

Assay Method Validation

Product name :	Ramithiazide Tablets
Lable claim :	Ramipril 10 mg & Hydrochlorothiazide 25 mg
B. No. :	GP170401
Test :	Filter study
Average wt (mg) :	199.83
LNB No./Pg. No.:	419/052

Analysis Date: 10-Jun-17

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

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

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

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

Sample details	Sample Weight (mg)	Area of Sample		% Assay	%Difference	% Assay		%Difference
		Hydrochlorothiazide	Ramipril			Hydrochlorothiazide	Ramipril	
Centrifuged	493.22	29587.724	7147.185	100.8	-	101.5	-	-
Filtered through 0.22 u filter	493.22	29593.813	7141.218	100.8	0.02	101.5	0.08	0.08
Filtered through 0.45 u filter	493.22	29632.069	7144.790	100.9	0.15	101.5	0.03	0.03

Done by: 
Date: 21-Jun-17

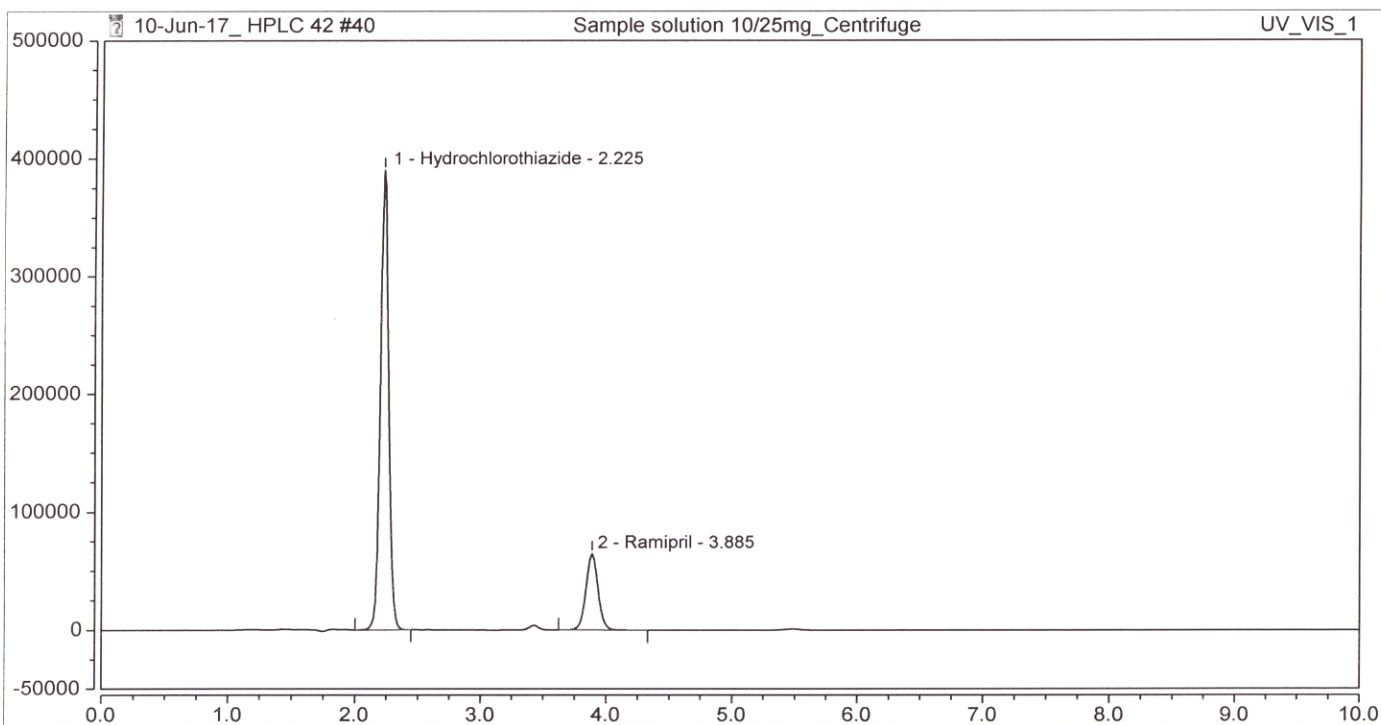
Checked by: 
Date: 22-Jun-17

QbD Research & Development Pvt.Ltd.

Injection Details

Injection Name:	Sample solution 10/25mg_Centrifuge	Run Time (min):	10.00
Vial Number:	1_25	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 42	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	11-Jun-17 05:56	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	2.225	29587.724	5668	1.13	11.43	80.54
2	Ramipril	3.885	7147.185	8141	1.06	n.a.	19.46
Total:							

Pankaj Gurav
21 Jun 17

Default/Integration

Pankaj Gurav
22 Jun 17

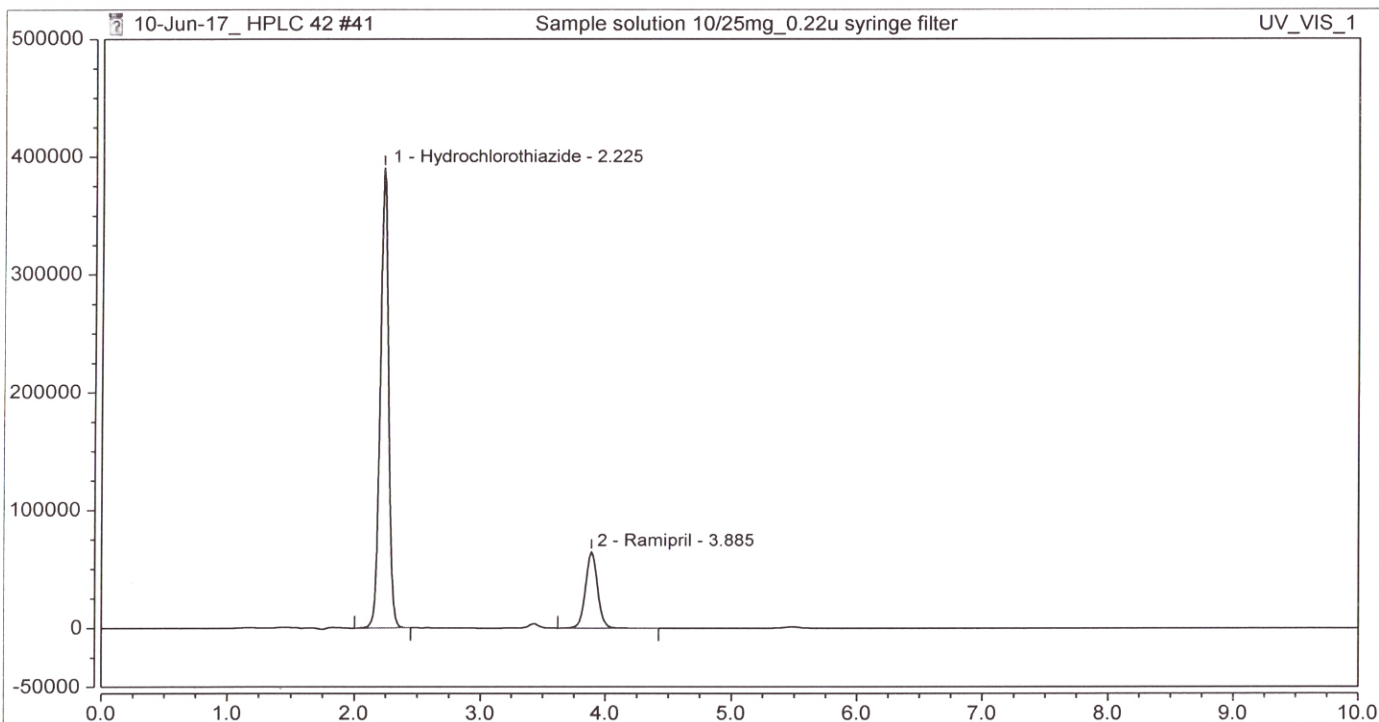
Chromeleon (c) Dionex
Version 7.2.4.8525

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Injection Details

Injection Name:	Sample solution 10/25mg_0.22u syringe filter	Run Time (min):	10.00
Vial Number:	1_26	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 42	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	11-Jun-17 06:07	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area μAU*min	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.225	29593.813	5683	1.13	11.45	80.56
2	Ramipril	3.885	7141.218	8161	1.06	n.a.	19.44
Total:							

Pankaj Gurav
21-Jun-17

Default/Integration

Pankaj Gurav
21-Jun-17

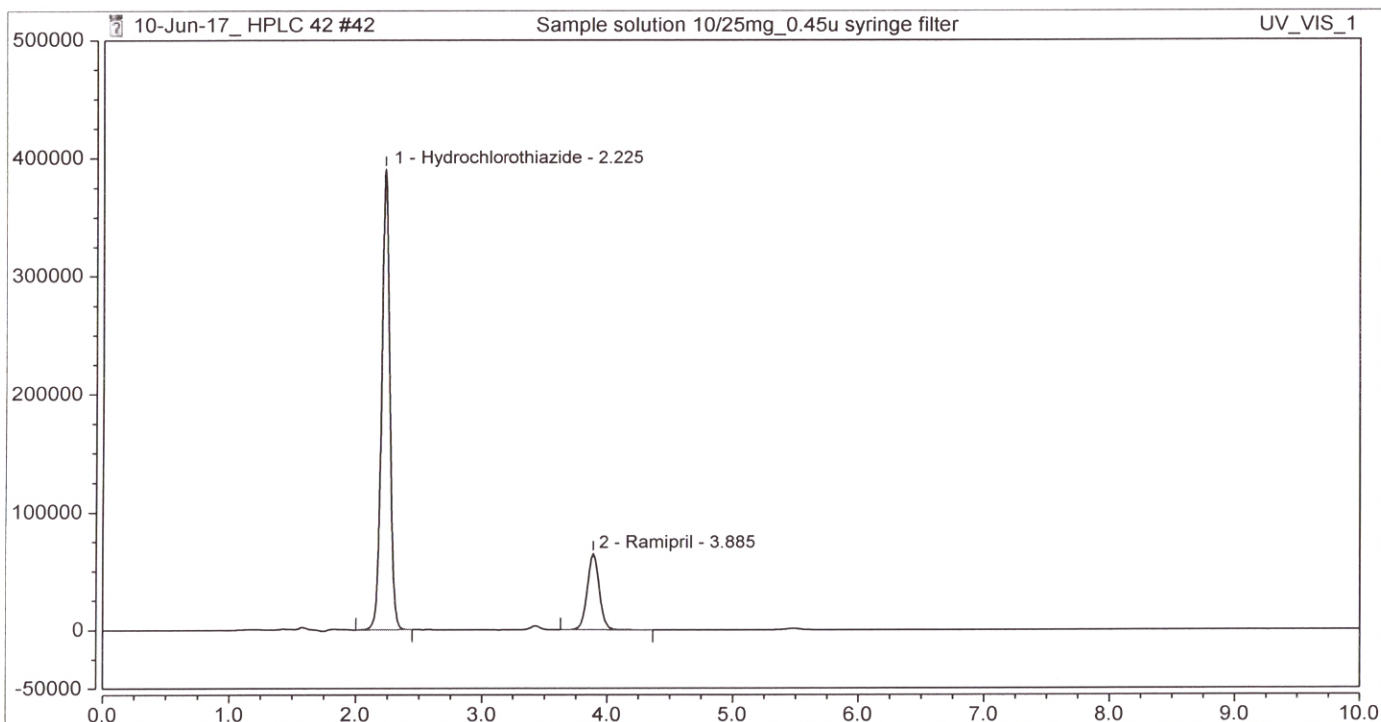
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Injection Details

Injection Name:	Sample solution 10/25mg_0.45u syringe filter	Run Time (min):	10.00
Vial Number:	1_27	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_1
Calibration Level:		Wavelength:	210
Instrument Method:	Ramithiazide Assay- HPLC_ 42	Bandwidth:	n.a.
Processing Method:	PR Method 1	Dilution Factor:	1.0000
Injection Date/Time:	11-Jun-17 06:18	Sample Weight:	1.0000
User Name:	Pankaj Gurav	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peak Name	Retention Time min	Area $\mu\text{AU} \cdot \text{min}$	Plates (USP)	Asymmetry (EP)	Resolution (USP)	Rel.Area %
1	Hydrochlorothiazide	2.225	29632.069	5675	1.12	11.44	80.57
2	Ramipril	3.885	7144.790	8148	1.05	n.a.	19.43
Total:							

Pankaj Gurav
21-Jun-17

Default/Integration

Pankaj Gurav
22-Jun-17

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