

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. :	GPI70403
LNB No./Pg. No.:	419/118

Date: 27-Jun-17

Name of standard	Standard B. No.	Standard purity (%)	Standard wt (mg)	Dilution details (mL)	Conc (ppm)
Hydrochlorothiazide	20140403	99.9	25.01	25 mL, 5 mL->50 mL	50.0

Injection No.	Retention Time	Area of Standard
1	2.103	26338.810
2	2.105	26355.539
3	2.110	26313.041
4	2.105	26421.229
5	2.105	26415.426
6	2.111	26394.816
Average	2.107	26376.477
SD	0.00	41.55
%RSD	0.15	0.16
System suitability results of Hydrochlorothiazide		
% RSD of Area	0.16	NMT 2.0
Tailing factor	1.16	NMT 2.0
Theoretical plates	3556	NLT 2000

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

Sample Type	Sample Weight (mg)	Area of Sample	% Assay	% Degradation	Peak purity Match
Untreated sample	494.30	26666.331	102.1	NA	1000
Acid treated sample (5 mL of 5N HCl, 15 min at 75°C)	493.66	26754.119	102.6	-0.5	1000
Base treated sample (5 mL of 5N NaOH 15 min at 75°C)	493.82	27789.303	106.5	-4.4	999
Hydrogen peroxide treated sample (5 mL of 30% H2O2, 15 min at 75°C)	493.41	26462.014	101.5	0.6	1000
Sample solution exposed to Heat (30 min at 75°C)	493.91	26513.183	101.6	0.5	1000

Done by:
Date:

Chen
28-Jun-17

Checked by:
Date:

Chen
28-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.:	419/118

Date: 27-Jun-17

Name of standard	Standard B. No.	Standard purity (%)	Standard wt (mg)	Dilution details (mL)	Conc (ppm)
Ramipril	RL14203	99.8	25.25	25 mL; 2 mL->100 mL	20.2

Injection No.	Retention Time	Area of Standard
1	3.929	6941.648
2	3.931	6942.284
3	3.936	6937.054
4	3.938	6956.517
5	3.938	6954.164
6	3.937	6950.315
Average	3.935	6946.997
SD	0.00	7.78
%RSD	0.10	0.11
System suitability results of Ramipril		
% RSD of Area	0.11	NMT 2.0
Tailing factor	1.12	NMT 2.0
Theoretical plates	4979	NLT 2000

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

Sample Type	Sample Weight (mg)	Average Area of Sample	% Assay	% Degradation	Peak purity Match
Untreated sample	494.30	6696.740	98.2	NA	1000
Acid treated sample (5 mL of 5N HCl, 15 min at 75°C)	493.66	6674.519	98.0	0.2	1000
Base treated sample ((5 mL of 5N NaOH 15 min at 75°C)	493.82	ND	NA	NA	NA
Hydrogen peroxide treated sample (5 mL of 30% H2O2, 15 min at 75°C)	493.41	6553.119	96.3	1.9	1000
Sample solution exposed to Heat (30 min at 75°C)	493.91	6726.975	98.7	-0.5	1000

Done by:

Date:

[Signature]
28 Jun-17

Checked by:

Date:

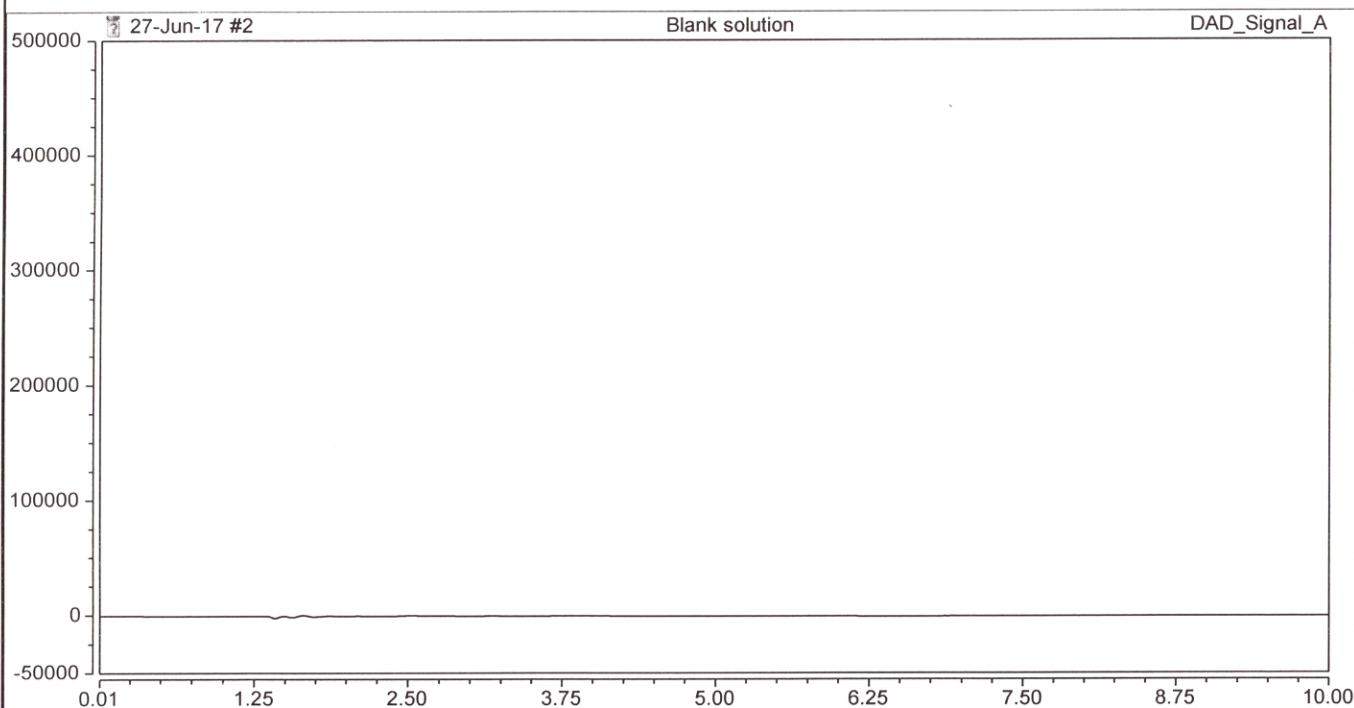
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28 Jun-17

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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
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC-05	Bandwidth:	n.a.
Processing Method:	PR Method_FD_02	Dilution Factor:	1.0000
Injection Date/Time:	27-Jun-17 22:23	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



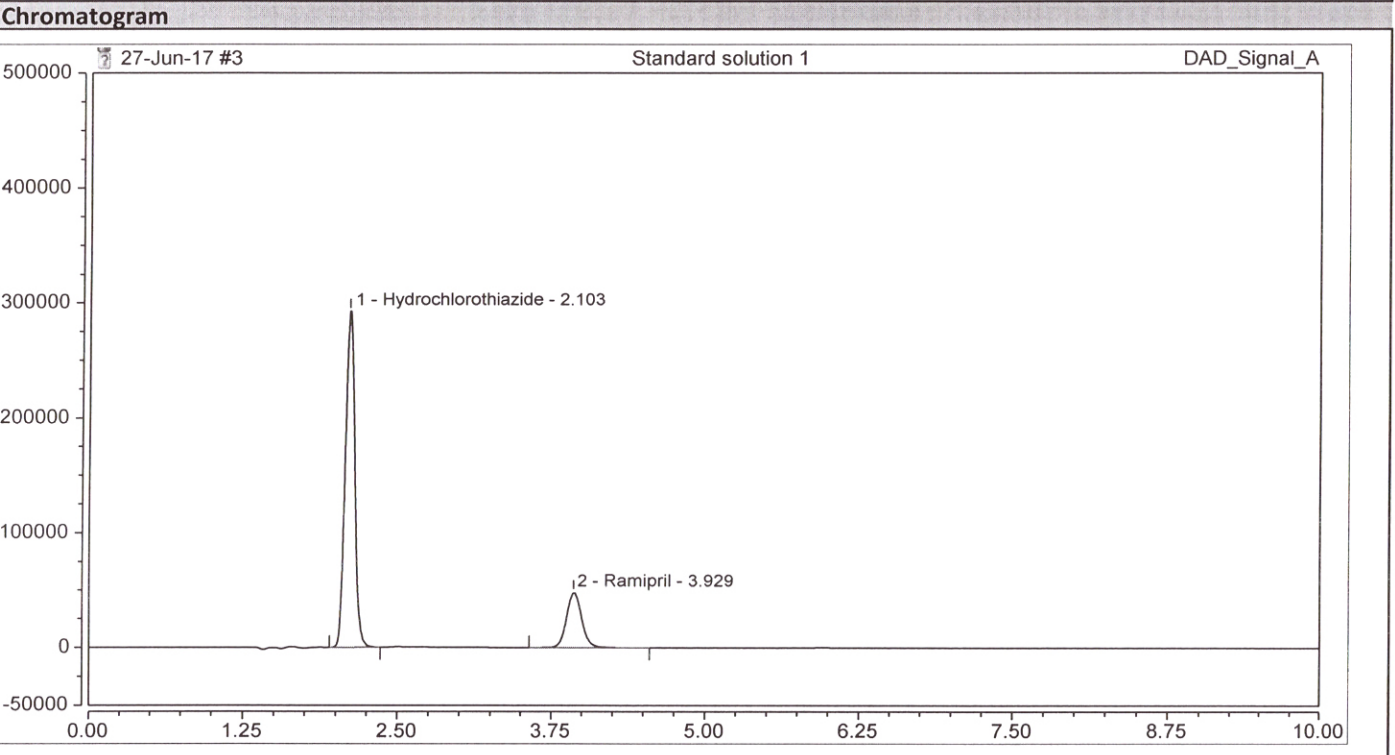
Integration Results

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

Pankaj Gurav
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28-Jun-17

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Injection Details			
Injection Name:	Standard solution 1	Run Time (min):	9.99
Vial Number:	Vial:2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC-05	Bandwidth:	n.a.
Processing Method:	PR Method_FD_02	Dilution Factor:	1.0000
Injection Date/Time:	27-Jun-17 22:34	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)	Match	Rel.Area %
1	Hydrochlorothiazide	2.103	26358.810	3556	1.16	10.04	1000	79.15
2	Ramipril	3.929	6941.648	4979	1.12	n.a.	1000	20.85
Total:								

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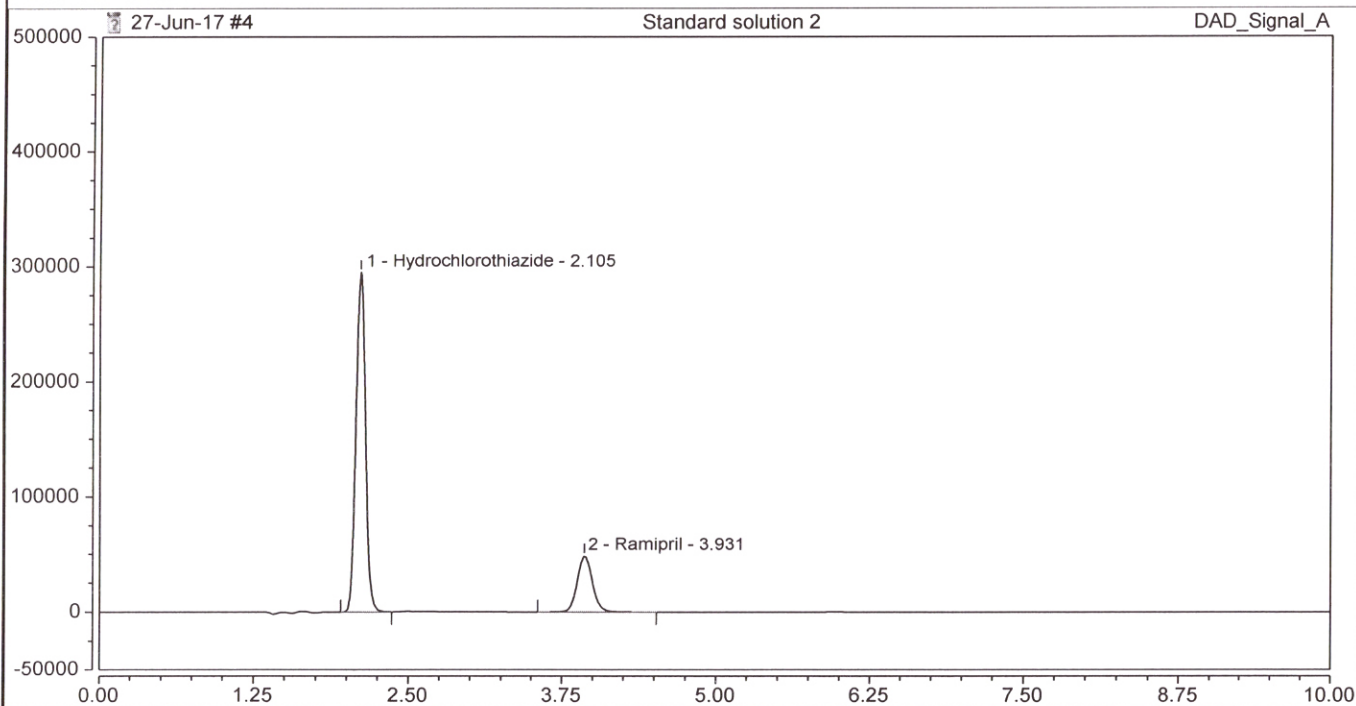
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28-Jun-17

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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
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC-05	Bandwidth:	n.a.
Processing Method:	PR Method_FD_02	Dilution Factor:	1.0000
Injection Date/Time:	27-Jun-17 22:46	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)	Match	Rel.Area %
1	Hydrochlorothiazide	2.105	26355.539	3620	1.13	10.10	1000	79.15
2	Ramipril	3.931	6942.284	5025	1.11	n.a.	1000	20.85
Total:								

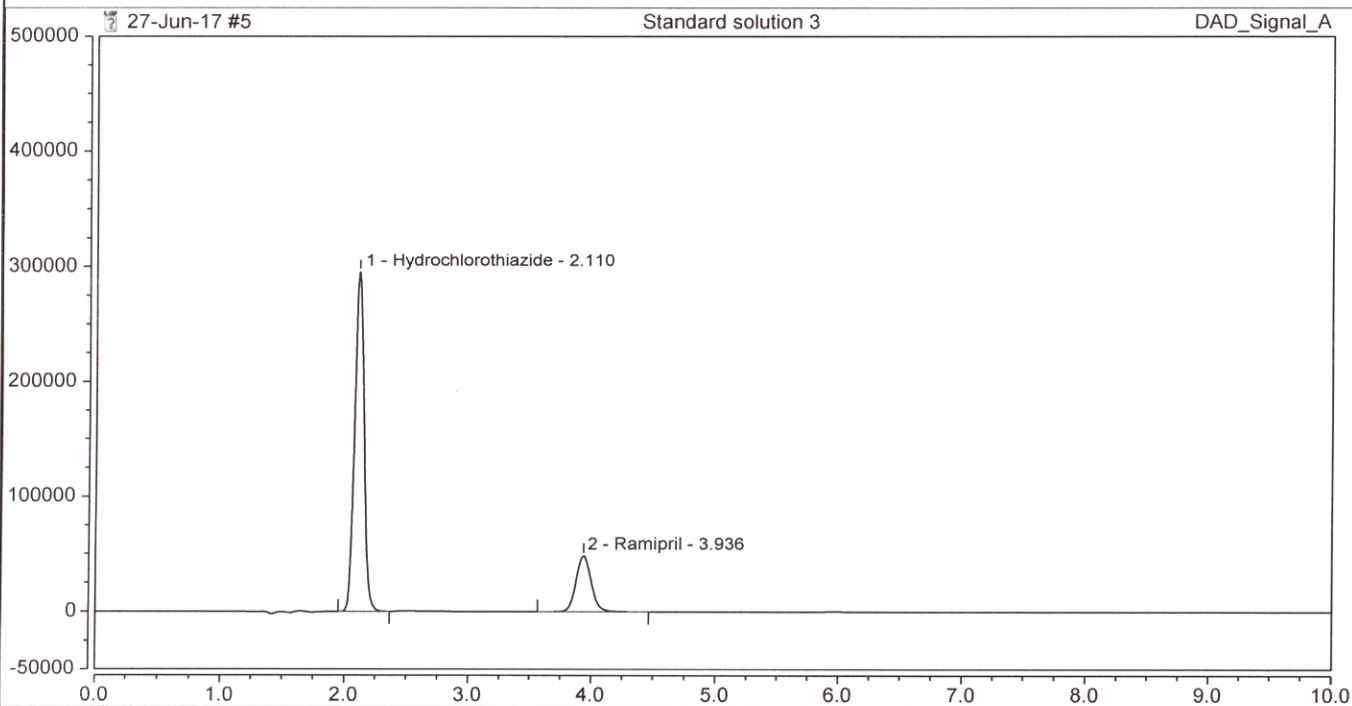
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28 Jun-17Pankaj
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Injection Details

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
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC-05	Bandwidth:	n.a.
Processing Method:	PR Method_FD_02	Dilution Factor:	1.0000
Injection Date/Time:	27-Jun-17 22:58	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)	Match	Rel.Area %
1	Hydrochlorothiazide	2.110	26313.041	3649	1.07	10.12	1000	79.14
2	Ramipril	3.936	6937.054	5068	1.08	n.a.	1000	20.86
Total:								

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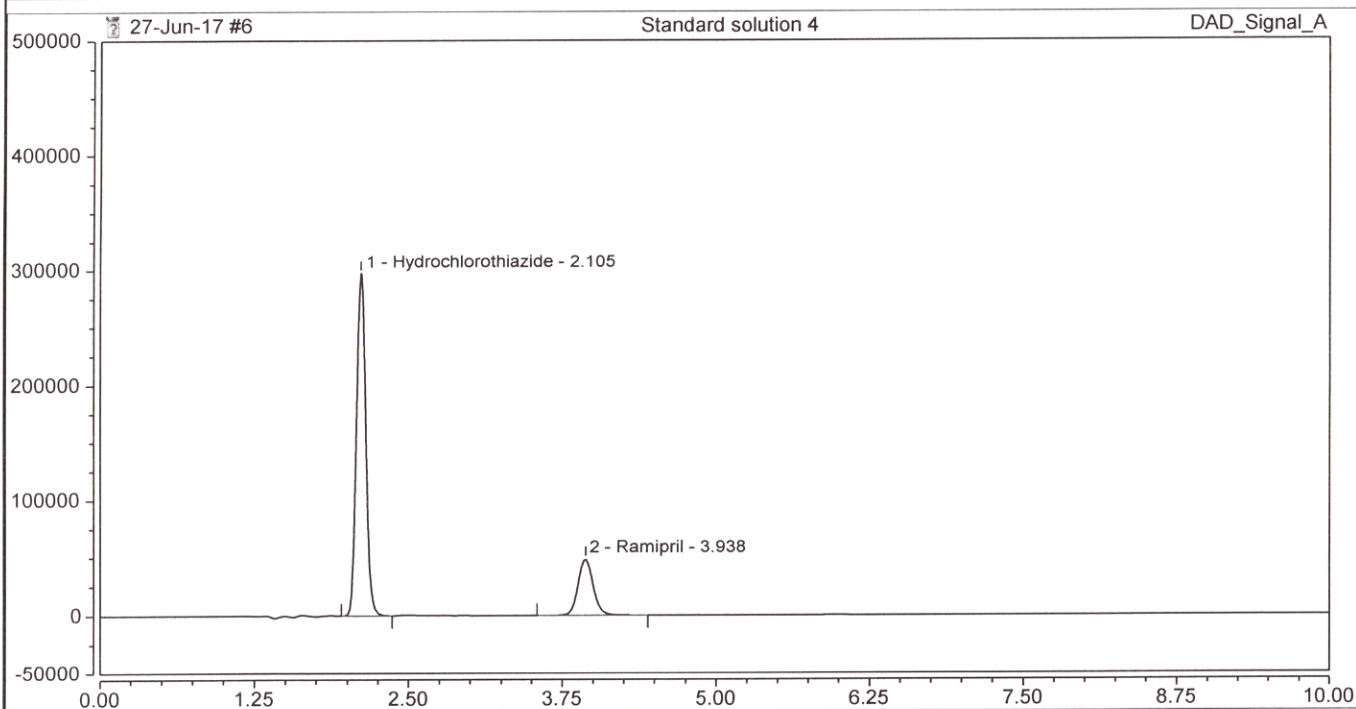
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Injection Details

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
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC-05	Bandwidth:	n.a.
Processing Method:	PR Method_FD_02	Dilution Factor:	1.0000
Injection Date/Time:	27-Jun-17 23:09	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)	Match	Rel.Area %
1	Hydrochlorothiazide	2.105	26421.229	3663	1.15	10.19	1000	79.16
2	Ramipril	3.938	6956.517	5088	1.07	n.a.	1000	20.84
Total:								

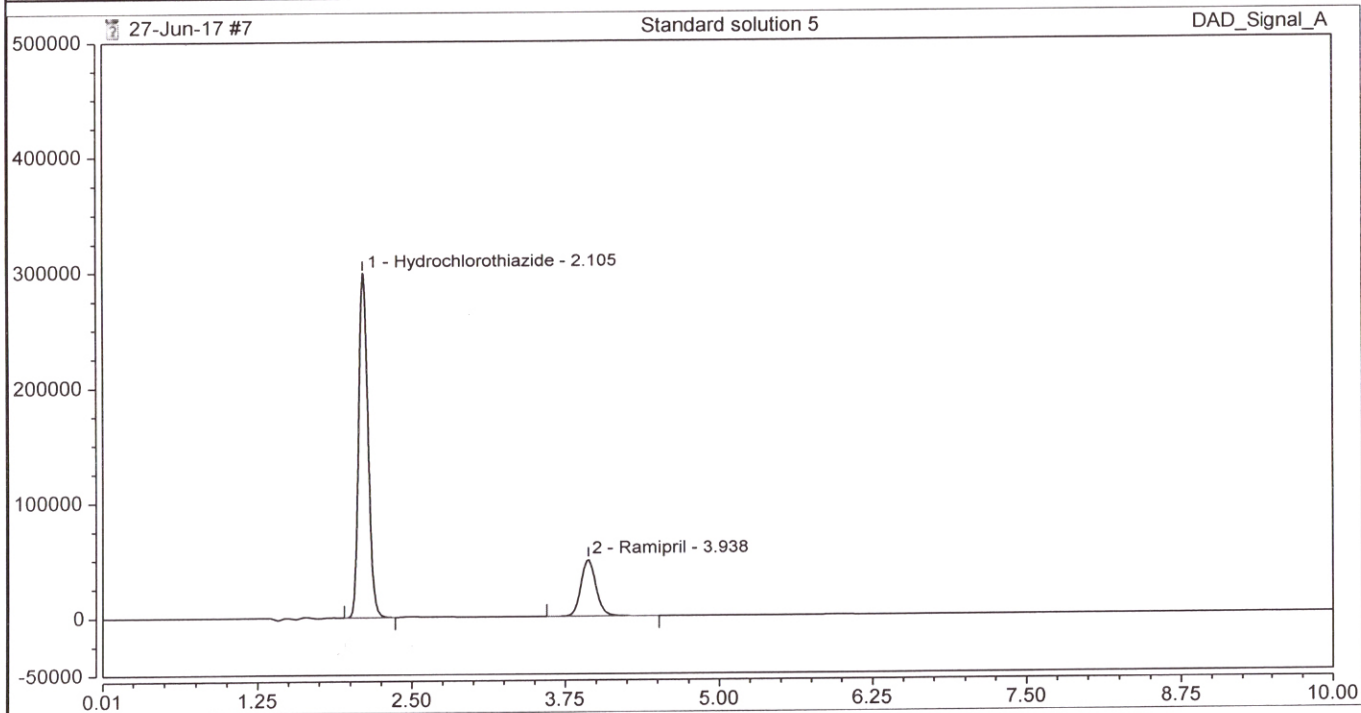
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Injection Details

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
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC-05	Bandwidth:	n.a.
Processing Method:	PR Method_FD_02	Dilution Factor:	1.0000
Injection Date/Time:	27-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)	Match	Rel.Area %
1	Hydrochlorothiazide	2.105	26415.426	3696	1.14	10.21	1000	79.16
2	Ramipril	3.938	6954.164	5104	1.08	n.a.	1000	20.84
Total:								

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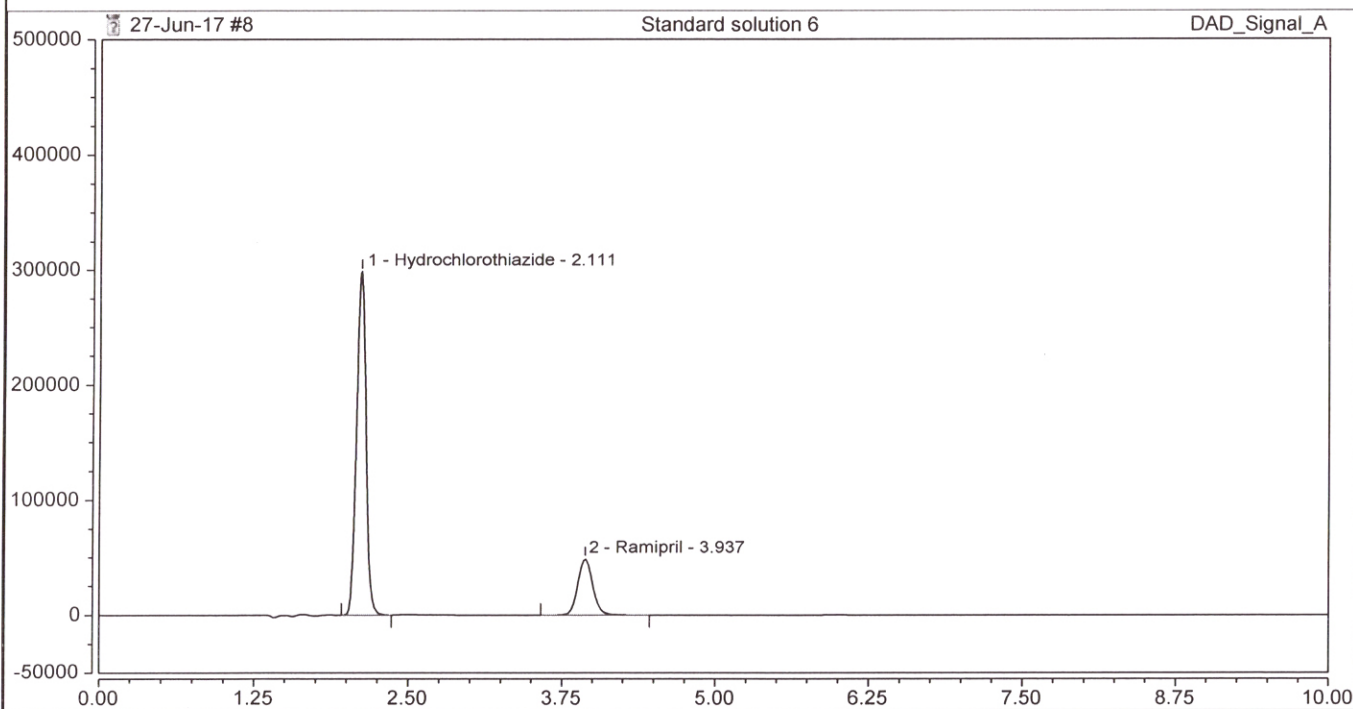
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Injection Details

Injection Name:	Standard solution 6	Run Time (min):	9.99
Vial Number:	Vial:2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC-05	Bandwidth:	n.a.
Processing Method:	PR Method_FD_02	Dilution Factor:	1.0000
Injection Date/Time:	27-Jun-17 23:33	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)	Match	Rel.Area %
1	Hydrochlorothiazide	2.111	26394.816	3702	1.07	10.16	1000	79.16
2	Ramipril	3.937	6950.315	5082	1.09	n.a.	1000	20.84
Total:								

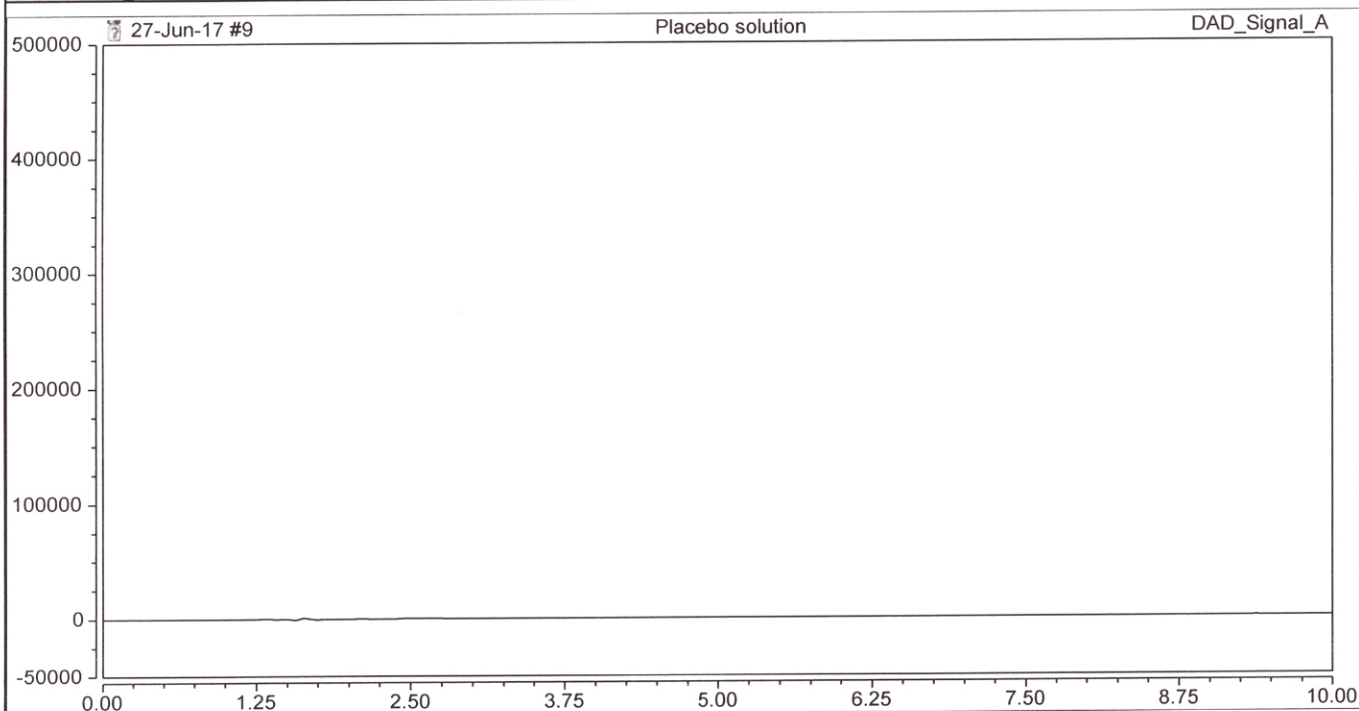
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Injection Details

Injection Name:	Placebo solution	Run Time (min):	9.99
Vial Number:	Vial:3	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC-05	Bandwidth:	n.a.
Processing Method:	PR Method_FD_02	Dilution Factor:	1.0000
Injection Date/Time:	27-Jun-17 23:45	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)	Match	Rel.Area %
Total:								

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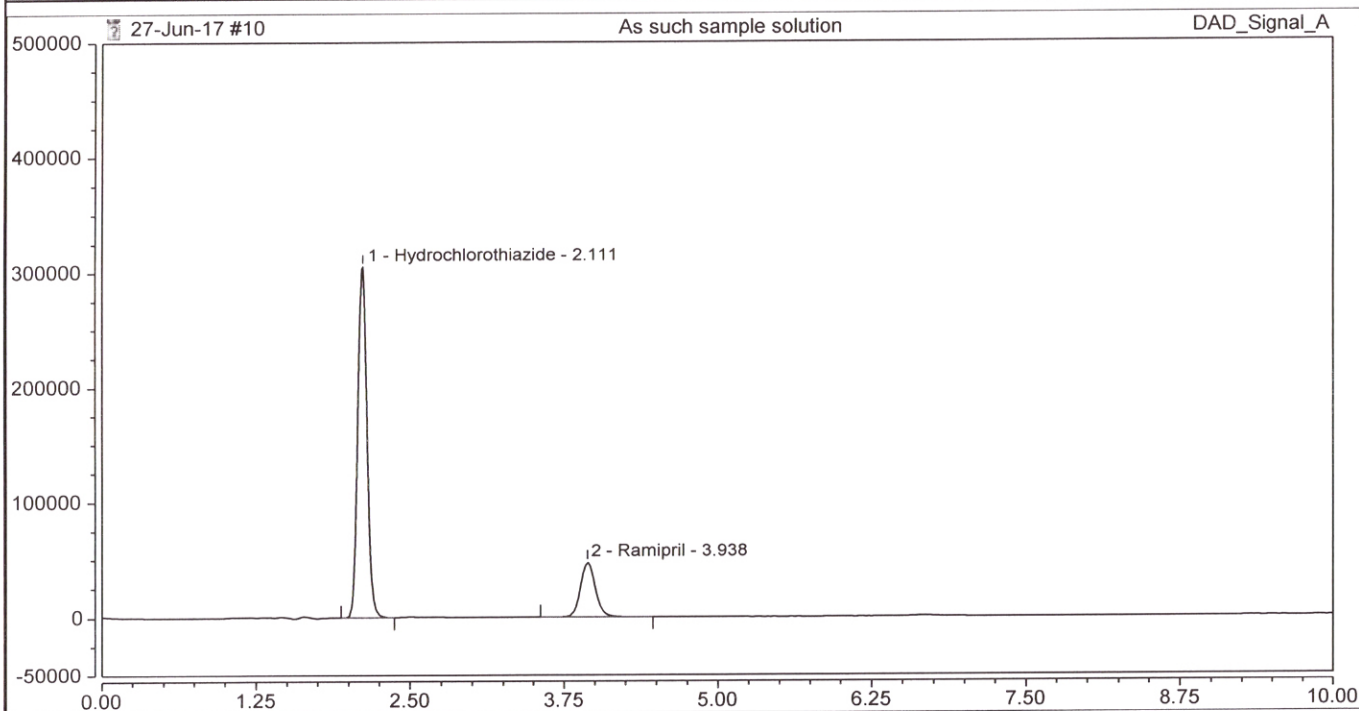
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Injection Details

Injection Name:	As such sample solution	Run Time (min):	9.99
Vial Number:	Vial:4	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC-05	Bandwidth:	n.a.
Processing Method:	PR Method_FD_02	Dilution Factor:	1.0000
Injection Date/Time:	27-Jun-17 23:56	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)	Match	Rel.Area %
1	Hydrochlorothiazide	2.111	26666.331	3801	1.07	10.23	1000	79.93
2	Ramipril	3.938	6696.740	5123	1.11	n.a.	1000	20.07
Total:								

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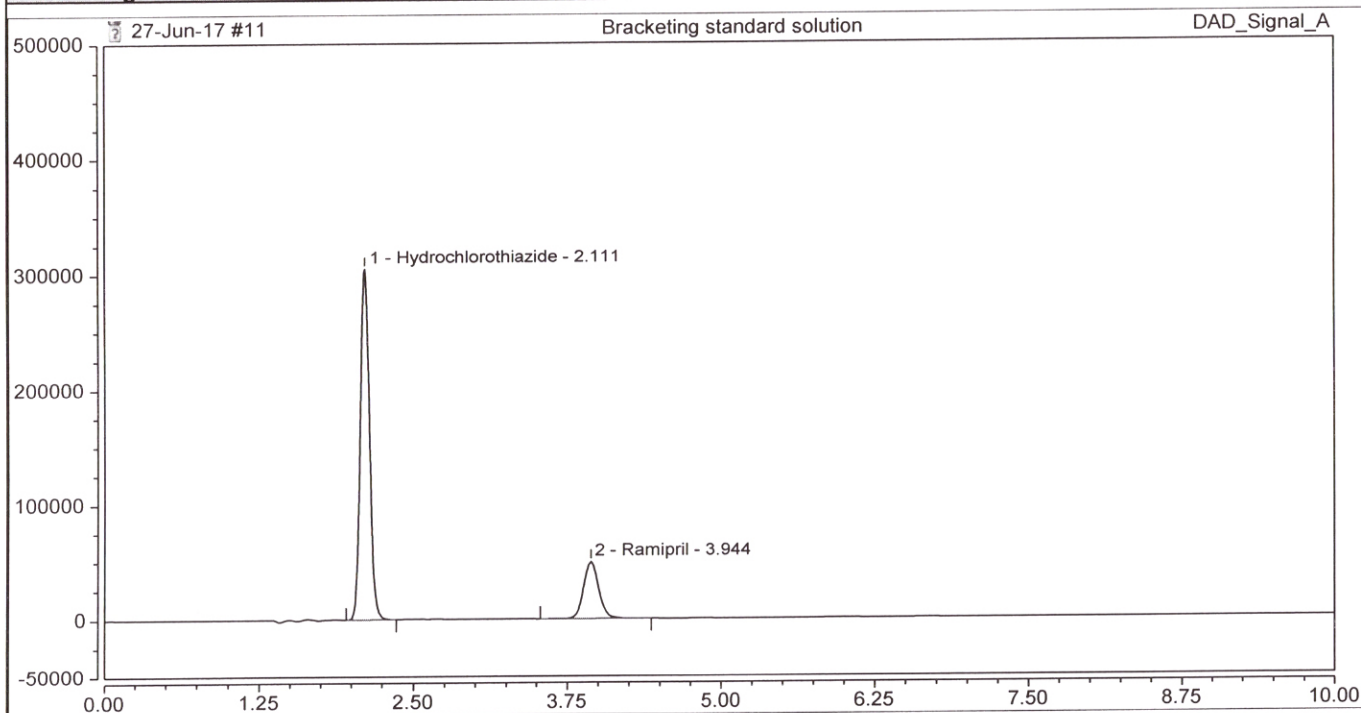
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28-Jun-17

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Injection Details

Injection Name:	Bracketing standard solution	Run Time (min):	9.99
Vial Number:	Vial:2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC-05	Bandwidth:	n.a.
Processing Method:	PR Method_FD_02	Dilution Factor:	1.0000
Injection Date/Time:	28-Jun-17 00:08	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)	Match	Rel.Area %
1	Hydrochlorothiazide	2.111	26437.705	3833	1.09	10.31	1000	79.15
2	Ramipril	3.944	6964.233	5170	1.07	n.a.	1000	20.85
Total:								

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28-Jun-17

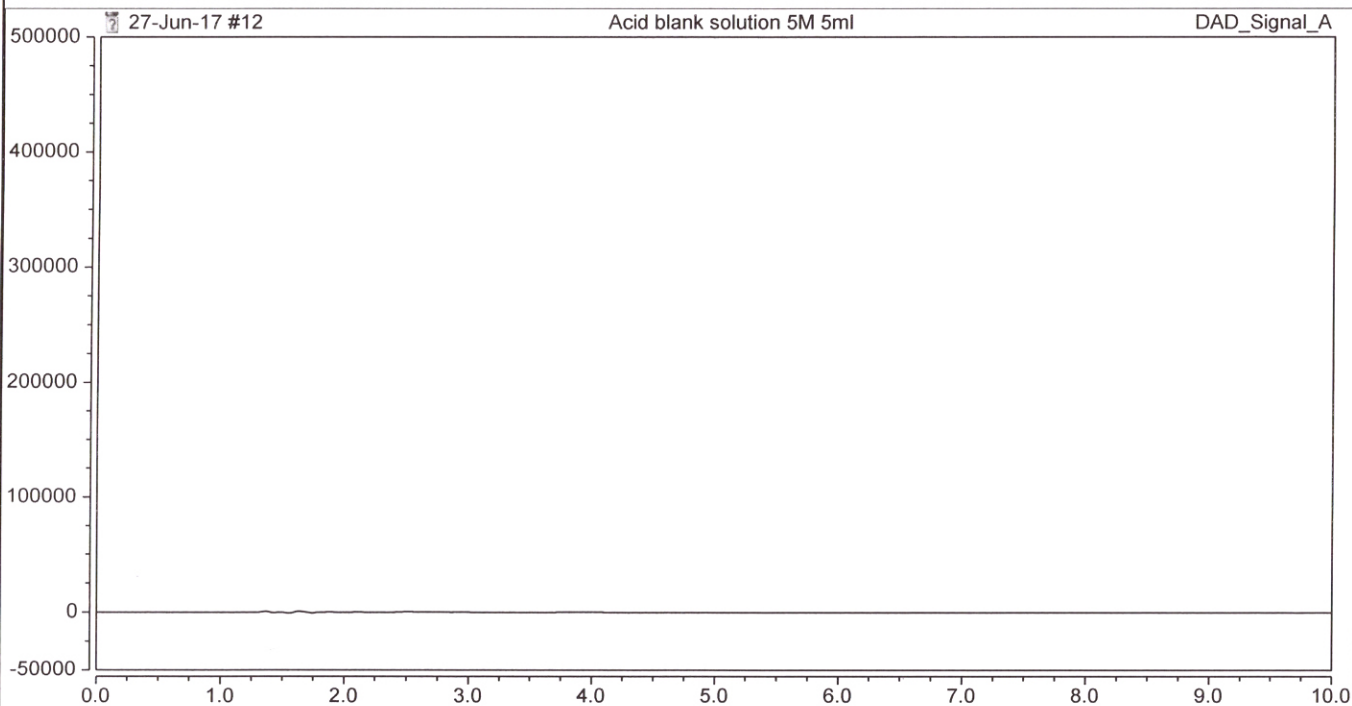
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28-Jun-17

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Injection Details

Injection Name:	Acid blank solution 5M 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-05	Bandwidth:	n.a.
Processing Method:	PR Method_FD_02	Dilution Factor:	1.0000
Injection Date/Time:	28-Jun-17 00:20	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

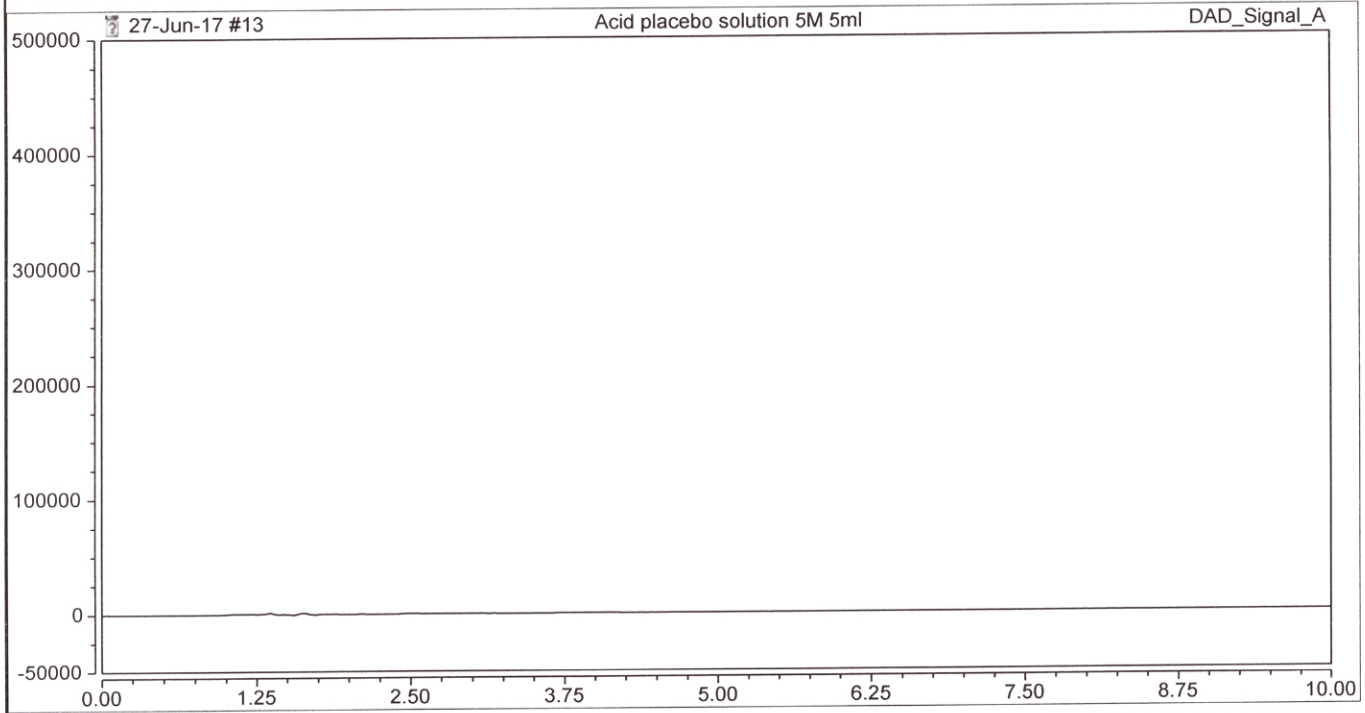
No.	Peak Name	Retention Time min	Area $\mu\text{AU}\cdot\text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Match	Rel.Area %
Total:								

Pankaj Gurav
28-Jun-17

Pankaj Gurav
28-Jun-17

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

Injection Name:	Acid placebo solution 5M 5ml	Run Time (min):	9.99
Vial Number:	Vial:6	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC-05	Bandwidth:	n.a.
Processing Method:	PR Method_FD_02	Dilution Factor:	1.0000
Injection Date/Time:	28-Jun-17 00:31	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)	Match	Rel.Area %
Total:								

Pankaj Gurav
28-Jun-17

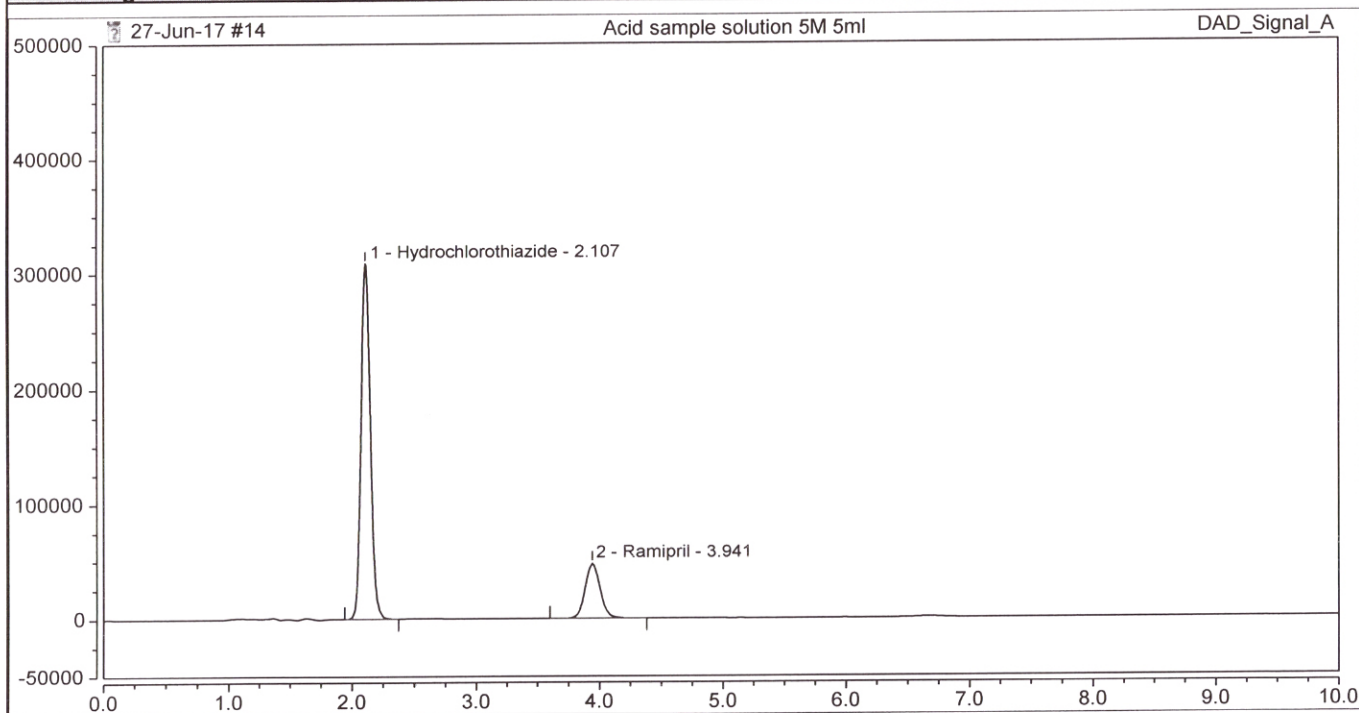
Pankaj Gurav
28-Jun-17

QbD Research & Developement Pvt.Ltd.

Injection Details

Injection Name:	Acid sample solution 5M 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-05	Bandwidth:	n.a.
Processing Method:	PR Method_FD_02	Dilution Factor:	1.0000
Injection Date/Time:	28-Jun-17 00:43	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)	Match	Rel.Area %
1	Hydrochlorothiazide	2.107	26754.119	3859	1.12	10.35	1000	80.03
2	Ramipril	3.941	6674.519	5204	1.10	n.a.	1000	19.97
Total:								

Pankaj
28-Jun-17

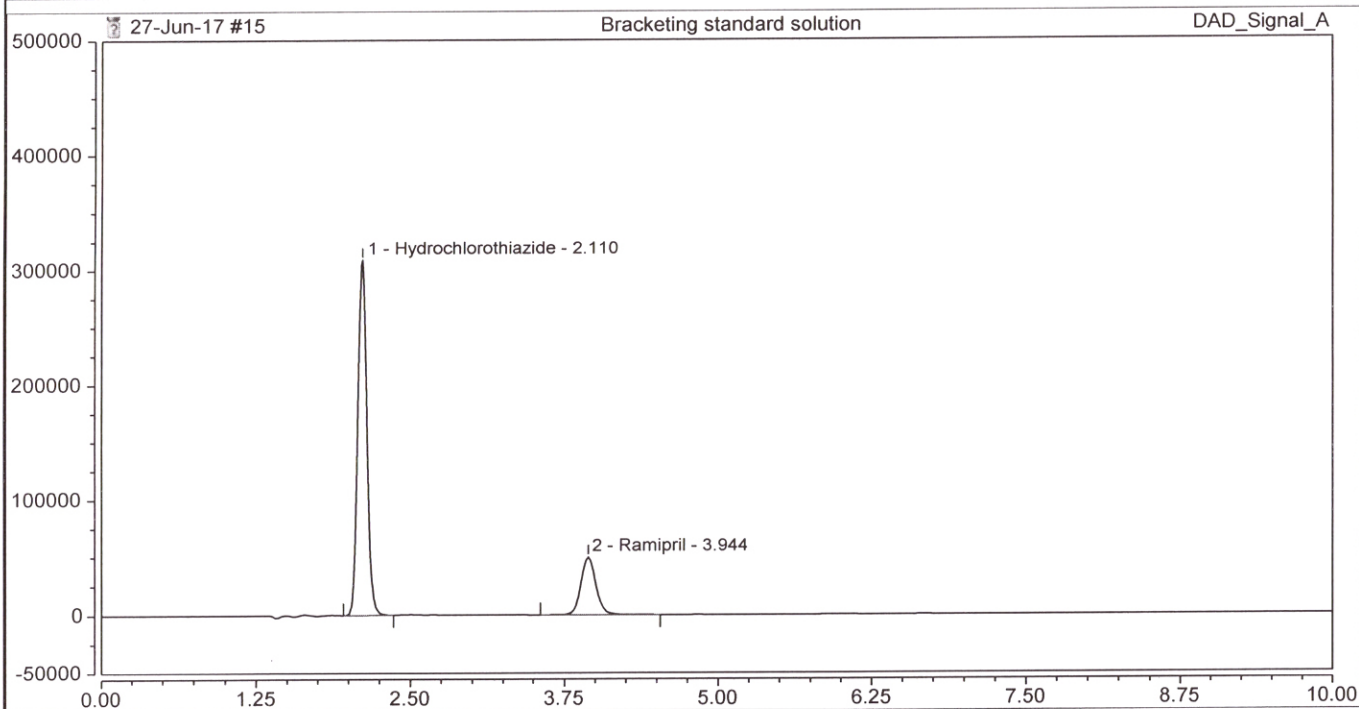
Pankaj
28-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Bracketing standard solution	Run Time (min):	9.99
Vial Number:	Vial:2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC-05	Bandwidth:	n.a.
Processing Method:	PR Method_FD_02	Dilution Factor:	1.0000
Injection Date/Time:	28-Jun-17 00:55	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



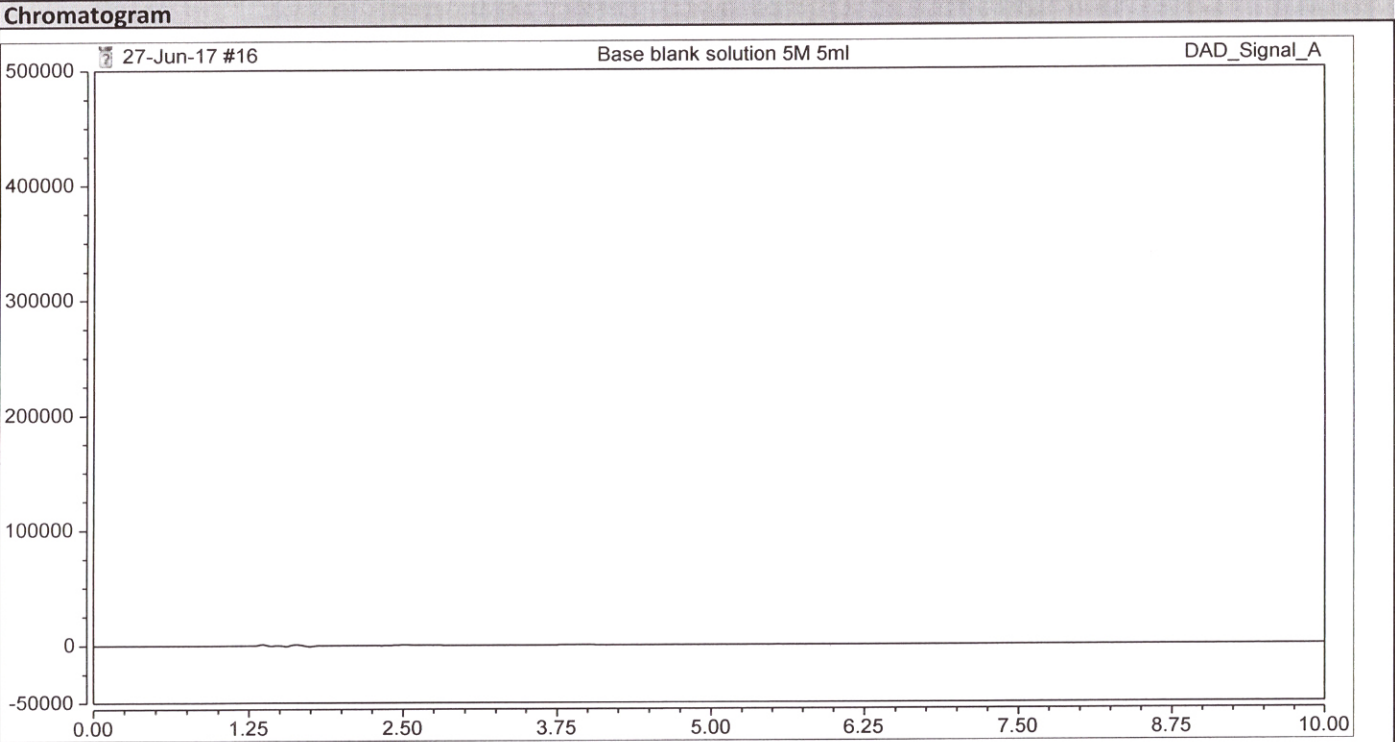
Integration Results

No.	Peak Name	Retention Time min	Area $\mu\text{AU}\cdot\text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Match	Rel.Area %
1	Hydrochlorothiazide	2.110	26434.308	3930	1.09	10.41	1000	79.13
2	Ramipril	3.944	6973.050	5249	1.07	n.a.	1000	20.87
Total:								

Pankaj Gurav
28-Jun-17

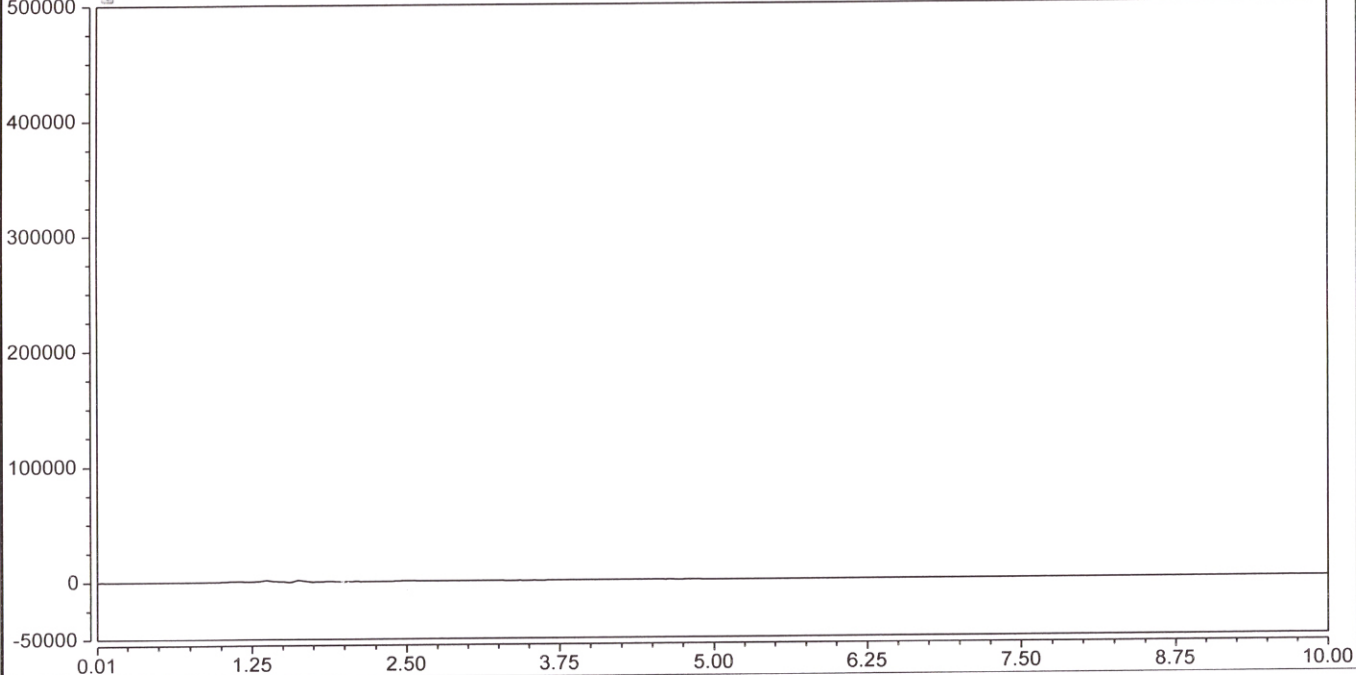
Pankaj Gurav
28-Jun-17

QbD Research & Developement Pvt.Ltd.		
Injection Details		
Injection Name:	Base blank solution 5M 5ml	Run Time (min): 9.99
Vial Number:	Vial:8	Injection Volume: 10.00
Injection Type:	Unknown	Channel: DAD_Signal_A
Calibration Level:		Wavelength: 210
Instrument Method:	Ramithiazide Assay HPLC-05	Bandwidth: n.a.
Processing Method:	PR Method_FD_02	Dilution Factor: 1.0000
Injection Date/Time:	28-Jun-17 01:06	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)	Match	Rel.Area %
Total:								

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28-Jun-17

QbD Research & Developement Pvt.Ltd.								
Injection Details								
Injection Name:	Base placebo solution 5M 5ml	Run Time (min):	9.99					
Vial Number:	Vial:9	Injection Volume:	10.00					
Injection Type:	Unknown	Channel:	DAD_Signal_A					
Calibration Level:		Wavelength:	210					
Instrument Method:	Ramithiazide Assay HPLC-05	Bandwidth:	n.a.					
Processing Method:	PR Method_FD_02	Dilution Factor:	1.0000					
Injection Date/Time:	28-Jun-17 01:18	Sample Weight:	1.0000					
User Name:	Pankaj Gurav	Sample Weight:	1.0000					
Chromatogram								
27-Jun-17 #17 Base placebo solution 5M 5ml DAD_Signal_A 								
Integration Results								
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Match	Rel.Area %
Total:								

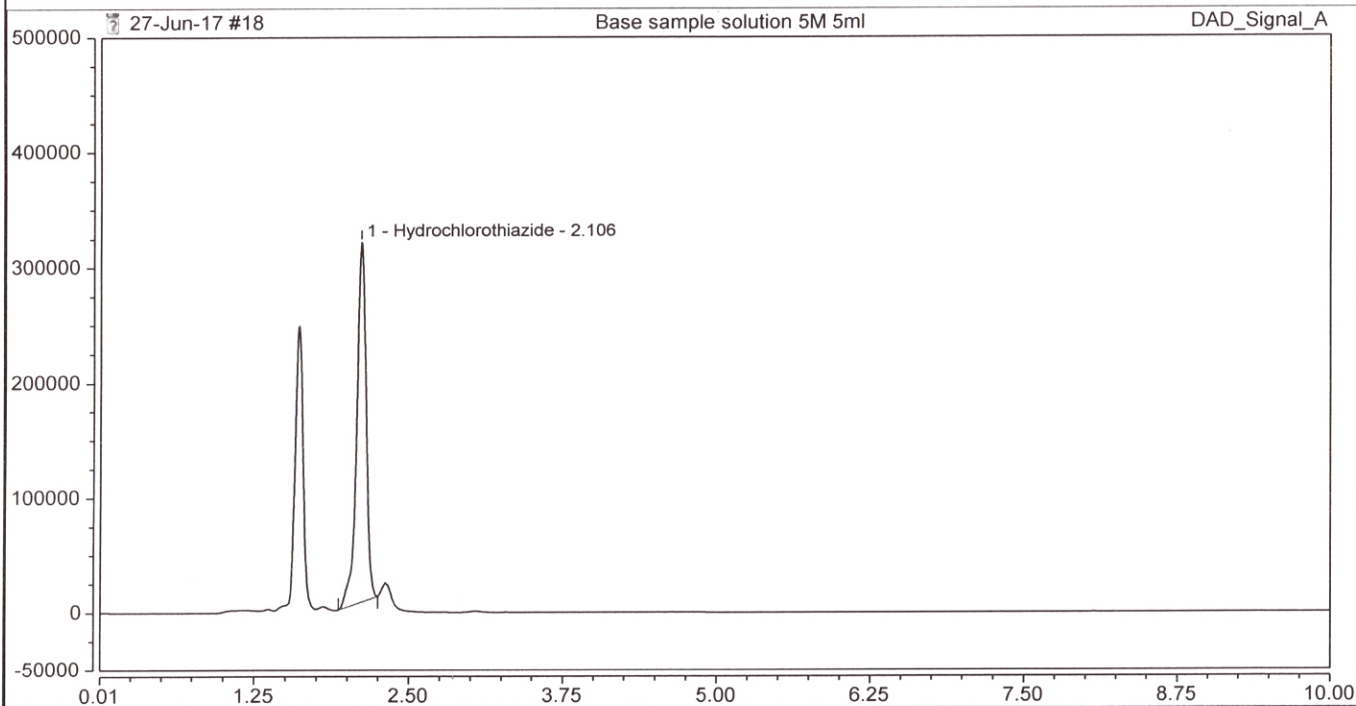
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QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Base sample solution 5M 5ml	Run Time (min):	9.99
Vial Number:	Vial:10	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC-05	Bandwidth:	n.a.
Processing Method:	PR Method_FD_02	Dilution Factor:	1.0000
Injection Date/Time:	28-Jun-17 01:30	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)	Match	Rel.Area %
1	Hydrochlorothiazide	2.106	27789.303	3959	0.88	n.a.	999	100.00
Total:								

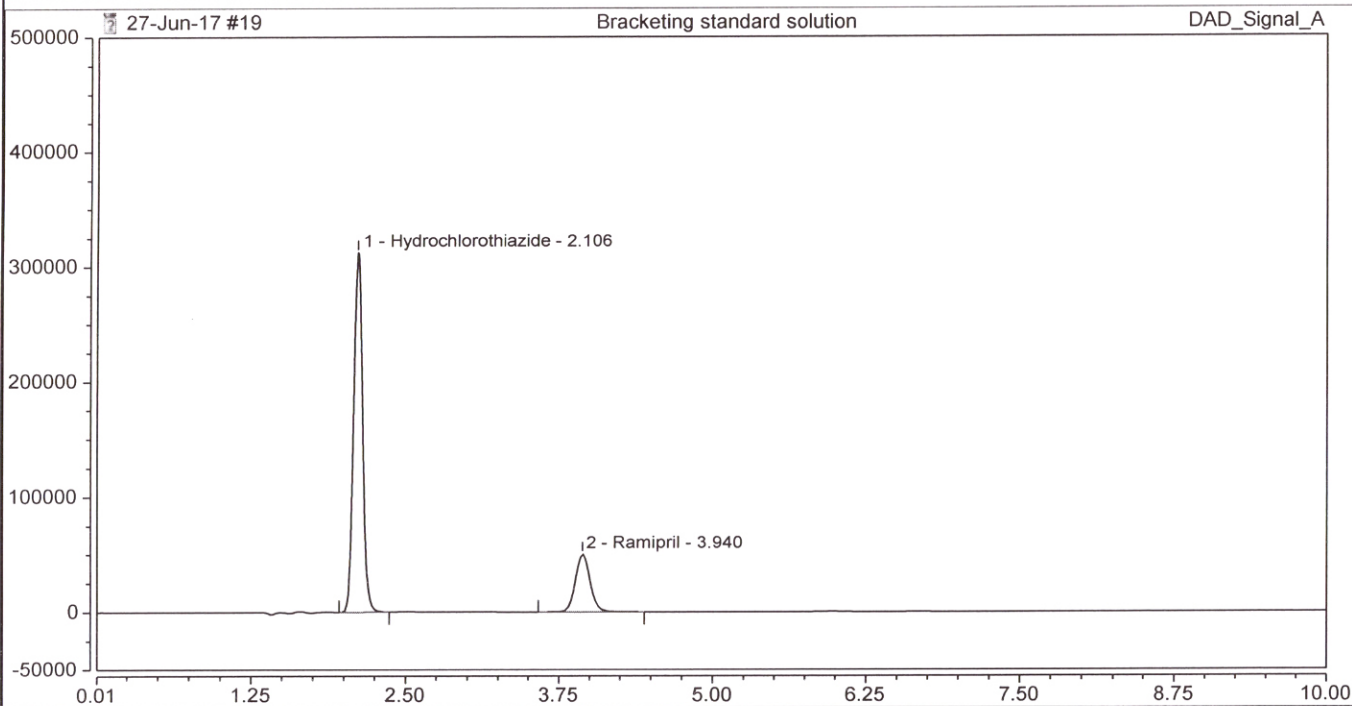
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QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Bracketing standard solution	Run Time (min):	9.99
Vial Number:	Vial:2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC-05	Bandwidth:	n.a.
Processing Method:	PR Method_FD_02	Dilution Factor:	1.0000
Injection Date/Time:	28-Jun-17 01:41	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)	Match	Rel.Area %
1	Hydrochlorothiazide	2.106	26440.681	4055	1.15	10.54	1000	79.13
2	Ramipril	3.940	6973.075	5347	1.10	n.a.	1000	20.87
Total:								

Pankaj
28-Jun-17

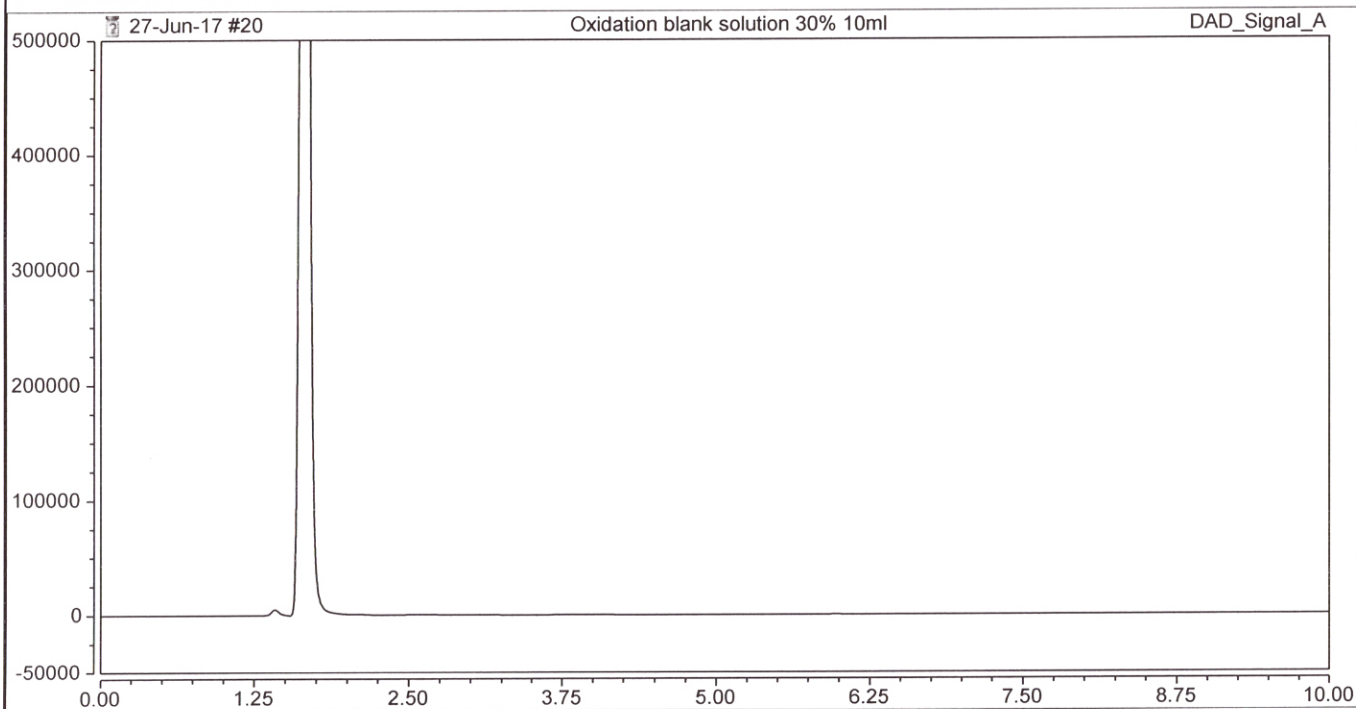
Pankaj
28-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Oxidation blank solution 30% 10ml	Run Time (min):	9.99
Vial Number:	Vial:11	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC-05	Bandwidth:	n.a.
Processing Method:	PR Method_FD_02	Dilution Factor:	1.0000
Injection Date/Time:	28-Jun-17 01:53	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)	Match	Rel.Area %
Total:								

Pankaj
28-Jun-17

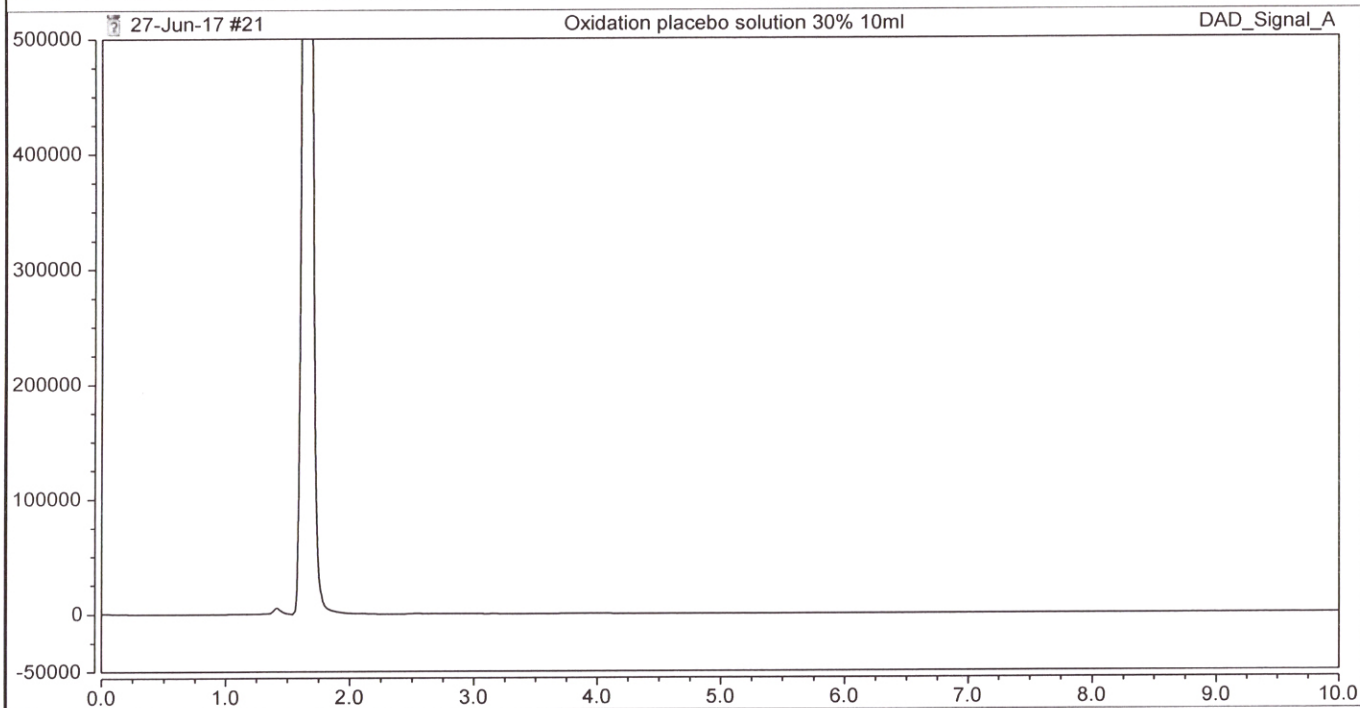
Pankaj
28-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Oxidation placebo solution 30% 10ml	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-05	Bandwidth:	n.a.
Processing Method:	PR Method_FD_02	Dilution Factor:	1.0000
Injection Date/Time:	28-Jun-17 02:05	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)	Match	Rel.Area %
Total:								

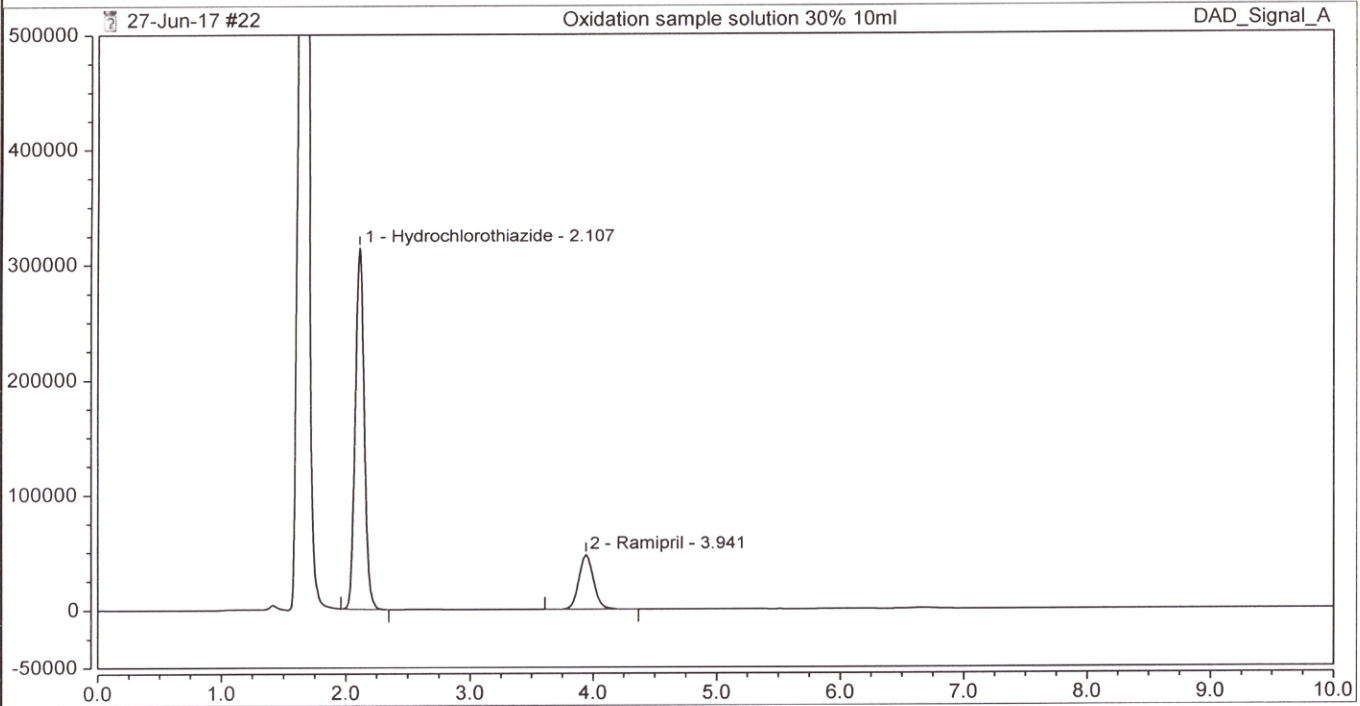
Pankaj
28 Jun-17Pankaj
28 Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Oxidation sample solution 30% 10ml	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-05	Bandwidth:	n.a.
Processing Method:	PR Method_FD_02	Dilution Factor:	1.0000
Injection Date/Time:	28-Jun-17 02:16	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)	Match	Rel.Area %
1	Hydrochlorothiazide	2.107	26462.014	4055	1.13	10.56	1000	80.15
2	Ramipril	3.941	6553.119	5387	1.09	n.a.	1000	19.85
Total:								

Pankaj
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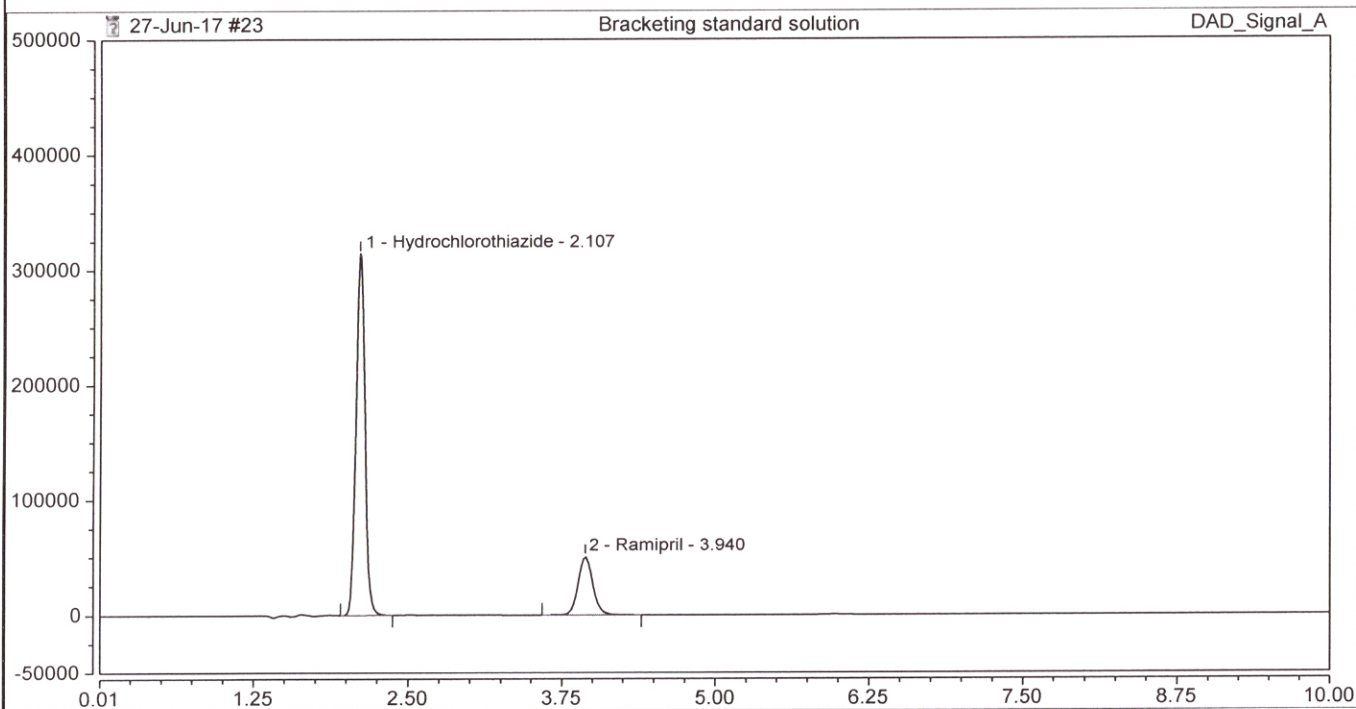
Pankaj
28-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Bracketing standard solution	Run Time (min):	9.99
Vial Number:	Vial:2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC-05	Bandwidth:	n.a.
Processing Method:	PR Method_FD_02	Dilution Factor:	1.0000
Injection Date/Time:	28-Jun-17 02:28	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



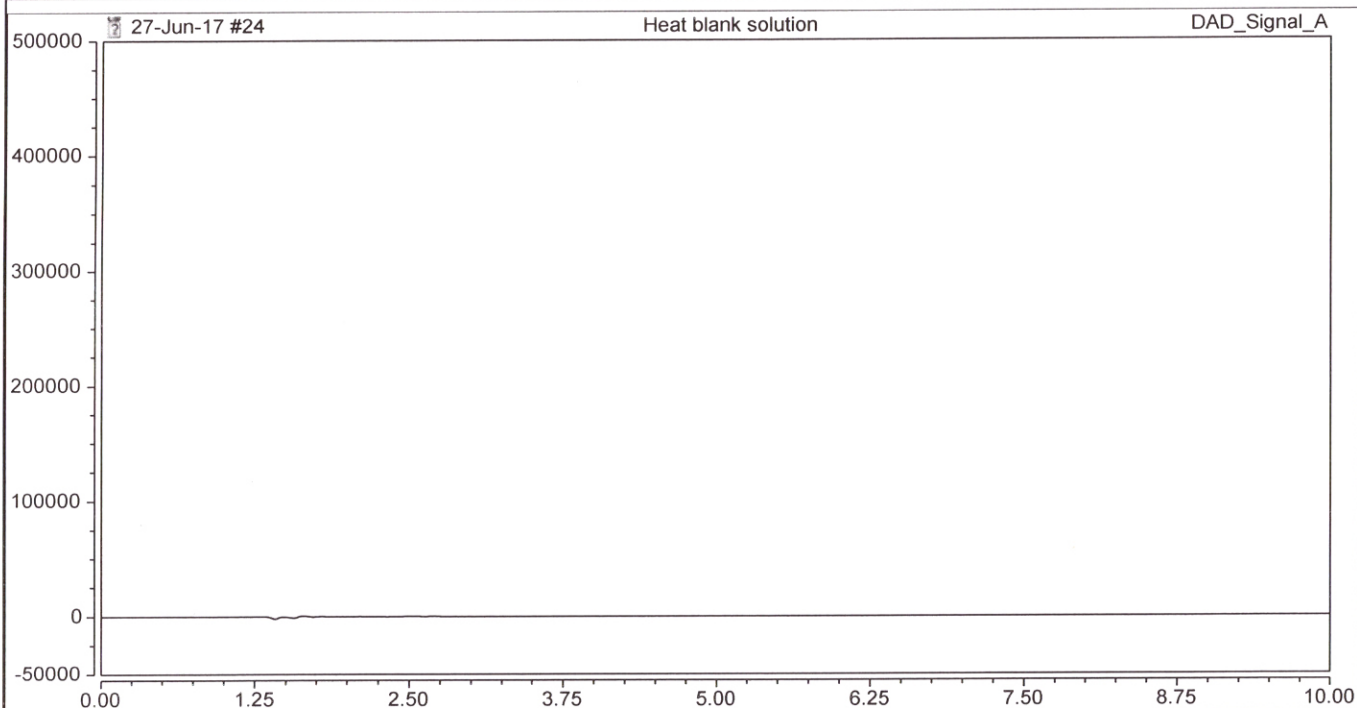
Integration Results

No.	Peak Name	Retention Time min	Area $\mu\text{AU}\cdot\text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Match	Rel.Area %
1	Hydrochlorothiazide	2.107	26454.568	4093	1.14	10.59	1000	79.15
2	Ramipril	3.940	6969.862	5391	1.09	n.a.	1000	20.85
Total:								

Pankaj Gurav
28-Jun-17Pankaj Gurav
28-Jun-17

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

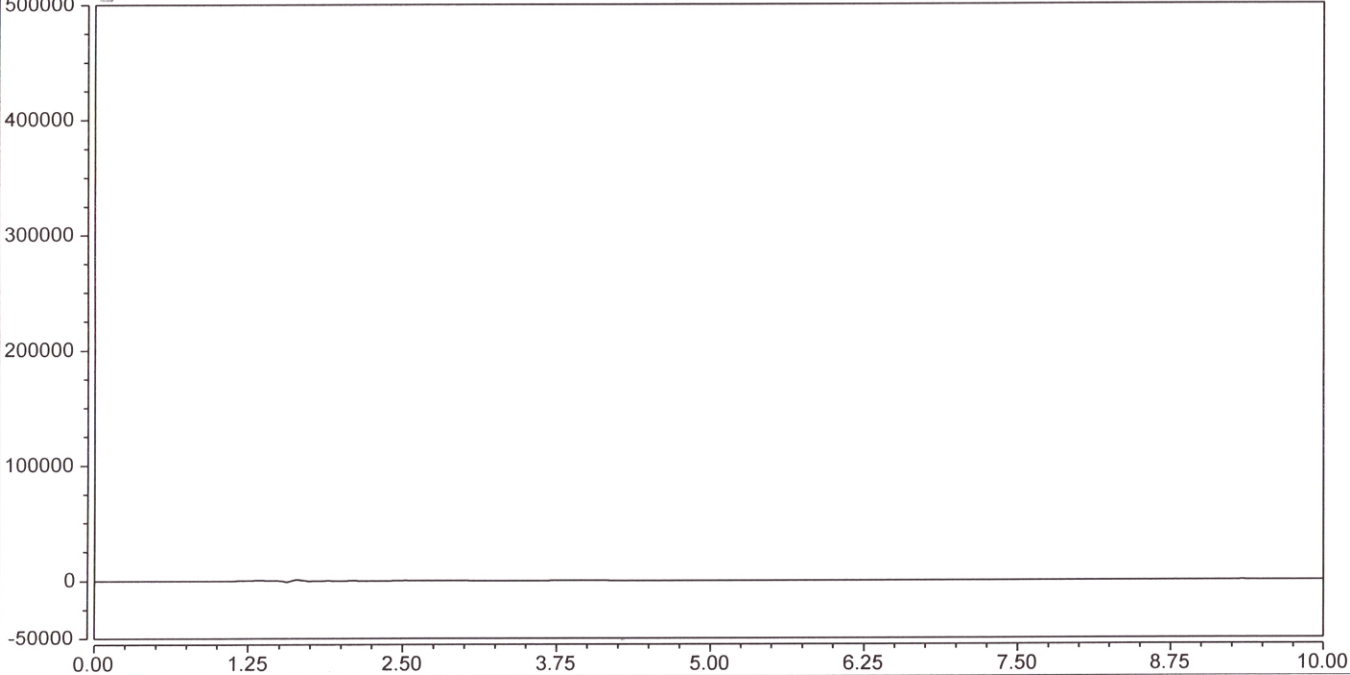
Injection Name:	Heat blank solution	Run Time (min):	9.99
Vial Number:	Vial:14	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC-05	Bandwidth:	n.a.
Processing Method:	PR Method_FD_02	Dilution Factor:	1.0000
Injection Date/Time:	28-Jun-17 02:40	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)	Match	Rel.Area %
Total:								

Pankaj
28-Jun-17

Pankaj
28-Jun-17

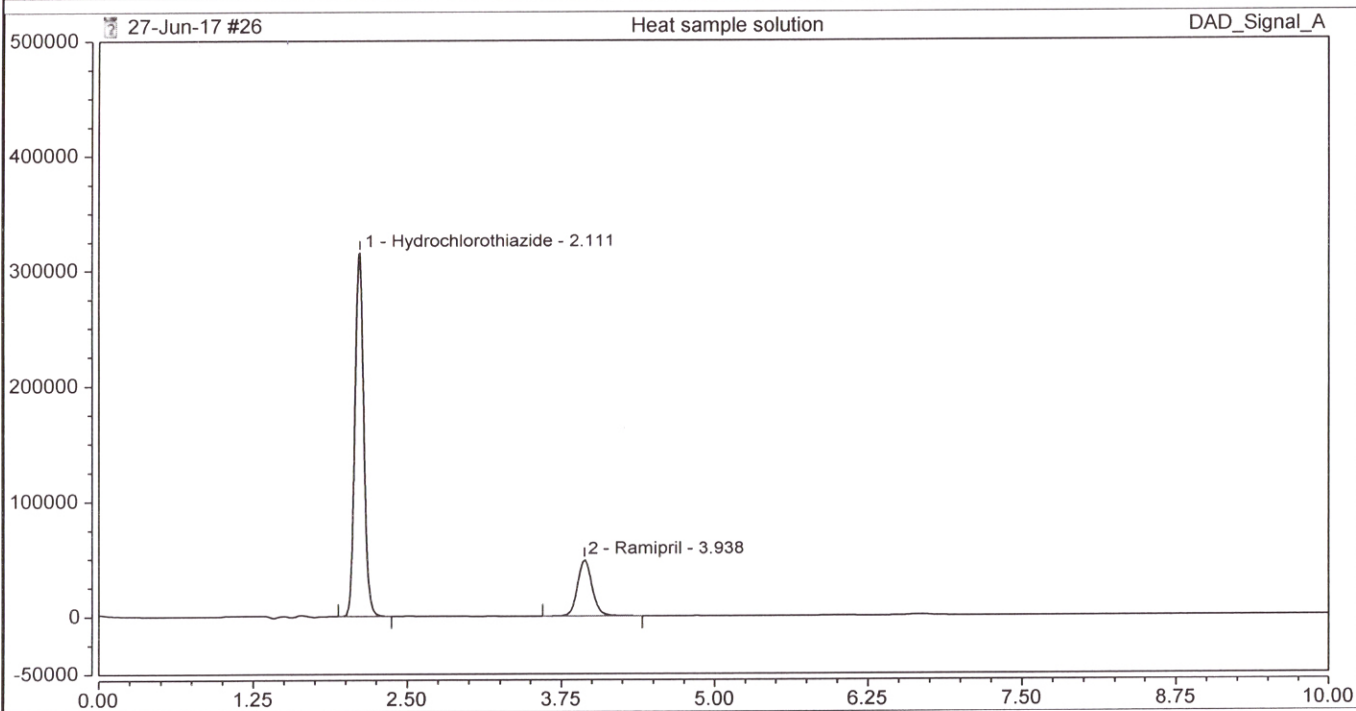
QbD Research & Developement Pvt.Ltd.								
Injection Details								
Injection Name:		Heat placebo solution			Run Time (min):		9.99	
Vial Number:		Vial:15			Injection Volume:		10.00	
Injection Type:		Unknown			Channel:		DAD_Signal_A	
Calibration Level:					Wavelength:		210	
Instrument Method:		Ramithiazide Assay HPLC-05			Bandwidth:		n.a.	
Processing Method:		PR Method_FD_02			Dilution Factor:		1.0000	
Injection Date/Time:		28-Jun-17 02:51			Sample Weight:		1.0000	
User Name:		Pankaj Gurav			Sample Weight:		1.0000	
Chromatogram								
27-Jun-17 #25 Heat placebo solution DAD_Signal_A 								
Integration Results								
No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Match	Rel.Area %
Total:								

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Heat sample solution	Run Time (min):	9.99
Vial Number:	Vial:16	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC-05	Bandwidth:	n.a.
Processing Method:	PR Method_FD_02	Dilution Factor:	1.0000
Injection Date/Time:	28-Jun-17 03:03	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)	Match	Rel.Area %
1	Hydrochlorothiazide	2.111	26513.183	4144	1.06	10.58	1000	79.76
2	Ramipril	3.938	6726.975	5406	1.10	n.a.	1000	20.24
Total:								

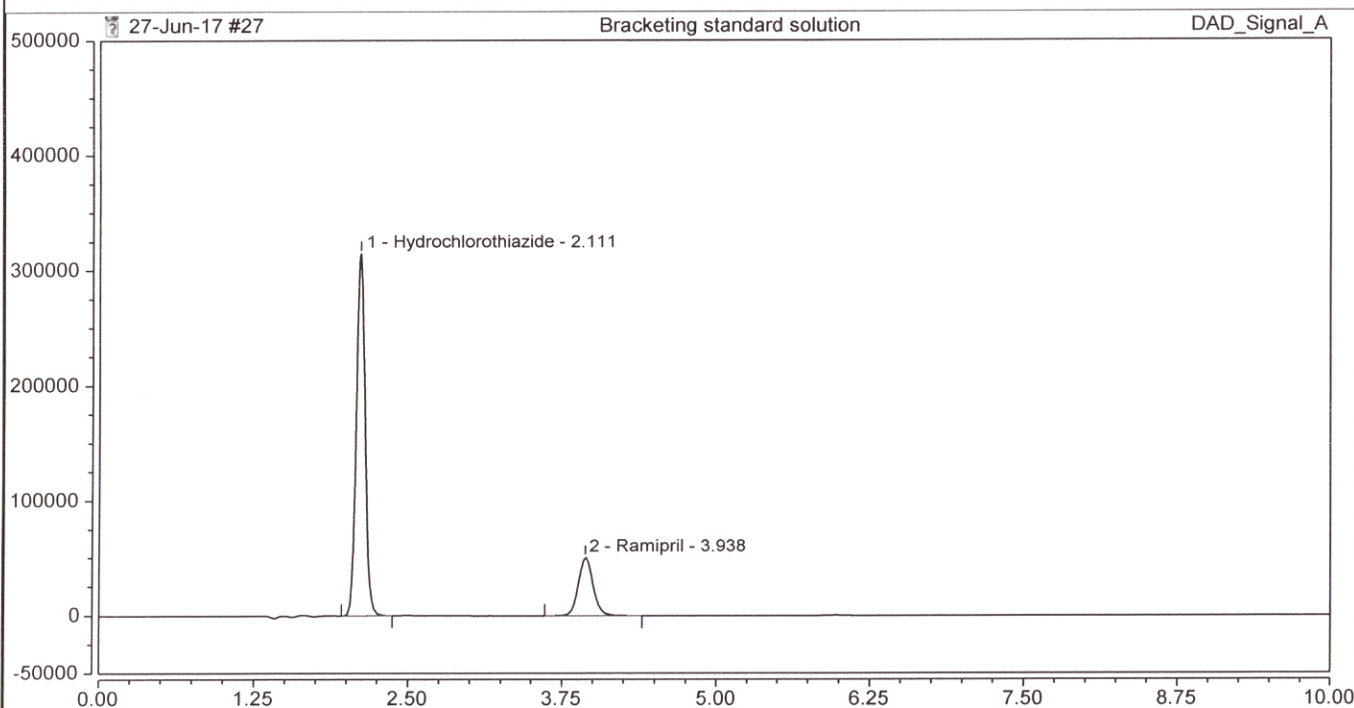
Pankaj
28-Jun-17Pankaj
28-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Bracketing standard solution	Run Time (min):	9.99
Vial Number:	Vial:2	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	DAD_Signal_A
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay HPLC-05	Bandwidth:	n.a.
Processing Method:	PR Method_FD_02	Dilution Factor:	1.0000
Injection Date/Time:	28-Jun-17 03:15	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)	Match	Rel.Area %
1	Hydrochlorothiazide	2.111	26460.682	4123	1.07	10.55	1000	79.15
2	Ramipril	3.938	6971.806	5384	1.11	n.a.	1000	20.85
Total:								

Pankaj
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28-Jun-17