

ASSAY METHOD VALIDATION

Product name :	Ramithiazide Tablet
Content :	Ramipril and Hydrochlorothiazide
Parameter :	Forced Degradation
Avg.wt. (mg)	199.8
Label claim (mg)	25
B. No. :	GP170403
LNB No./Pg. No.:	419/060

Date: 12-Jun-17

Name of standard	Standard purity (%)	Standard wt (mg)	Dilution details (mL)	Conc (ppm)
Hydrochlorothiazide	99.8	25.11	50 mL; 5 mL->50 mL	50.2

Injection No.	Retention Time	Area of Standard	Retention Time	Area of Standard
1	2.146	26533.941	4.15	7131.027
2	2.144	26555.379	4.15	7078.064
3	2.144	26620.305	4.15	7124.869
4	2.140	26611.268	4.15	7131.529
5	3.312	26610.794	5.32	7109.973
6	2.140	26650.629	4.15	7131.090
Average	2.34	26597.053	4.34	7117.759
SD	0.48	43.64	0.48	21.12
%RSD	20.42	0.16	10.99	0.30
System suitability results of Hydrochlorothiazide				
% RSD of Area	0.16	NMT 2.0		
Tailing factor	1.06	NMT 2.0		
Theoretical plates	5235	NLT 2000		

Test Solution :	50 mg of sample	250.0	mL with Diluent
	Further	5 mL	25.0 mL with Diluent

Sample Type	Water content (%)	2.69	Residual solvent (%)	0.41	
	Sample Weight (mg)	Area of Sample	% Assay	% Degradation	Peak purity Match
Untreated sample	494.71	26437.902	100.6	NA	999
Acid treated sample (5 mL of 1N HCl, 20 min at 70°C)	493.79	26539.404	101.2	-0.6	999
Base treated sample (5 mL of 1N NaOH, 20 min at 70°C)	493.79	26555.589	101.2	-0.6	999
Hydrogen peroxide treated sample (5 mL of 30% H2O2, 20 min at 70°C)	494.31	26541.634	101.1	-0.5	999
Acid treated sample (2 mL of 1N HCl, 20 min at 70°C)	493.96	26502.271	101.0	-0.4	999
Base treated sample (2 mL of 1N NaOH, 20 min at 70°C)	494.26	26475.967	100.8	-0.2	999
Sample solution exposed to Heat	493.70	26918.472	102.6	-2.0	999

Done by:
Date:

21-Jun-17
Checked by:
Date:

19-Jun-17

ASSAY METHOD VALIDATION

Product name:	Ramithiazide Tablet
Content:	Ramipril and Hydrochlorothiazide
Parameter:	Forced Degradation
B. No.:	GP170403
Avg. wt. (mg)	199.8
Label claim (mg)	10
LNB No./Pg. No.:	419/060

Date: 12-Jun-17

Name of standard	Standard purity (%)	Standard wt (mg)	Dilution details (mL)	Conc (ppm)
Ramipril	99.8	25.09	25 mL, 2 mL → 100 mL	20.1

Injection No.	Retention Time	Area of Standard	Retention Time	Area of Standard
1	2.146	26533.941	4.146	7131.027
2	2.144	26555.379	4.151	7078.064
3	2.144	26620.305	4.151	7124.869
4	2.140	26611.268	4.147	7131.529
5	3.312	26610.794	5.318	7109.973
6	2.140	26650.629	4.147	7131.090
Average	2.34	26597.053	4.34	7117.759
SD	0.48	43.64	0.48	21.12
%RSD	20.42	0.16	10.99	0.30
System suitability results of Ramipril				
% RSD of Area	0.30	NMT 2.0		
Tailing factor	1.09	NMT 2.0		
Theoretical plates	6328	NLT 2000		

Test Solution :	25 mg of sample	250.0	mL with Diluent
	Further 5 ml	25.0	mL with Diluent

Sample Type	Sample Weight (mg)	Average Area of Sample	% Assay	% Degradation	Peak purity Match
Untreated sample	494.71	6990.951	99.3	NA	999
Acid treated sample (5 mL of 1N HCl, 20 min at 70°C)	493.79	6975.559	99.3	0.0	999
Base treated sample (5 mL of 1N NaOH, 20 min at 70°C)	493.79	6896.102	98.2	1.1	999
Hydrogen peroxide treated sample (5 mL of 30% H ₂ O ₂ , 20 min at 70°C)	494.31	6921.174	98.4	0.9	999
Acid treated sample (2 mL of 1N HCl, 20 min at 70°C)	493.96	6963.870	99.1	0.2	999
Base treated sample (2 mL of 1N NaOH, 20 min at 70°C)	494.26	6918.869	98.4	0.9	999
Sample solution exposed to Heat	493.70	7082.866	100.8	-1.5	999

Done by:
Date:

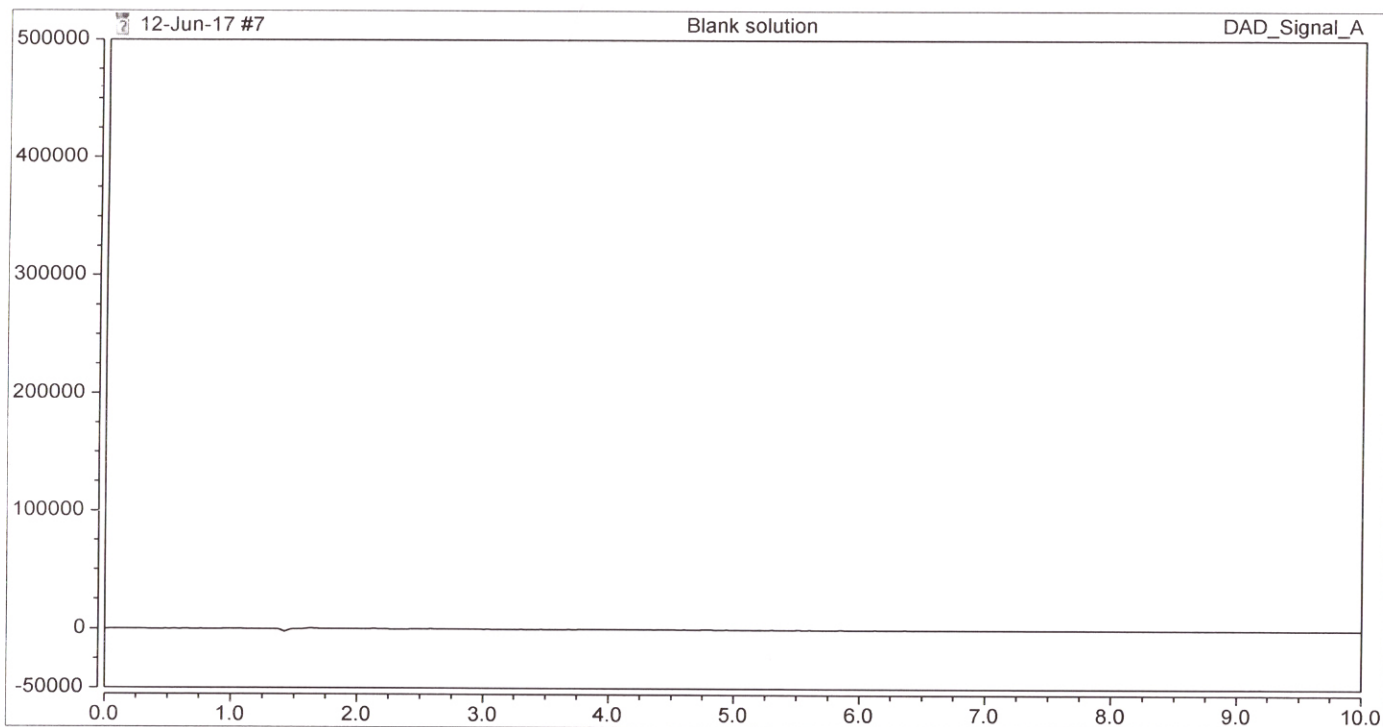
B. Manu
21-Jun-17

Checked by:
Date:

S. S. S. S.
21-Jun-17

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

Injection Name:	Blank solution	Run Time (min):	10.00
Vial Number:	Vial:1	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	12-Jun-17 22:03	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram**Integration Results**

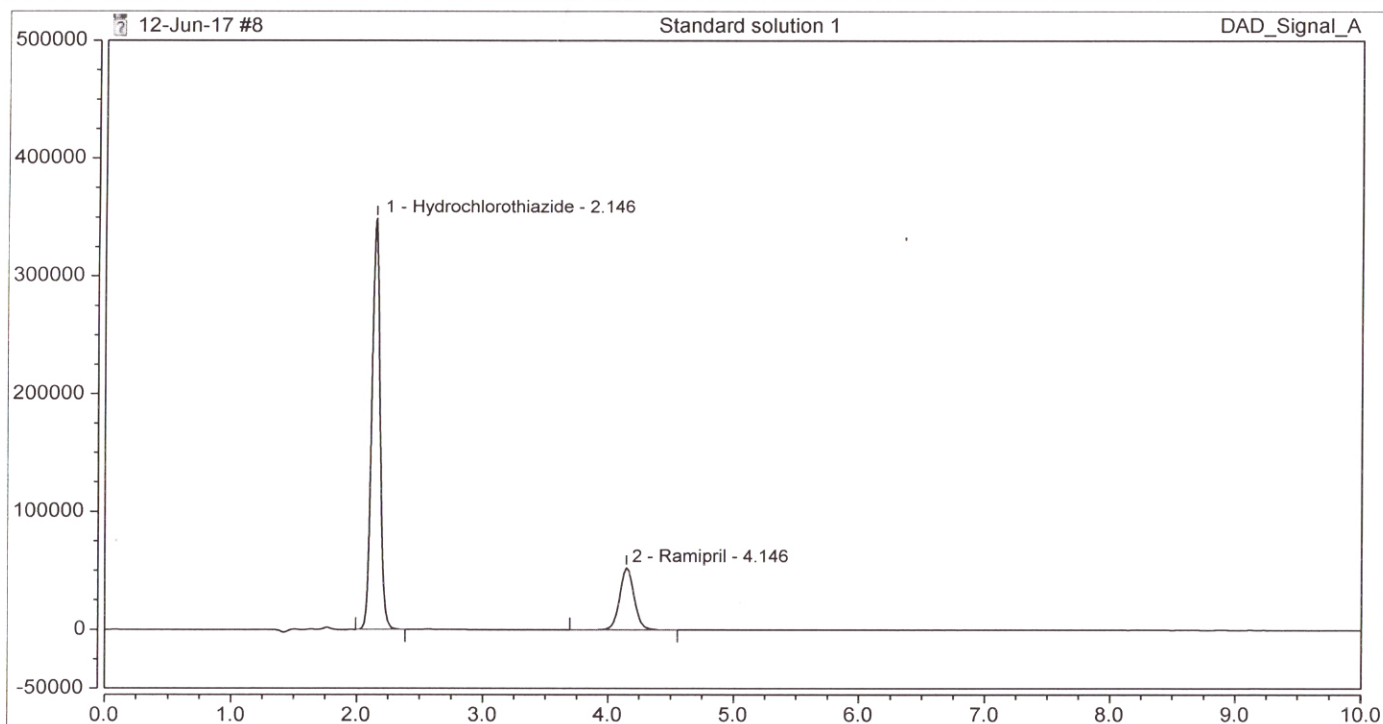
No.	Peak Name	Retention Time min	Area $\mu\text{AU} \cdot \text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
Total:							

Pankaj Gurav
21-Jun-17

Pankaj Gurav
21-Jun-17

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

Injection Name:	Standard solution 1	Run Time (min):	10.00
Vial Number:	Vial:2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	12-Jun-17 22:15	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	2.146	26533.941	5235	1.06	12.23	78.82
2	Ramipril	4.146	7131.027	6328	1.09	n.a.	21.18
Total:							

Pankaj Gurav
21-Jun-17

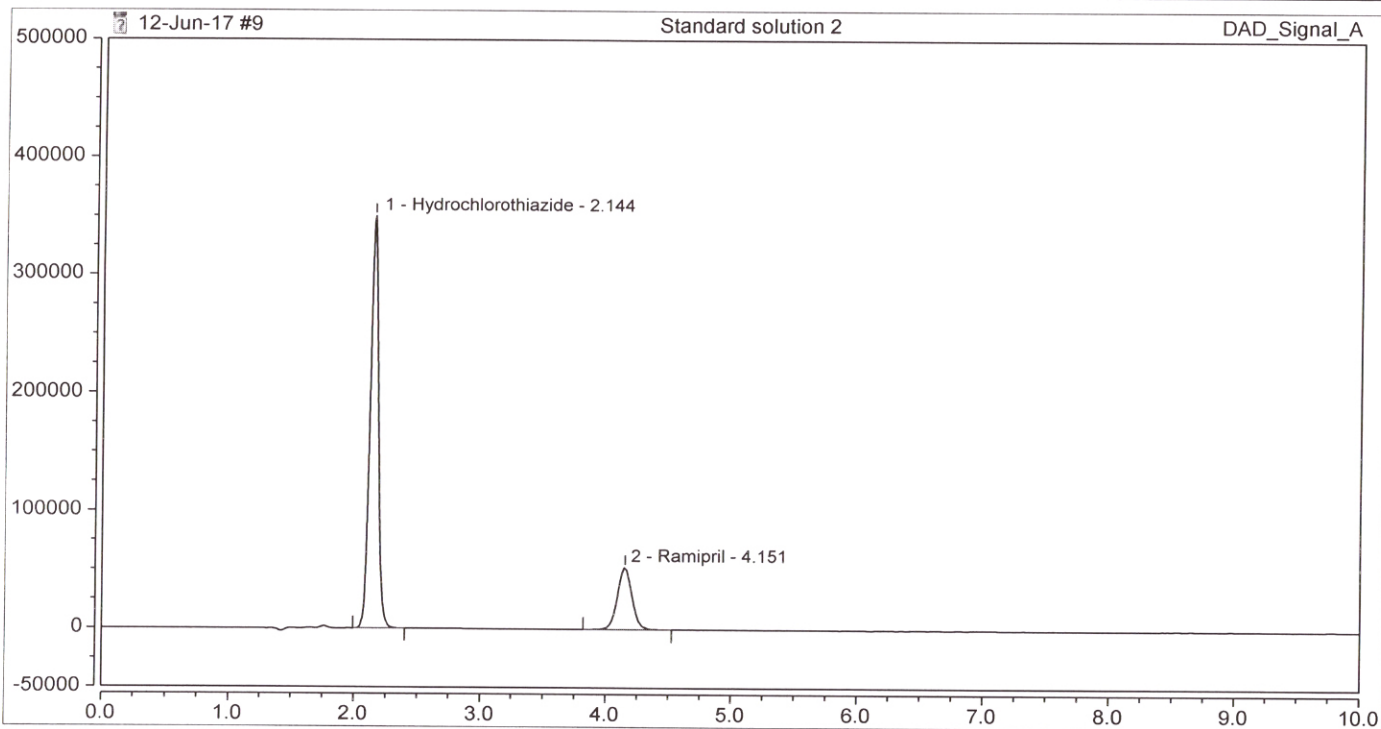
Default - Copy/Integration

Pankaj Gurav
29-Jun-17

Chromeleon (c) Dionex
Version 7.2.4.8525

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

Injection Name:	Standard solution 2	Run Time (min):	10.00
Vial Number:	Vial:2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	12-Jun-17 22:27	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	2.144	26555.379	5217	1.08	12.28	78.96
2	Ramipril	4.151	7078.064	6361	1.04	n.a.	21.04
Total:							

Pankaj Gurav
21-Jun-17

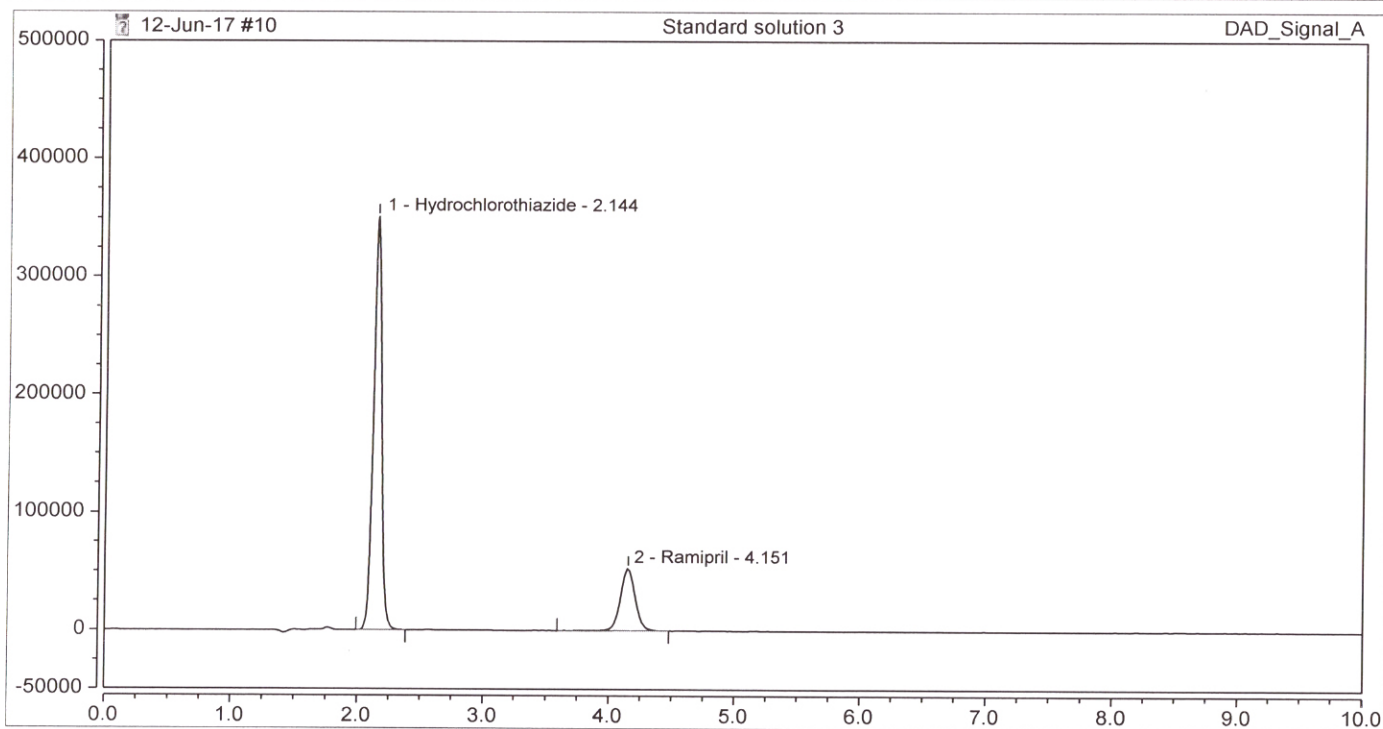
Pankaj Gurav
21-Jun-17

Qbd Research & Development Pvt.Ltd.

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
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	12-Jun-17 22:38	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	2.144	26620.305	5223	1.08	12.26	78.89
2	Ramipril	4.151	7124.869	6334	1.04	n.a.	21.11
Total:							

Pankaj Gurav
21-Jun-17

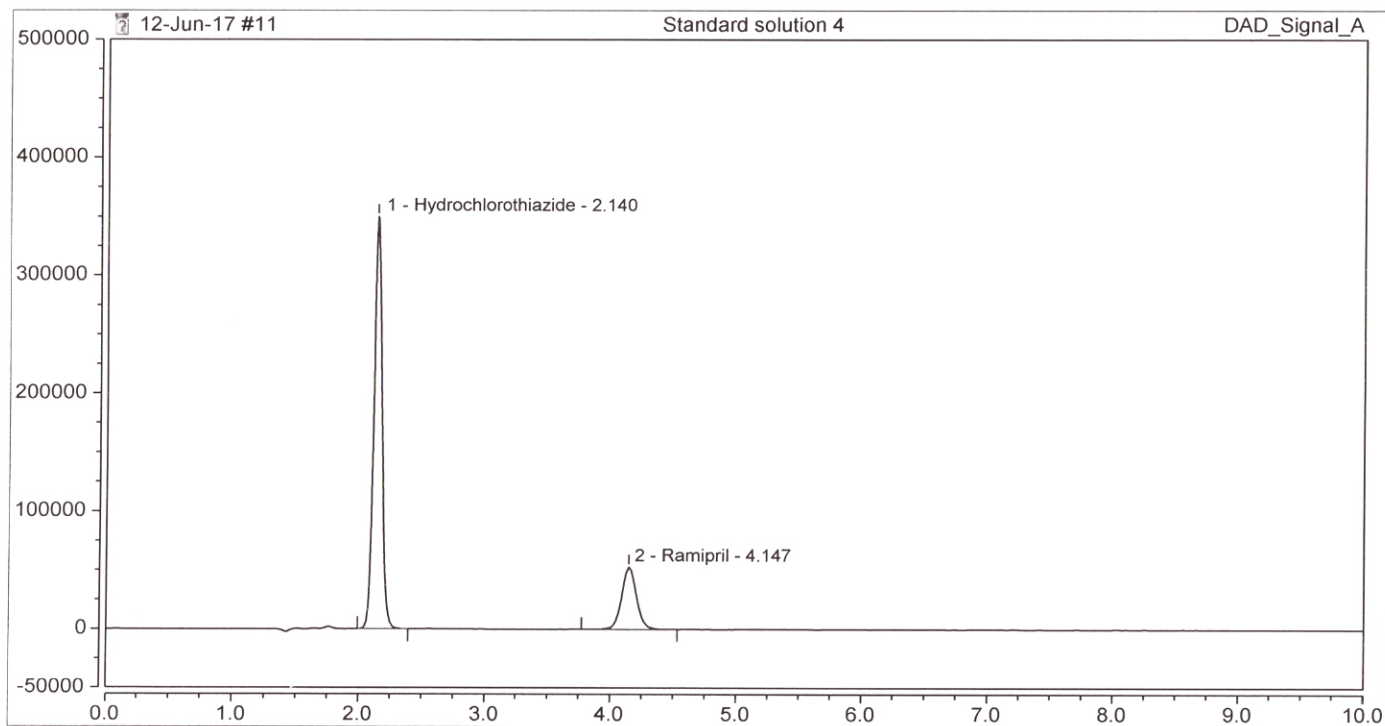
Pankaj Gurav
23-Jun-17

QbD Research & Developement Pvt.Ltd.

Injection Details

Injection Name:	Standard solution 4	Run Time (min):	10.00
Vial Number:	Vial:2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	12-Jun-17 22:50	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	2.140	26611.268	5202	1.14	12.25	78.87
2	Ramipril	4.147	7131.529	6304	1.08	n.a.	21.13
Total:							

Banerjee
21-Jun-17

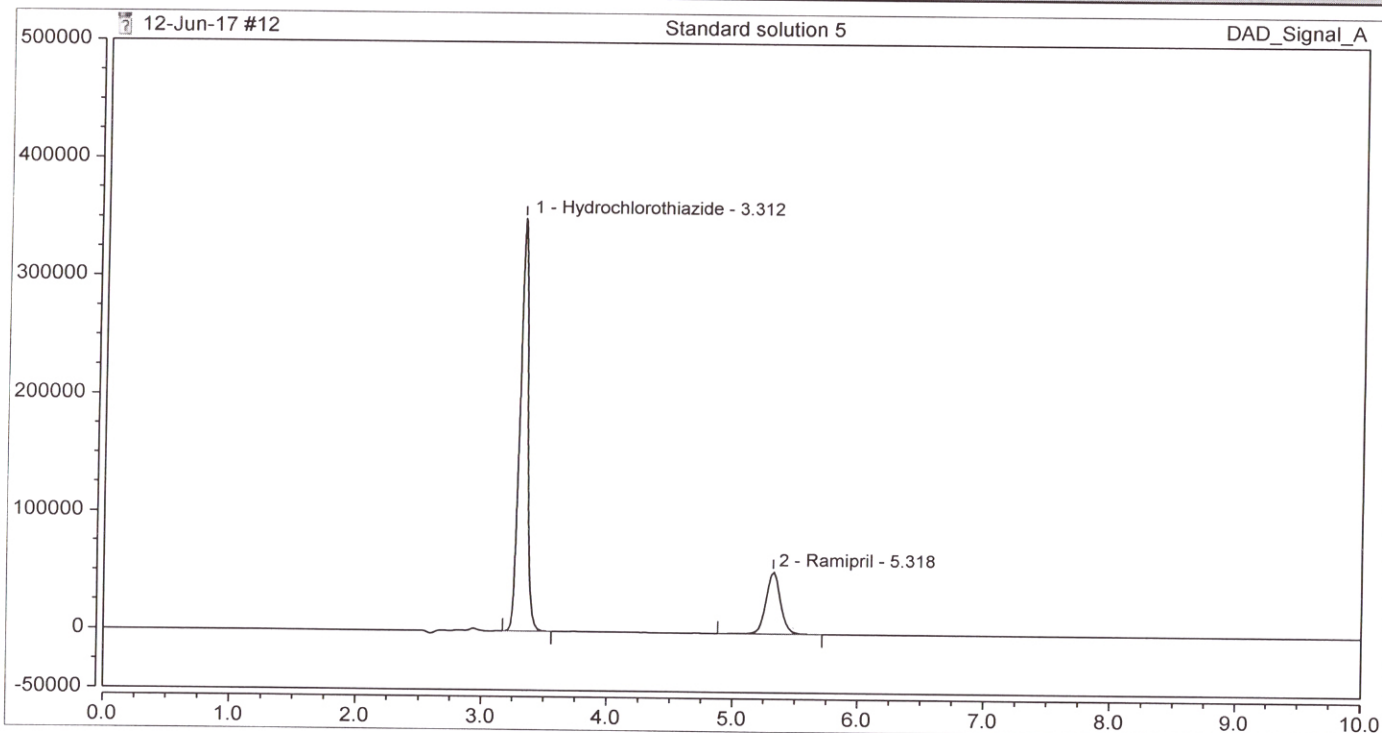
Rajan
23-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Standard solution 5	Run Time (min):	10.00
Vial Number:	Vial:2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	12-Jun-17 23:01	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	3.312	26610.794	12502	1.14	12.28	78.92
2	Ramipril	5.318	7109.973	10416	1.08	n.a.	21.08
Total:							

Pankaj
21-Jun-17

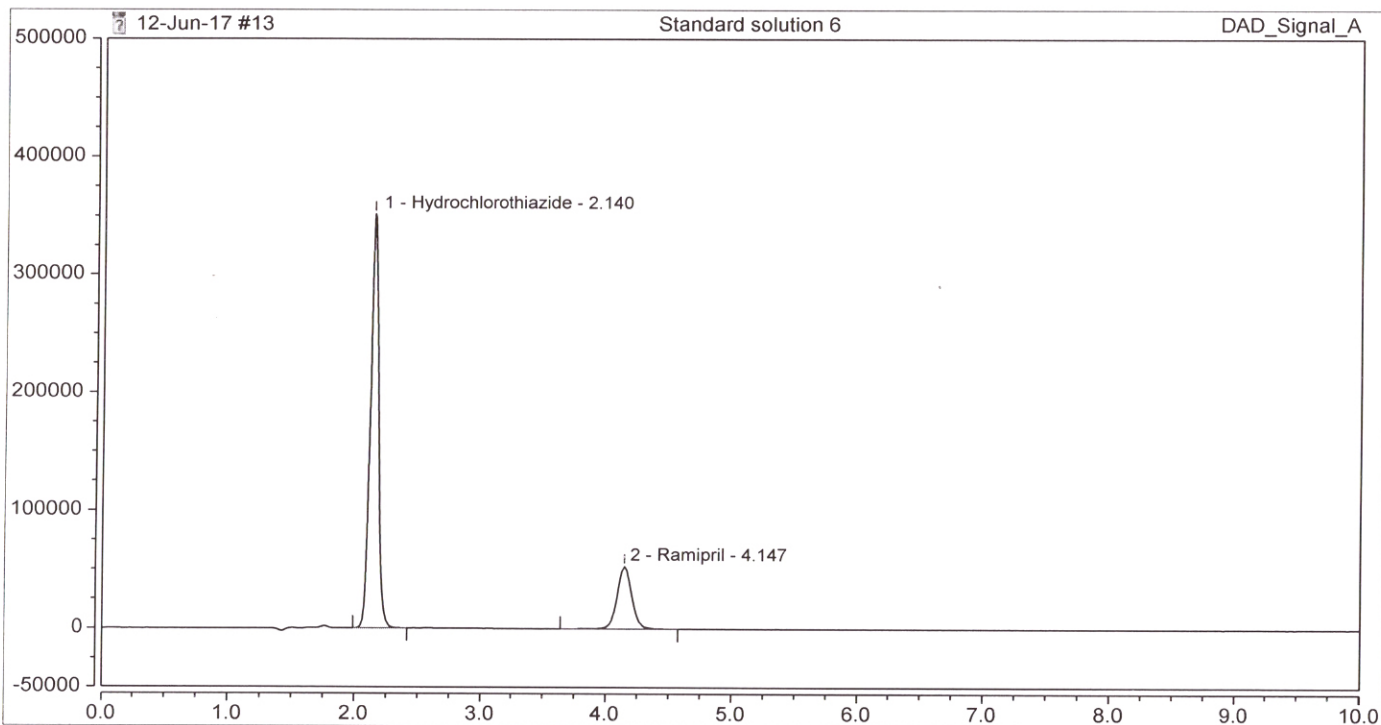
Pankaj
23-Jun-17

Qbd Research & Developement Pvt.Ltd.

Injection Details

Injection Name:	Standard solution 6	Run Time (min):	10.00
Vial Number:	Vial:2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	12-Jun-17 23:13	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	2.140	26650.629	5214	1.13	12.28	78.89
2	Ramipril	4.147	7131.090	6340	1.06	n.a.	21.11
Total:							

Pankaj
21-Jun-17

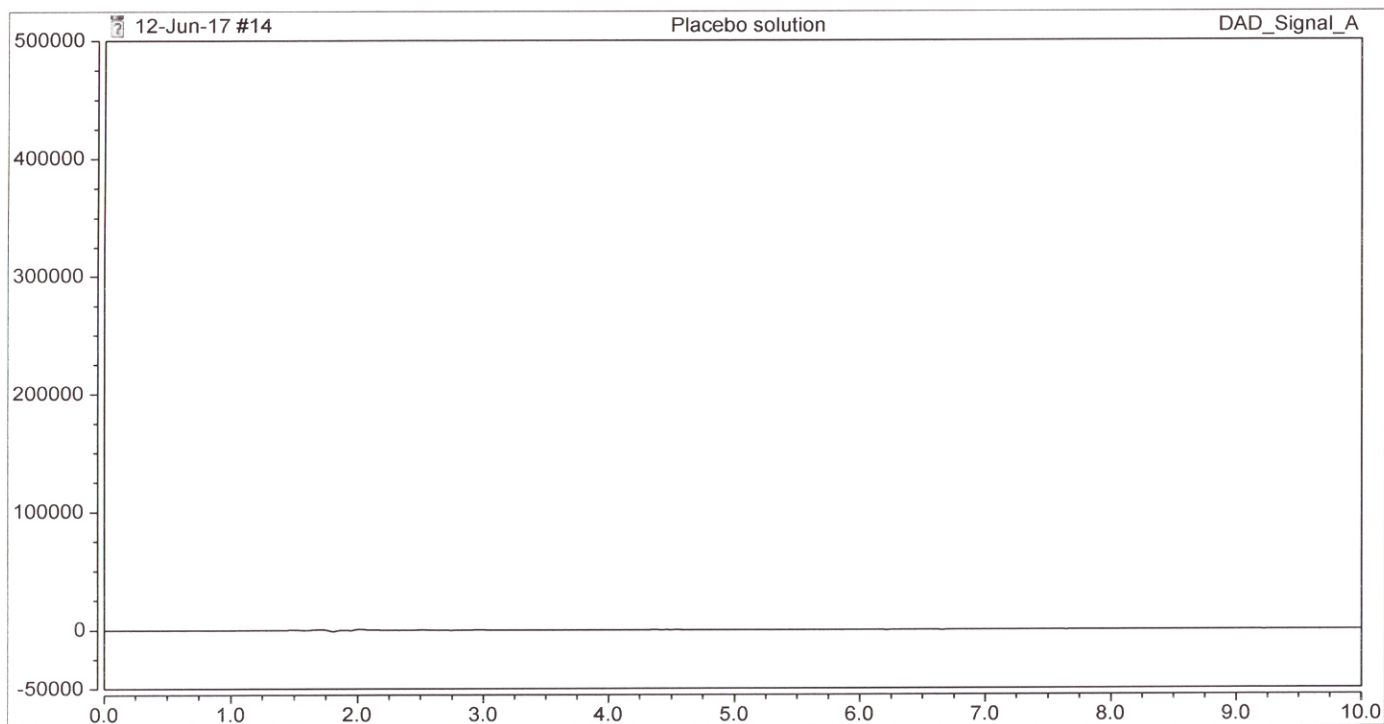
Default - Copy/Integration

Pankaj
21-Jun-17

Chromeleon (c) Dionex
Version 7.2.4.8525

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

Injection Name:	Placebo solution	Run Time (min):	10.00
Vial Number:	Vial:3	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	12-Jun-17 23:24	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:							

Chrom
24-Jun-17

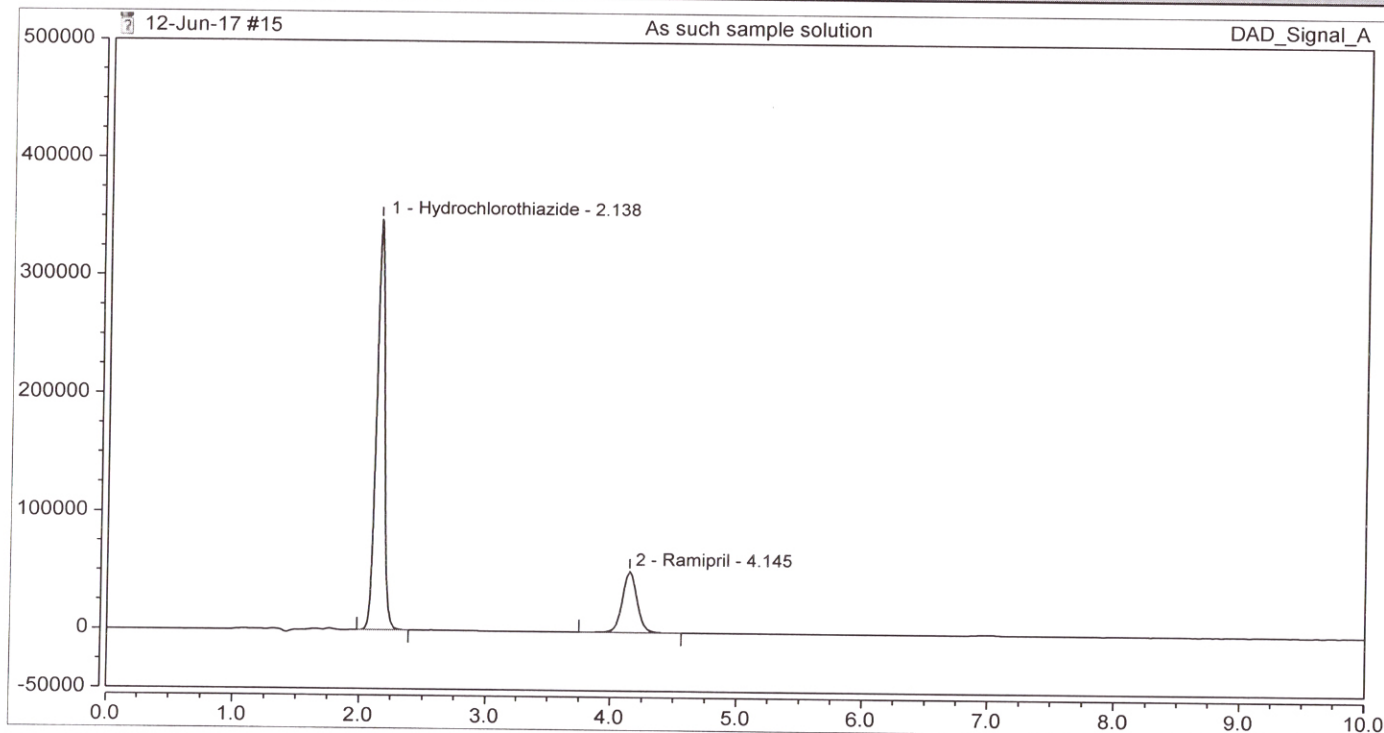
Chrom
25-Jun-17

QbD Research & Developement Pvt.Ltd.

Injection Details

Injection Name:	As such sample solution	Run Time (min):	10.00
Vial Number:	Vial:4	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	12-Jun-17 23:36	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	2.138	26437.902	5228	1.14	12.28	79.09
2	Ramipril	4.145	6990.951	6324	1.07	n.a.	20.91
Total:							

Pankaj Gurav
21-Jun-17

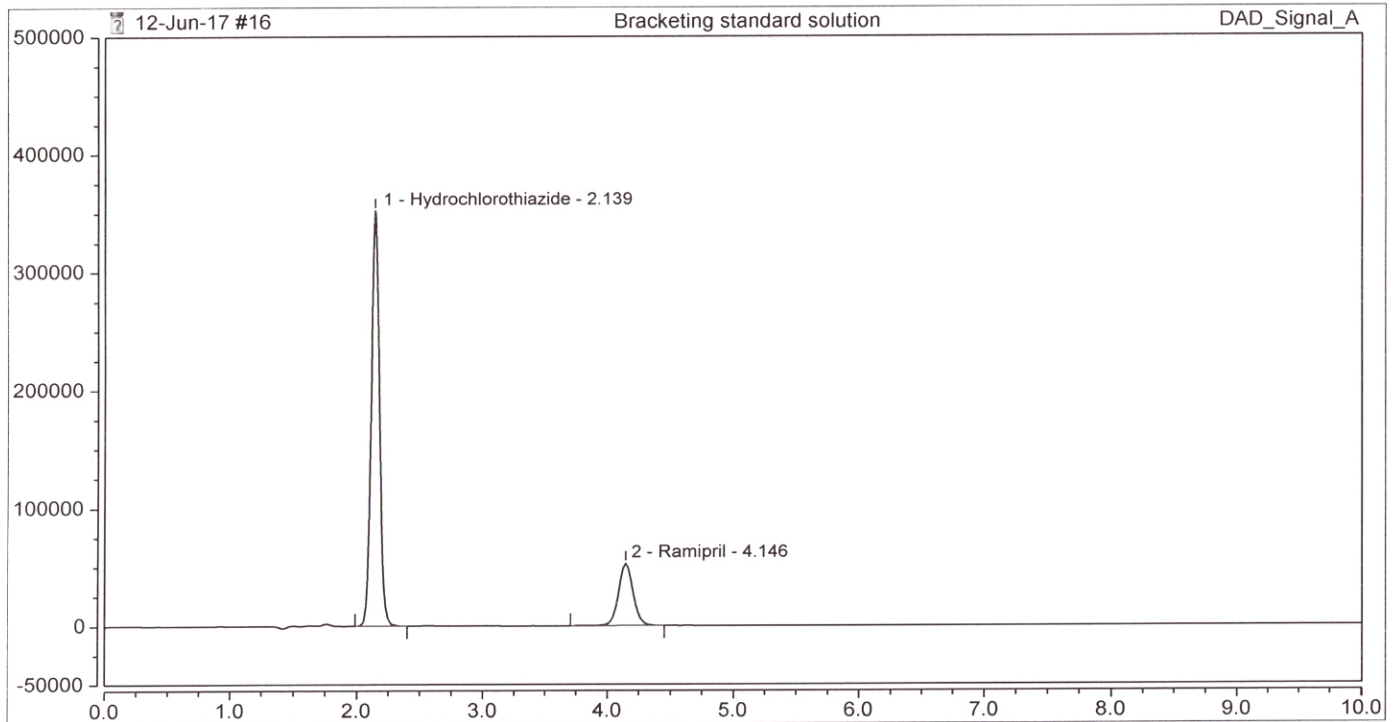
Pankaj Gurav
23-Jun-17

QbD Research & Development Pvt.Ltd.

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
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	12-Jun-17 23:48	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	2.139	26659.657	5224	1.12	12.27	78.95
2	Ramipril	4.146	7108.984	6320	1.06	n.a.	21.05
Total:							

Pankaj
21-Jun-17

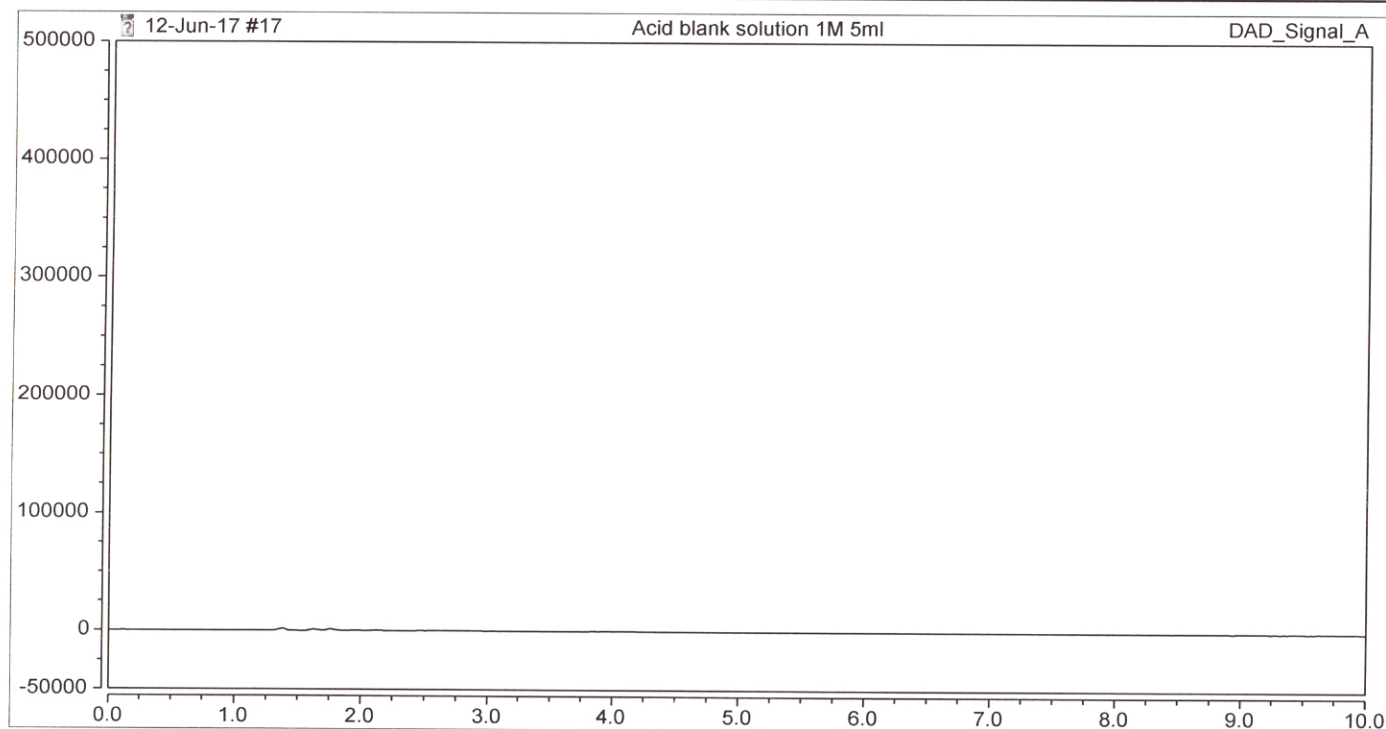
Pankaj
23-Jun-17

QbD Research & Developement Pvt.Ltd.

Injection Details

Injection Name:	Acid blank solution 1M 5ml	Run Time (min):	10.00
Vial Number:	Vial:5	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	13-Jun-17 00:00	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

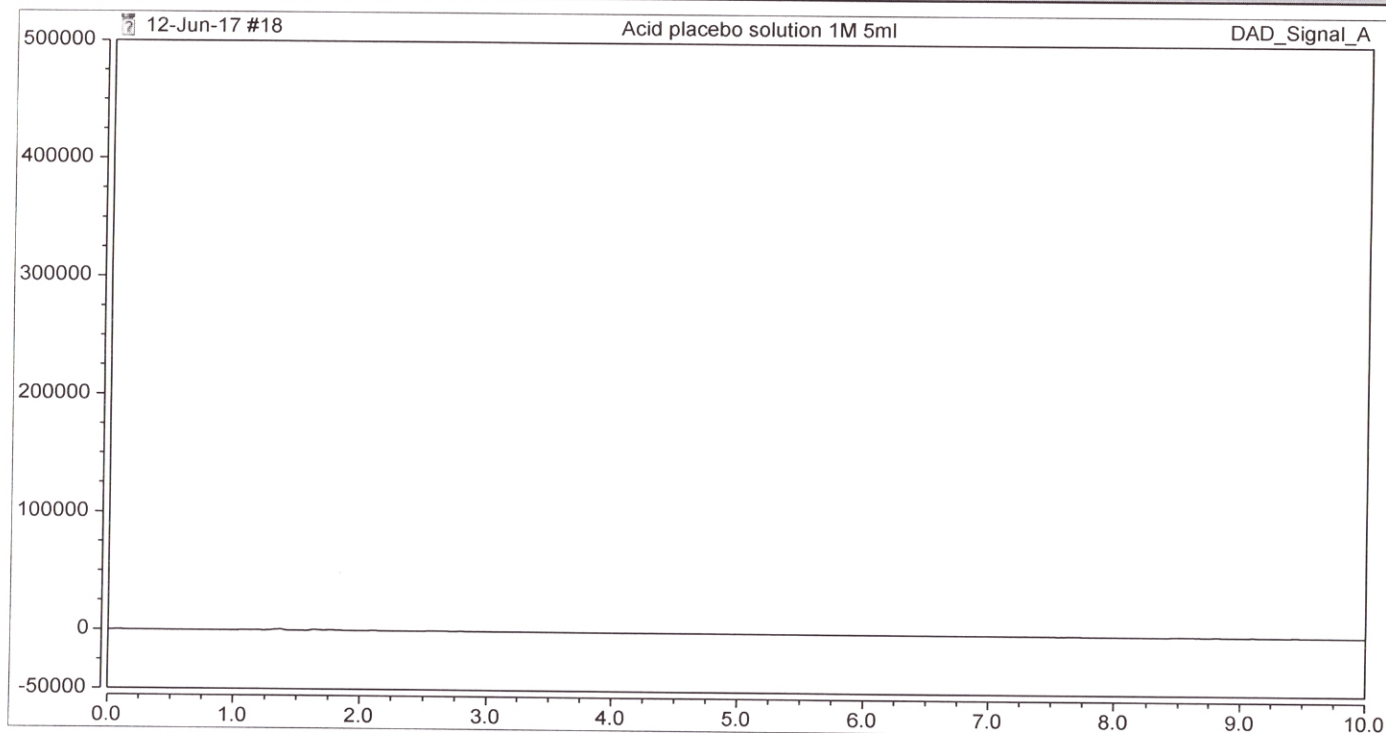
No.	Peak Name	Retention Time min	Area μ AU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
Total:							

Pankaj Gurav
24-Jun-17

Pankaj Gurav
24-Jun-17

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

Injection Name:	Acid placebo solution 1M 5ml	Run Time (min):	10.00
Vial Number:	Vial:6	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	13-Jun-17 00:11	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram**Integration Results**

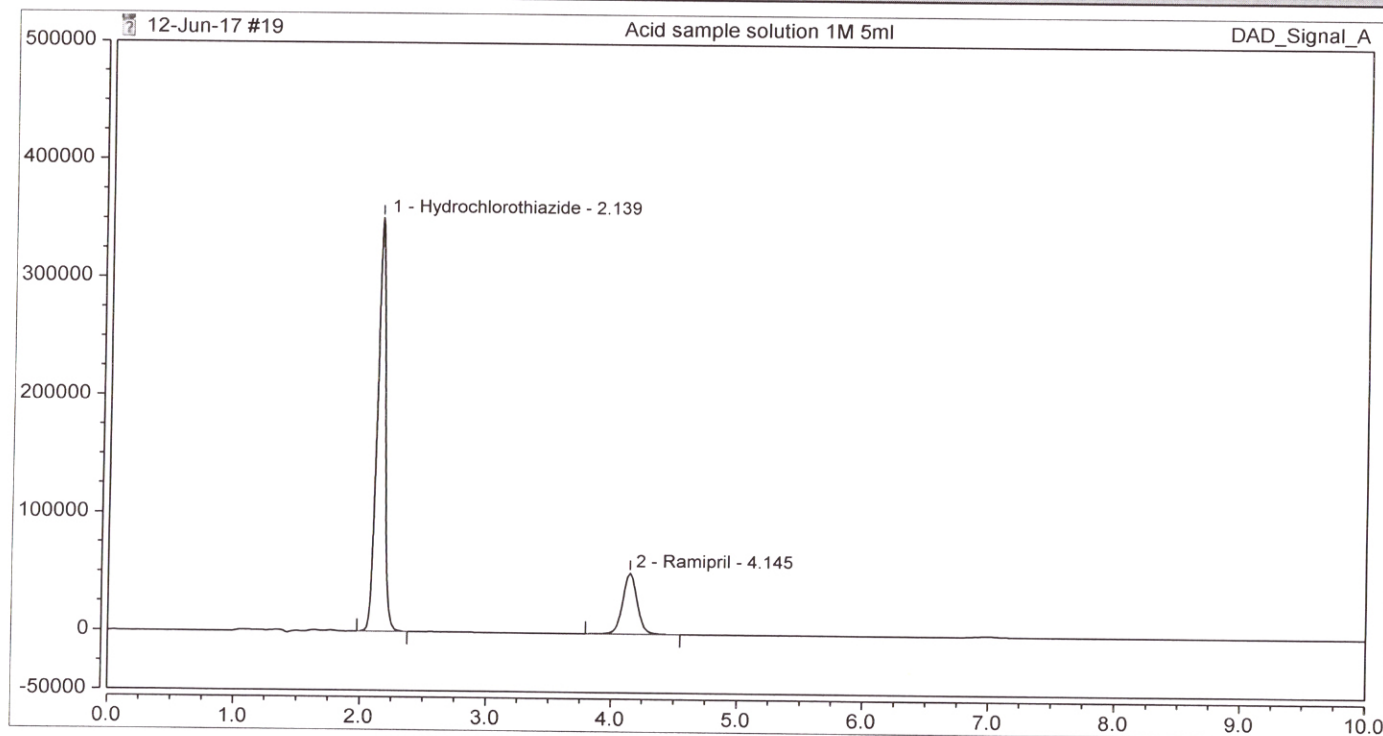
No.	Peak Name	Retention Time min	Area $\mu\text{AU} \cdot \text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
Total:							

Pankaj
21-Jun-17

Pankaj
23-Jun-17

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

Injection Name:	Acid sample solution 1M 5ml	Run Time (min):	10.00
Vial Number:	Vial:7	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	13-Jun-17 00:23	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram**Integration Results**

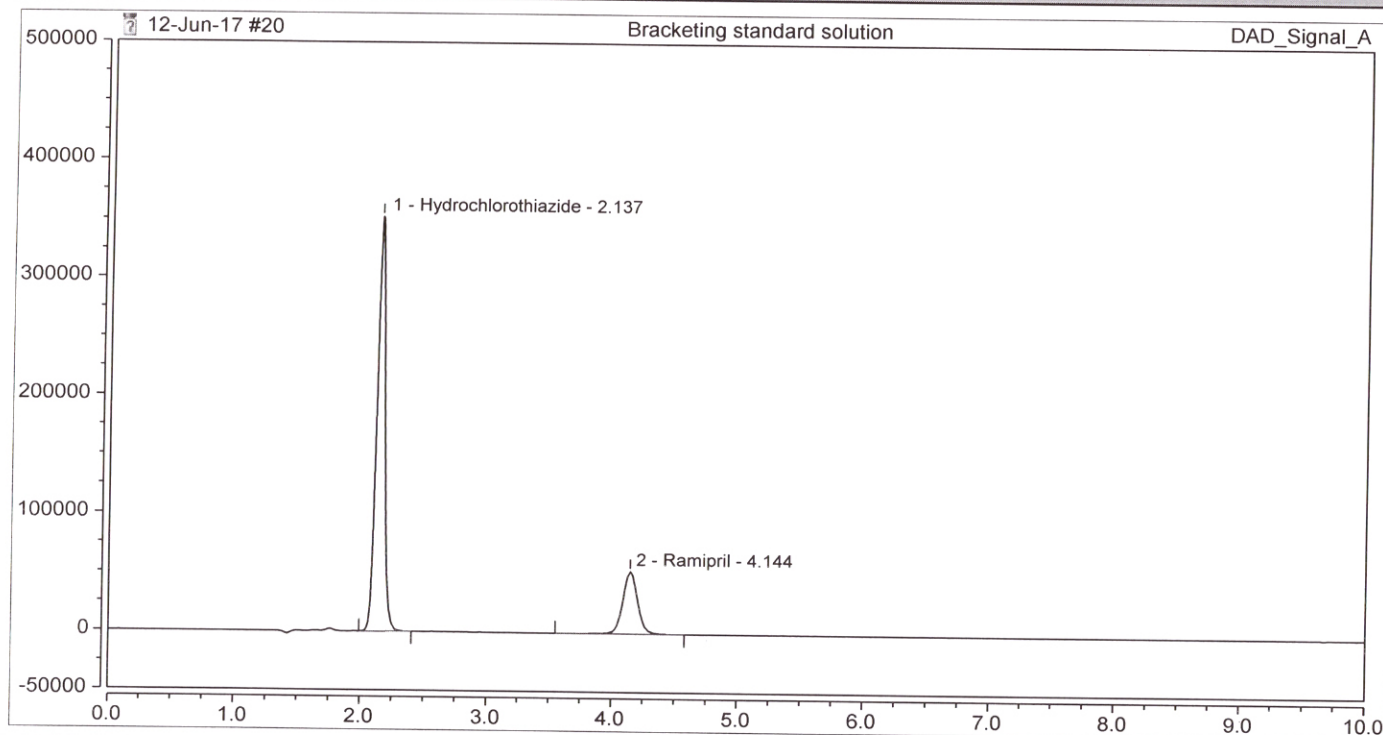
No.	Peak Name	Retention Time min	Area $\mu\text{AU}\cdot\text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.139	26539.404	5245	1.11	12.28	79.19
2	Ramipril	4.145	6975.559	6318	1.05	n.a.	20.81
Total:							

Pankaj Gurav
21-Jun-17

Pankaj Gurav
29-Jun-17

QbD Research & Development Pvt.Ltd.**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
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	13-Jun-17 00:35	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram**Integration Results**

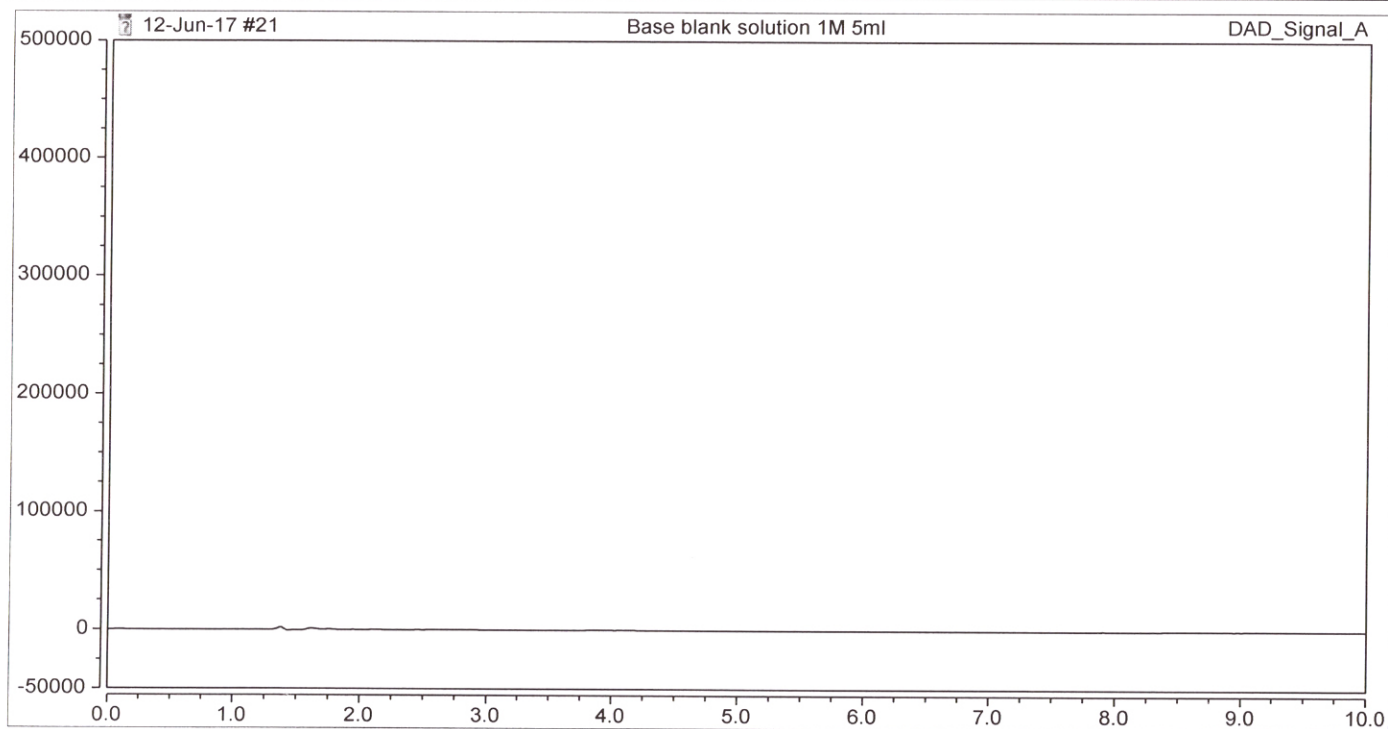
No.	Peak Name	Retention Time min	Area $\mu\text{AU}\cdot\text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.137	26707.430	5245	1.14	12.28	78.81
2	Ramipril	4.144	7181.144	6308	1.07	n.a.	21.19
Total:							

Pankaj
21-Jun-17

Pankaj
23-Jun-17

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

Injection Name:	Base blank solution 1M 5ml	Run Time (min):	10.00
Vial Number:	Vial:8	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	13-Jun-17 00:47	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram**Integration Results**

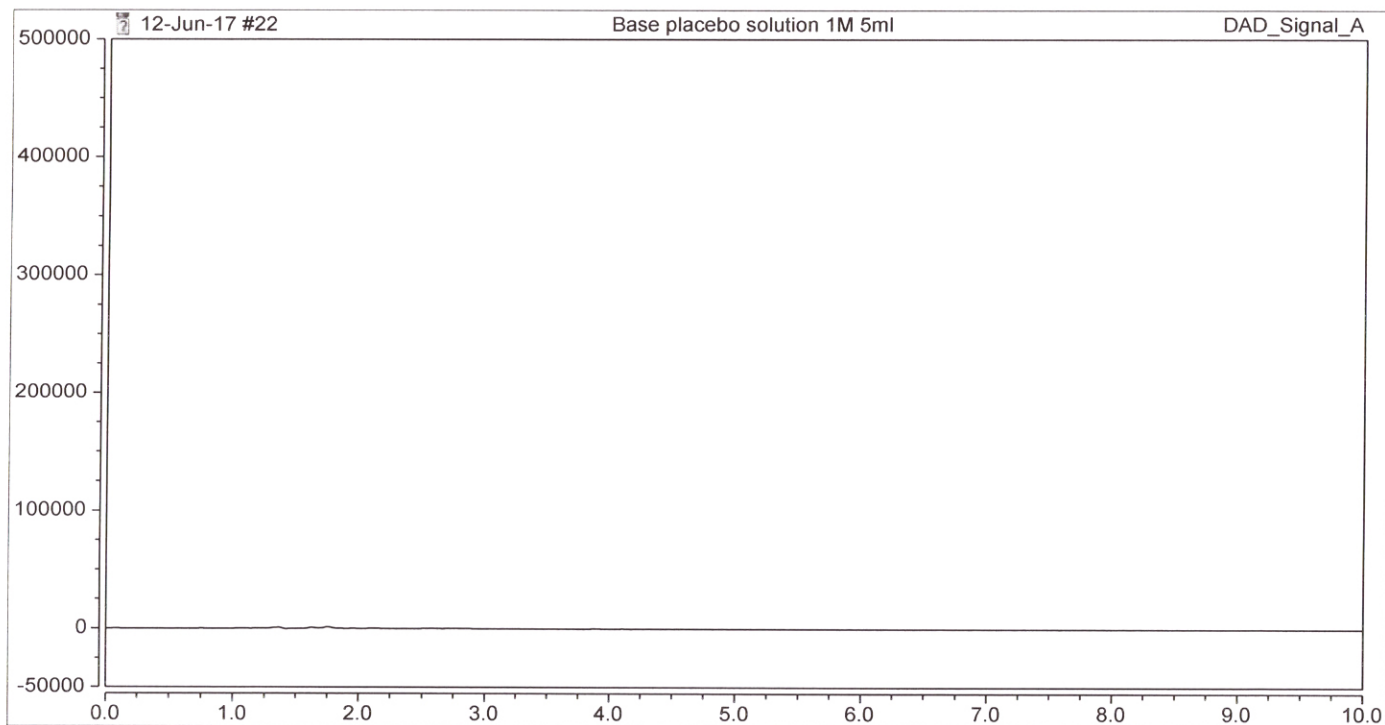
No.	Peak Name	Retention Time min	Area $\mu\text{AU} \cdot \text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
Total:							

Pankaj Gurav
21-Jun-17

Pankaj Gurav
23-Jun-17

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

Injection Name:	Base placebo solution 1M 5ml	Run Time (min):	10.00
Vial Number:	Vial:9	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	13-Jun-17 00:58	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
21-Jun-17

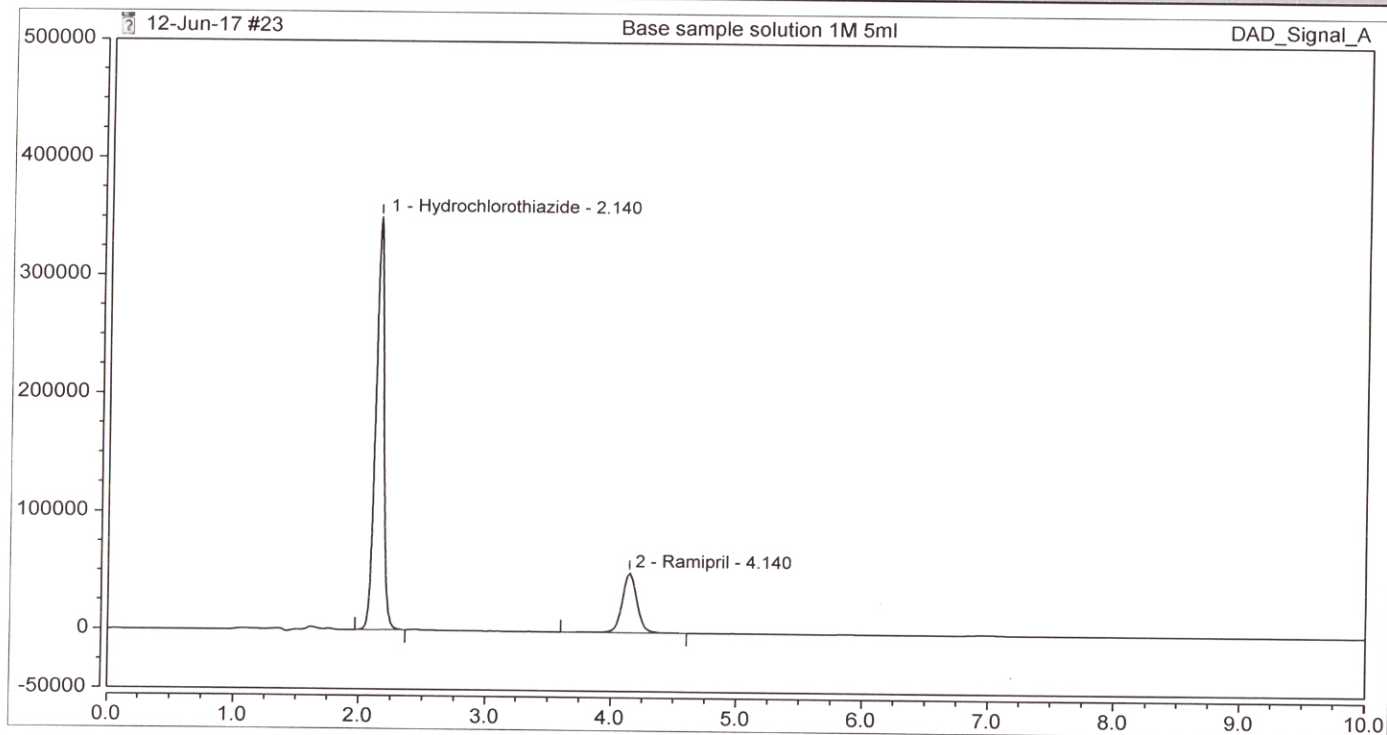
Pankaj
29-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Base sample solution 1M 5ml	Run Time (min):	10.00
Vial Number:	Vial:10	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	13-Jun-17 01:10	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

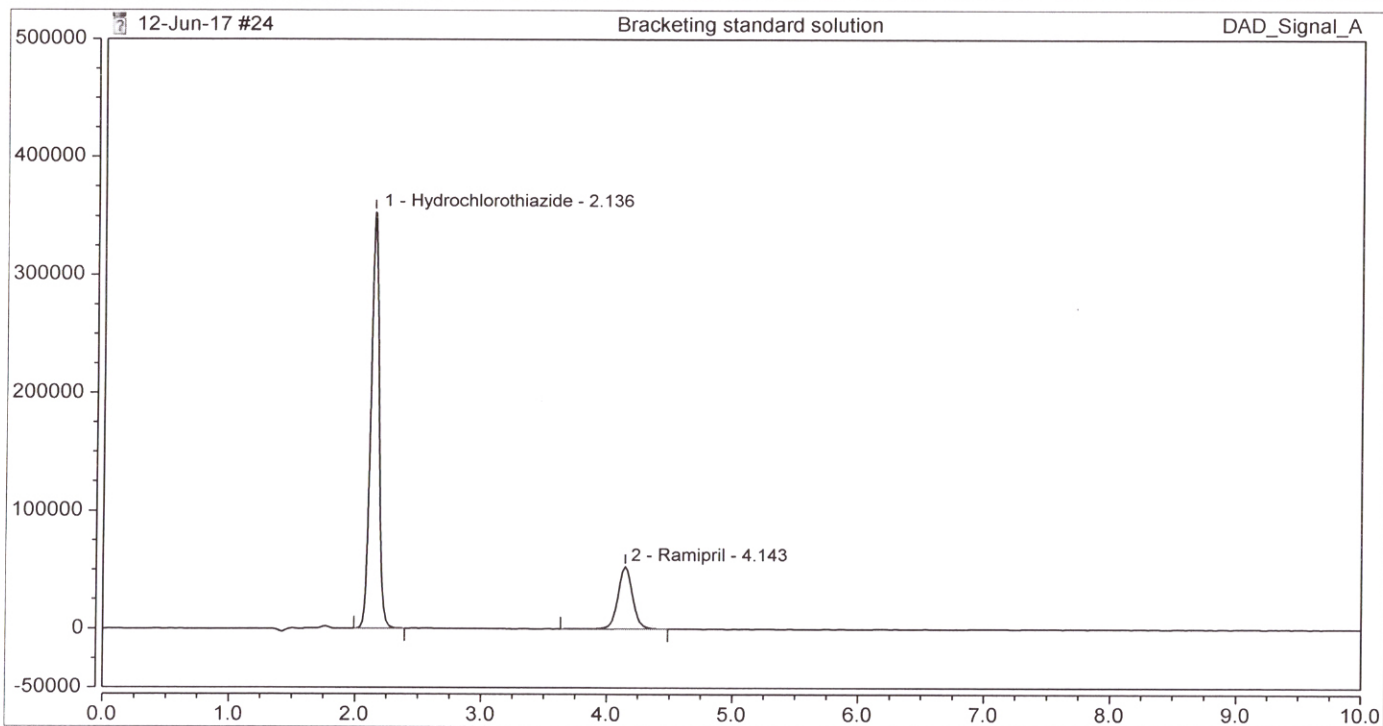
No.	Peak Name	Retention Time min	Area $\mu\text{AU} \cdot \text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.140	26555.589	5231	1.08	12.25	79.38
2	Ramipril	4.140	6896.102	6328	1.08	n.a.	20.62
Total:							

ORG
21-Jun-17

ORG
29-Jun-17

QbD Research & Development Pvt.Ltd.**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
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	13-Jun-17 01:22	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram**Integration Results**

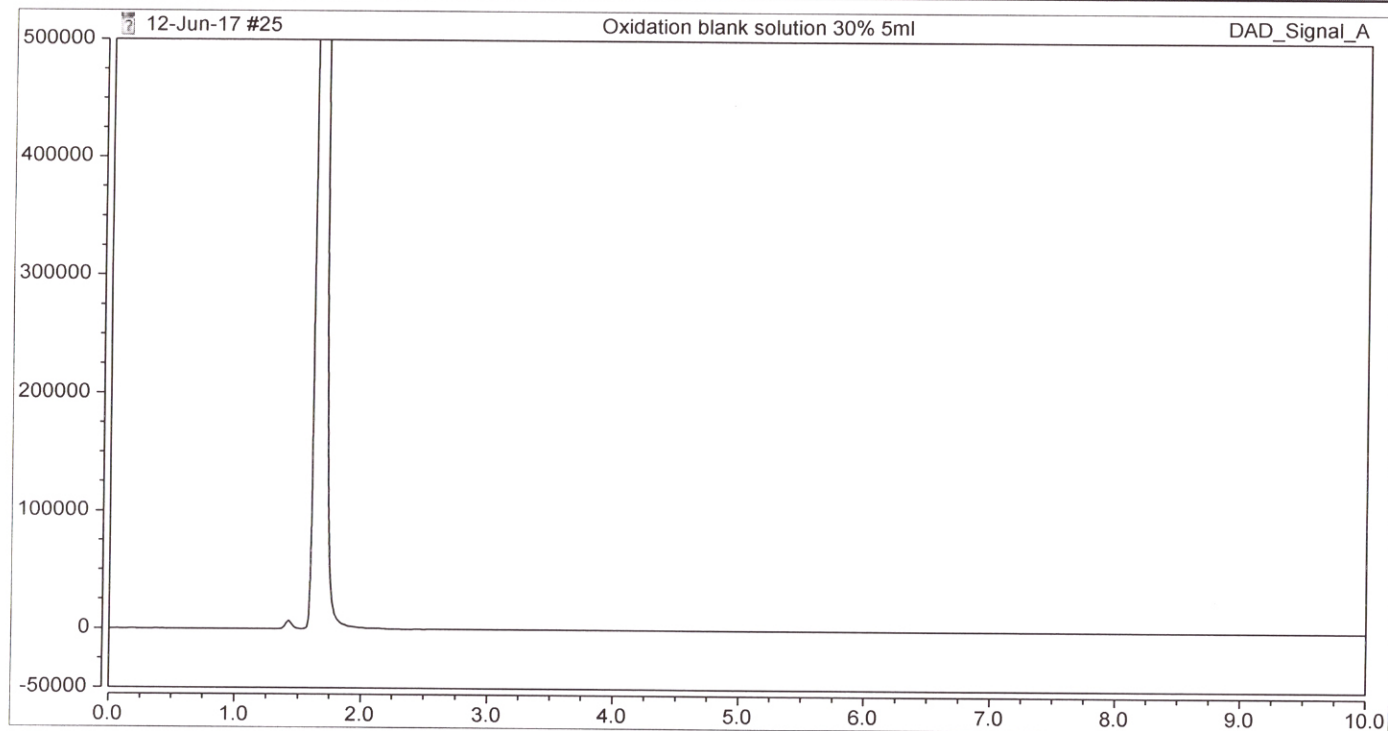
No.	Peak Name	Retention Time min	Area $\mu\text{AU}\cdot\text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.136	26748.962	5251	1.15	12.30	78.87
2	Ramipril	4.143	7166.910	6328	1.06	n.a.	21.13
Total:							

Pankaj
21-Jun-17

Pankaj
23-Jun-17

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

Injection Name:	Oxidation blank solution 30% 5ml	Run Time (min):	10.00
Vial Number:	Vial:11	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	13-Jun-17 01:34	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram**Integration Results**

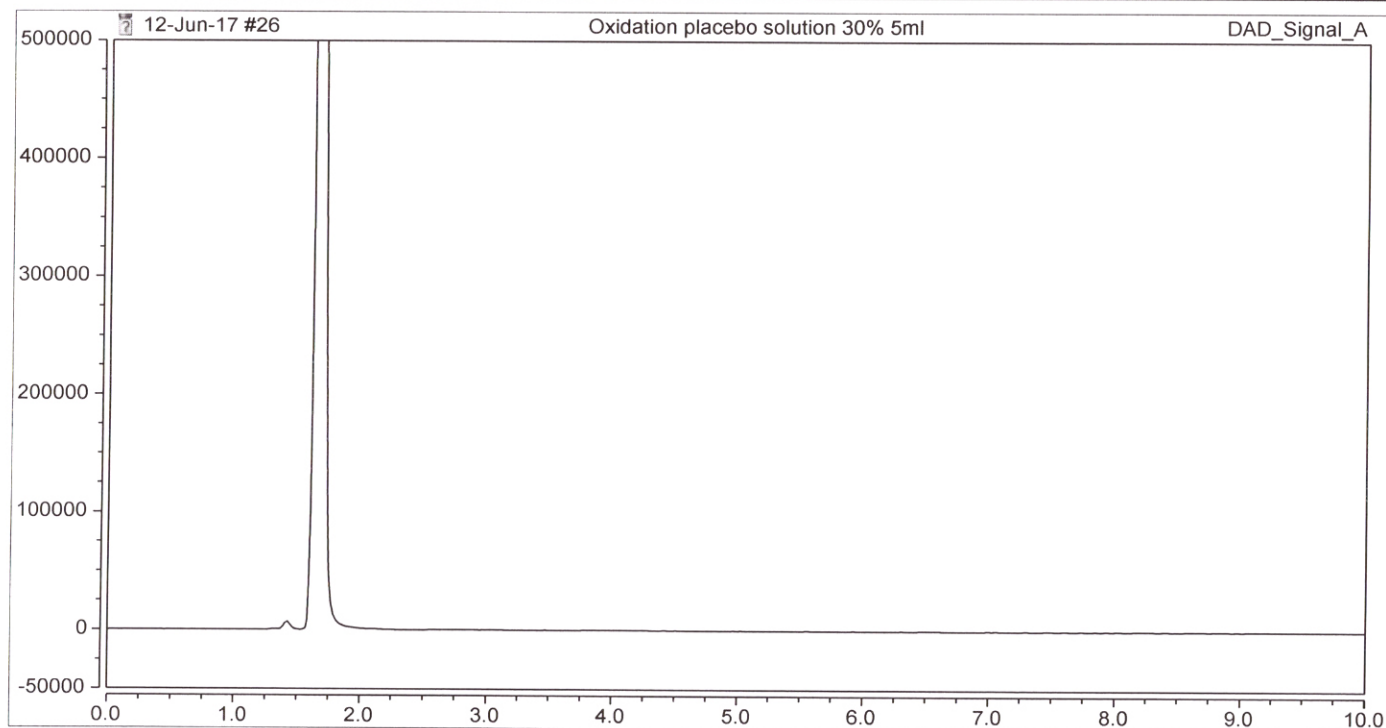
No.	Peak Name	Retention Time min	Area $\mu\text{AU} \cdot \text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
Total:							

Pankaj Gurav
21-Jun-17

Pankaj Gurav
29-Jun-17

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

Injection Name:	Oxidation placebo solution 30% 5ml	Run Time (min):	10.00
Vial Number:	Vial:12	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	13-Jun-17 01:46	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

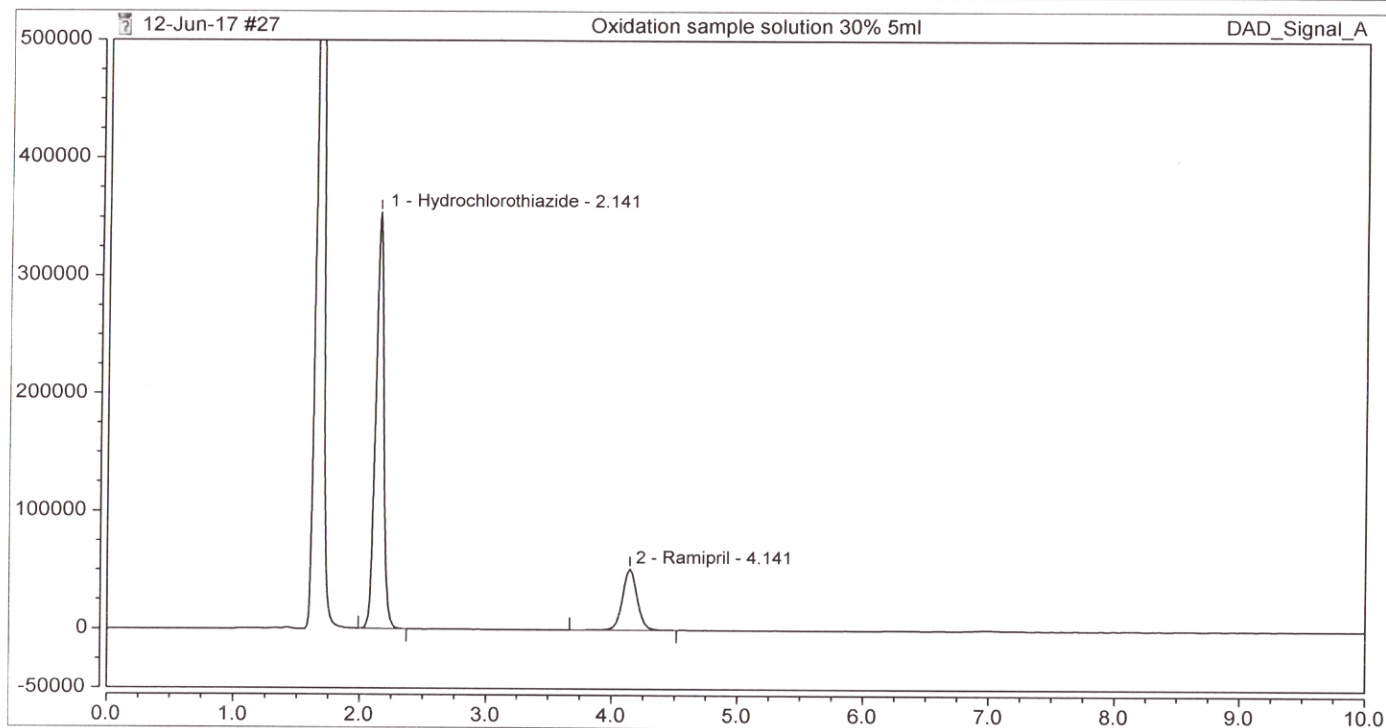
Pankaj Gurav
29-Jun-17

QbD Research & Developement Pvt.Ltd.

Injection Details

Injection Name:	Oxidation sample solution 30% 5ml	Run Time (min):	10.00
Vial Number:	Vial:13	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	13-Jun-17 01:57	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	2.141	26541.634	5319	1.09	12.33	79.32
2	Ramipril	4.141	6921.174	6408	1.05	n.a.	20.68
Total:							

Pankaj Gurav
21-Jun-17

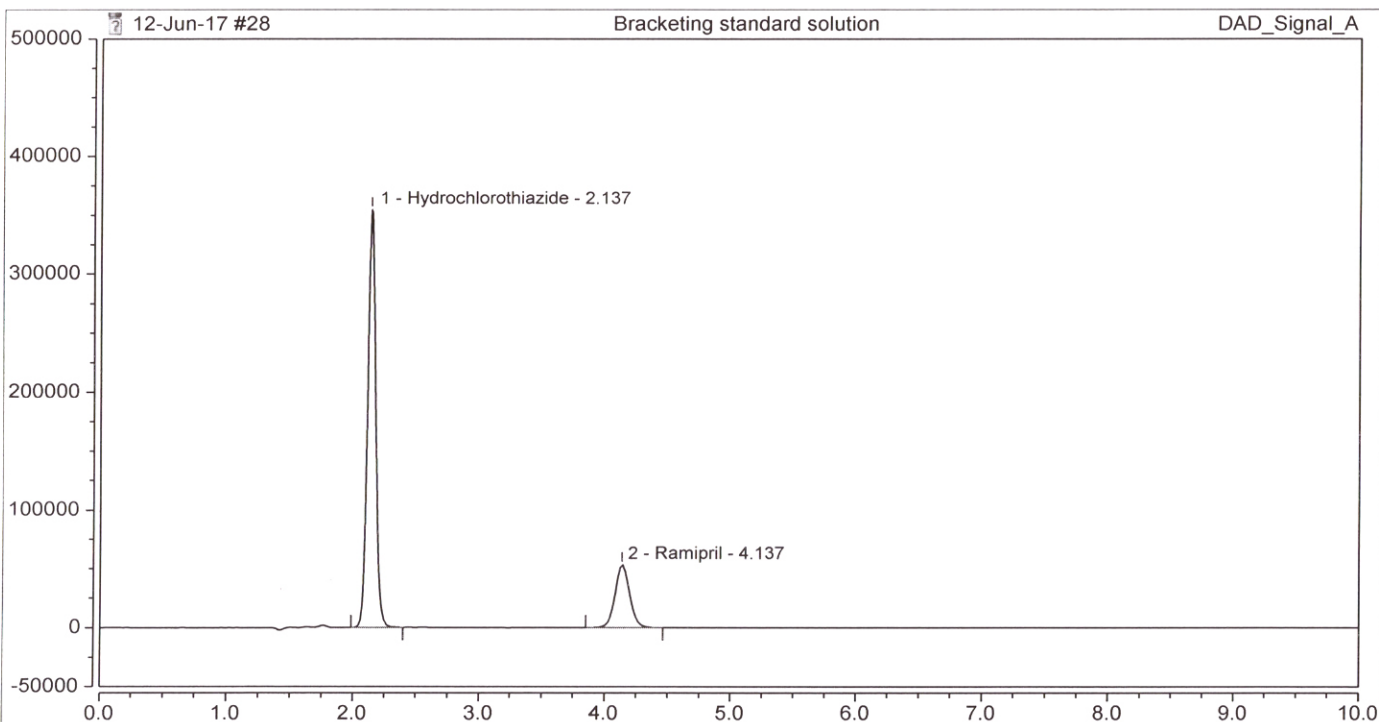
Pankaj Gurav
23-Jun-17

QbD Research & Development Pvt.Ltd.

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
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	13-Jun-17 02:09	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

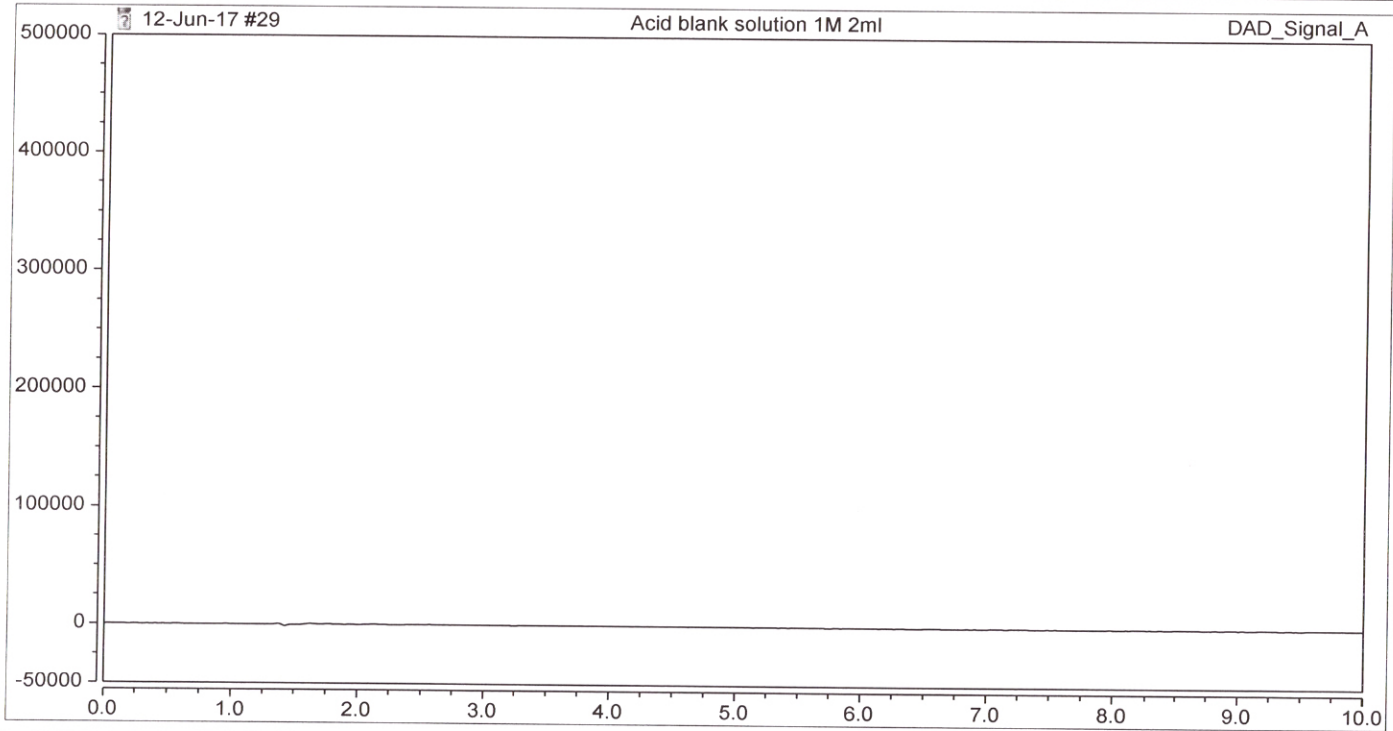
No.	Peak Name	Retention Time min	Area $\mu\text{AU} \cdot \text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.137	26747.556	5286	1.14	12.32	79.00
2	Ramipril	4.137	7111.065	6380	1.08	n.a.	21.00
Total:							

Bruno
21-Jun-17

OPG
23-Jun-17

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

Injection Name:	Acid blank solution 1M 2ml	Run Time (min):	10.00
Vial Number:	Vial:14	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	13-Jun-17 02:21	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram**Integration Results**

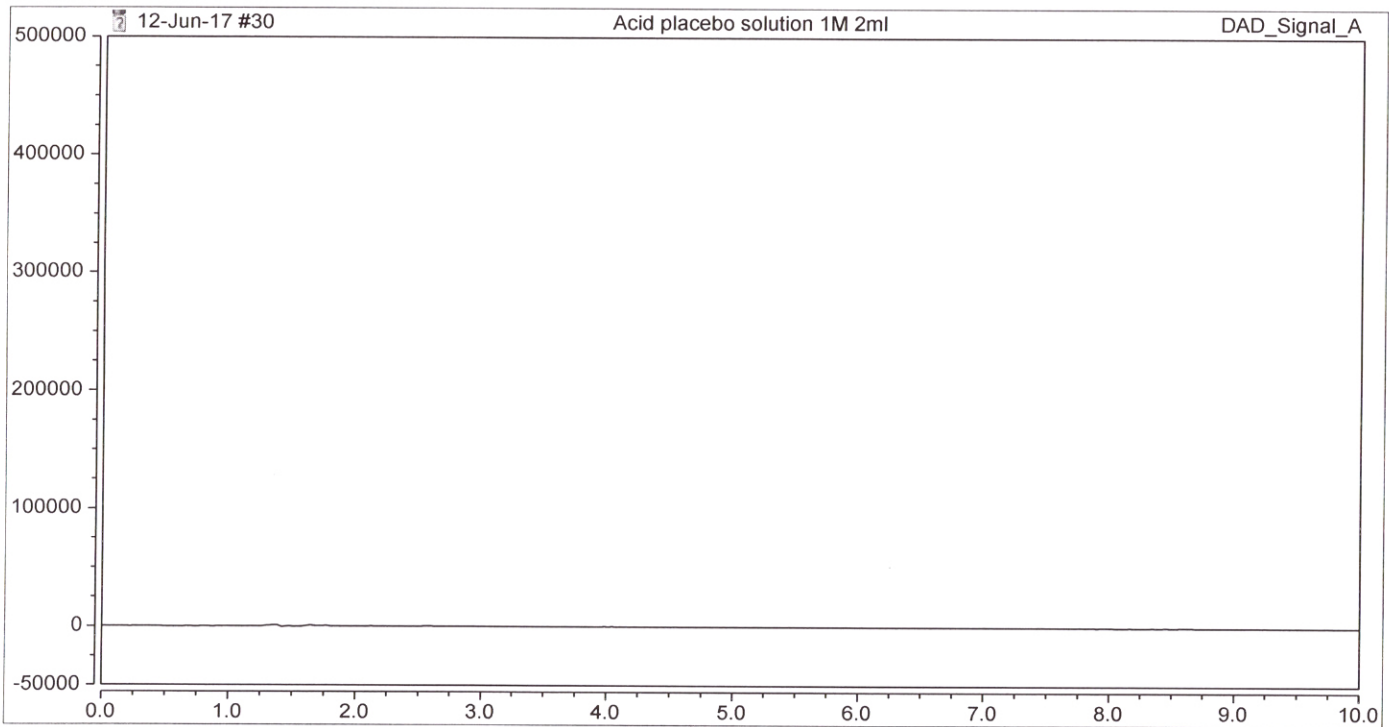
No.	Peak Name	Retention Time min	Area $\mu\text{AU}\cdot\text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
Total:							

Pankaj Gurav
21-Jun-17

Pankaj Gurav
23-Jun-17

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

Injection Name:	Acid placebo solution 1M 2ml	Run Time (min):	10.00
Vial Number:	Vial:15	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	13-Jun-17 02:33	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram**Integration Results**

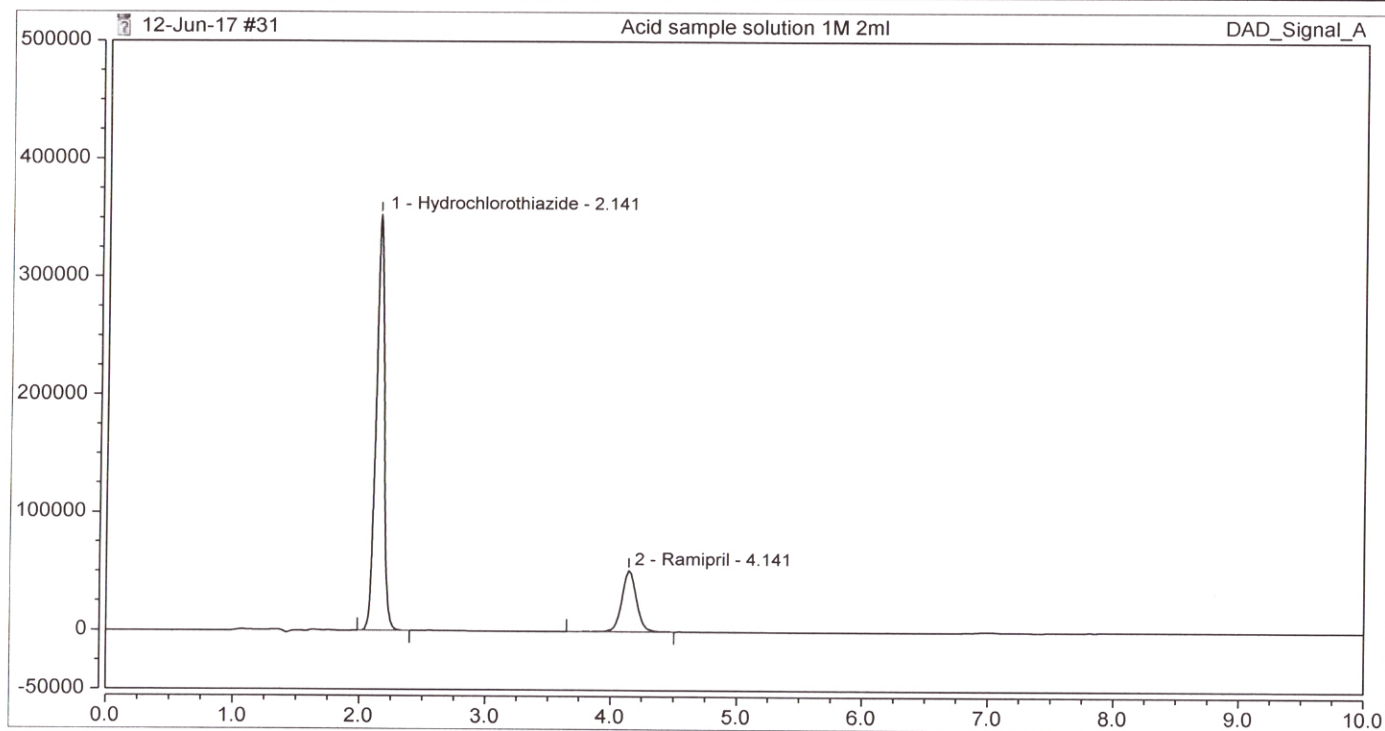
No.	Peak Name	Retention Time min	Area $\mu\text{AU}\cdot\text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
Total:							

Pankaj
21-Jun-17

Pankaj
21-Jun-17

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

Injection Name:	Acid sample solution 1M 2ml	Run Time (min):	10.00
Vial Number:	Vial:16	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	13-Jun-17 02:45	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	2.141	26502.271	5323	1.11	12.31	79.19
2	Ramipril	4.141	6963.870	6371	1.08	n.a.	20.81
Total:							

Pankaj
21-Jun-17

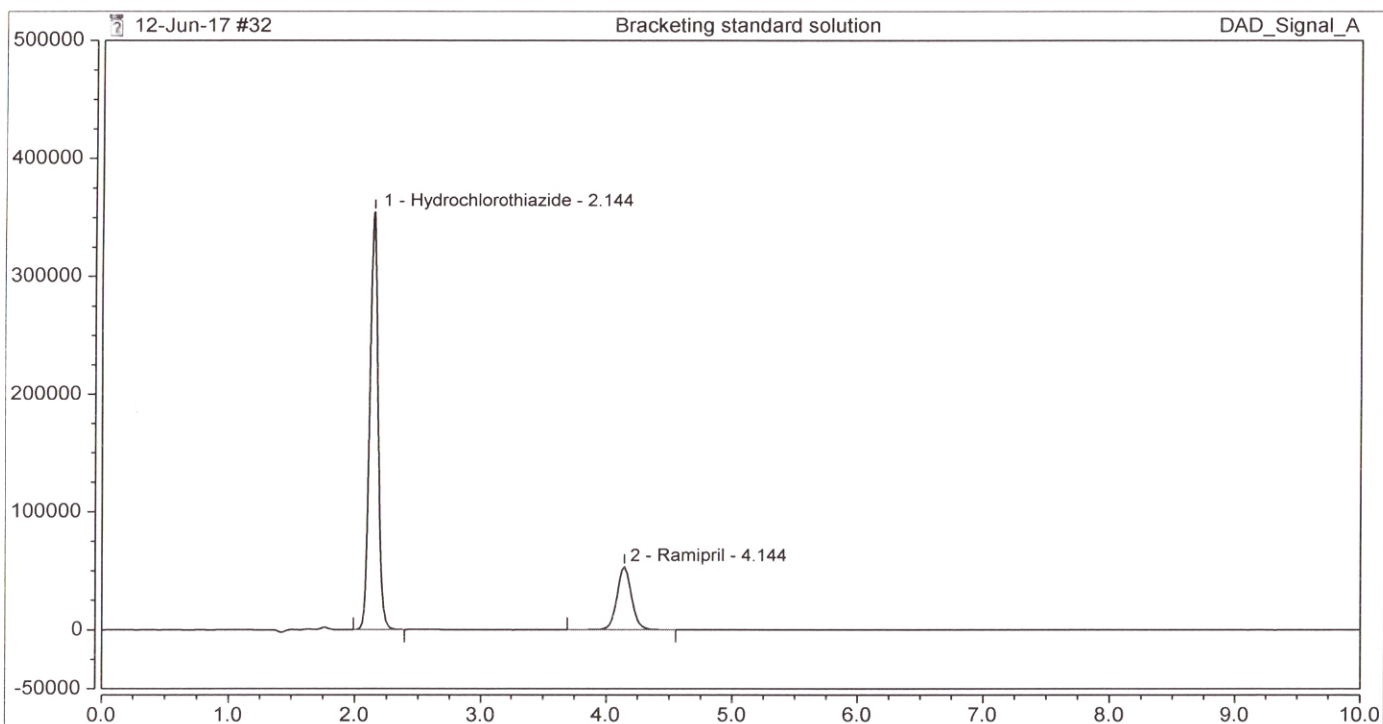
Pankaj
23-Jun-17

QbD Research & Development Pvt.Ltd.

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
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	13-Jun-17 02:56	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



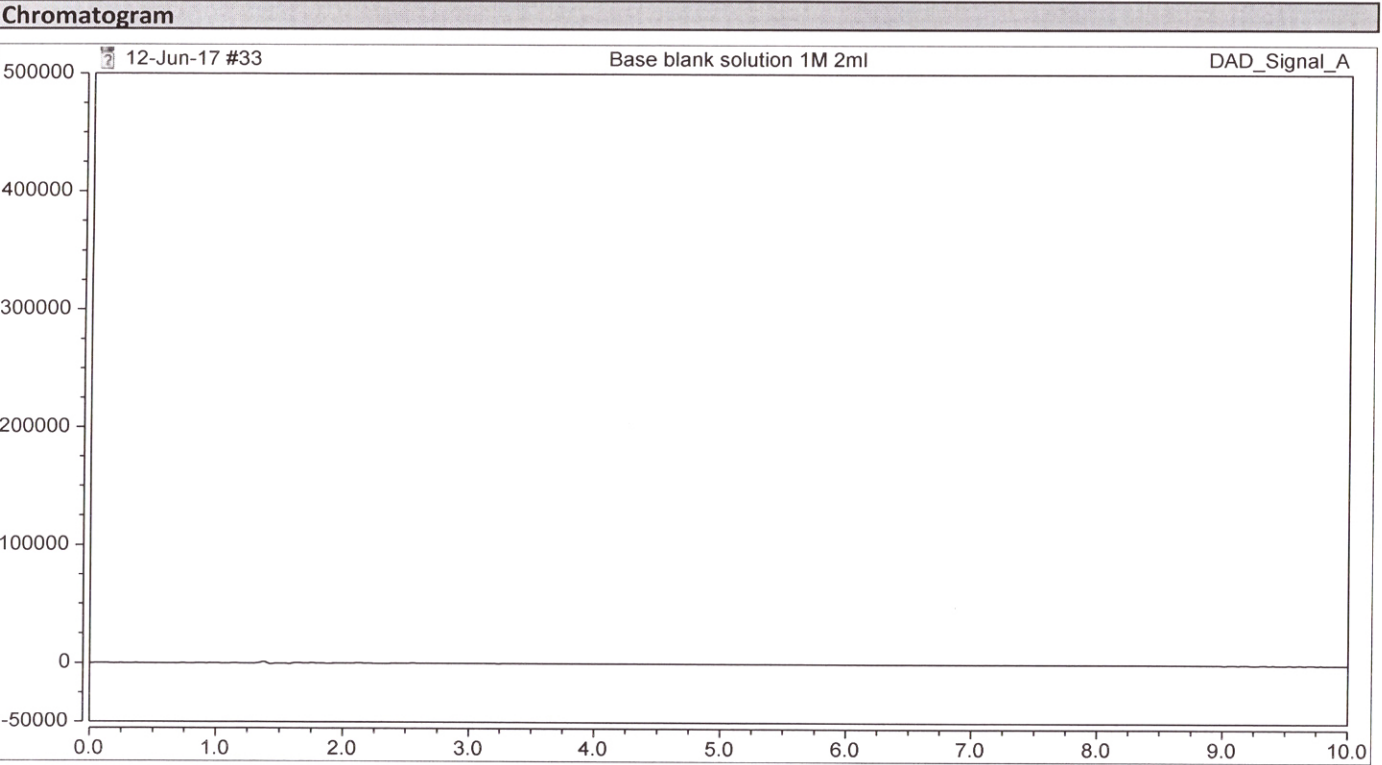
Integration Results

No.	Peak Name	Retention Time min	Area $\mu\text{AU} \cdot \text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.144	26796.095	5351	1.06	12.33	78.87
2	Ramipril	4.144	7180.239	6402	1.04	n.a.	21.13
Total:							

Pankaj
21-Jun-17

Pankaj
23-Jun-17

QbD Research & Developement Pvt.Ltd.					
Injection Details					
Injection Name:	Base blank solution 1M 2ml	Run Time (min):	10.00		
Vial Number:	Vial:17	Injection Volume:	10.00		
Injection Type:	Unknown	Channel:	DAD_Signal_A		
Calibration Level:		Wavelength:	210		
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.		
Processing Method:	PR Method 1	Dilution Factor:	1.0000		
Injection Date/Time:	13-Jun-17 03:08	Sample Weight:	1.0000		
User Name:	Pankaj Gurav	Sample Weight:	1.0000		

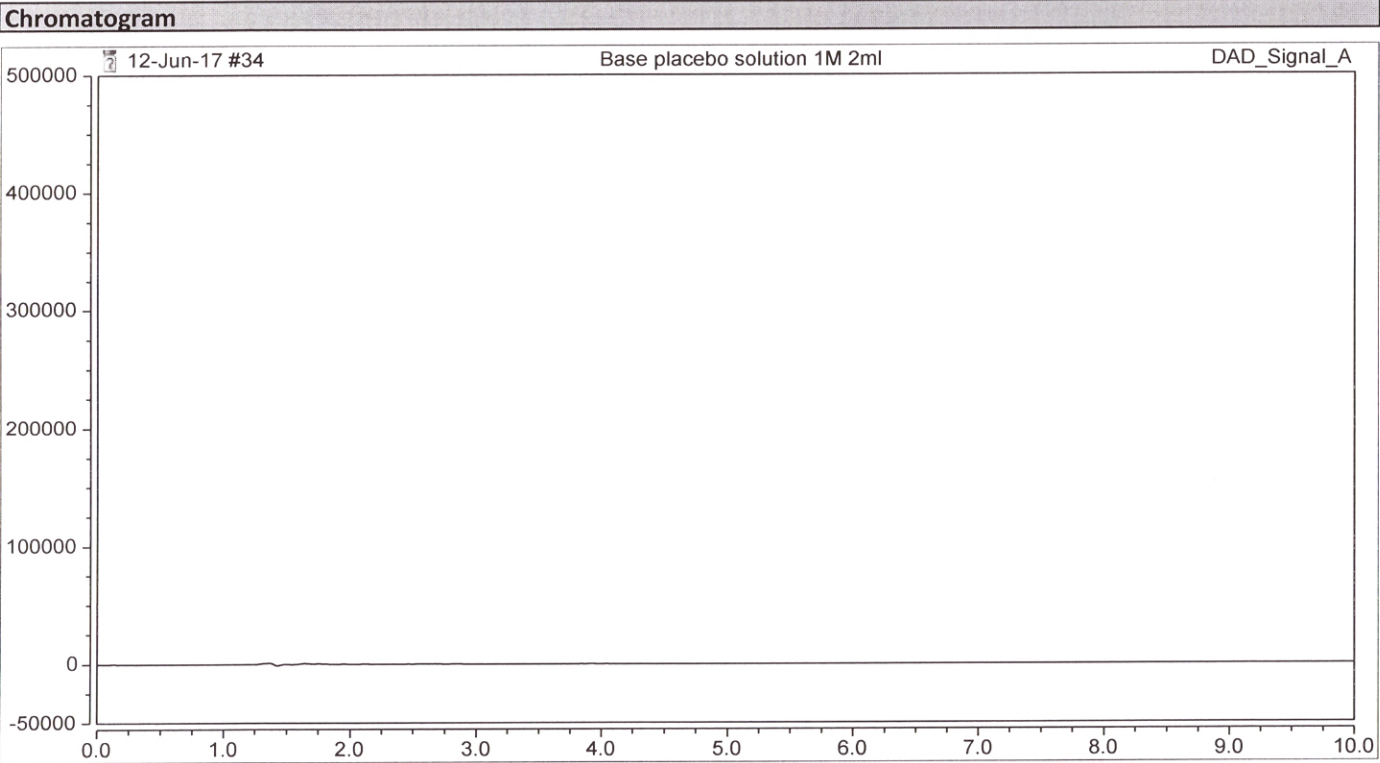


Integration Results							
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
Total:							

Pankaj Gurav
21-Jun-17

Pankaj Gurav
23-Jun-17

QbD Research & Developement Pvt.Ltd.					
Injection Details					
Injection Name:	Base placebo solution 1M 2ml	Run Time (min):	10.00		
Vial Number:	Vial:18	Injection Volume:	10.00		
Injection Type:	Unknown	Channel:	DAD_Signal_A		
Calibration Level:		Wavelength:	210		
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.		
Processing Method:	PR Method 1	Dilution Factor:	1.0000		
Injection Date/Time:	13-Jun-17 03:20	Sample Weight:	1.0000		
User Name:	Pankaj Gurav	Sample Weight:	1.0000		



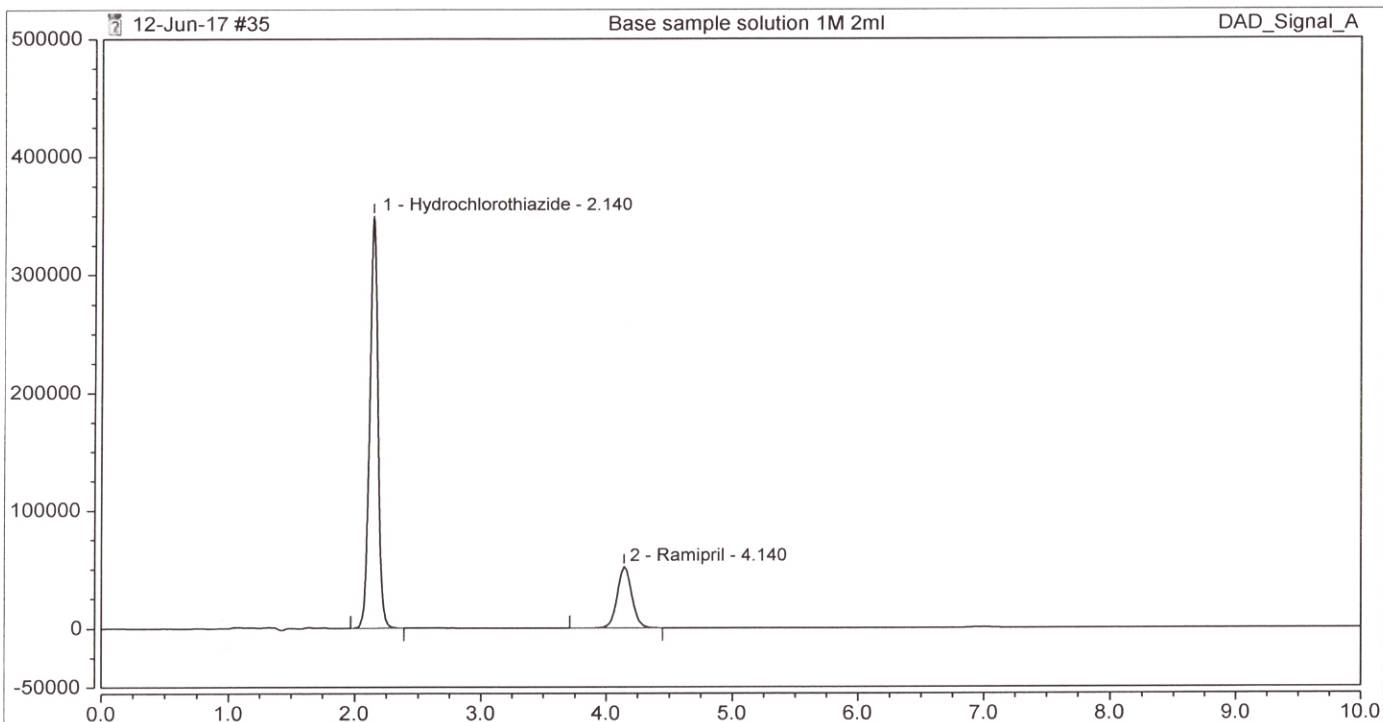
Integration Results							
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
Total:							

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Base sample solution 1M 2ml	Run Time (min):	10.00
Vial Number:	Vial:19	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	13-Jun-17 03:32	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	2.140	26475.967	5273	1.10	12.33	79.28
2	Ramipril	4.140	6918.869	6425	1.08	n.a.	20.72
Total:							

21-Jun-17

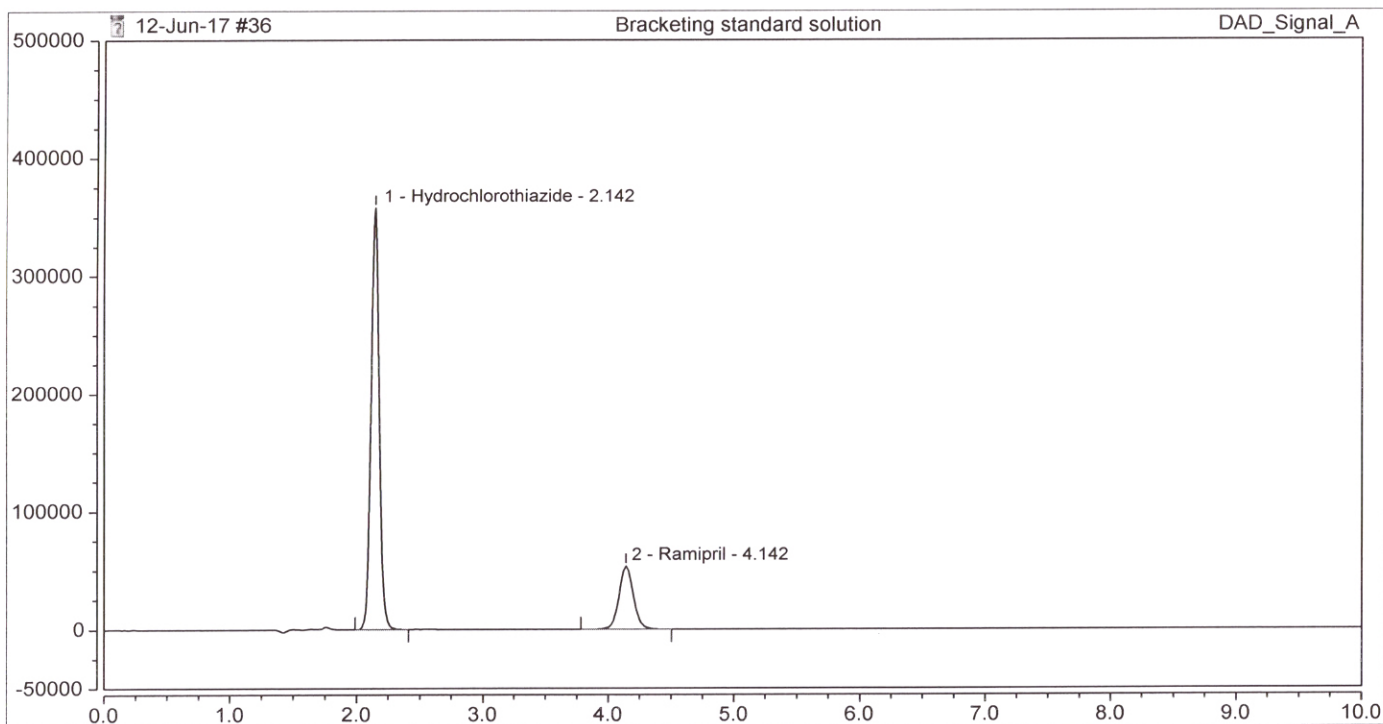
21-Jun-17

QbD Research & Development Pvt.Ltd.

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
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	13-Jun-17 03:44	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	2.142	26835.537	5345	1.09	12.35	78.93
2	Ramipril	4.142	7163.663	6419	1.06	n.a.	21.07
Total:							

21-Jun-17

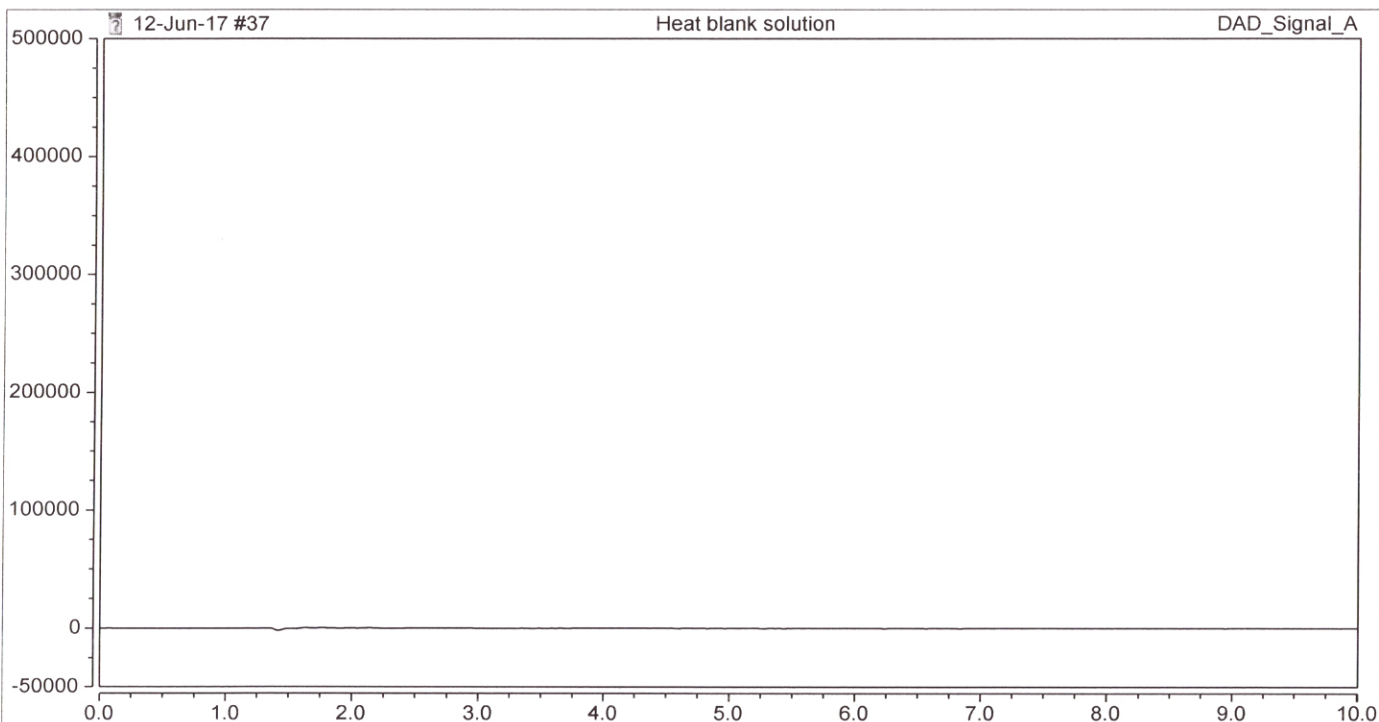
23-Jun-17

QbD Research & Developement Pvt.Ltd.

Injection Details

Injection Name:	Heat blank solution	Run Time (min):	10.00
Vial Number:	Vial:20	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	13-Jun-17 03:56	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

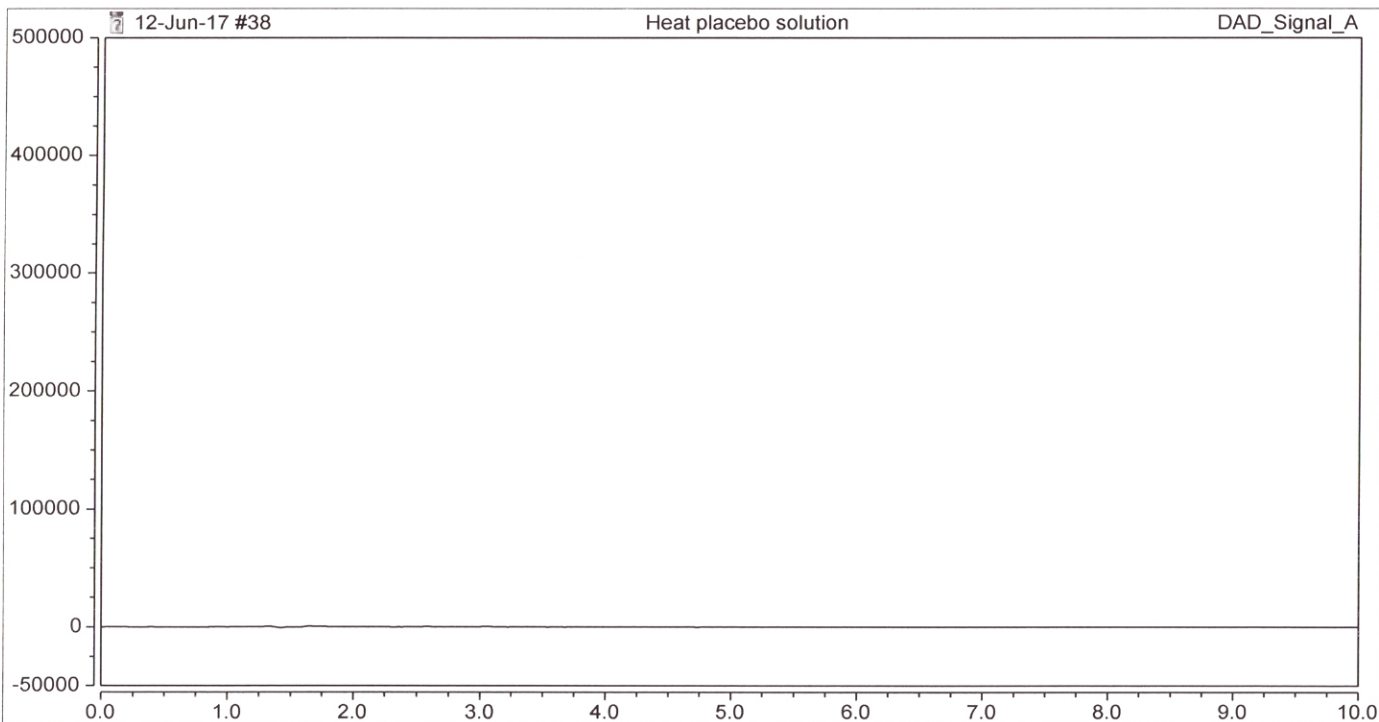
No.	Peak Name	Retention Time min	Area $\mu\text{AU}\cdot\text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
Total:							

Pankaj Gurav
21-Jun-17

Pankaj Gurav
21-Jun-17

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

Injection Name:	Heat placebo solution	Run Time (min):	10.00
Vial Number:	Vial:21	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	13-Jun-17 04:08	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram**Integration Results**

No.	Peak Name	Retention Time min	Area μ AU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
Total:							

Chromatogram
21-Jun-17

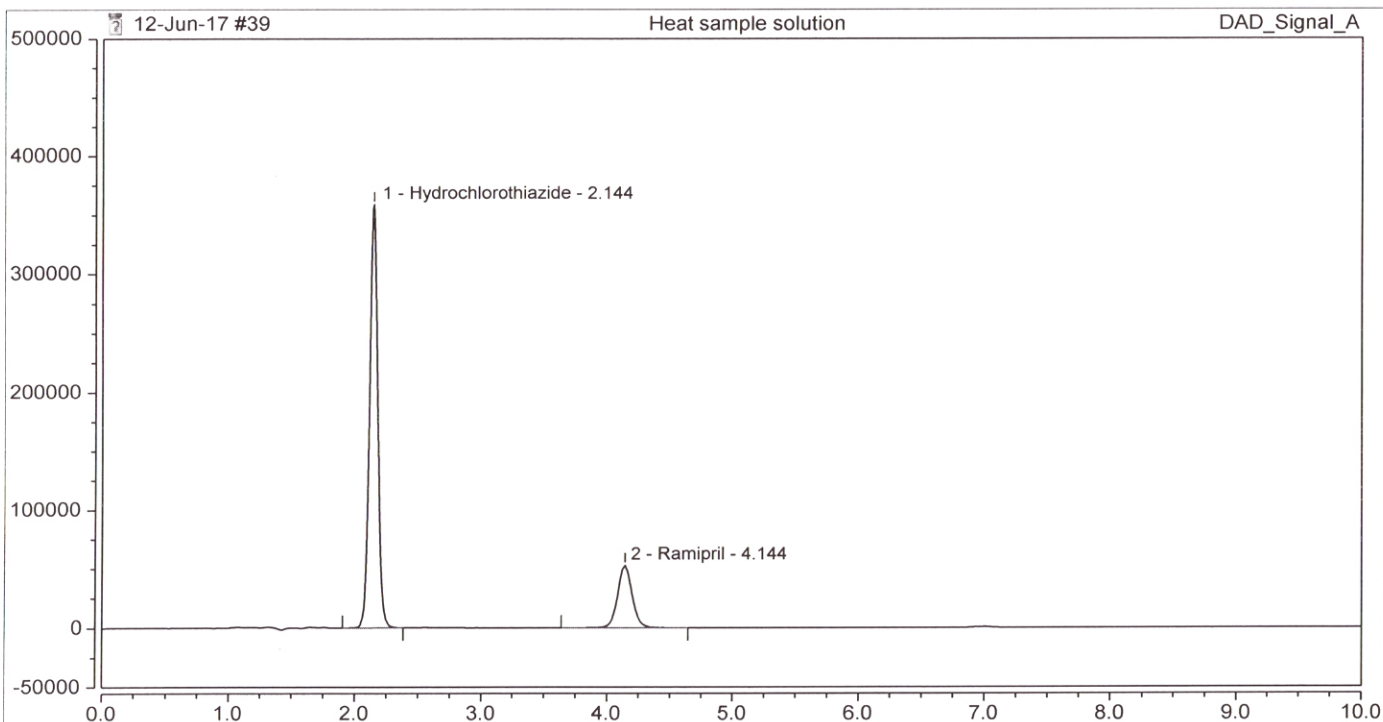
Pankaj
25-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Heat sample solution	Run Time (min):	10.00
Vial Number:	Vial:22	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	13-Jun-17 04:19	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	2.144	26918.472	5394	1.07	12.38	79.17
2	Ramipril	4.144	7082.866	6445	1.04	n.a.	20.83
Total:							

Chrom
21-Jun-17

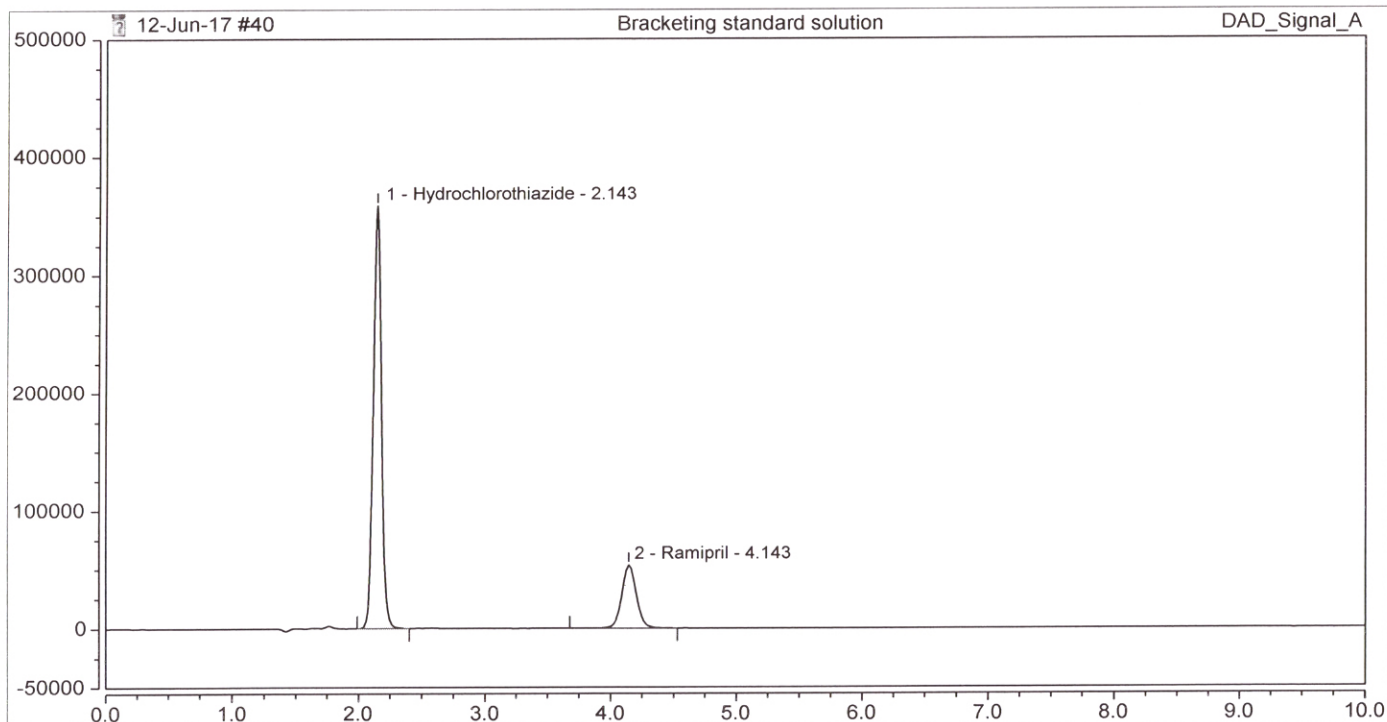
Chrom
21-Jun-17

QbD Research & Development Pvt.Ltd.

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
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC_ 51	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	13-Jun-17 04:31	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	2.143	26874.693	5364	1.12	12.35	78.90
2	Ramipril	4.143	7188.697	6424	1.08	n.a.	21.10
Total:							

Pankaj Gurav
21-Jun-17

Pankaj Gurav
21-Jun-17

Name	Ramithiazide Assay HPLC_ 51
Data Vault	XVault
Path	chrom://qbd-pc-07/XVault/Qbd-INST-HPLC-51/428/12-Jun-17.seq/Ramithiazide Assay HPLC_ 51.instmeth
Comment	instrument method updsted
Description	
Run time	10.000 [min]
Instrument	Qbd-INST-HPLC-51 on qbd-pc-07
Created	07-Jun-2017 20:43 +05:30 Sachin Pujari
Last Update	12-Jun-2017 15:53 +05:30 Sachin Pujari


12-Jun-17


12-Jun-17

Stage	Time min	Command	Value	Comment
Instrument Setup	initial			
Inject Preparation	0.000	Wait	LCSystem.Ready	
Inject	0.000	LCSystem.ALS.Inject	Blank=Inject	
Start Run	0.000	LCSystem.ALS_Temperature.AcqOn LCSystem.QuatPump_Dir_PistonA.AcqOn LCSystem.QuatPump_Flow.AcqOn LCSystem.QuatPump_Pressure.AcqOn LCSystem.QuatPump_SolventRatioA.AcqOn LCSystem.QuatPump_SolventRatioB.AcqOn LCSystem.QuatPump_SolventRatioC.AcqOn LCSystem.QuatPump_SolventRatioD.AcqOn LCSystem.TCC_Left_Temperature.AcqOn LCSystem.TCC_Right_Temperature.AcqOn LCSystem.DAD_Signal_A.AcqOn LCSystem.DAD_Spectra.AcqOn		
Run			Duration = 10.000 [min]	
Stop Run	0.000			
	10.000	LCSystem.ALS_Temperature.AcqOff LCSystem.QuatPump_Dir_PistonA.AcqOff LCSystem.QuatPump_Flow.AcqOff LCSystem.QuatPump_Pressure.AcqOff LCSystem.QuatPump_SolventRatioA.AcqOff LCSystem.QuatPump_SolventRatioB.AcqOff LCSystem.QuatPump_SolventRatioC.AcqOff LCSystem.QuatPump_SolventRatioD.AcqOff LCSystem.TCC_Left_Temperature.AcqOff LCSystem.TCC_Right_Temperature.AcqOff LCSystem.DAD_Signal_A.AcqOff LCSystem.DAD_Spectra.AcqOff		
End				

Pujari
12-Jun-17

Pujari
12-Jun-17

Property	Value
Settings for module Quat. Pump (G1311A - 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 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
Enable Analysis Left Temperature	0.80 [°C]
Value	

Sachin
12-Jun-17

Pankaj
12-Jun-17

Section Right Temperature Control (RightTemperatureControl)	
Right temperature Control Mode	Temperature Set
Right temperature	25.00 [°C]
Section Enable Analysis Right Temperature (RightTemperatureControl_NotReadyLimit)	
Enable Analysis Right Temperature	Yes
On	
Enable Analysis Right Temperature	0.80 [°C]
Value	
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 (G1315B - DAD: DAD.0)	
Peakwidth	> 0.1 min (2 s response time) (2.5 Hz)
Slit	4 nm
UV Lamp Required	Yes
Vis Lamp Required	No
Section Analog Output 1 (AnalogOutput1)	
Analog 1 Zero Offset	5 [%]
Analog 1 Attenuation	1000 [mAU]
Section Analog Output 2 (AnalogOutput2)	
Analog 2 Zero Offset	5 [%]
Analog 2 Attenuation	1000 [mAU]
Section Signals (Signals)	
Signal table (Signals_Signal)	
0	
Use Sig.	Yes
Signal	Signal A
Wavelength	210 [nm]
Bandwidth	4 [nm]
Use Ref.	No
1	
Use Sig.	No
Signal	Signal B
2	
Use Sig.	No
Signal	Signal C
3	
Use Sig.	No
Signal	Signal D
4	
Use Sig.	No
Signal	Signal E
Section Prepare Mode (PrepareMode)	
Margin for negative Absorbance	100 [mAU]
Section Autobalance (PrepareAutomation)	
Autobalance Prerun	Yes

[Signature]
12-Jun-17

[Signature]
12-Jun-17

Autobalance Postrun	No
Section Spectrum (SpectraAcquisition)	
Spectrum Range WL from	190 [nm]
Spectrum Range WL to	400 [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)	
Settings for module Sampler (G1329A - 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]
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 Thermostat (Thermostat)	
Not Ready Temperature Mode	Enable Analysis With Any Temperature
Thermostat Control	Turned Off
Section Stop Time (StopTime)	
Stoptime Mode	As pump/No limit
Section Post Time (PostTime)	
Posttime Mode	Off
Section Timetable (Timetable)	
Timetable (Timetable_TimetableEntry)	

B. Pujari
12-06-17

P. Gurav
12-06-17

Property	Value
Settings for module Sampler (G1329A - Pretreatment (PretreatmentInstruction)	

P. Gurav
12-Jun-17

P. Gurav
12-Jun-17