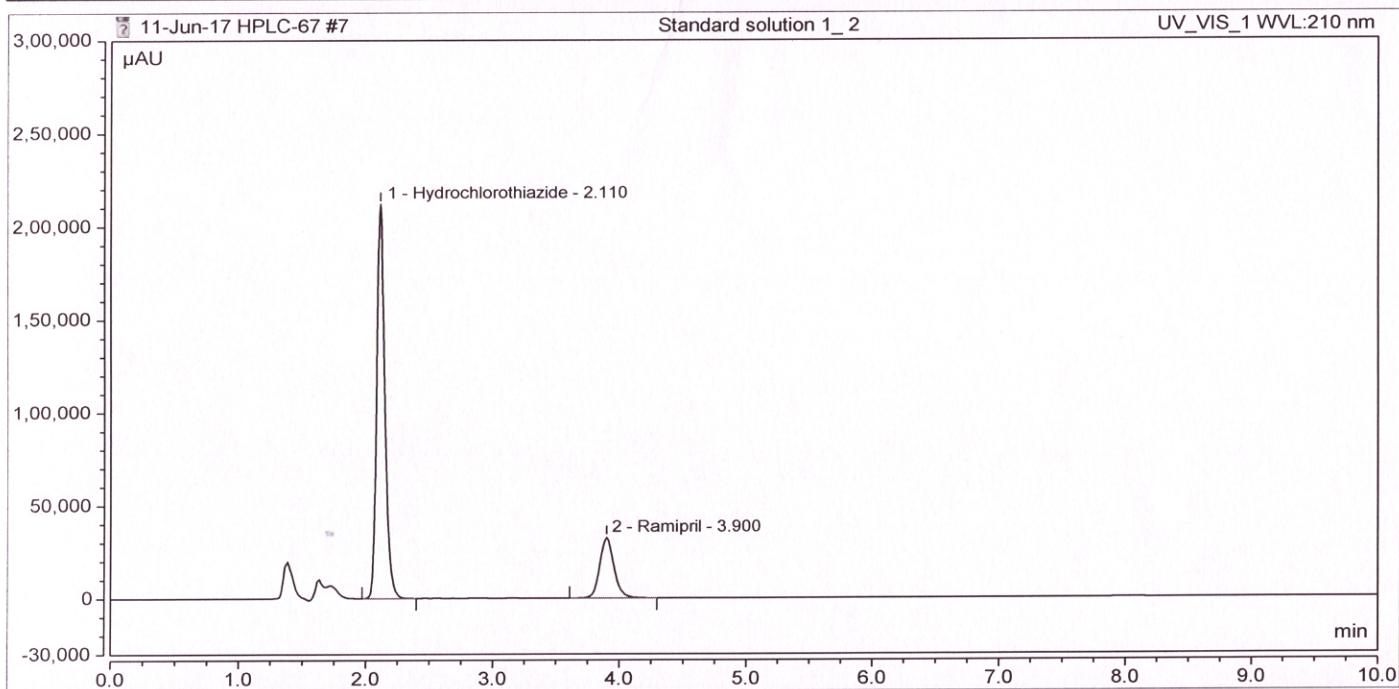
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazide	2.110	15961.064	5413	1.31	116.2	78.89
2	Ramipril	3.900	4272.241	6092	1.13	655.0	21.11
Total:							

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Injection Details

Injection Name:	Standard solution 1_2	Run Time (min):	10.00
Vial Number:	RA2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Dissolution	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution PR	Dilution Factor:	1.0000
Injection Date/Time:	11-Jun-17 20:06	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazid	2.110	15804.359	5462	1.31	124.8	78.90
2	Ramipril	3.900	4225.293	6084	1.13	555.1	21.10
Total:							

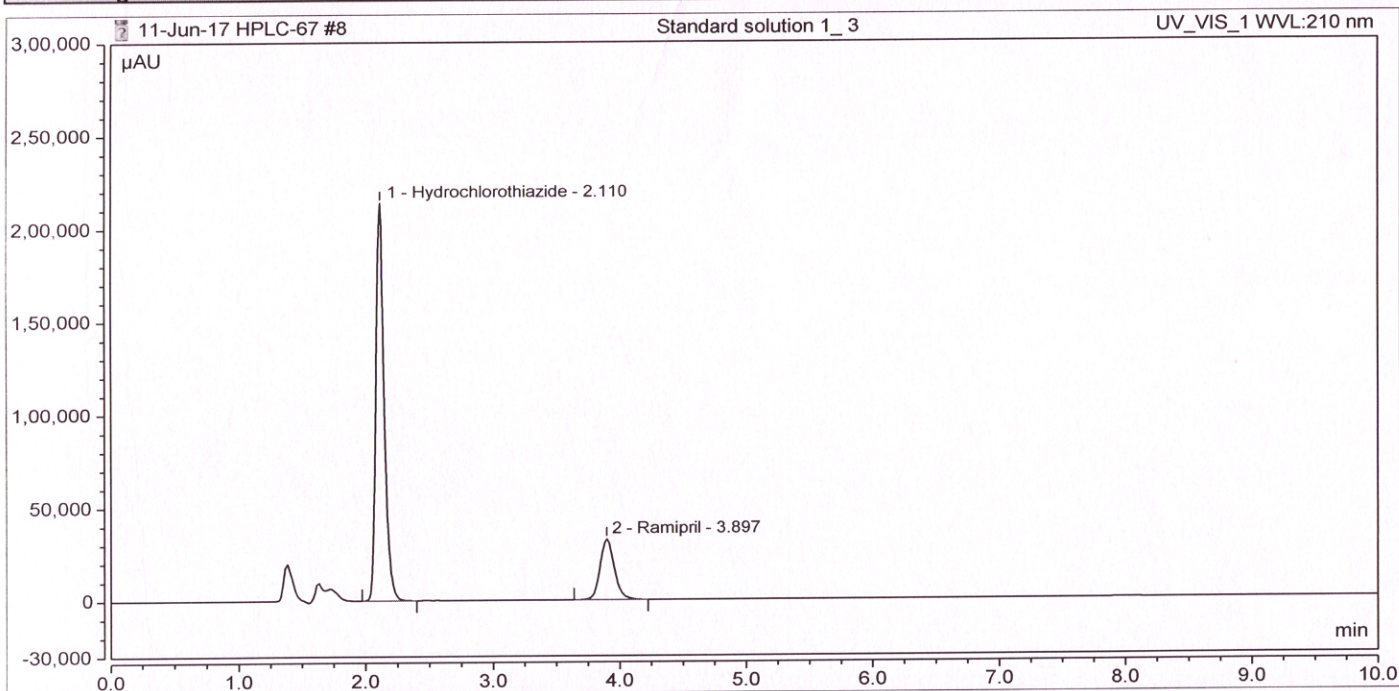
QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name: Standard solution 1_3
Vial Number: RA2
Injection Type: Unknown
Calibration Level:
Instrument Method: Ramithiazide Dissolution
Processing Method: Ramithiazide Dissolution PR
Injection Date/Time: 11-Jun-17 20:18
User Name: Avinash Patil

Run Time (min): 10.00
Injection Volume: 10.00
Channel: UV_VIS_1
Wavelength: 210
Bandwidth: 1
Dilution Factor: 1.0000
Sample Weight: 1.0000
Sample Weight: 1.0000

Chromatogram



Integration Results

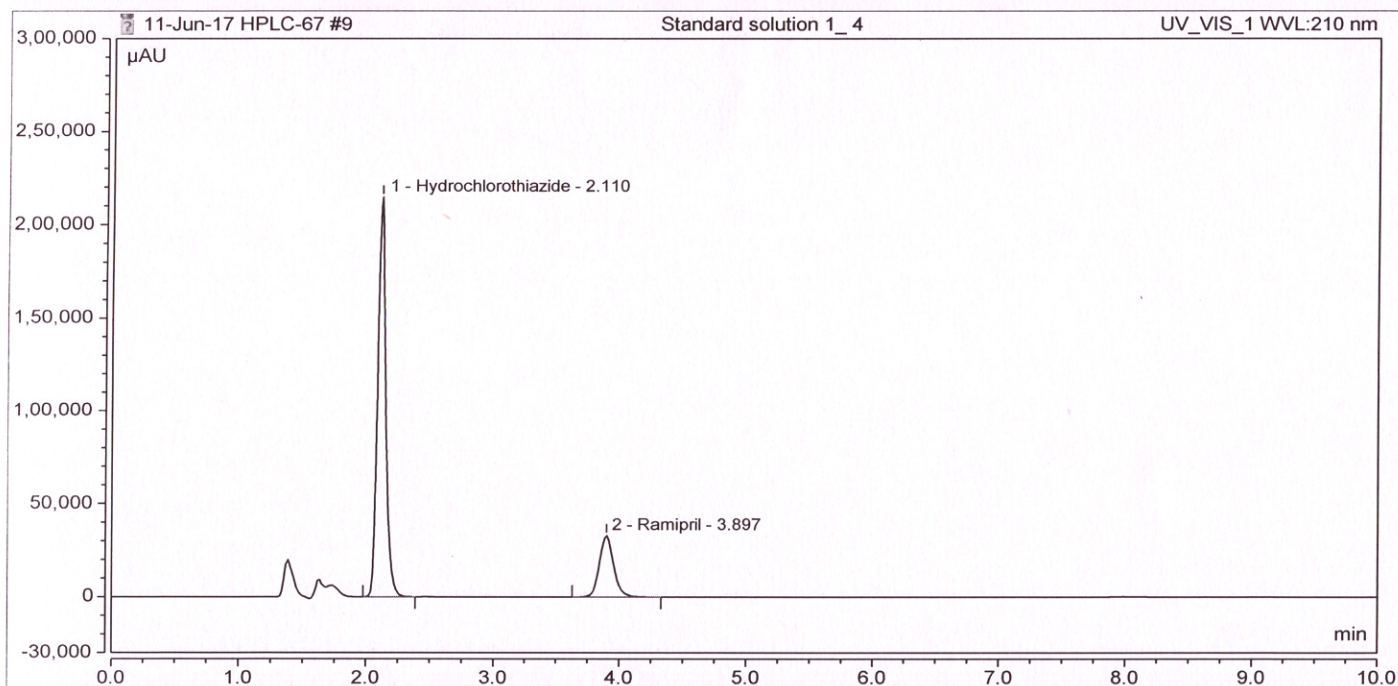
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazid	2.110	15949.549	5479	1.31	132.4	78.98
2	Ramipril	3.897	4245.073	6094	1.15	543.7	21.02
Total:							

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Standard solution 1_4	Run Time (min):	10.00
Vial Number:	RA2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Dissolution	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution PR	Dilution Factor:	1.0000
Injection Date/Time:	11-Jun-17 20:29	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

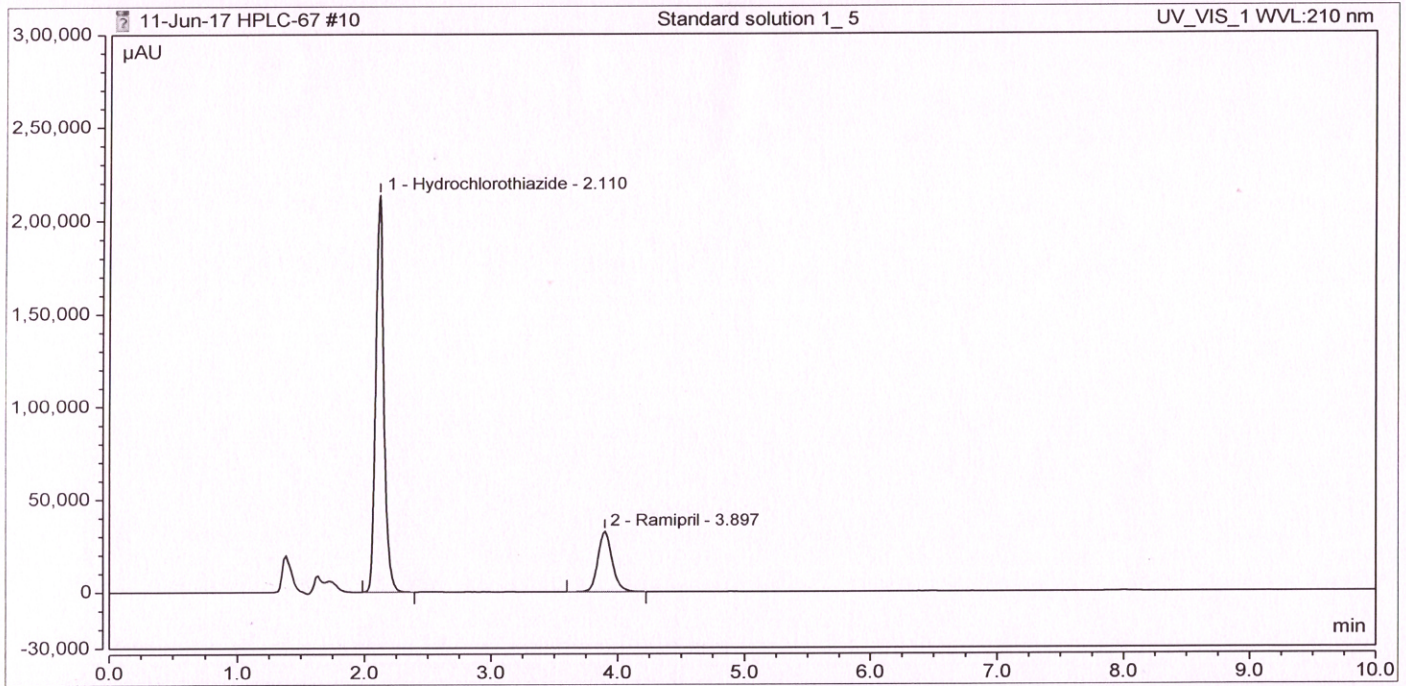
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazid	2.110	16012.887	5493	1.29	138.3	78.90
2	Ramipril	3.897	4281.227	6143	1.14	757.5	21.10
Total:							

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Injection Details

Injection Name:	Standard solution 1_5	Run Time (min):	10.00
Vial Number:	RA2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Dissolution	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution PR	Dilution Factor:	1.0000
Injection Date/Time:	11-Jun-17 20:41	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

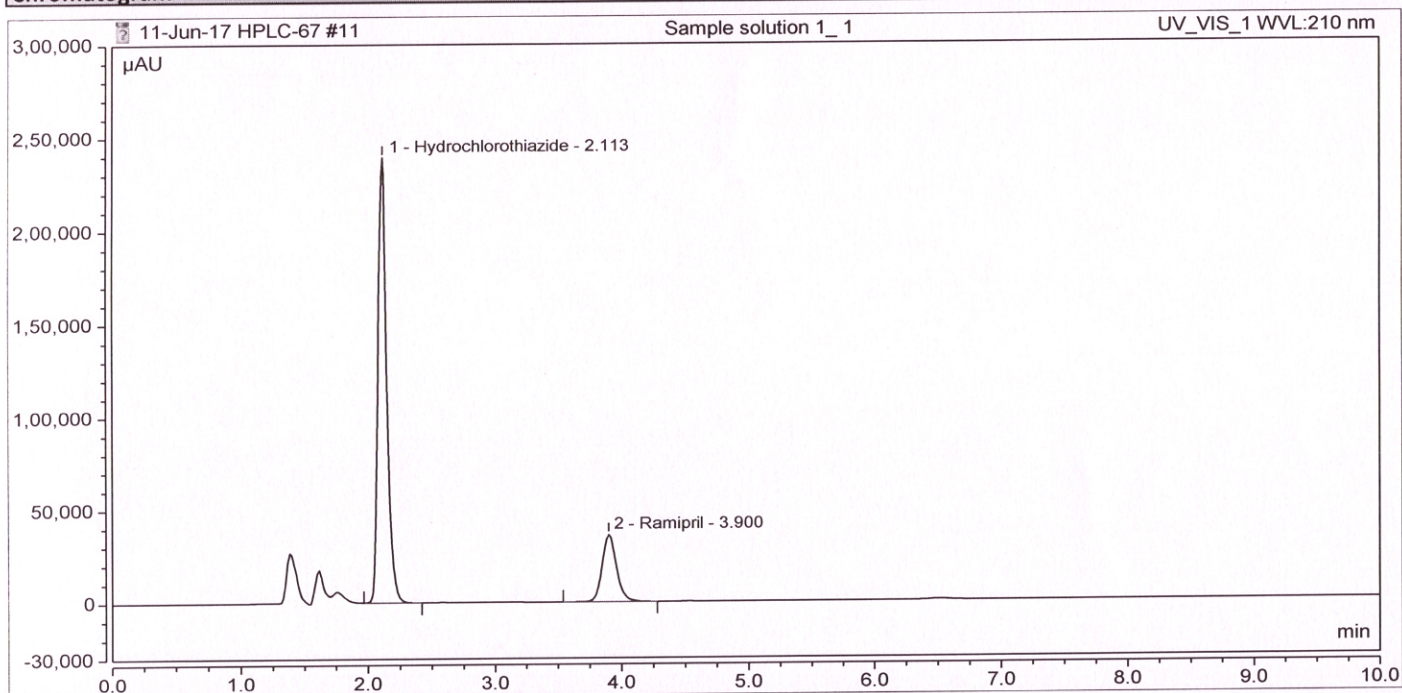
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazid	2.110	15850.270	5547	1.29	139.8	78.94
2	Ramipril	3.897	4229.499	6131	1.14	562.3	21.06
Total:							

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Injection Details

Injection Name:	Sample solution 1_1	Run Time (min):	10.00
Vial Number:	RA3	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Dissolution	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution PR	Dilution Factor:	1.0000
Injection Date/Time:	11-Jun-17 20:53	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazid	2.113	18811.421	4886	1.24	204.5	79.97
2	Ramipril	3.900	4710.447	6070	1.15	325.8	20.03
Total:							

Default/Integration

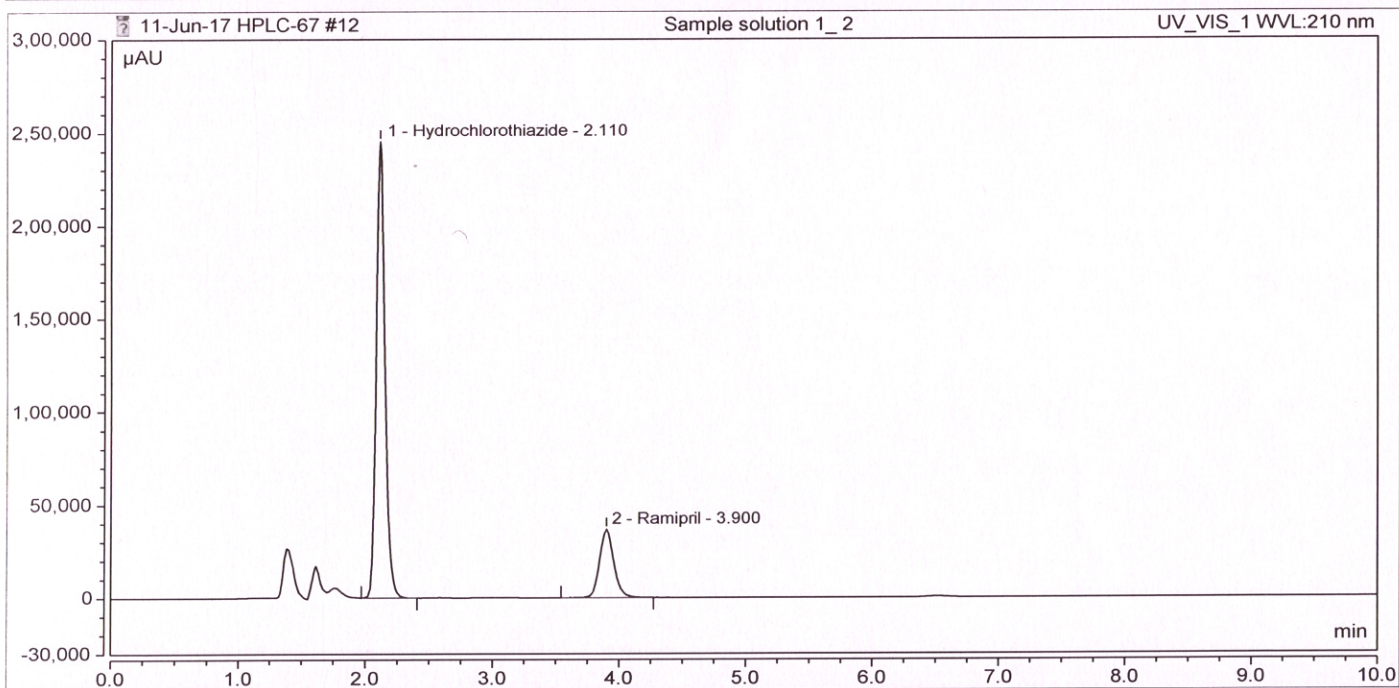
Chromeleon (c) Dionex
Version 7.2.4.8525

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Sample solution 1_2	Run Time (min):	10.00
Vial Number:	RA4	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Dissolution	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution PR	Dilution Factor:	1.0000
Injection Date/Time:	11-Jun-17 21:05	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

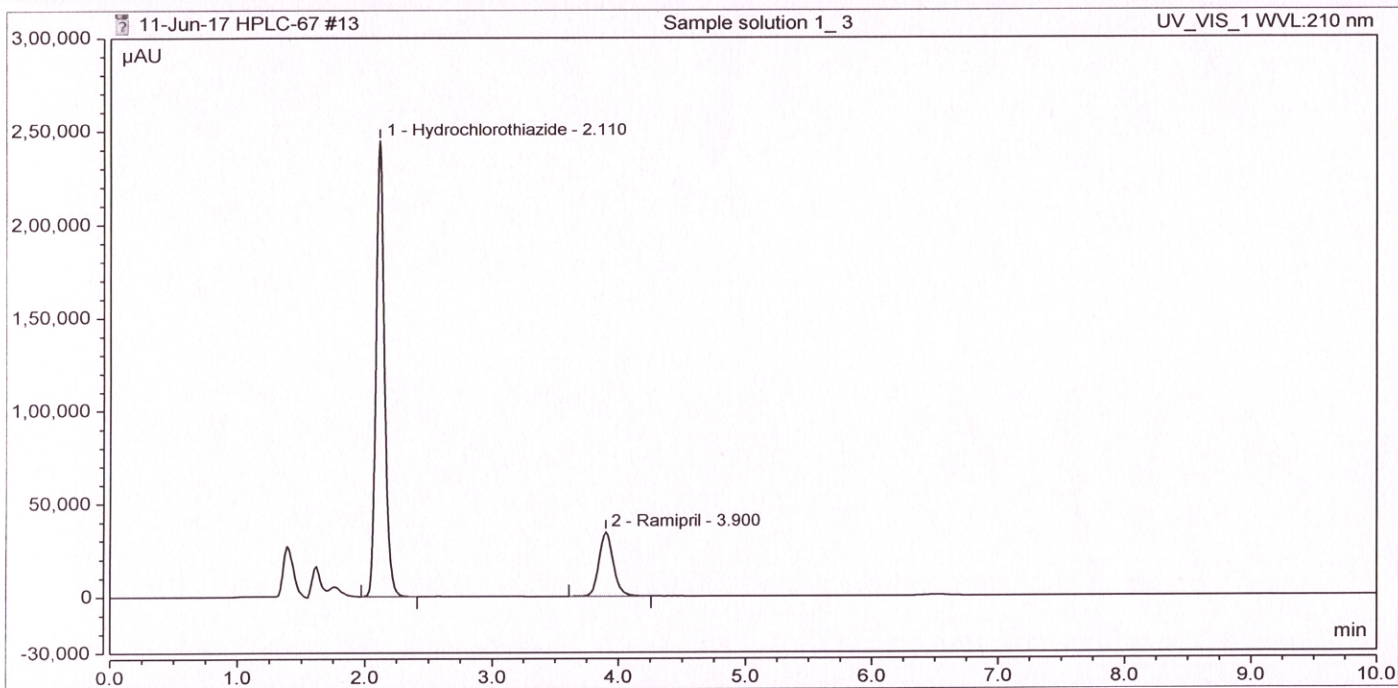
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazid	2.110	19314.615	4844	1.30	228.8	80.21
2	Ramipril	3.900	4766.643	6082	1.14	339.9	19.79
Total:							

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Sample solution 1_3	Run Time (min):	10.00
Vial Number:	RA5	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Dissolution	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution PR	Dilution Factor:	1.0000
Injection Date/Time:	11-Jun-17 21:16	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

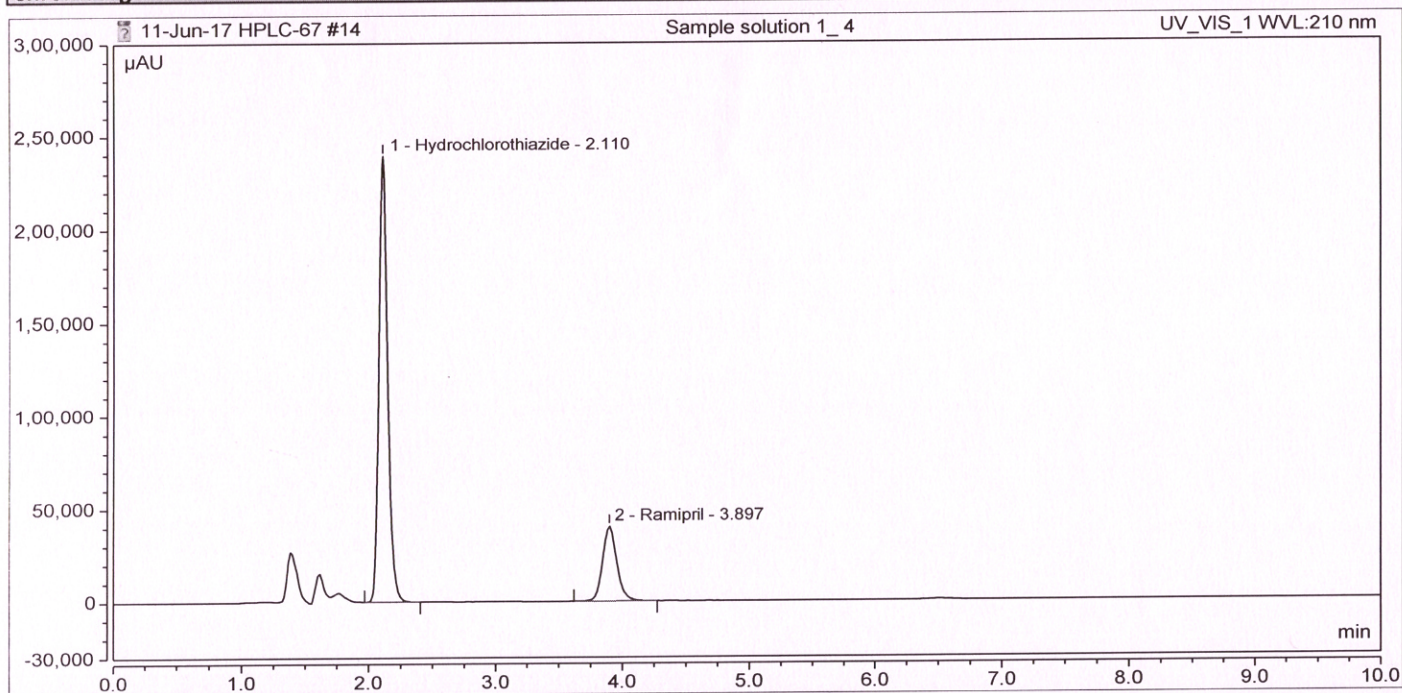
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazide	2.110	19101.337	4947	1.31	227.0	80.95
2	Ramipril	3.900	4495.822	6081	1.14	401.5	19.05
Total:							

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Sample solution 1_4	Run Time (min):	10.00
Vial Number:	RA6	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Dissolution	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution PR	Dilution Factor:	1.0000
Injection Date/Time:	11-Jun-17 21:28	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

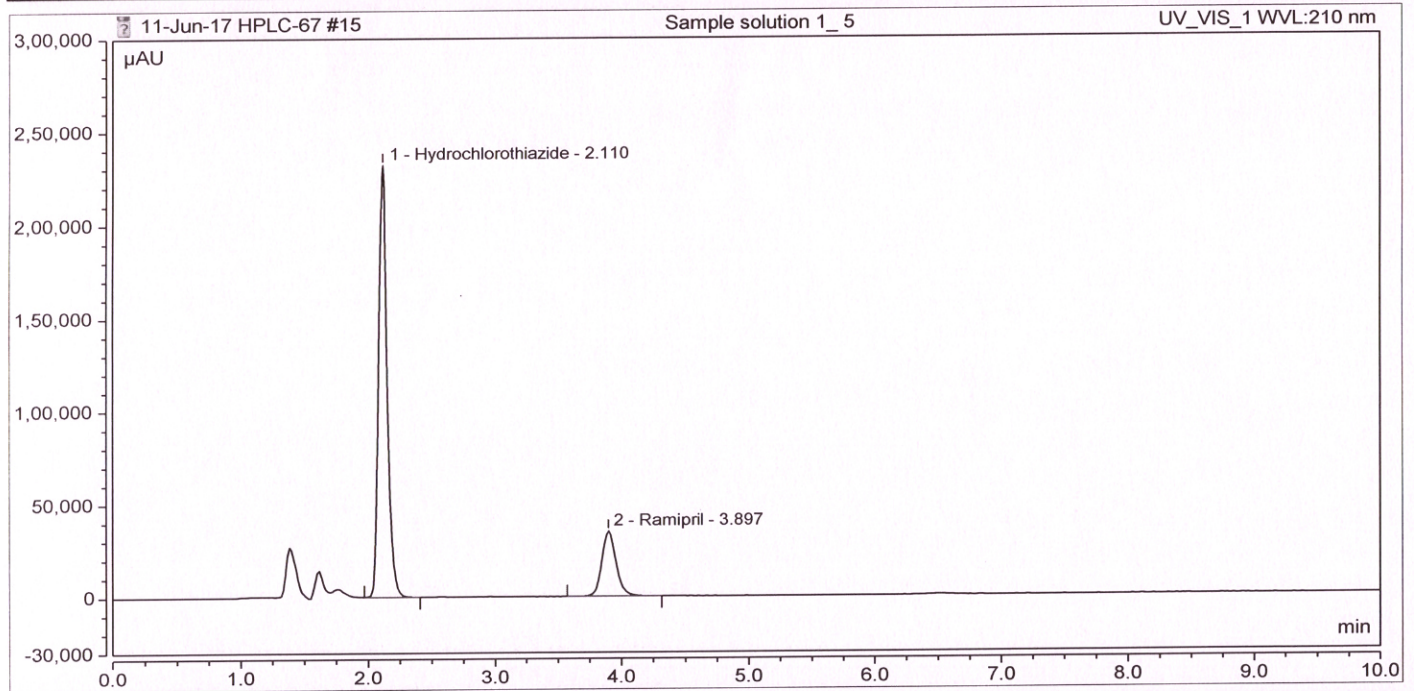
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazid	2.110	18854.587	4824	1.28	251.9	78.30
2	Ramipril	3.897	5224.250	6049	1.15	415.2	21.70
Total:							

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Sample solution 1_ 5	Run Time (min):	10.00
Vial Number:	RA7	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Dissolution	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution PR	Dilution Factor:	1.0000
Injection Date/Time:	11-Jun-17 21:40	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

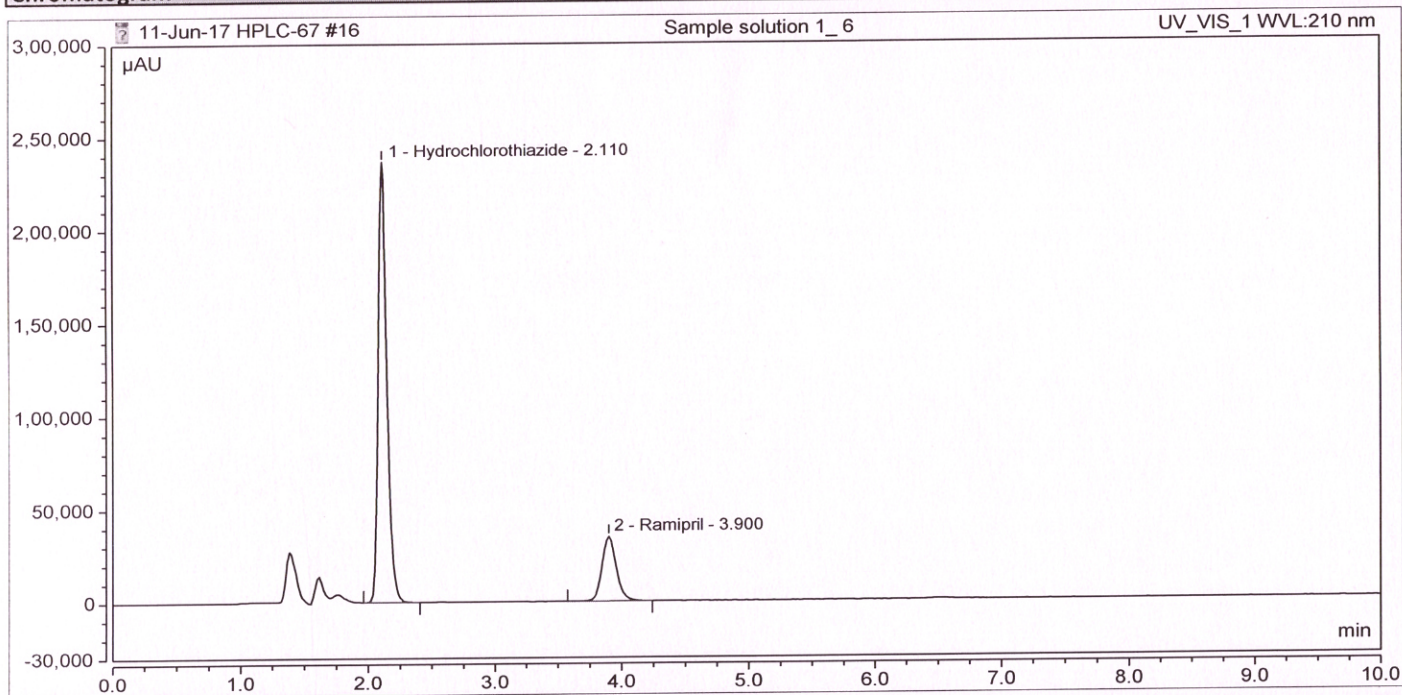
No.	Peak Name	Retention Time min	Area $\mu\text{AU} \cdot \text{min}$	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazid	2.110	18147.927	4907	1.28	257.7	79.92
2	Ramipril	3.897	4559.695	6085	1.17	339.9	20.08
Total:							

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Sample solution 1_6	Run Time (min):	10.00
Vial Number:	RA8	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Dissolution	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution PR	Dilution Factor:	1.0000
Injection Date/Time:	11-Jun-17 21:51	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

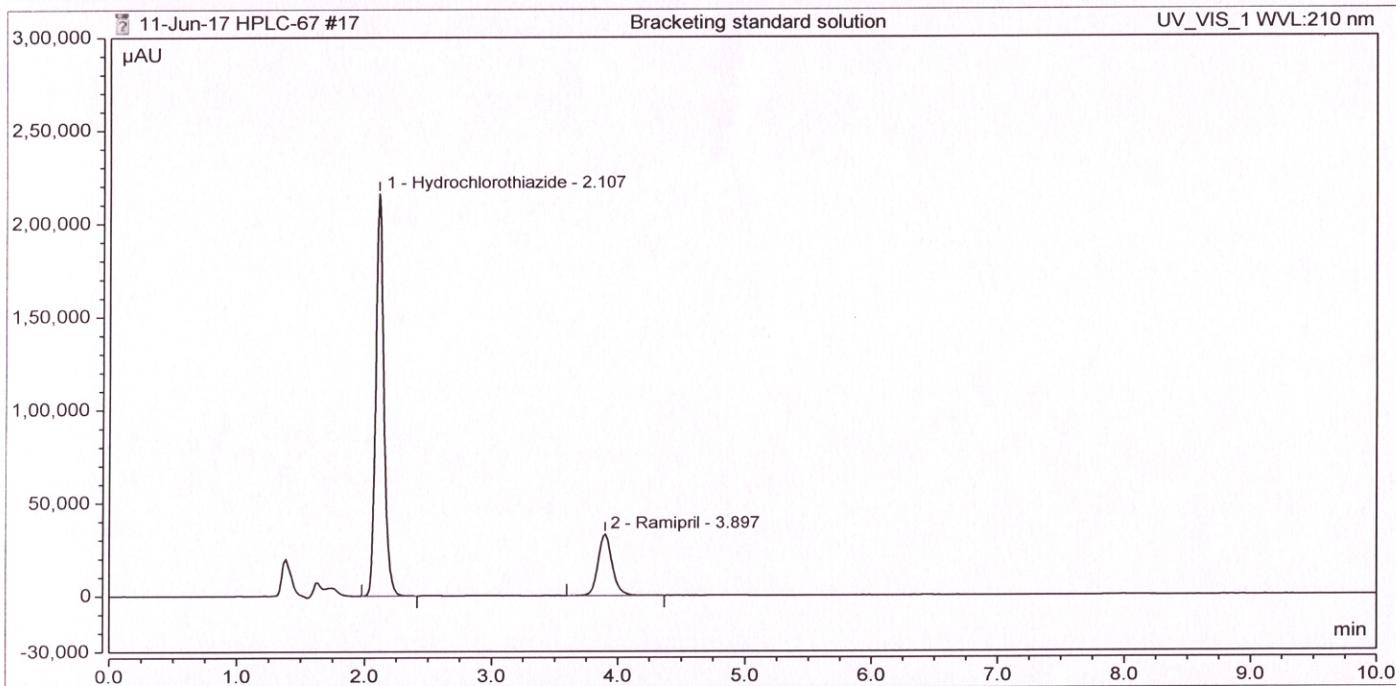
No.	Peak Name	Retention Time min	Area $\mu\text{AU}\cdot\text{min}$	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazid	2.110	18568.694	4892	1.30	275.2	80.35
2	Ramipril	3.900	4539.750	6067	1.14	383.5	19.65
Total:							

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Bracketing standard solution	Run Time (min):	10.00
Vial Number:	RA2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Dissolution	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution PR	Dilution Factor:	1.0000
Injection Date/Time:	11-Jun-17 22:03	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram

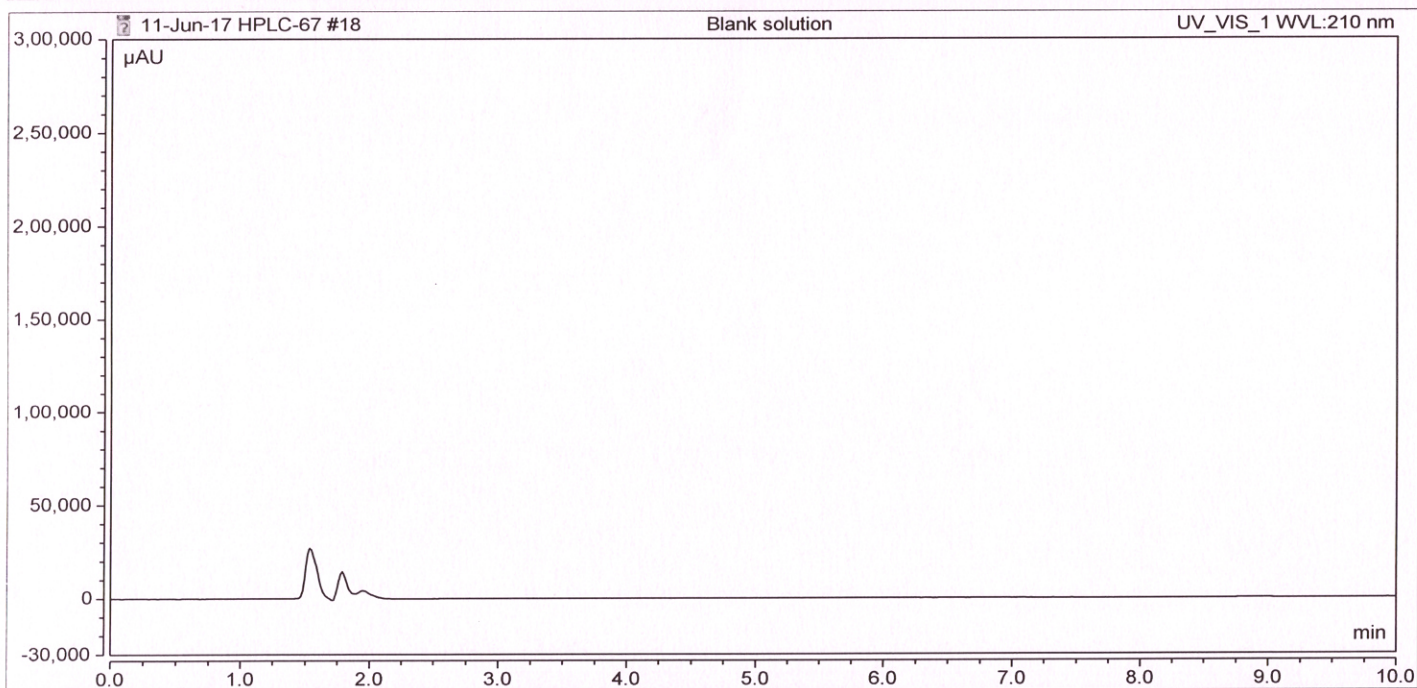


Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazide	2.107	16022.997	5556	1.34	191.5	78.90
2	Ramipril	3.897	4285.911	6207	1.13	607.1	21.10
Total:							

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

Injection Name:	Blank solution	Run Time (min):	10.00
Vial Number:	RA1	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay-Robustness (-) flow HPLC_	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution FR Decrease PR	Dilution Factor:	1.0000
Injection Date/Time:	11-Jun-17 22:15	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram**Integration Results**

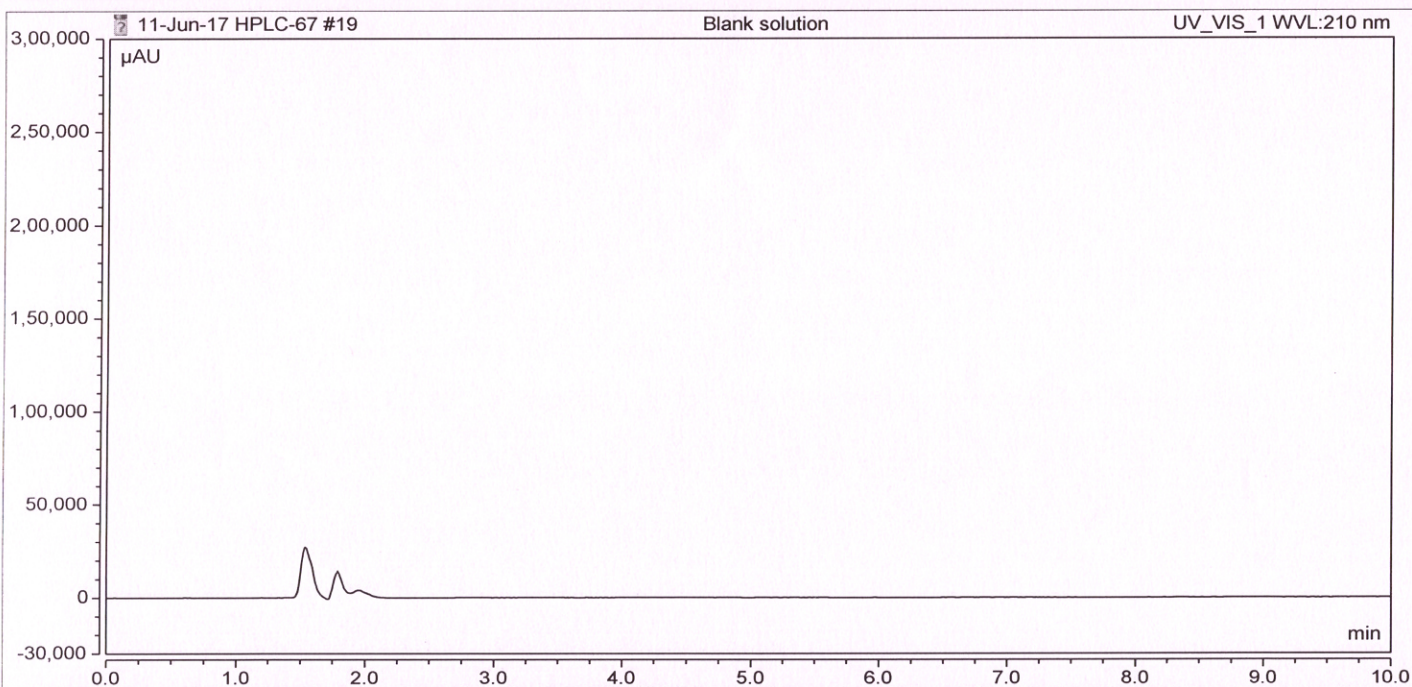
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
Total:							

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Blank solution	Run Time (min):	10.00
Vial Number:	RA1	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay-Robustness (-) flow HPLC_	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution FR Decrease PR	Dilution Factor:	1.0000
Injection Date/Time:	11-Jun-17 22:26	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

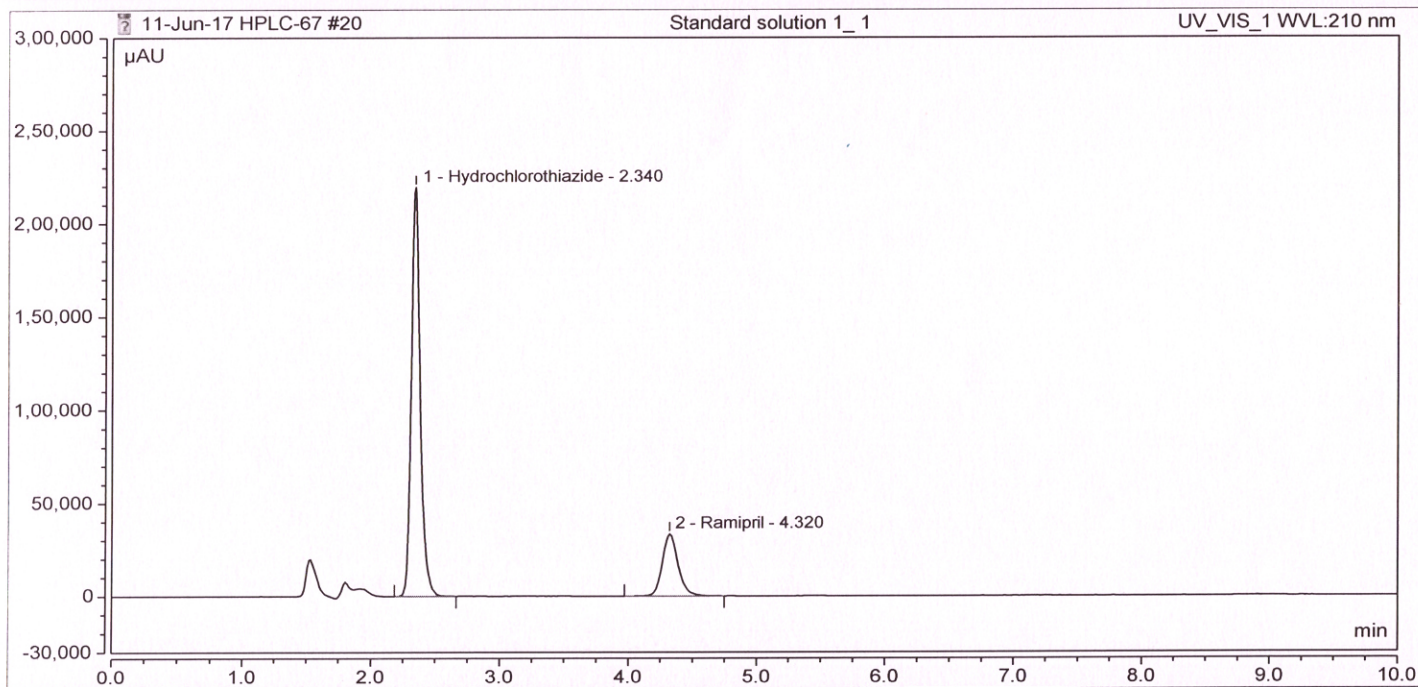
No.	Peak Name	Retention Time min	Area $\mu\text{AU}\cdot\text{min}$	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
Total:							

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Standard solution 1_1	Run Time (min):	10.00
Vial Number:	RA2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay-Robustness (-) flow HPLC_	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution FR Decrease PR	Dilution Factor:	1.0000
Injection Date/Time:	11-Jun-17 22:38	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

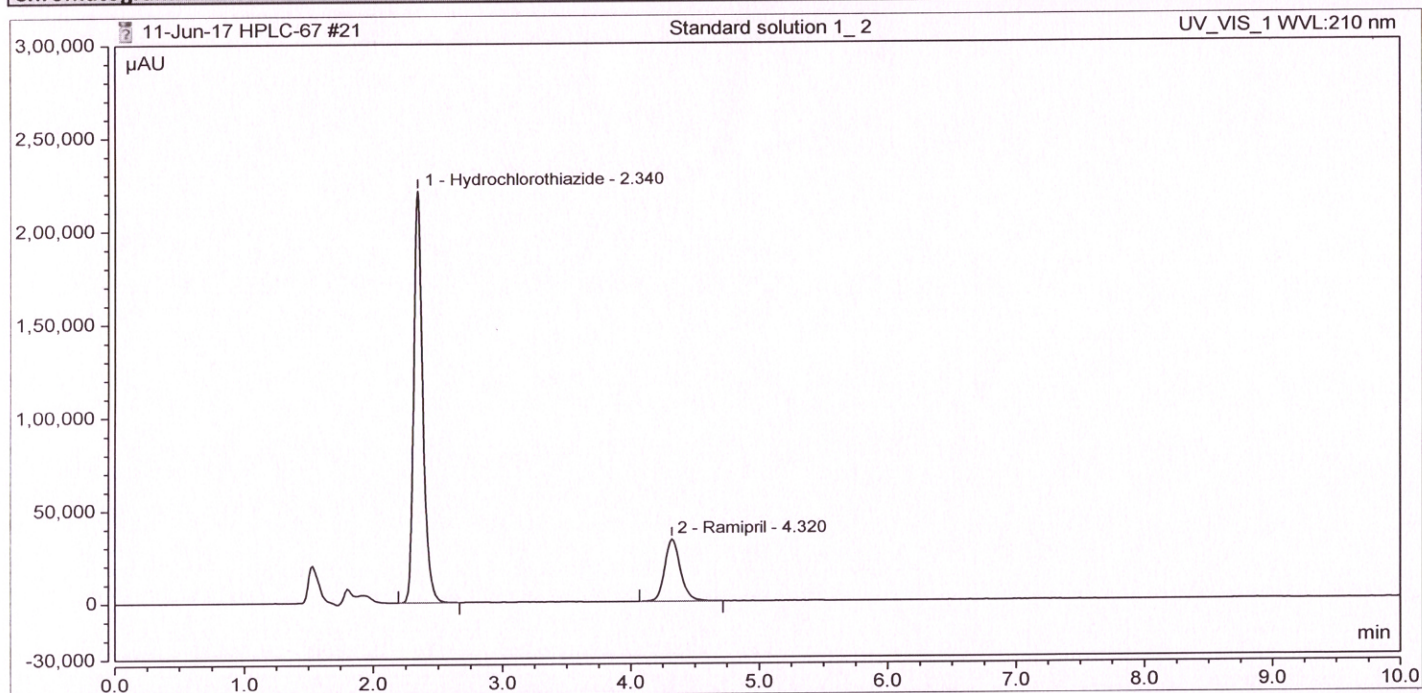
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazide	2.340	17566.916	6038	1.31	207.2	78.86
2	Ramipril	4.320	4707.854	6473	1.18	594.0	21.14
Total:							

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Standard solution 1_2	Run Time (min):	10.00
Vial Number:	RA2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay-Robustness (-) flow HPLC_	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution FR Decrease PR	Dilution Factor:	1.0000
Injection Date/Time:	11-Jun-17 22:50	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

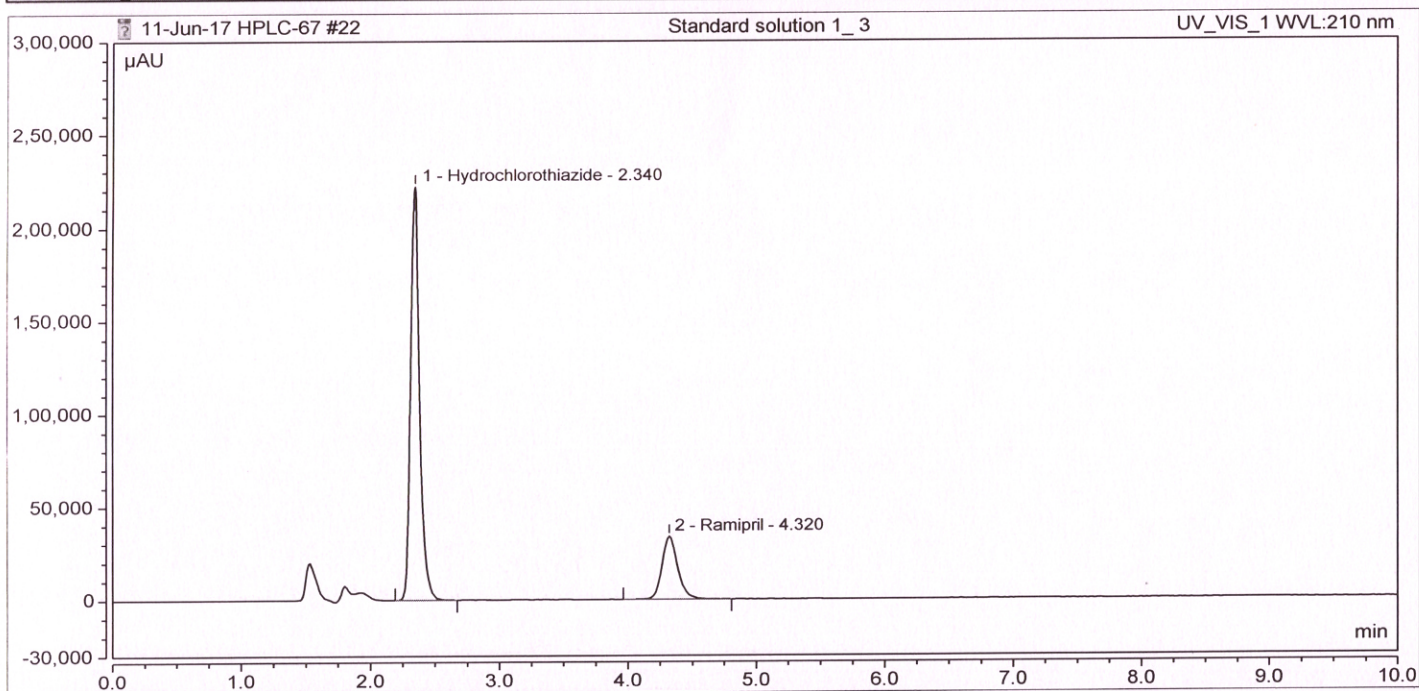
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazide	2.340	17761.238	5940	1.33	201.1	78.99
2	Ramipril	4.320	4723.778	6464	1.17	643.4	21.01
Total:							

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Standard solution 1_3	Run Time (min):	10.00
Vial Number:	RA2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay-Robustness (-) flow HPLC_	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution FR Decrease PR	Dilution Factor:	1.0000
Injection Date/Time:	11-Jun-17 23:02	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram

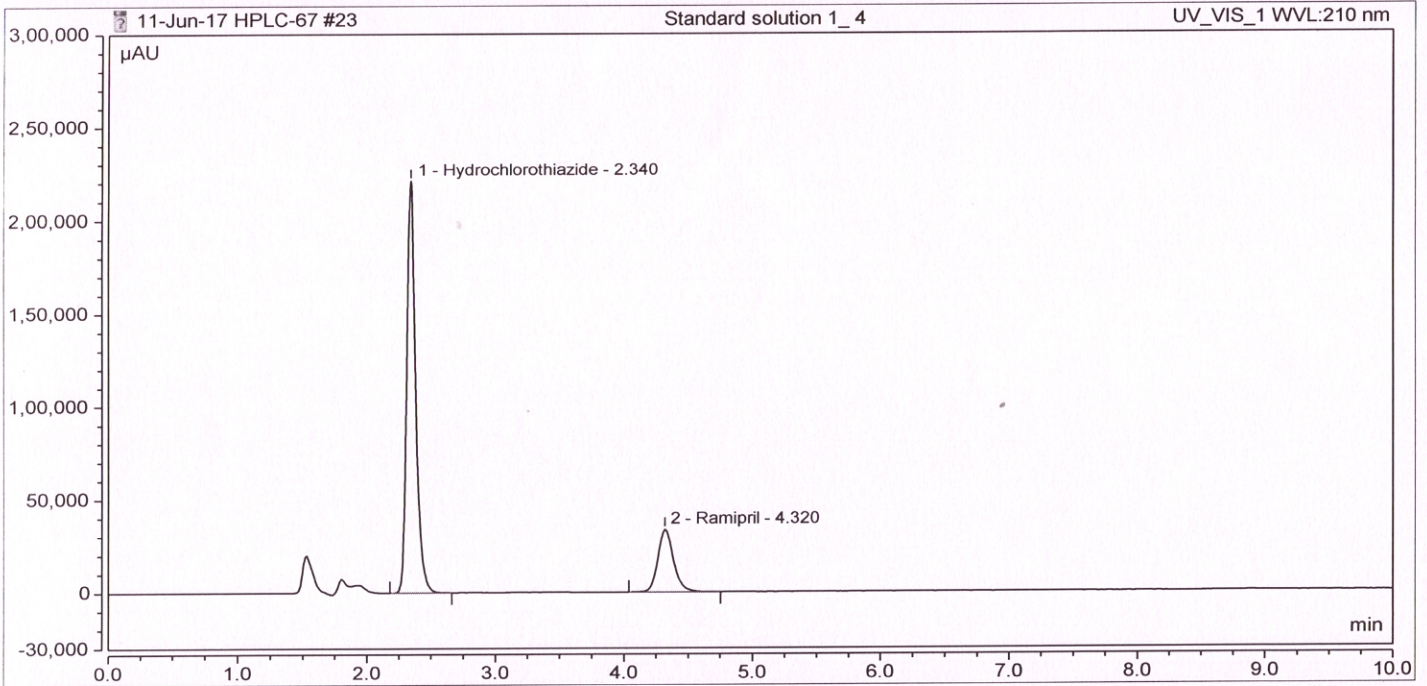


Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazide	2.340	17812.386	6012	1.31	207.1	78.88
2	Ramipril	4.320	4770.437	6466	1.17	751.5	21.12
Total:							

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

Injection Name:	Standard solution 1_4	Run Time (min):	10.00
Vial Number:	RA2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay-Robustness (-) flow HPLC_	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution FR Decrease PR	Dilution Factor:	1.0000
Injection Date/Time:	11-Jun-17 23:13	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram**Integration Results**

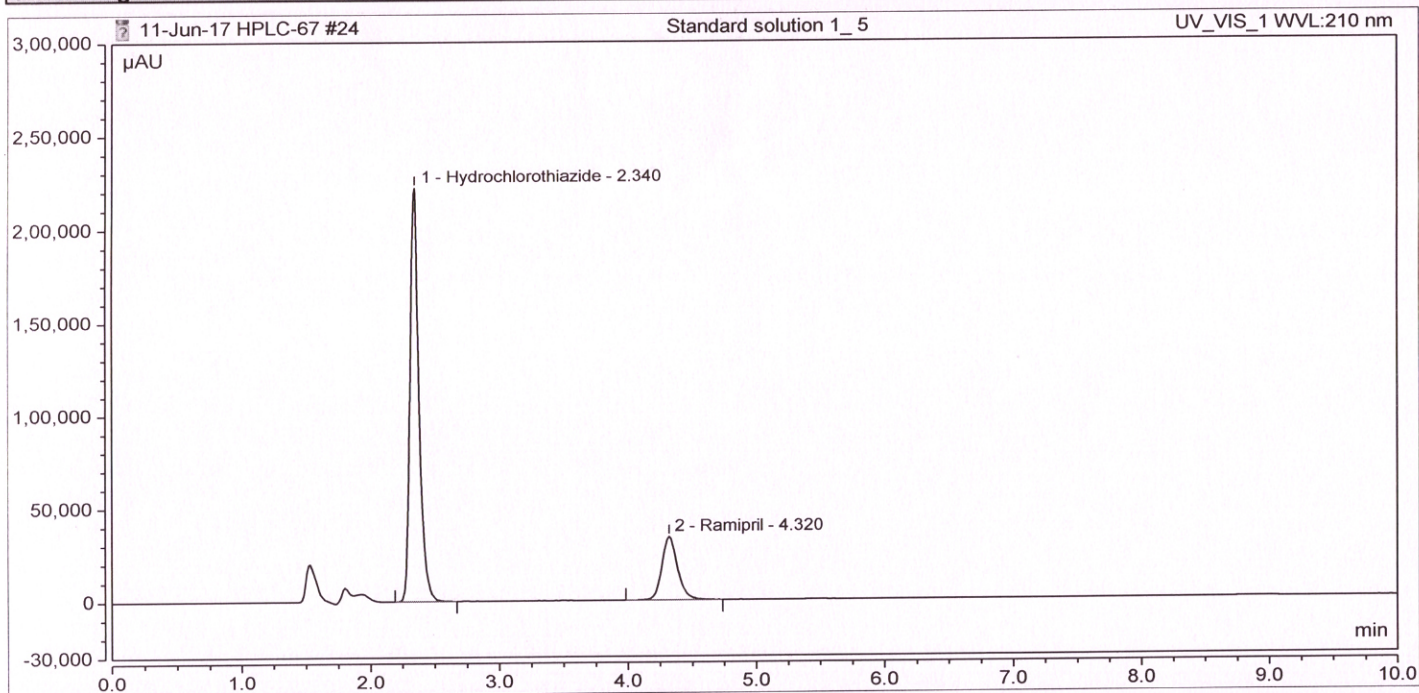
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazide	2.340	17708.996	5985	1.33	208.7	78.93
2	Ramipril	4.320	4727.686	6429	1.18	788.4	21.07
Total:							

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Standard solution 1_ 5	Run Time (min):	10.00
Vial Number:	RA2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay-Robustness (-) flow HPLC_	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution FR Decrease PR	Dilution Factor:	1.0000
Injection Date/Time:	11-Jun-17 23:25	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

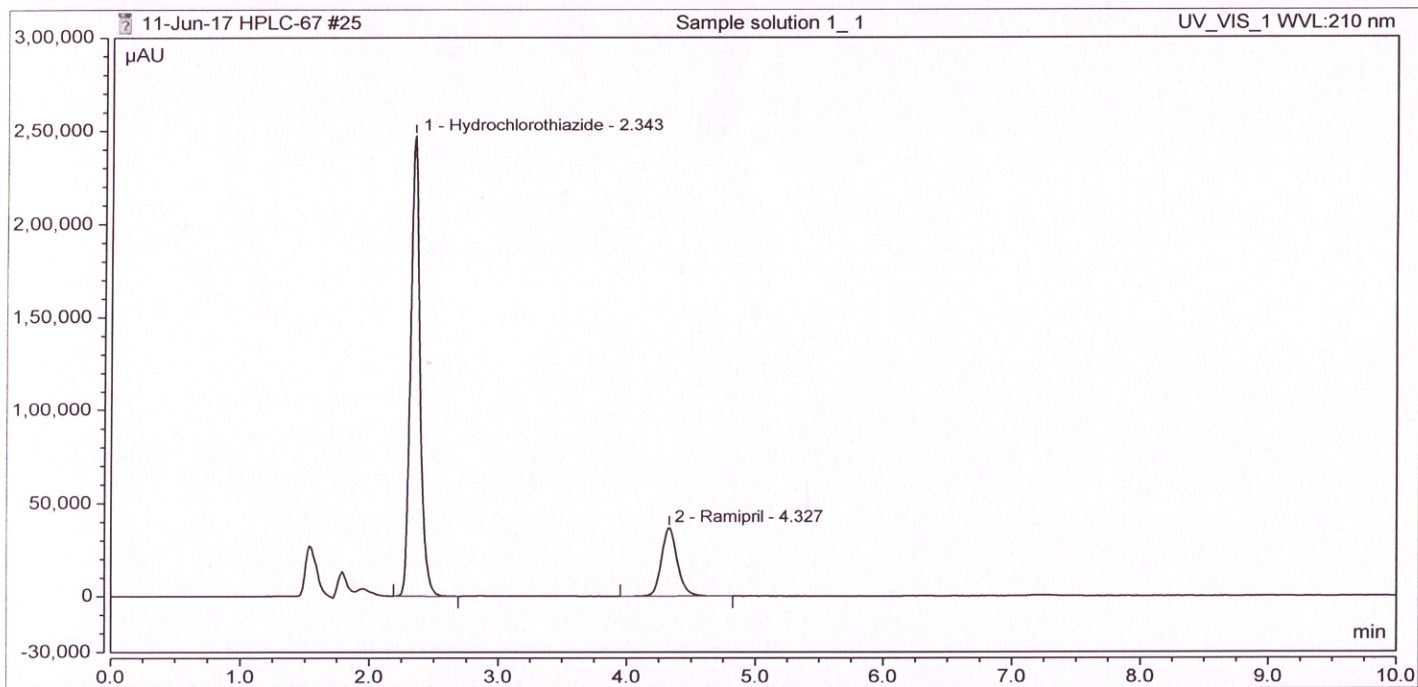
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazide	2.340	17830.016	5984	1.31	205.0	78.88
2	Ramipril	4.320	4773.284	6491	1.17	611.7	21.12
Total:							

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Sample solution 1_1	Run Time (min):	10.00
Vial Number:	RA3	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay-Robustness (-) flow HPLC_	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution FR Decrease PR	Dilution Factor:	1.0000
Injection Date/Time:	11-Jun-17 23:37	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazide	2.343	20785.953	5394	1.29	197.4	79.96
2	Ramipril	4.327	5210.217	6416	1.16	340.3	20.04
Total:							

15-Jun-17

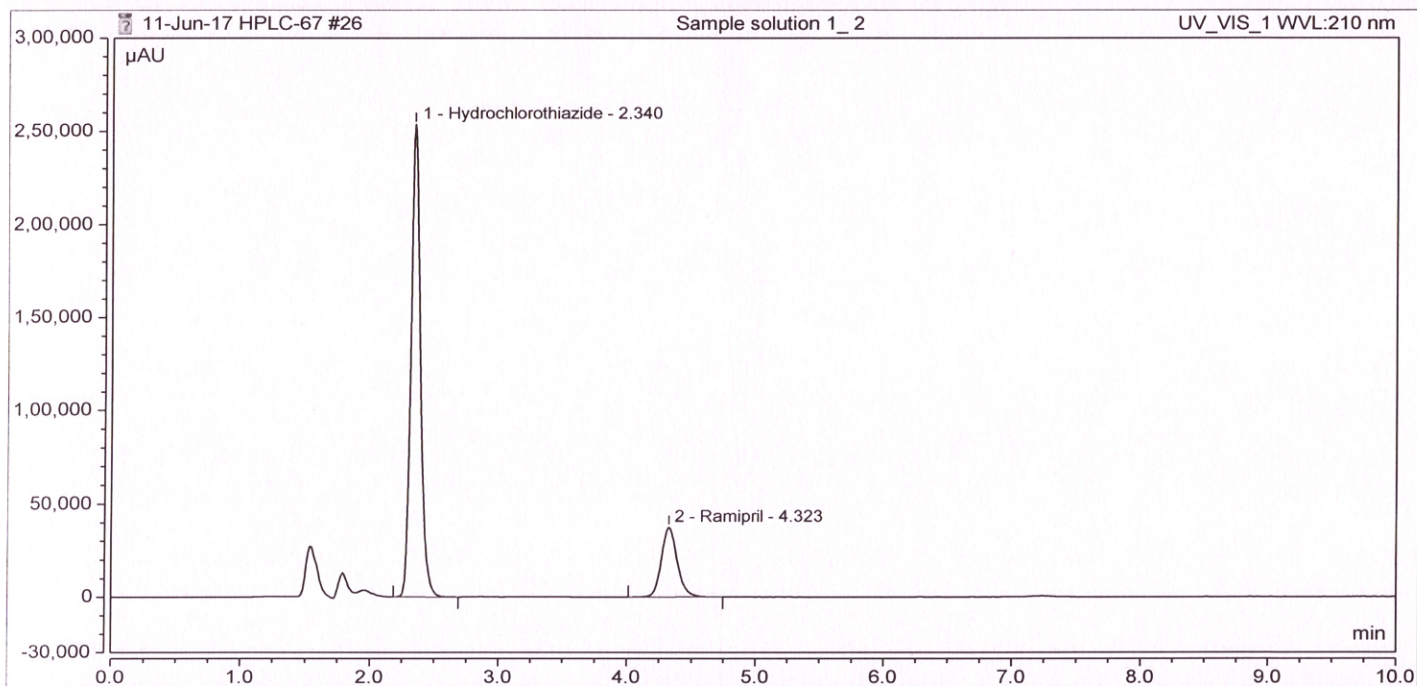
18-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Sample solution 1_ 2	Run Time (min):	10.00
Vial Number:	RA4	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay-Robustness (-) flow HPLC_	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution FR Decrease PR	Dilution Factor:	1.0000
Injection Date/Time:	11-Jun-17 23:48	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazide	2.340	21534.941	5253	1.34	208.4	80.28
2	Ramipril	4.323	5289.433	6369	1.18	341.5	19.72
Total:							

By
15 Jun 17

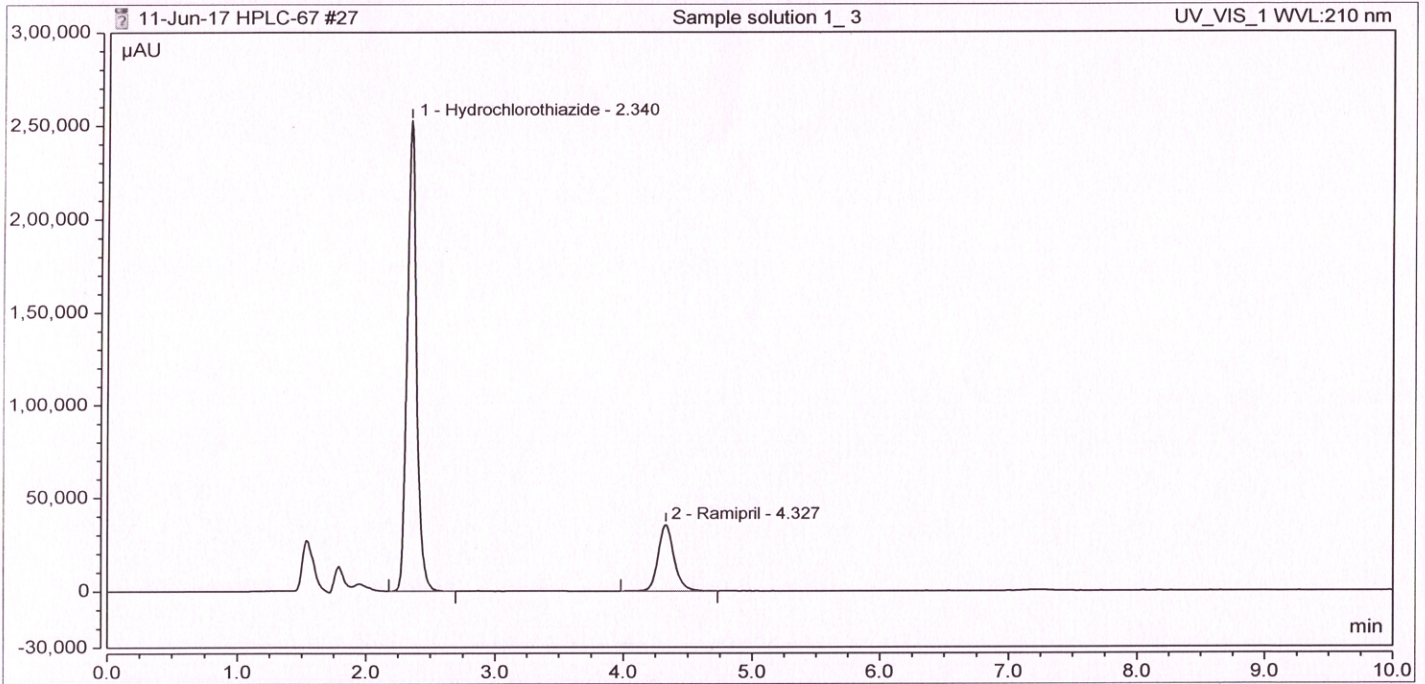
By
16 Jun 17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Sample solution 1_3	Run Time (min):	10.00
Vial Number:	RA5	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay-Robustness (-) flow HPLC_	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution FR Decrease PR	Dilution Factor:	1.0000
Injection Date/Time:	12-Jun-17 00:00	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

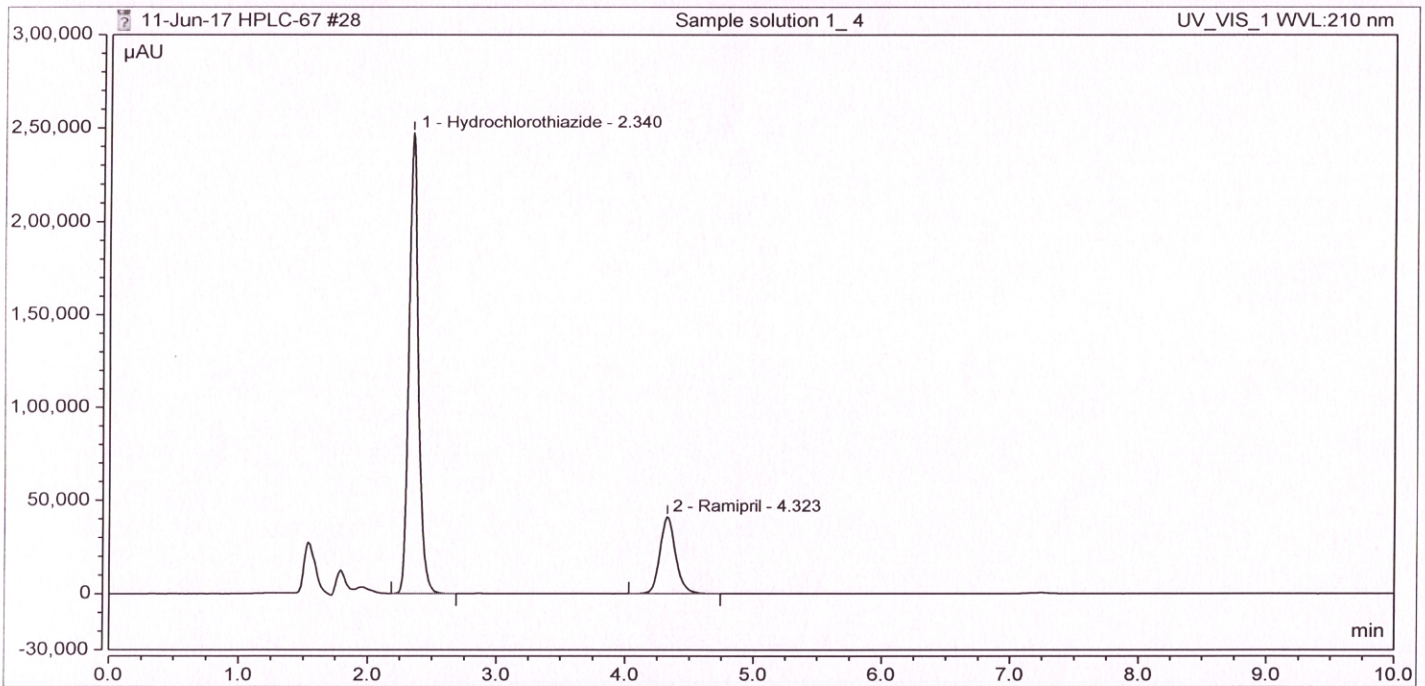
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazide	2.340	21259.473	5360	1.33	215.7	80.92
2	Ramipril	4.327	5012.056	6435	1.16	398.2	19.08
Total:							

QbD
15-Jun-17

QbD
16-Jun-17

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

Injection Name:	Sample solution 1_ 4	Run Time (min):	10.00
Vial Number:	RA6	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay-Robustness (-) flow HPLC_	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution FR Decrease PR	Dilution Factor:	1.0000
Injection Date/Time:	12-Jun-17 00:12	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram**Integration Results**

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazide	2.340	20955.135	5274	1.34	218.0	78.34
2	Ramipril	4.323	5793.806	6378	1.18	410.9	21.66
Total:							

Signature
12-Jun-17

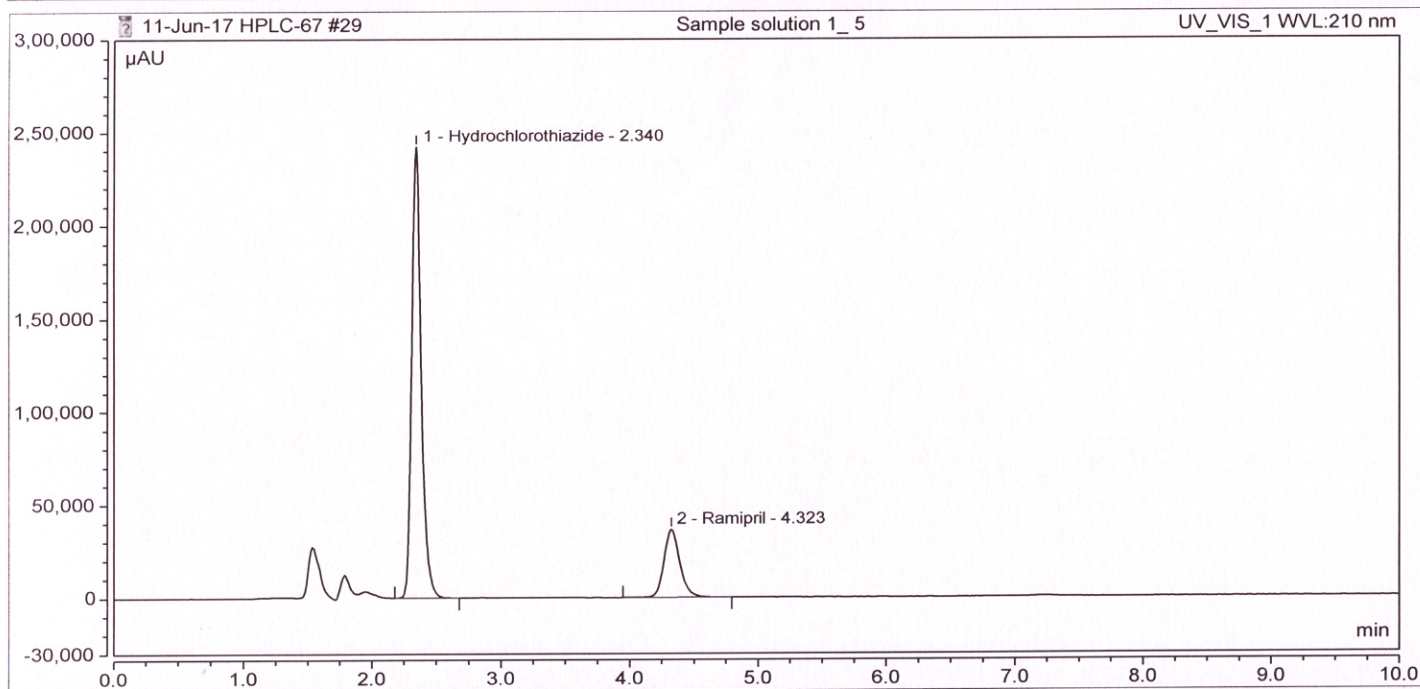
Signature
16-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Sample solution 1_ 5	Run Time (min):	10.00
Vial Number:	RA7	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay-Robustness (-) flow HPLC_	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution FR Decrease PR	Dilution Factor:	1.0000
Injection Date/Time:	12-Jun-17 00:23	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazide	2.340	20459.248	5324	1.33	215.7	79.88
2	Ramipril	4.323	5153.679	6412	1.18	355.4	20.12
Total:							

15-Jun-17

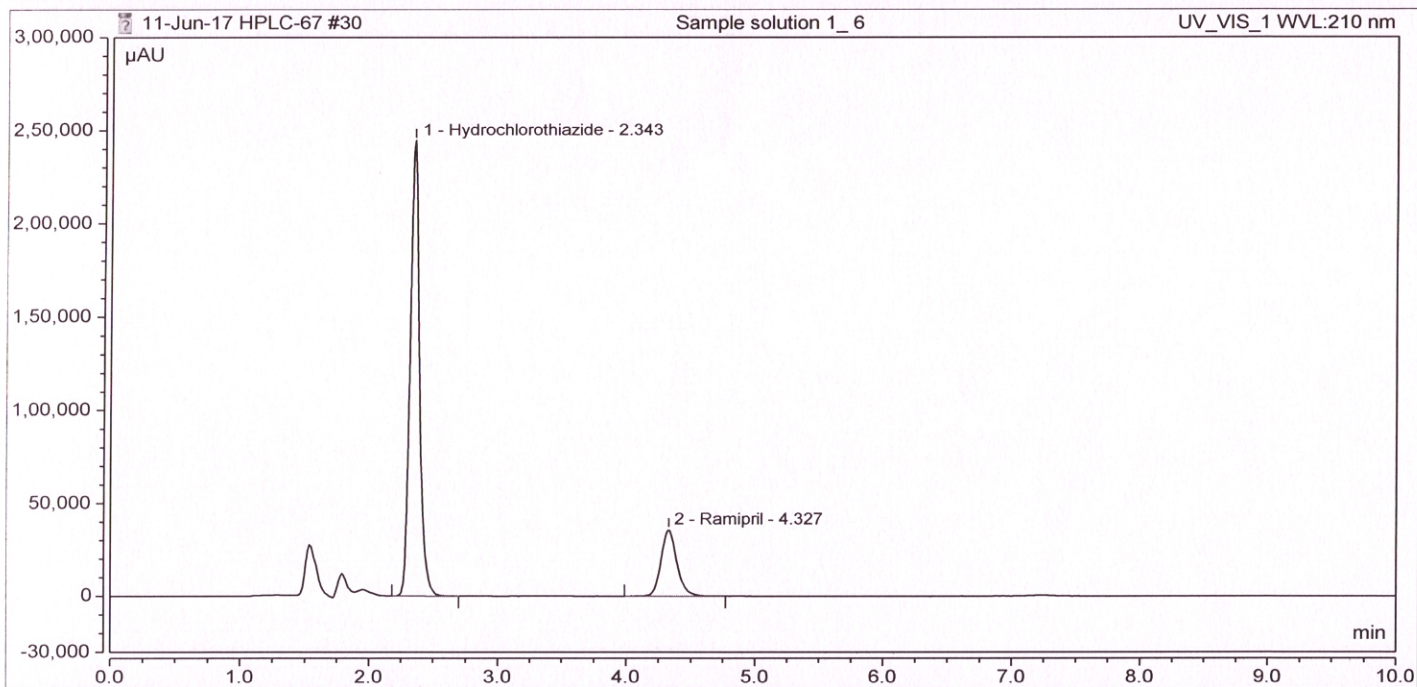
16-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Sample solution 1_ 6	Run Time (min):	10.00
Vial Number:	RA8	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay-Robustness (-) flow HPLC_	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution FR Decrease PR	Dilution Factor:	1.0000
Injection Date/Time:	12-Jun-17 00:35	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

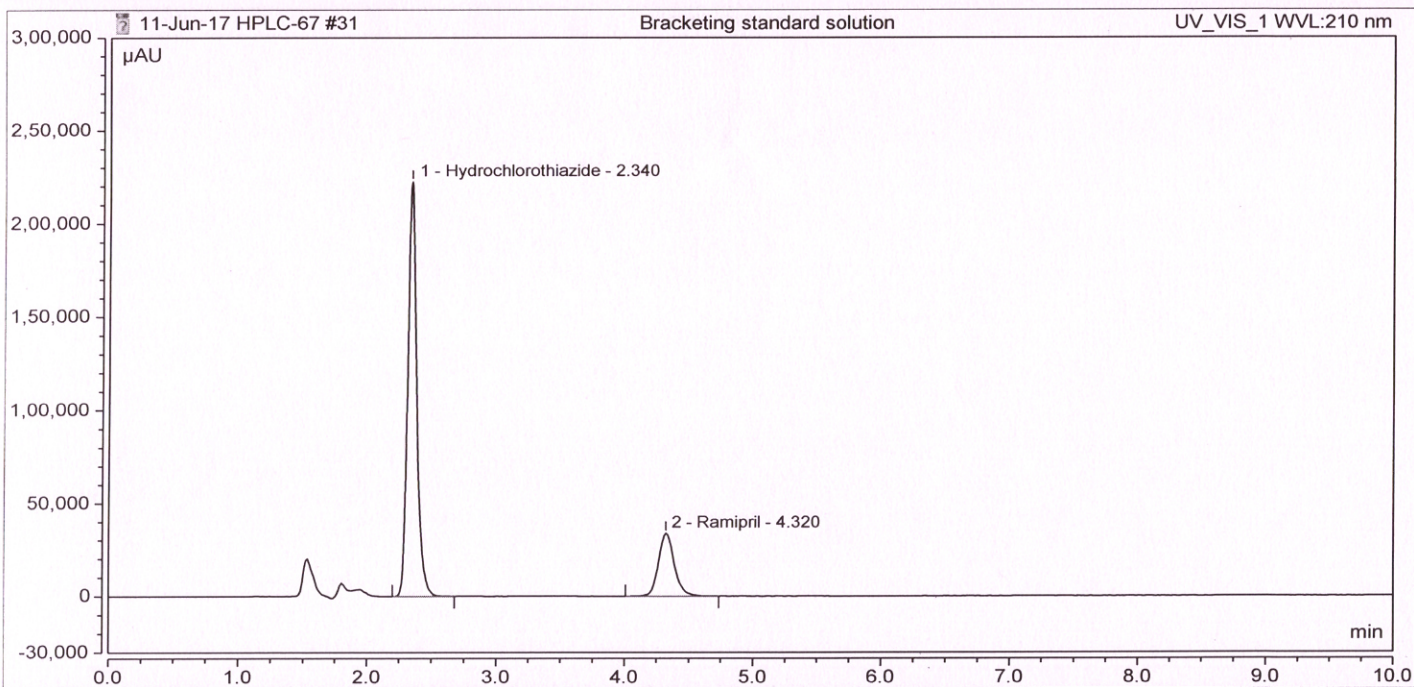
No.	Peak Name	Retention Time min	Area $\mu\text{AU} \cdot \text{min}$	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazide	2.343	20623.819	5340	1.29	226.9	80.34
2	Ramipril	4.327	5047.462	6374	1.16	379.7	19.66
Total:							

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Bracketing standard solution	Run Time (min):	10.00
Vial Number:	RA2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay-Robustness (-) flow HPLC_	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution FR Decrease PR	Dilution Factor:	1.0000
Injection Date/Time:	12-Jun-17 00:47	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

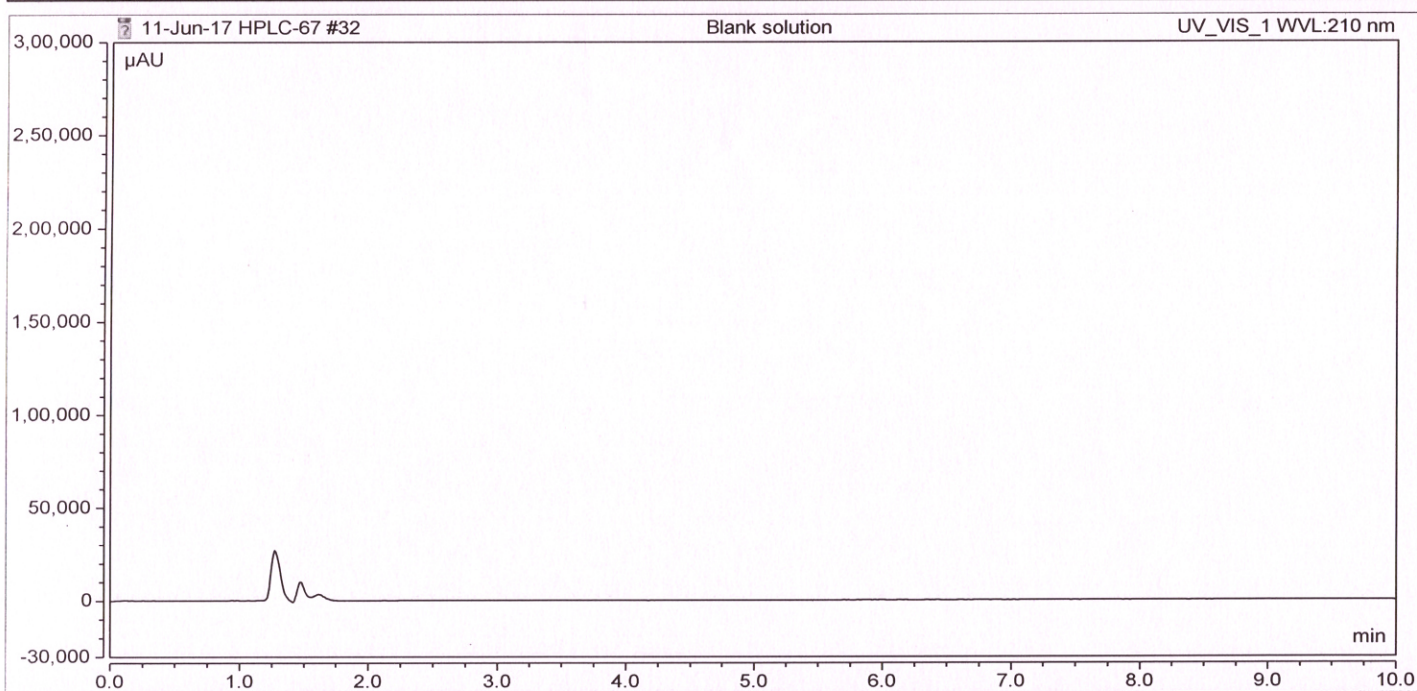
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazide	2.340	17844.272	5995	1.32	231.5	78.93
2	Ramipril	4.320	4763.138	6500	1.17	673.8	21.07
Total:							

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Blank solution	Run Time (min):	10.00
Vial Number:	RA1	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay-Robustness (+) flow HPLC_	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution FR Increase PR	Dilution Factor:	1.0000
Injection Date/Time:	12-Jun-17 00:59	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

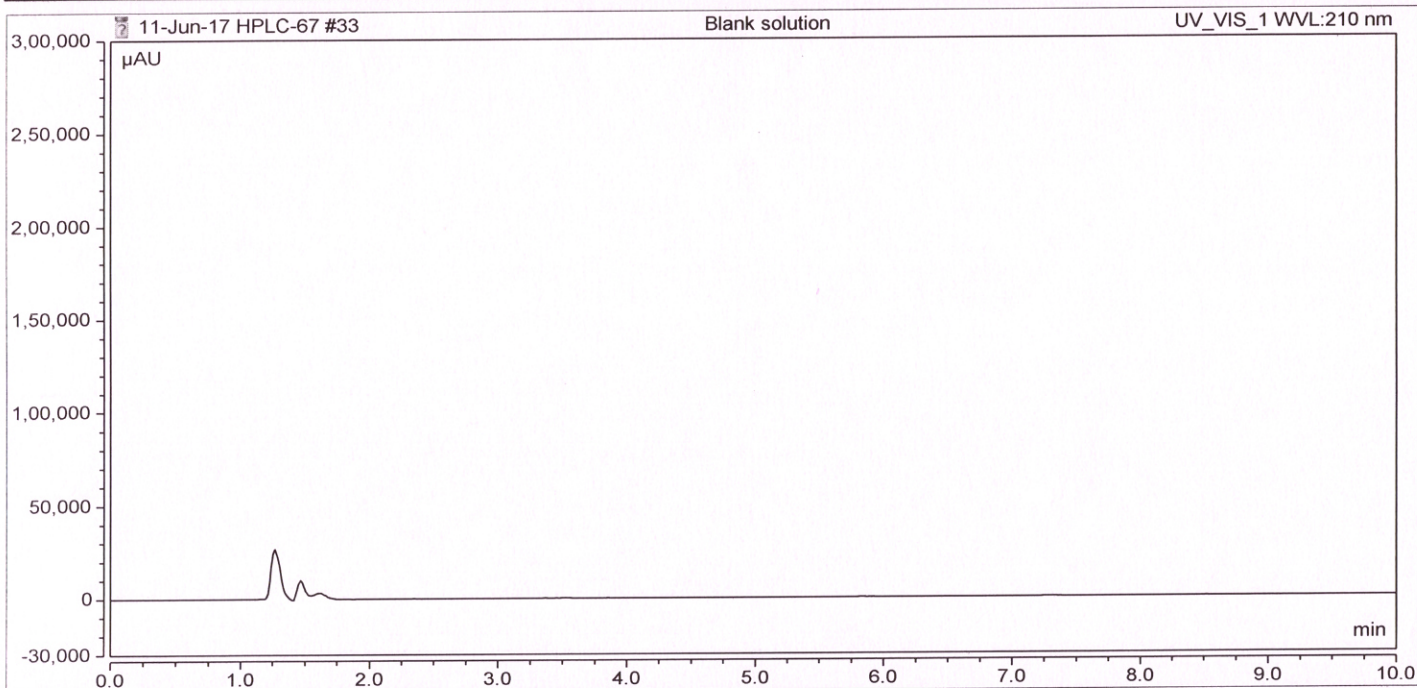
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
Total:							

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Blank solution	Run Time (min):	10.00
Vial Number:	RA1	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay-Robustness (+) flow HPLC_	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution FR Increase PR	Dilution Factor:	1.0000
Injection Date/Time:	12-Jun-17 01:10	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

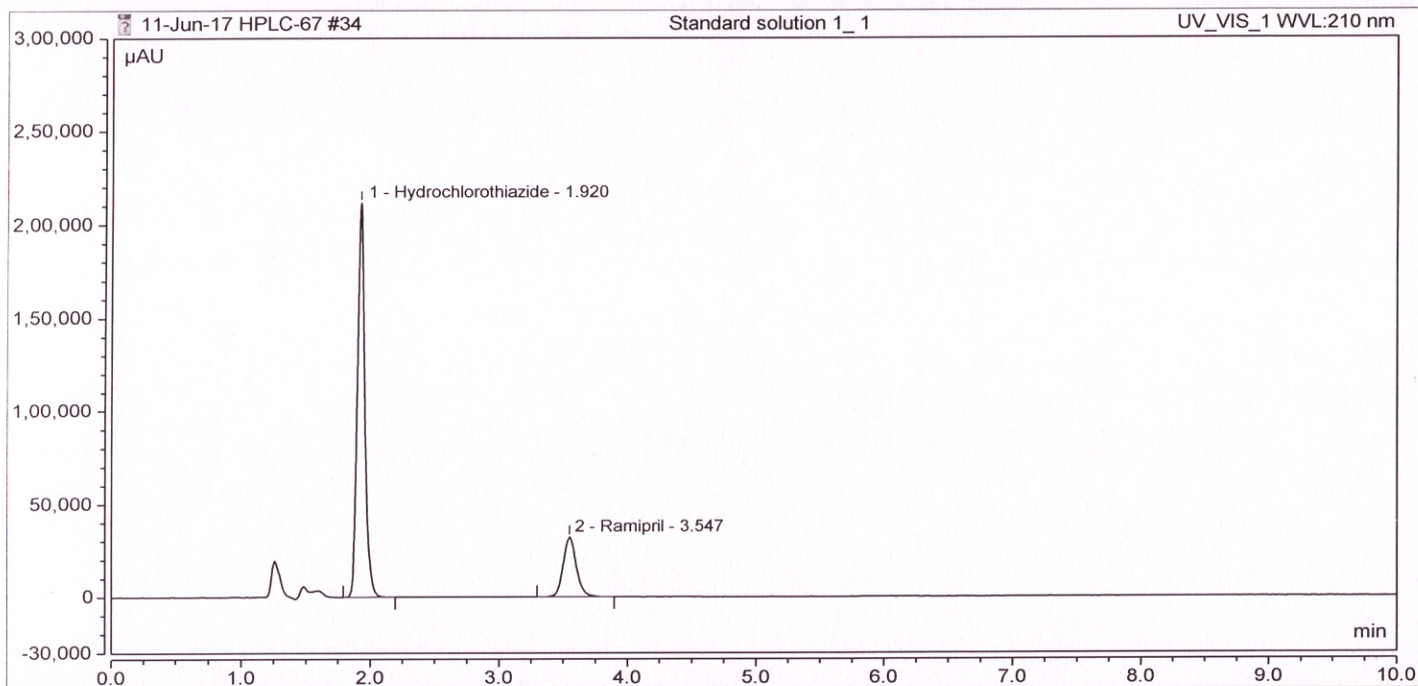
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
Total:							

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Standard solution 1_1	Run Time (min):	10.00
Vial Number:	RA2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay-Robustness (+) flow HPLC_	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution FR Increase PR	Dilution Factor:	1.0000
Injection Date/Time:	12-Jun-17 01:22	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

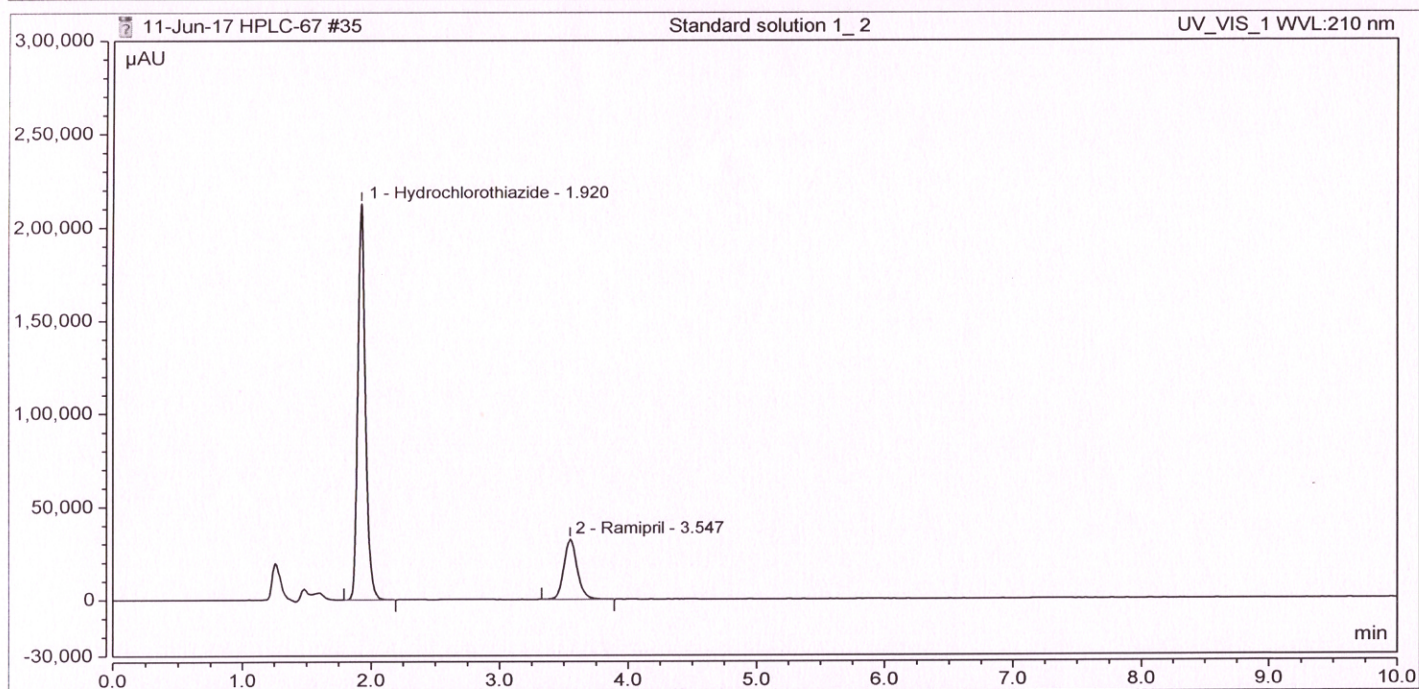
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazide	1.920	14409.197	5428	1.28	221.0	78.95
2	Ramipril	3.547	3840.955	5983	1.15	742.4	21.05
Total:							

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Standard solution 1_2	Run Time (min):	10.00
Vial Number:	RA2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay-Robustness (+) flow HPLC_	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution FR Increase PR	Dilution Factor:	1.0000
Injection Date/Time:	12-Jun-17 01:34	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

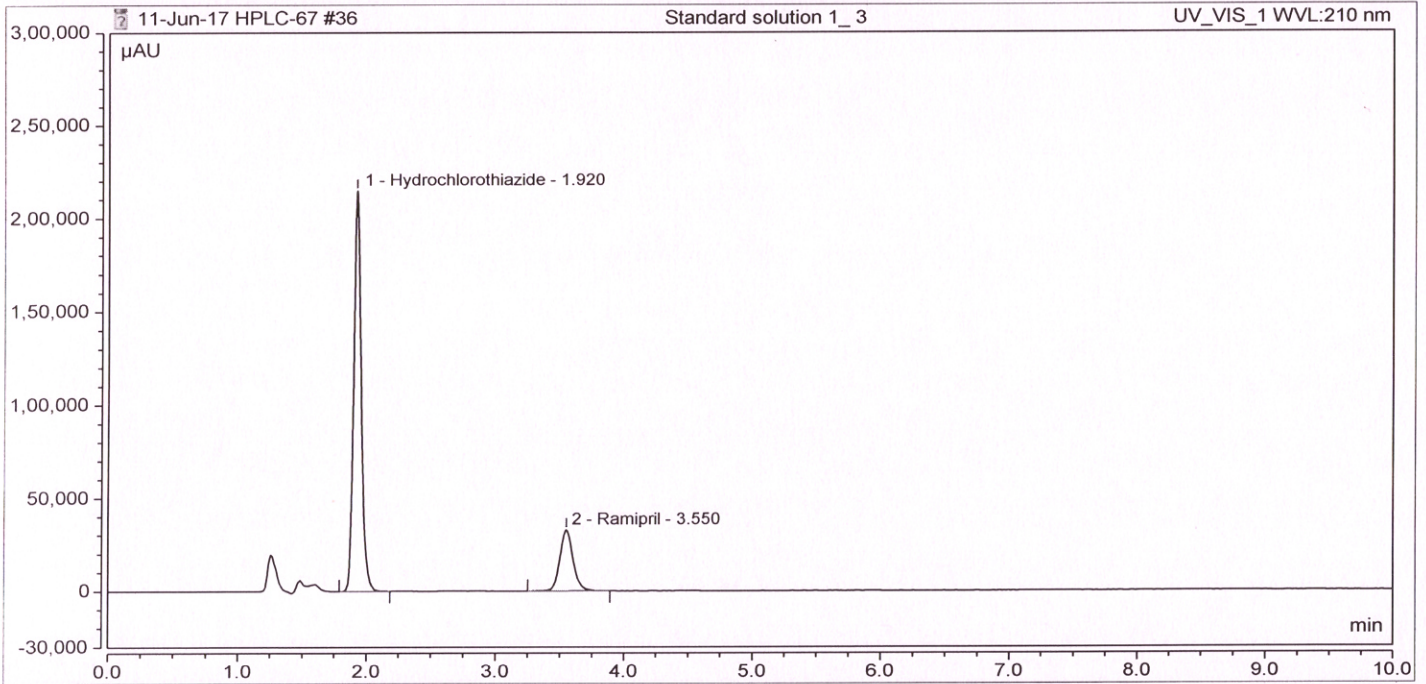
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazide	1.920	14546.271	5381	1.29	220.7	78.98
2	Ramipril	3.547	3871.573	5932	1.15	605.1	21.02
Total:							

QbD Research & Developement Pvt.Ltd.

Injection Details

Injection Name:	Standard solution 1_3	Run Time (min):	10.00
Vial Number:	RA2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay-Robustness (+) flow HPLC_	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution FR Increase PR	Dilution Factor:	1.0000
Injection Date/Time:	12-Jun-17 01:45	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

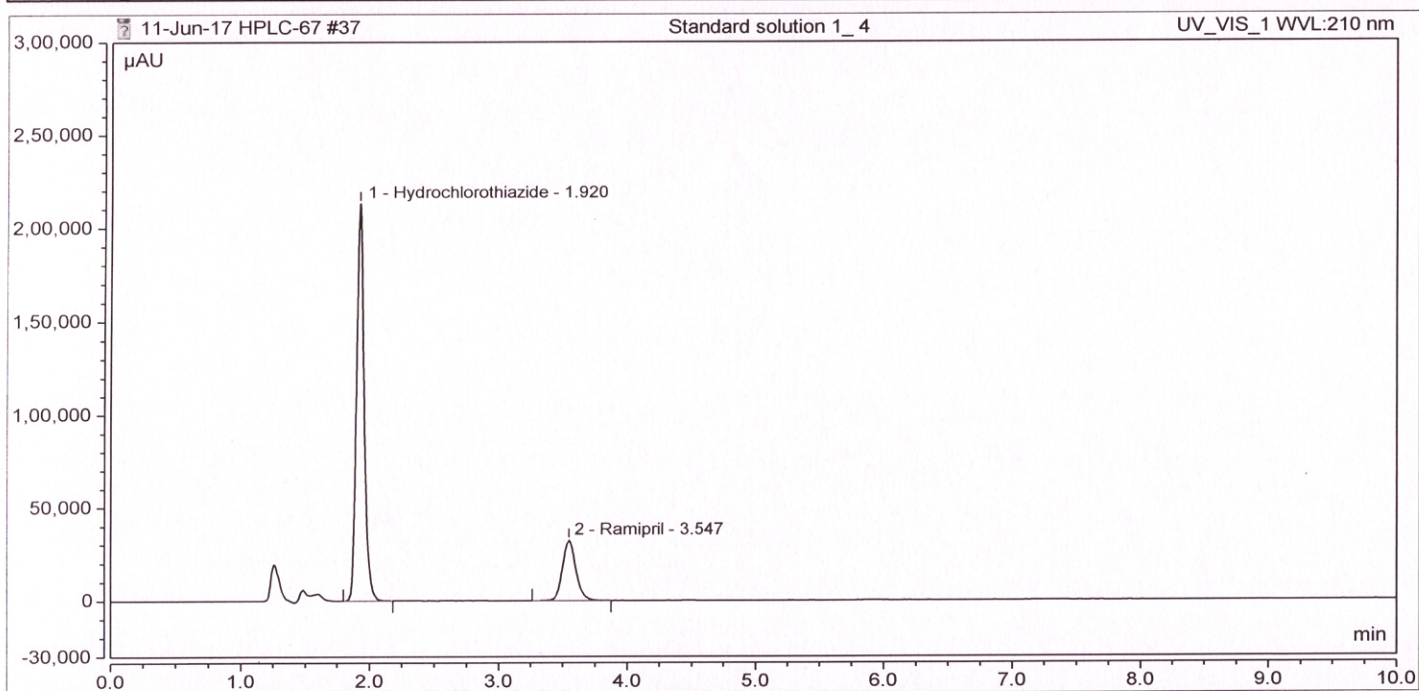
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazide	1.920	14573.800	5480	1.29	216.0	78.93
2	Ramipril	3.550	3890.064	6058	1.12	772.0	21.07
Total:							

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Standard solution 1_ 4	Run Time (min):	10.00
Vial Number:	RA2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay-Robustness (+) flow HPLC_	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution FR Increase PR	Dilution Factor:	1.0000
Injection Date/Time:	12-Jun-17 01:57	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

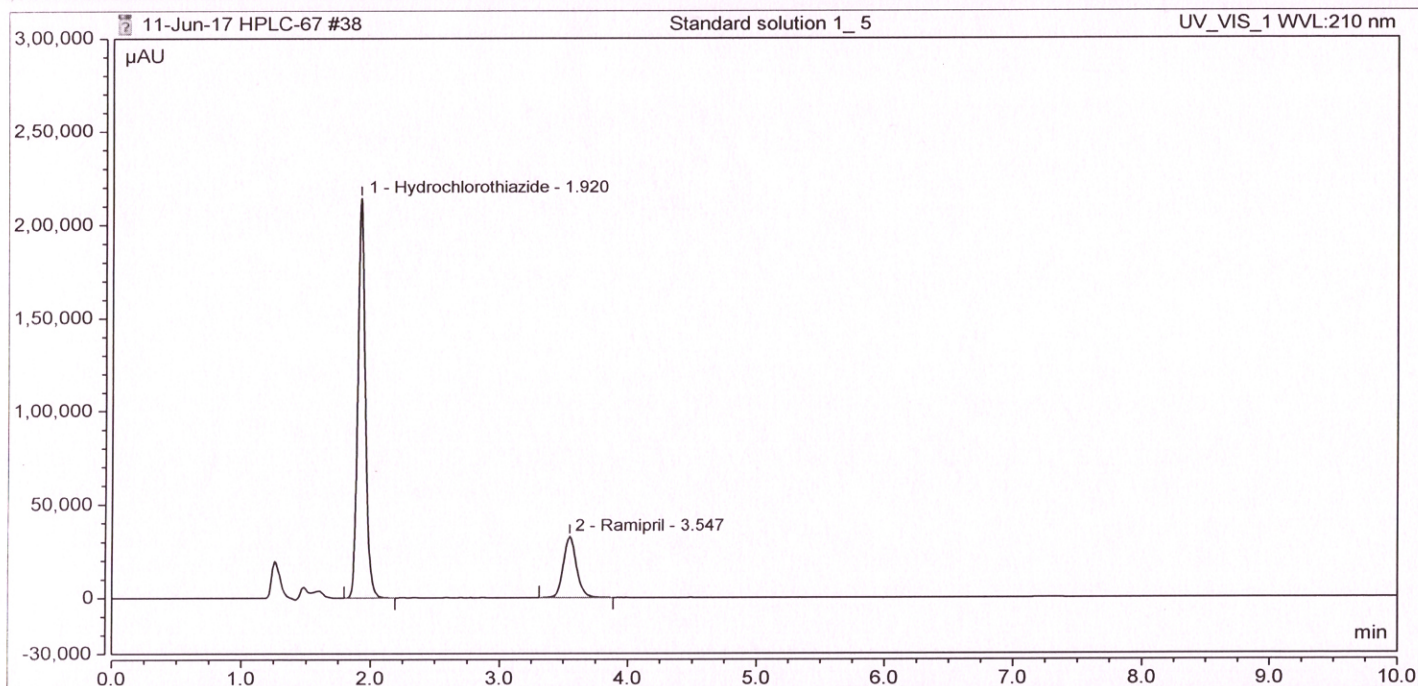
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazide	1.920	14536.461	5407	1.29	210.0	78.93
2	Ramipril	3.547	3880.312	5946	1.14	520.9	21.07
Total:							

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Standard solution 1_ 5	Run Time (min):	10.00
Vial Number:	RA2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay-Robustness (+) flow HPLC_	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution FR Increase PR	Dilution Factor:	1.0000
Injection Date/Time:	12-Jun-17 02:09	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

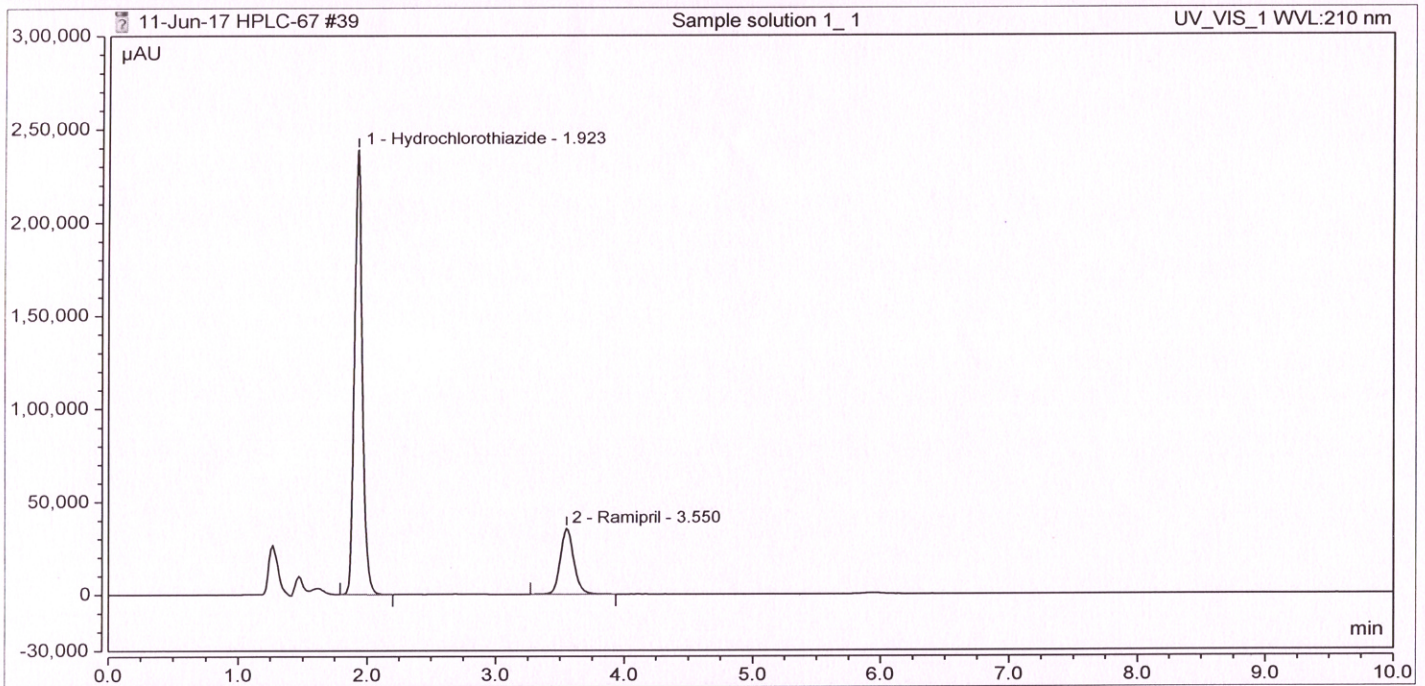
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazide	1.920	14587.097	5454	1.27	212.5	78.92
2	Ramipril	3.547	3896.581	6010	1.14	679.0	21.08
Total:							

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Sample solution 1_ 1	Run Time (min):	10.00
Vial Number:	RA3	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay-Robustness (+) flow HPLC_	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution FR Increase PR	Dilution Factor:	1.0000
Injection Date/Time:	12-Jun-17 02:20	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram

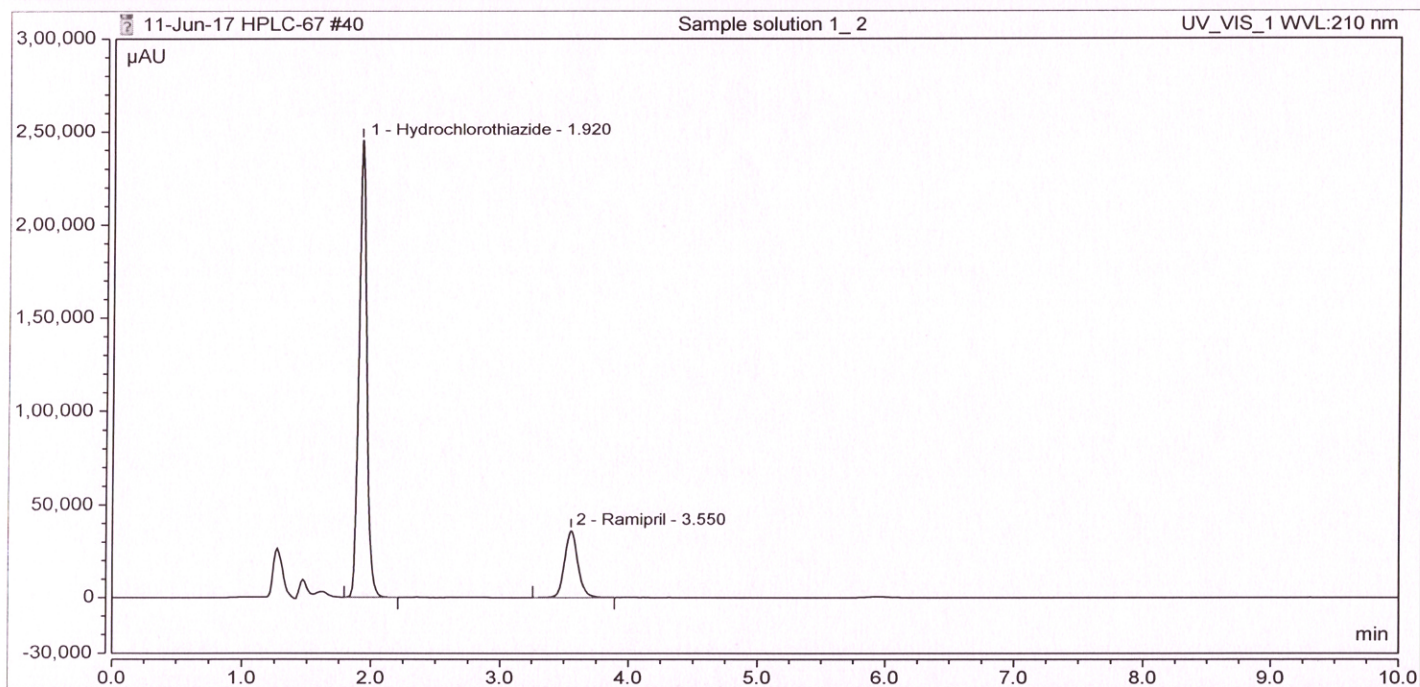


Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazide	1.923	17101.767	4881	1.24	345.7	79.97
2	Ramipril	3.550	4282.835	5907	1.15	282.3	20.03
Total:							

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

Injection Name:	Sample solution 1_ 2	Run Time (min):	10.00
Vial Number:	RA4	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay-Robustness (+) flow HPLC_	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution FR Increase PR	Dilution Factor:	1.0000
Injection Date/Time:	12-Jun-17 02:32	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram**Integration Results**

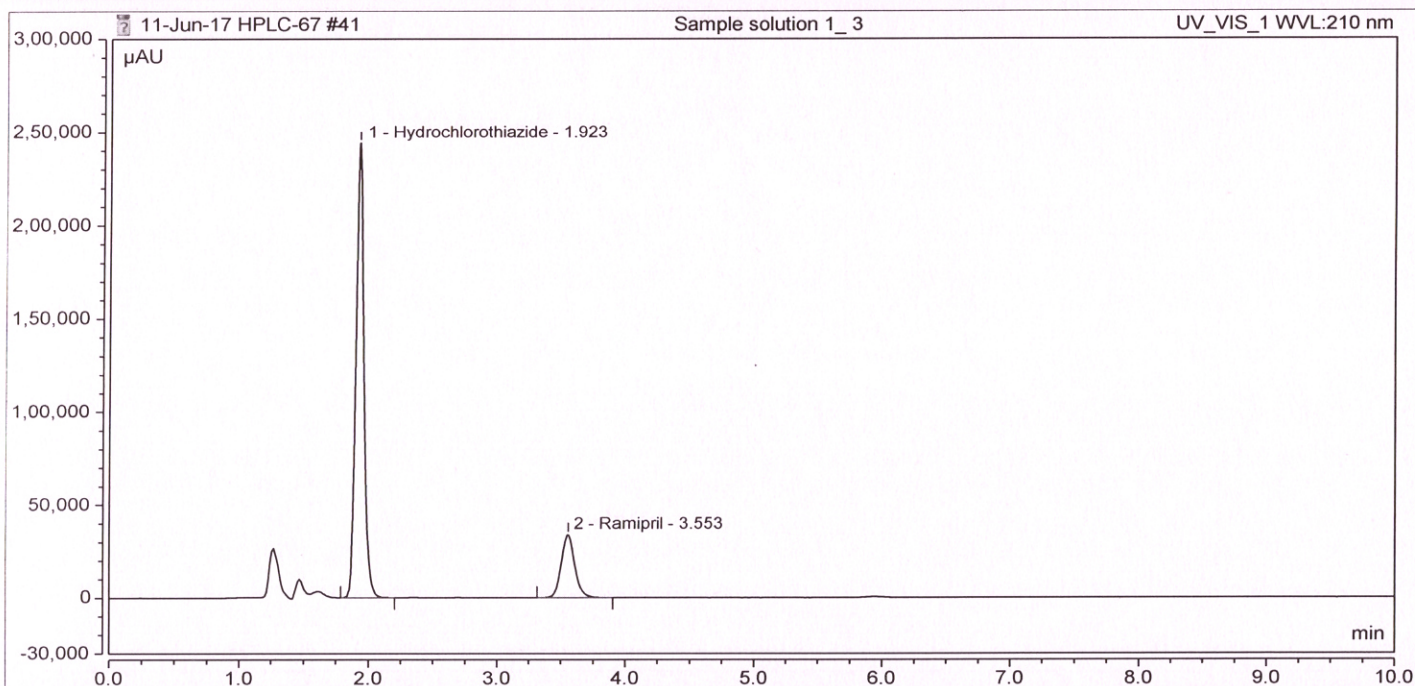
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazide	1.920	17587.600	4848	1.30	394.2	80.22
2	Ramipril	3.550	4337.566	5960	1.16	357.8	19.78
Total:							

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Sample solution 1_3	Run Time (min):	10.00
Vial Number:	RA5	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay-Robustness (+) flow HPLC_	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution FR Increase PR	Dilution Factor:	1.0000
Injection Date/Time:	12-Jun-17 02:44	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazide	1.923	17415.607	4924	1.24	373.1	81.03
2	Ramipril	3.553	4076.178	5928	1.13	334.4	18.97
Total:							

15-Jun-17

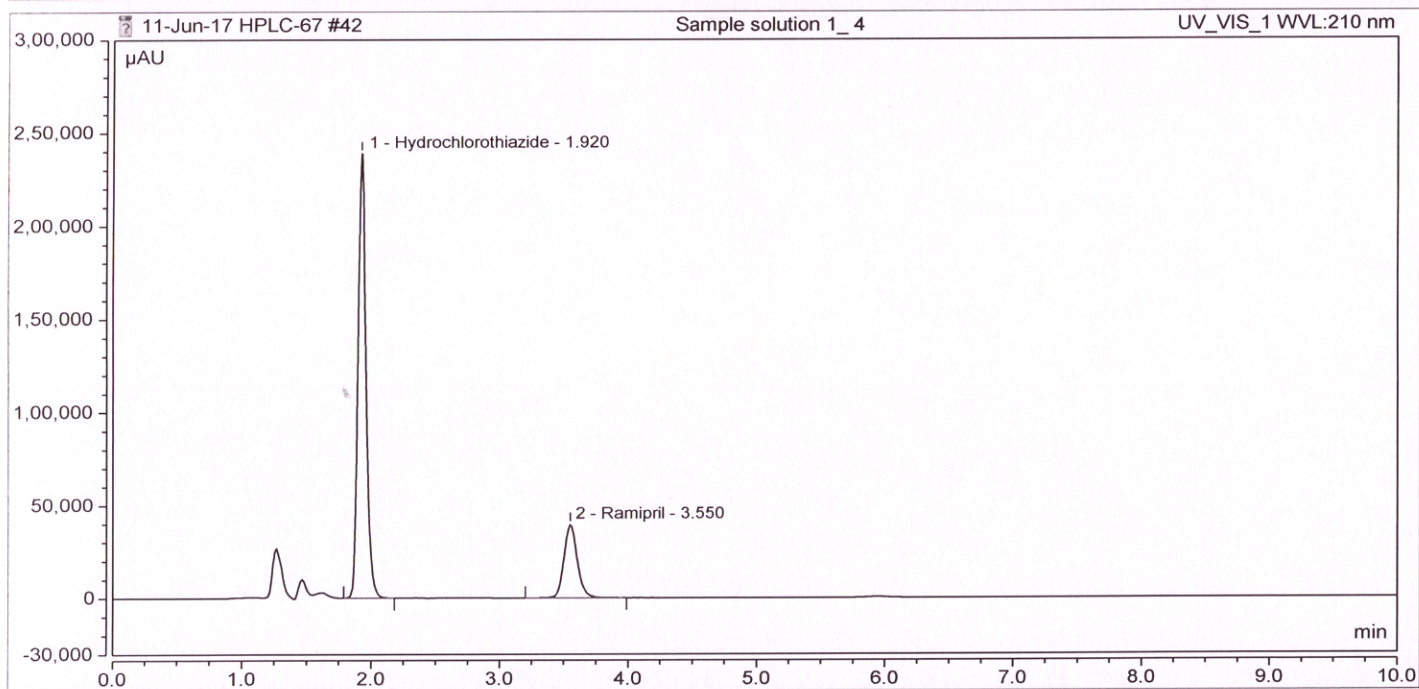
15-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Sample solution 1_4	Run Time (min):	10.00
Vial Number:	RA6	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay-Robustness (+) flow HPLC_	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution FR Increase PR	Dilution Factor:	1.0000
Injection Date/Time:	12-Jun-17 02:55	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

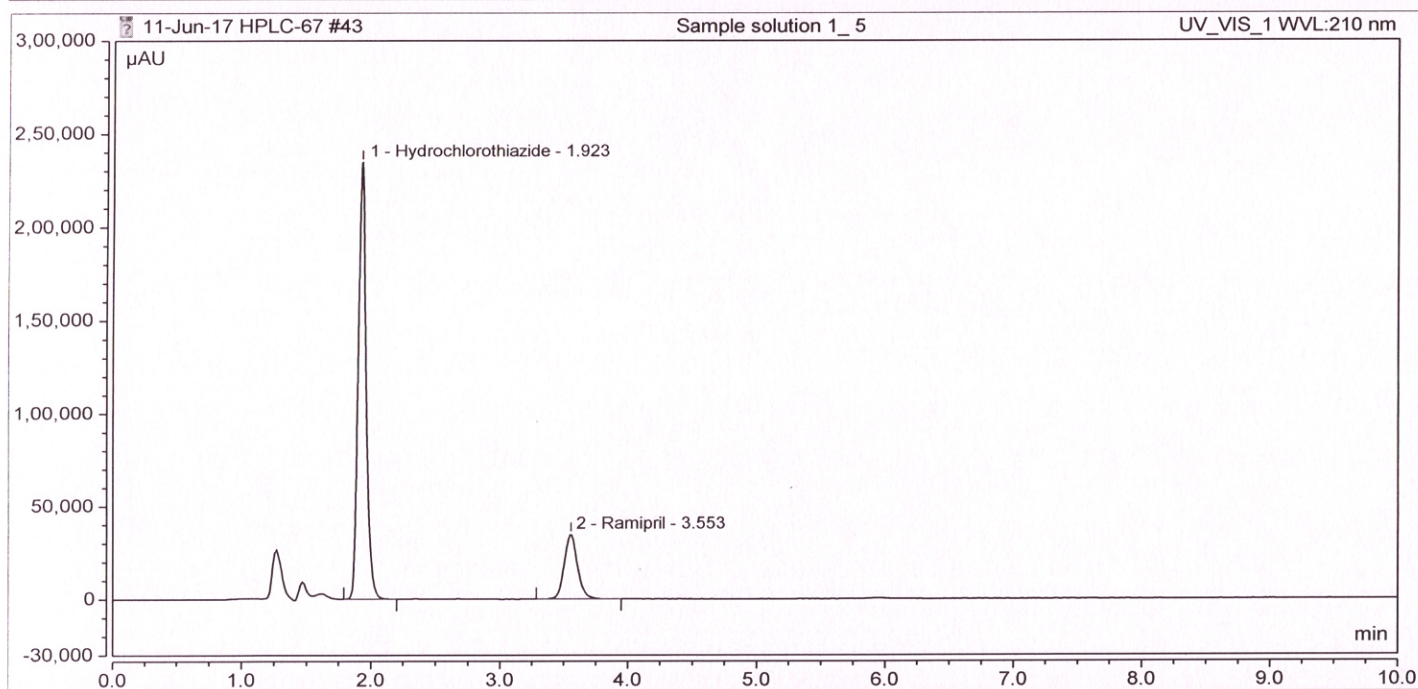
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazide	1.920	17162.485	4830	1.30	396.2	78.27
2	Ramipril	3.550	4763.683	5931	1.15	426.2	21.73
Total:							

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Sample solution 1_ 5	Run Time (min):	10.00
Vial Number:	RA7	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay-Robustness (+) flow HPLC_	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution FR Increase PR	Dilution Factor:	1.0000
Injection Date/Time:	12-Jun-17 03:07	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram

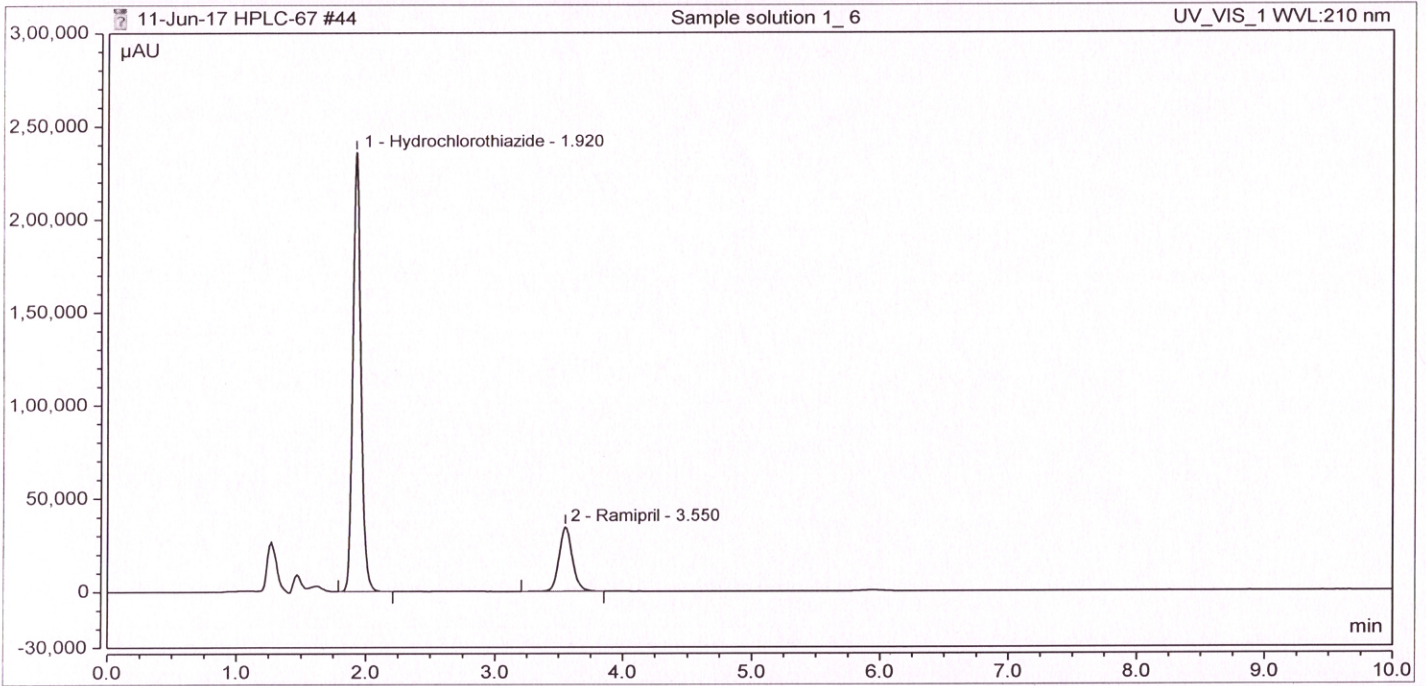


Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazide	1.923	16736.493	4939	1.25	370.6	79.98
2	Ramipril	3.553	4190.655	5925	1.13	336.8	20.02
Total:							

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

Injection Name:	Sample solution 1_ 6	Run Time (min):	10.00
Vial Number:	RA8	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay-Robustness (+) flow HPLC_	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution FR Increase PR	Dilution Factor:	1.0000
Injection Date/Time:	12-Jun-17 03:19	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram**Integration Results**

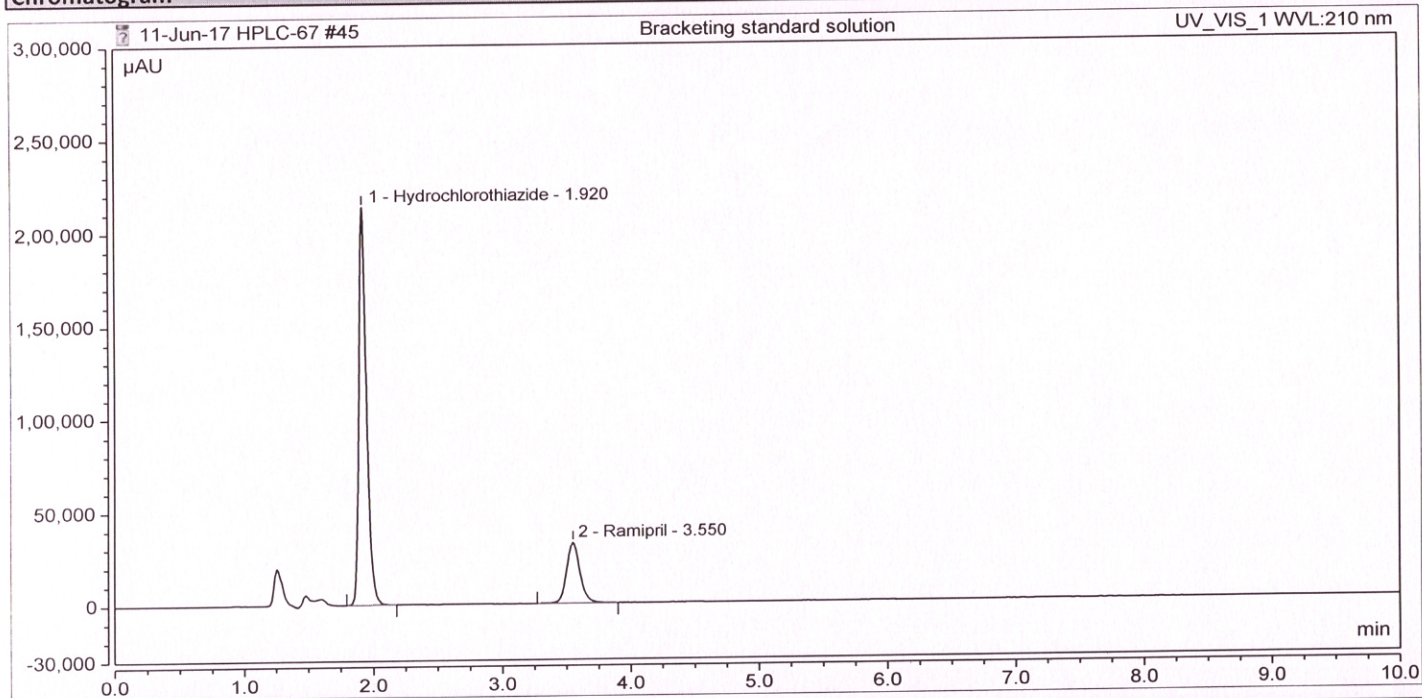
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazide	1.920	16921.581	4841	1.30	395.6	80.32
2	Ramipril	3.550	4147.267	5933	1.15	435.7	19.68
Total:							

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Bracketing standard solution	Run Time (min):	10.00
Vial Number:	RA2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay-Robustness (+) flow HPLC_	Bandwidth:	1
Processing Method:	Ramithiazide Dissolution FR Increase PR	Dilution Factor:	1.0000
Injection Date/Time:	12-Jun-17 03:31	Sample Weight:	1.0000
User Name:	Avinash Patil	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area $\mu\text{AU} \cdot \text{min}$	Plates (USP)	Asymmetry (EP)	S/N	Rel.Area %
1	Hydrochlorothiazide	1.920	14537.990	5446	1.29	214.9	78.95
2	Ramipril	3.550	3876.506	5970	1.12	633.9	21.05
Total:							

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15 Jun-17

V_VIS	Name	Type	Position	Volume [µl]	Instrument Method	Processing Method	Status	Inject Time
	Pre Blank	Unknown	RA1	10.000	Ramithiazide Dissolution	Ramithiazide Dissolution	Finished	11-Jun-2017 17:41
	Pre Blank	Unknown	RA1	10.000	Ramithiazide Dissolution	Ramithiazide Dissolution	Finished	11-Jun-2017 17:56
	Standard	Unknown	RA2	10.000	Ramithiazide Dissolution	Ramithiazide Dissolution	Finished	11-Jun-2017 18:08
None	Blank solution	Unknown	RA1	10.000	Ramithiazide Dissolution	Ramithiazide Dissolution	Idle	
None	Standard solution 1_1	Unknown	RA2	10.000	Ramithiazide Dissolution	Ramithiazide Dissolution	Idle	
None	Standard solution 1_2	Unknown	RA2	10.000	Ramithiazide Dissolution	Ramithiazide Dissolution	Idle	
None	Standard solution 1_3	Unknown	RA2	10.000	Ramithiazide Dissolution	Ramithiazide Dissolution	Idle	
None	Standard solution 1_4	Unknown	RA2	10.000	Ramithiazide Dissolution	Ramithiazide Dissolution	Idle	
None	Standard solution 1_5	Unknown	RA2	10.000	Ramithiazide Dissolution	Ramithiazide Dissolution	Idle	
None	Sample solution 1_1	Unknown	RA3	10.000	Ramithiazide Dissolution	Ramithiazide Dissolution	Idle	
None	Sample solution 1_2	Unknown	RA4	10.000	Ramithiazide Dissolution	Ramithiazide Dissolution	Idle	
None	Sample solution 1_3	Unknown	RA5	10.000	Ramithiazide Dissolution	Ramithiazide Dissolution	Idle	
None	Sample solution 1_4	Unknown	RA6	10.000	Ramithiazide Dissolution	Ramithiazide Dissolution	Idle	
None	Sample solution 1_5	Unknown	RA7	10.000	Ramithiazide Dissolution	Ramithiazide Dissolution	Idle	
None	Sample solution 1_6	Unknown	RA8	10.000	Ramithiazide Dissolution	Ramithiazide Dissolution	Idle	
None	Bracketing standard solution	Unknown	RA2	10.000	Ramithiazide Dissolution	Ramithiazide Dissolution	Idle	
None	Blank solution	Unknown	RA1	10.000	Ramithiazide Assay-Robu	Ramithiazide Dissolution	Idle	
None	Blank solution	Unknown	RA1	10.000	Ramithiazide Assay-Robu	Ramithiazide Dissolution	Idle	
None	Standard solution 1_1	Unknown	RA2	10.000	Ramithiazide Assay-Robu	Ramithiazide Dissolution	Idle	
None	Standard solution 1_2	Unknown	RA2	10.000	Ramithiazide Assay-Robu	Ramithiazide Dissolution	Idle	
None	Standard solution 1_3	Unknown	RA2	10.000	Ramithiazide Assay-Robu	Ramithiazide Dissolution	Idle	
None	Standard solution 1_4	Unknown	RA2	10.000	Ramithiazide Assay-Robu	Ramithiazide Dissolution	Idle	
None	Standard solution 1_5	Unknown	RA2	10.000	Ramithiazide Assay-Robu	Ramithiazide Dissolution	Idle	
None	Sample solution 1_1	Unknown	RA3	10.000	Ramithiazide Assay-Robu	Ramithiazide Dissolution	Idle	

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Avinash Patil

None	2 Sample solution 1_2	Unknown	RA4	10.000	Ramithiazide Assay-Robu	Ramithiazide Dissolution	Idle
None	2 Sample solution 1_3	Unknown	RA5	10.000	Ramithiazide Assay-Robu	Ramithiazide Dissolution	Idle
None	2 Sample solution 1_4	Unknown	RA6	10.000	Ramithiazide Assay-Robu	Ramithiazide Dissolution	Idle
None	2 Sample solution 1_5	Unknown	RA7	10.000	Ramithiazide Assay-Robu	Ramithiazide Dissolution	Idle
None	2 Sample solution 1_6	Unknown	RA8	10.000	Ramithiazide Assay-Robu	Ramithiazide Dissolution	Idle
None	2 Bracketing standard solution	Unknown	RA2	10.000	Ramithiazide Assay-Robu	Ramithiazide Dissolution	Idle
None	2 Blank solution	Unknown	RA1	10.000	Ramithiazide Assay-Robu	Ramithiazide Dissolution	Idle
None	2 Blank solution	Unknown	RA1	10.000	Ramithiazide Assay-Robu	Ramithiazide Dissolution	Idle
None	2 Standard solution 1_1	Unknown	RA2	10.000	Ramithiazide Assay-Robu	Ramithiazide Dissolution	Idle
None	2 Standard solution 1_2	Unknown	RA2	10.000	Ramithiazide Assay-Robu	Ramithiazide Dissolution	Idle
None	2 Standard solution 1_3	Unknown	RA2	10.000	Ramithiazide Assay-Robu	Ramithiazide Dissolution	Idle
None	2 Standard solution 1_4	Unknown	RA2	10.000	Ramithiazide Assay-Robu	Ramithiazide Dissolution	Idle
None	2 Standard solution 1_5	Unknown	RA2	10.000	Ramithiazide Assay-Robu	Ramithiazide Dissolution	Idle
None	2 Sample solution 1_1	Unknown	RA3	10.000	Ramithiazide Assay-Robu	Ramithiazide Dissolution	Idle
None	2 Sample solution 1_2	Unknown	RA4	10.000	Ramithiazide Assay-Robu	Ramithiazide Dissolution	Idle
None	2 Sample solution 1_3	Unknown	RA5	10.000	Ramithiazide Assay-Robu	Ramithiazide Dissolution	Idle
None	2 Sample solution 1_4	Unknown	RA6	10.000	Ramithiazide Assay-Robu	Ramithiazide Dissolution	Idle
None	2 Sample solution 1_5	Unknown	RA7	10.000	Ramithiazide Assay-Robu	Ramithiazide Dissolution	Idle
None	2 Sample solution 1_6	Unknown	RA8	10.000	Ramithiazide Assay-Robu	Ramithiazide Dissolution	Idle
None	2 Bracketing standard solution	Unknown	RA2	10.000	Ramithiazide Assay-Robu	Ramithiazide Dissolution	Idle

11-Jun-17
Avinash Patil

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[illegible]

Admission

[illegible]

11-11-2017

~~11/11/2020~~

Name **Ramithiazide Assay-Robustness (-) flow HPLC_ 67**
Data Vault **QbD_2017**
Path **chrom://qbdser03/QbD_2017/Method Validation/Generic Health
Care/Ramithiazide Tablets/Dissolution/11-Jun-17 HPLC-
67.seq/Ramithiazide Assay-Robustness (-) flow HPLC_
67.instmeth**
Comment **Ramithiazide**
Description
Run time **10.000 [min]**
Instrument **QbD-INST-HPLC-67 on qbd-pc-19**
Created **15-May-2017 18:22 +05:30 Santosh Padmere**
Last Update **03-Jun-2017 22:50 +05:30 Sachin Pujari**

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11-Jun-17

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11-Jun-17

Stage	Time min	Command	Value	Comment
Instrument Setup				
	initial			
		DAD.3DFIELD.MinWavelength	190.0 [nm]	
		DAD.3DFIELD.MaxWavelength	400.0 [nm]	
		DAD.3DFIELD.BunchWidth	1 [nm]	
		DAD.ResponseTime	1.000 [s]	
		DAD.Data_Collection_Rate	5 [Hz]	
		ColumnOven.TempCtrl	On	
		ColumnOven.Temperature.Nominal	25.0 [°C]	
		ColumnOven.Temperature.LowerLimit	5.0 [°C]	
		ColumnOven.Temperature.UpperLimit	80.0 [°C]	
		ColumnOven.EquilibrationTime	0.5 [min]	
		ColumnOven.ReadyTempDelta	1.1 [°C]	
		ColumnOven.Column_A.ActiveColumn	No	
		ColumnOven.Column_A.SystemPressure	"Pump"	
		ColumnOven.Column_B.ActiveColumn	No	
		ColumnOven.Column_B.SystemPressure	"Pump"	
		Sampler.InjectWash	Both	
		Sampler.WashSpeed	20.000 [µl/s]	
		Sampler.WashVolume	200.000 [µl]	
		Sampler.SampleHeight	2.000 [mm]	
		Sampler.WasteSpeed	32.000 [µl/s]	
		Sampler.DispenseDelay	0.000 [s]	
		Sampler.DispSpeed	20.000 [µl/s]	
		Sampler.DrawSpeed	5.000 [µl/s]	
		Sampler.DrawDelay	3.000 [s]	
		Sampler.InjectMode	Normal	
		Sampler.PumpDevice	"Pump"	
		Sampler.SyncWithPump	On	
		Sampler.LoopWashFactor	2.000	
		Sampler.TempCtrl	On	
		Sampler.Temperature.Nominal	25.0 [°C]	
		Sampler.ReadyTempDelta	1.5 [°C]	
		Sampler.Temperature.LowerLimit	4.0 [°C]	
		Sampler.Temperature.UpperLimit	45.0 [°C]	
		PumpModule.Pump.%A.Equate	"%A"	
		PumpModule.Pump.%B.Equate	"%B"	
		PumpModule.Pump.%C.Equate	"%C"	
		PumpModule.Pump.%D.Equate	"%D"	
		PumpModule.Pump.Pressure.LowerLimit	0 [bar]	
		PumpModule.Pump.Pressure.UpperLimit	600 [bar]	
		PumpModule.Pump.MaximumFlowRampUp	6.000 [ml/min ²]	
		PumpModule.Pump.MaximumFlowRampDown	5.998 [ml/min ²]	
		DAD.UV_VIS_1.Wavelength	210.0 [nm]	
		DAD.UV_VIS_1.Bandwidth	1 [nm]	

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11-06-17

		DAD.UV_VIS_1.RefWavelength	Off
		DAD.UV_VIS_1.RefBandwidth	1 [nm]
		DAD.UV_VIS_2.RefWavelength	Off
		DAD.UV_VIS_3.RefWavelength	Off
		DAD.UV_VIS_2.Wavelength	230.0 [nm]
		DAD.UV_VIS_3.Wavelength	234.0 [nm]
		DAD.UV_VIS_2.Bandwidth	1 [nm]
		DAD.UV_VIS_3.Bandwidth	1 [nm]
		DAD.UV_VIS_2.RefBandwidth	1 [nm]
		DAD.UV_VIS_3.RefBandwidth	1 [nm]
		DAD.3DFIELD.RefWavelength	800.0 [nm]
		DAD.3DFIELD.RefBandwidth	1 [nm]
Inject Preparation	0.000	DAD.Autozero	
		Wait	DAD.Ready And ColumnOven.Re ady And Sampler.Ready And PumpModule.Pu mp.Ready
Inject	0.000		
		Sampler.Inject	
Start Run	0.000		
		DAD.UV_VIS_1.AcqOn	
		DAD.Temp_Lamphouse.AcqOn	
		ColumnOven.ColumnOven_Temp.AcqOn	
		PumpModule.Pump.Pump_Pressure.AcqOn	
		DAD.UV_VIS_2.AcqOn	
		DAD.UV_VIS_3.AcqOn	
		DAD.3DFIELD.AcqOn	
Run	0.000		Duration = 10.000 [min]
		PumpModule.Pump.Flow.Nominal	0.900 [ml/min]
		PumpModule.Pump.%B.Value	0.0 [%]
		PumpModule.Pump.%C.Value	0.0 [%]
		PumpModule.Pump.%D.Value	0.0 [%]
		PumpModule.Pump.Curve	5
	10.000		
		PumpModule.Pump.Flow.Nominal	0.900 [ml/min]
		PumpModule.Pump.%B.Value	0.0 [%]
		PumpModule.Pump.%C.Value	0.0 [%]
		PumpModule.Pump.%D.Value	0.0 [%]
		PumpModule.Pump.Curve	5
Stop Run	10.000		

Handwritten signature and date: 11-Jun-17

DAD.UV_VIS_1.AcqOff
DAD.Temp_Lamphouse.AcqOff
ColumnOven.ColumnOven_Temp.AcqOff
PumpModule.Pump.Pump_Pressure.AcqOf
f
DAD.UV_VIS_2.AcqOff
DAD.UV_VIS_3.AcqOff
DAD.3DFIELD.AcqOff
End

SP
11-Jun-17

SP
11-Jun-17