

Dissolution Assay METHOD VALIDATION

Product name :	Ramithiazide Tablets
Label claim (mg) :	25
Content :	Hydrochlorothiazide
B. No. :	GP170403
Parameter :	Linearity
Avg weight :	197.4

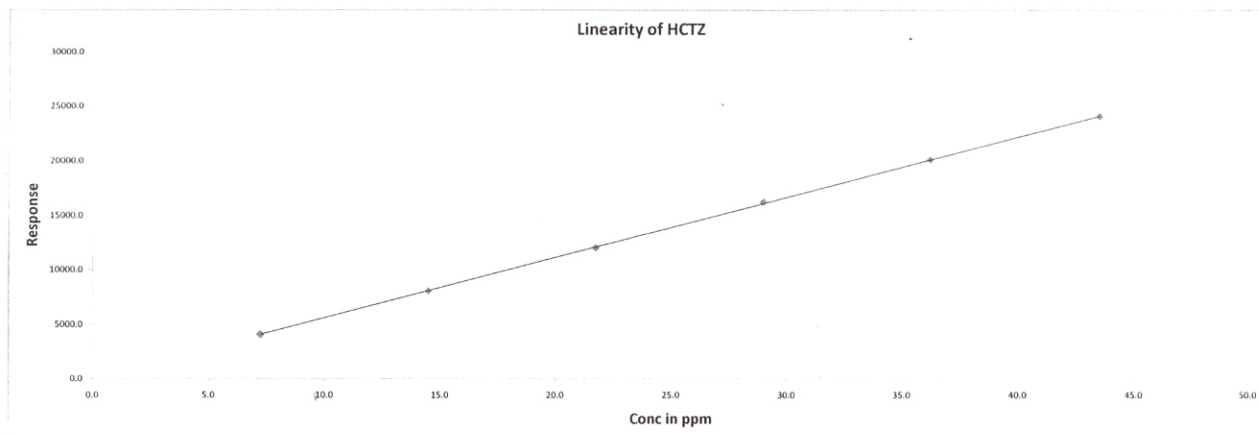
Analysis Date: 5-Jun-17

Name of Standard	Standard Purity(%)	Standard Wt (mg)	Dilution Details	Conc (ppm)
Ramipril	99.8	25.53	250 mL, 3 mL -> 25 mL	12.3
Hydrochlorothiazide	99.9	30.16	250 mL, 6 mL -> 25 mL	29.0

Injection No.	Retention Time	Area of Standard
1	2.213	16393.666
2	2.213	16300.718
3	2.213	16265.507
4	2.213	16273.524
5	2.213	16318.812
Average	2.213	16310.446
SD	0.000	51.169
%RSD	0.000	0.314
System Suitability Results		
% RSD of Area	0.31	NMT 1.5%
Tailing Factor	1.19	NMT 2.0
Theoretical Plates	4323	NLT 2000

Linearity Stock Solution				
Name of Standard	Standard Purity(%)	Standard Wt (mg)	Dilution Details	Conc (ppm)
Ramipril	99.8	30.16	250	144.8

Level	Linearity level (%)	ml of Standard Stock Solution added	Diluted to volume (mL)	Actual Concentration (ppm)	Area of sample	Average area
1	25	1.50	25	7.2	4108.377	4102.807
					4098.371	
					4103.076	
					4102.985	
					4103.983	
					4100.051	
2	50	3.00	25	14.5	8111.711	8075.987
					8058.520	
					8057.730	
3	75	4.50	25	21.7	12097.737	12036.995
					12006.775	
					12006.473	
4	100	6.00	25	29.0	16233.327	16219.790
					16166.768	
					16259.276	
5	125	7.50	25	36.2	20081.864	20085.256
					20099.317	
					20074.587	
6	150	9.00	25	43.4	24021.387	24091.550
					24088.856	
					24087.047	
					24109.205	
					24129.946	
					24112.861	



Slope	553.22
y-intercept	86.63
Correlation coefficient	1.0000

Done by: *slp*
Date: *10-Jun-17*

Checked by: *slp*
Date: *10-Jun-17*

DISSOLUTION METHOD VALIDATION

Product Name :	Ramithiazide Tablets
Label Claim (mg) :	10
Content :	Ramipril
B. No. :	GP170403
Parameter :	Linearity
Avg weight :	197.4

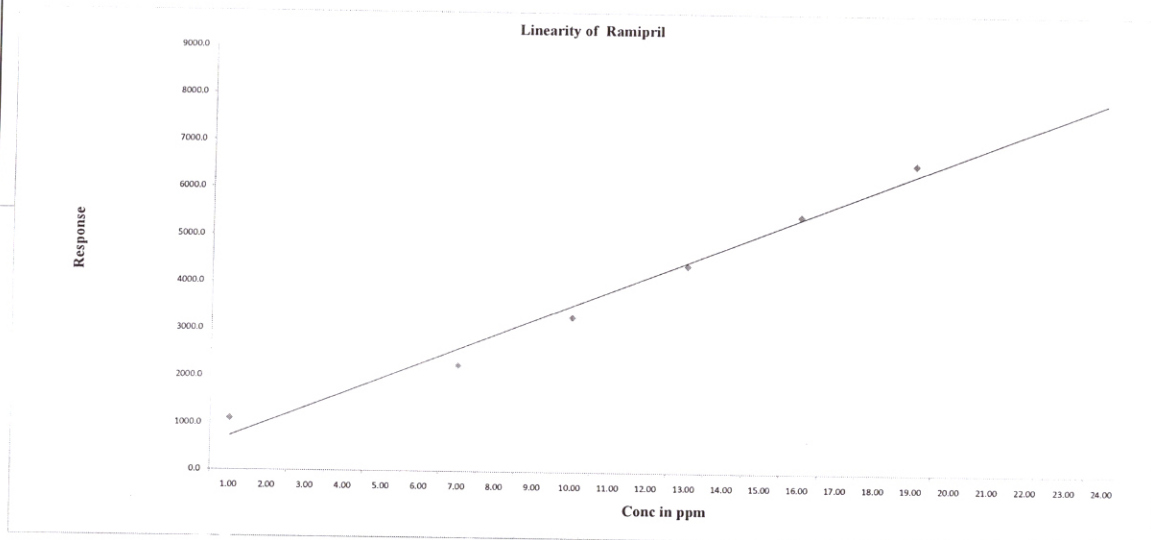
Analysis Date: 6-Jun-17

Name of Standard	Standard Purity(%)	Standard Wt (mg)	Dilution Details	Conc (ppm)
Ramipril	99.8	25.53	250 mL; 3 mL -> 25 mL	12.3
Hydrochlorothiazide	99.9	30.16	250 mL; 6 mL -> 25 mL	14.5

Injection No.	Retention Time	Area of Standard
1	4.300	4413.183
2	4.300	4391.896
3	4.300	4387.098
4	4.295	4383.716
5	4.295	4394.023
Average	4.298	4393.983
SD	0.003	11.47
%RSD	0.06	0.26
System suitability results		
% RSD of Area	0.26	NMT 2.0%
Tailing factor	1.02	NMT 2.0
Theoretical plates	5757	NLT 2000

Linearity Sstock Solution				
Name of Standard	Standard Purity(%)	Standard Wt (mg)	Dilution Details	Conc (ppm)
Ramipril	99.8	25.53	250	122.5

Level	Linearity level (%)	ml of Standard Stock Solution added	Diluted to volume (mL)	Actual Concentration (ppm)	Area of sample	Average area
1	25	0.75	25	3.1	1106.260	1105.106
					1104.019	
					1104.517	
					1106.878	
					1103.886	
					1105.076	
2	50	1.50	25	6.1	2242.621	2238.404
					2235.066	
					2237.525	
					3288.544	
3	75	2.25	25	9.2	3276.074	3279.522
					3273.948	
					4396.359	
4	100	3.00	25	12.3	4380.366	4393.220
					4402.936	
					5455.809	
5	125	3.75	25	15.3	5461.386	5458.614
					5458.646	
					6544.987	
6	150	4.50	25	18.4	6568.676	6566.147
					6568.118	
					6565.379	
					6580.626	
					6569.096	



Slope	355.13
y-intercept	32.22
Correlation coefficient	1.0000

Done by:
Date:

10-Jun-17

Checked by:
Date:

10-Jun-17

VWD_Signal_A	Name	Type	Level	Position	Volume [µL]	Instrument Method	Processing Method	Status	Inject Time	Lock Status	Replicate ID
None	Blank	Unknown		Vial:1	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	Standard 1	Unknown		Vial:2	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	Standard 2	Unknown		Vial:2	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	Standard 3	Unknown		Vial:2	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	Standard 4	Unknown		Vial:2	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	Standard 5	Unknown		Vial:2	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	25 % Level 1	Unknown		Vial:2	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	25 % Level 2	Unknown		Vial:3	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	25 % Level 3	Unknown		Vial:3	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	25 % Level 4	Unknown		Vial:3	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	25 % Level 5	Unknown		Vial:3	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	25 % Level 6	Unknown		Vial:3	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	50 % Level 1	Unknown		Vial:3	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	50 % Level 2	Unknown		Vial:4	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	50 % Level 3	Unknown		Vial:4	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	75 % Level 1	Unknown		Vial:4	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	75 % Level 2	Unknown		Vial:5	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	75 % Level 3	Unknown		Vial:5	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	100 % Level 1	Unknown		Vial:5	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	100 % Level 2	Unknown		Vial:6	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	100 % Level 3	Unknown		Vial:6	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	125 % Level 1	Unknown		Vial:6	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	125 % Level 2	Unknown		Vial:7	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	125 % Level 3	Unknown		Vial:7	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	150 % Level 1	Unknown		Vial:8	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	150 % Level 2	Unknown		Vial:8	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	150 % Level 3	Unknown		Vial:8	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	150 % Level 4	Unknown		Vial:8	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	150 % Level 5	Unknown		Vial:8	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	150 % Level 6	Unknown		Vial:8	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	Bracketing Standard	Unknown		Vial:2	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	Wash	Unknown		Vial:1	10.00	Ramithiazide Dissolution	Ramithiazide Dissolution PR	Idle			
None	Shut	Unknown		Vial:1	10.00	Shut method _HPLC 59	Ramithiazide Dissolution PR	Idle			

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06-Jun-17

[illegible]

4-17-90
skp

Name	Ramithiazide Dissolution HPLC-59
Data Vault	QbD_2017
Path	chrom://qbdser03/QbD_2017/Method Validation/Generic Health Care/Ramithiazide Tablets/Dissolution/06-Jun- 17_01.seq/Ramithiazide Dissolution HPLC-59.instmeth
Comment	Ramithiazide
Description	Dissolution
Run time	10.000 [min]
Instrument	QbD-INST-HPLC-59 on qbd-pc-17
Created	06-Jun-17 11:20 +05:30 Santosh Padmere
Last Update	06-Jun-17 14:25 +05:30 Santosh Padmere

S.P.
06-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.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.VWD_Board_Temperature.AcqOn LCSystem.VWD_Reference_Intensity.AcqOn LCSystem.VWD_Sample_Intensity.AcqOn LCSystem.VWD_UVLamp_AnodeVoltage.AcqOn LCSystem.VWD_Signal_A.AcqOn		
Run			Duration = 10.000 [min]	
	0.000			
Stop Run	10.000	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		

SP
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```
LCSystem.TCC_Right_Temperature.AcqOff  
LCSystem.VWD_Board_Temperature.Acq  
Off  
LCSystem.VWD_Reference_Intensity.AcqO  
ff  
LCSystem.VWD_Sample_Intensity.AcqOff  
LCSystem.VWD_UVLamp_AnodeVoltage.A  
cqOff  
LCSystem.VWD_Signal_A.AcqOff
```

End

SP
06-Jun-17

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

stp
06-Jun-17


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Section High throughput (HighThroughput)

    Section Overlapped Injection
    (HighThroughput_OverlappedInjection)
        Enable Overlapped Injection                No
    Section Stop Time (StopTime)
        Stoptime Mode                               As pump/No limit
    Section Post Time (PostTime)
        Posttime Mode                               Off
    Section Timetable (Timetable)
        Timetable (Timetable_TimetableEntry)

Settings for module Column Comp. (G1316A -
Column Comp.: COLCOMP.0)
    Section Left Temperature Control
    (LeftTemperatureControl)
        Temperature Control Mode                    Temperature Set
        Temperature                                25.00 [°C]
    Section Enable Analysis Left
    Temperature
    (LeftTemperatureControl_NotReadyLimit)
        Enable Analysis Left Temperature On Yes
        Enable Analysis Left Temperature            0.80 [°C]
Value
    Section Right Temperature Control
    (RightTemperatureControl)
        Right temperature Control Mode                Combined
    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 VWD (G1314B - VWD: VWD.0)

    Signal Peakwidth                                > 0.1 min (2 s resp.
                                                    time) (3.43 Hz)
    Analog Output Source Channel                    1
    Signal Polarity                                Positive (+)
    Lamp on required for aquisition                Yes
    Acquire Signal without Reference                No
    Acquire Reference only                          No
    Section Analog Output (AnalogOutput)
        Analog Zero Offset                           5 [%]
        Analog Attenuation                           1000 [mAU]
    Section Signals (Signals)

```

Stop
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Section Signal (Signals_Signal)	
Use Signal	Yes
Signal ID	Signal A
Signal Wavelength	210 [nm]
Section Prepare Mode (PrepareMode)	
Margin for negative Absorbance	100 [mAU]
Section Autobalance (PrepareAutomation)	
Autobalance Prerun	Yes
Autobalance Postrun	No
Section Scan Variables (ScanVariables)	
Scan Range From	190 [nm]
Scan Range To	400 [nm]
Scan Range Step	2 [nm]
Section Stoptime (StopTime)	
Stoptime Mode	As pump/injector
Section Posttime (PostTime)	
Posttime Mode	Off
Section Timetable (Timetable)	
Timetable (Timetable_TimetableEntry)	

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06-JUN-17

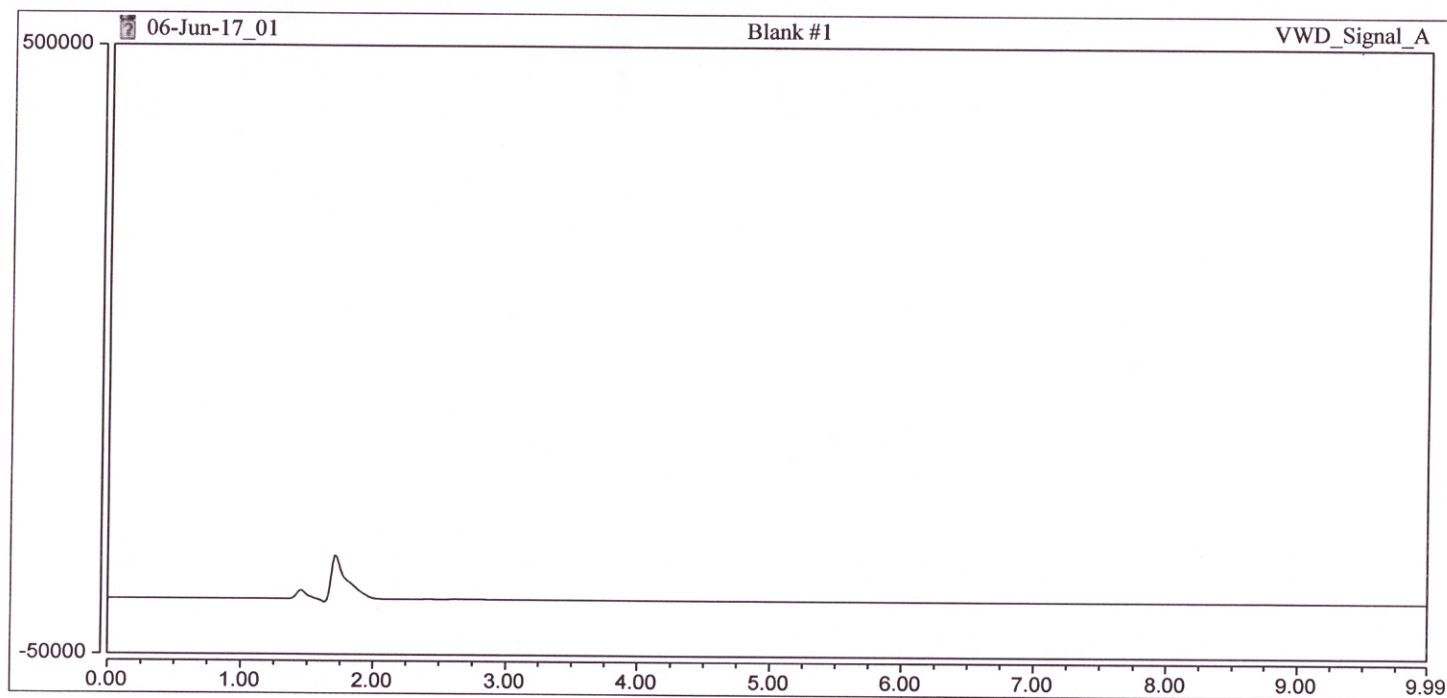
Property	Value
Settings for module Sampler (G1329B - Pretreatment (PretreatmentInstruction)	

SP
06-Jun-17



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	Blank	AR. No. :-	D010620172169-71
Sample Number :-	1	Instrument Method :-	Ramithiazide Dissolution HPLC-
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmere
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:1	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmere
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 14:38:32	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



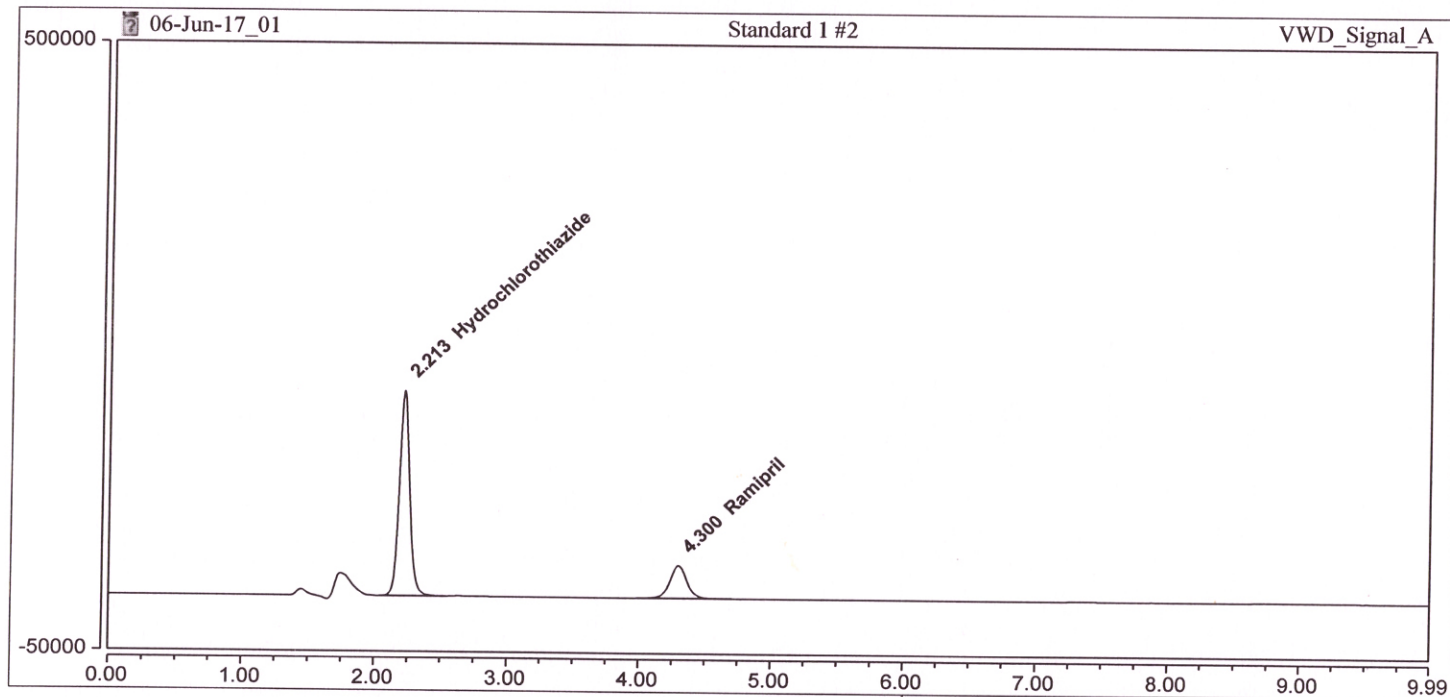
Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
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Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	Standard 1	AR. No. :-	D010620172169-71
Sample Number :-	2	Instrument Method :-	Ramithiazide Dissolution HPLC-
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmere
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:2	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmere
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 14:50:06	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



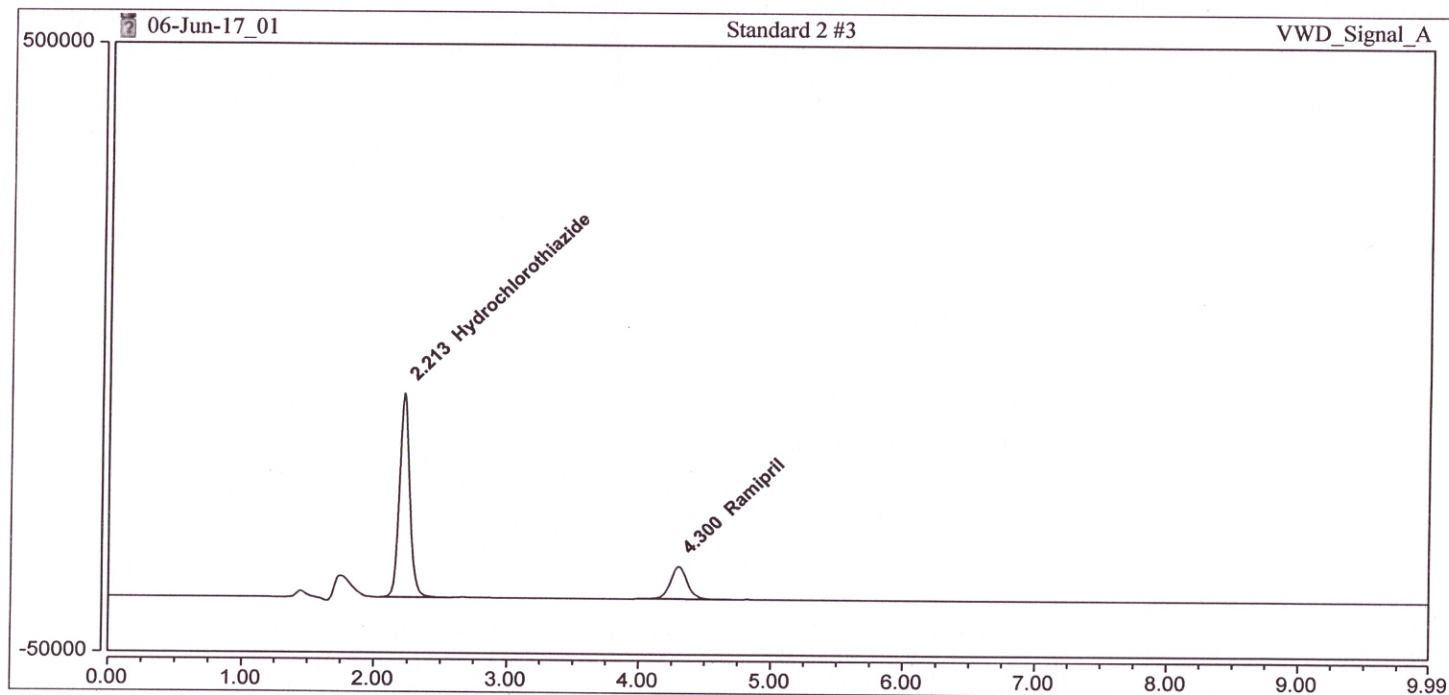
Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.213	16393.666	78.79	1.19	4323	n.a.
2	Ramipril	4.300	4413.183	21.21	1.02	5757	11.58

5/17
07-Jun-17



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Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	Standard 2	AR. No. :-	D010620172169-71
Sample Number :-	3	Instrument Method :-	Ramithiazide Dissolution HPLC-
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmere
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:2	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmere
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 15:01:44	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



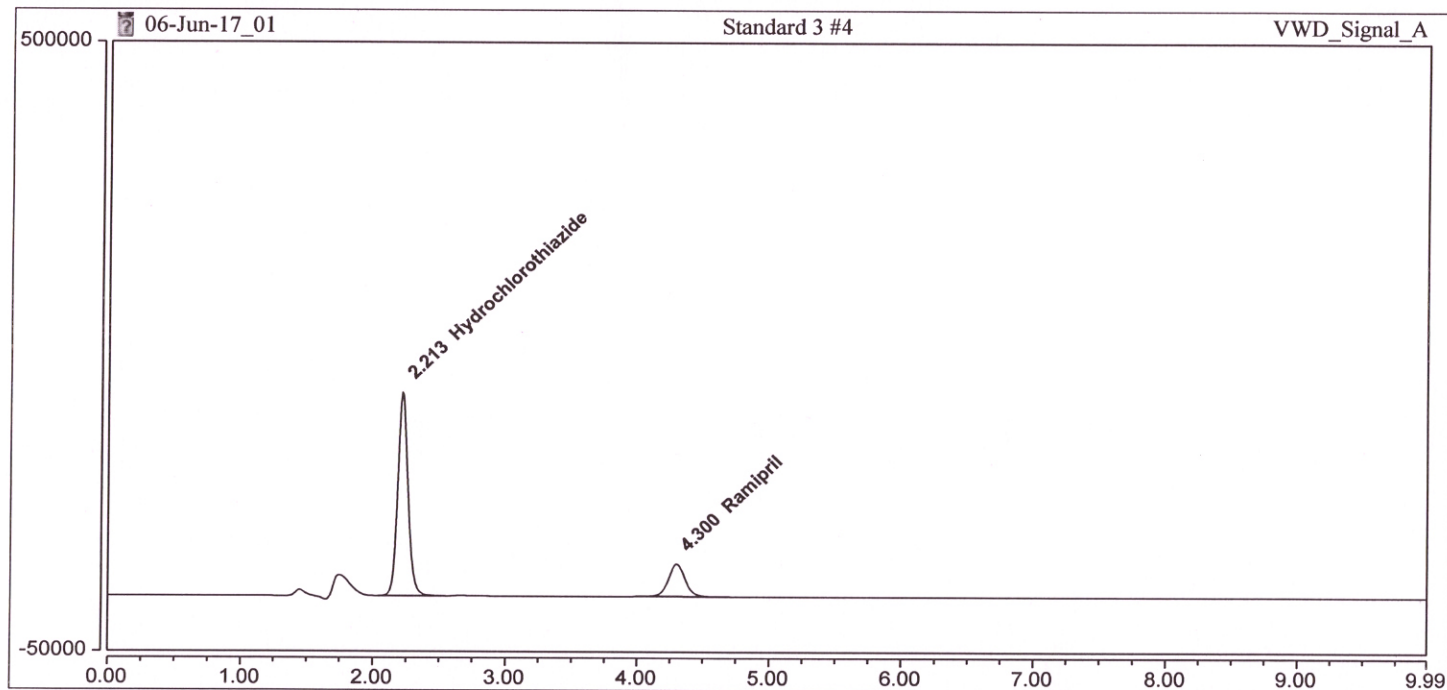
Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.213	16300.718	78.78	1.21	4324	n.a.
2	Ramipril	4.300	4391.896	21.22	1.04	5786	11.60

SP
07-Jun-17



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Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	Standard 3	AR. No. :-	D010620172169-71
Sample Number :-	4	Instrument Method :-	Ramithiazide Dissolution HPLC-
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmere
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:2	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmere
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 15:13:21	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



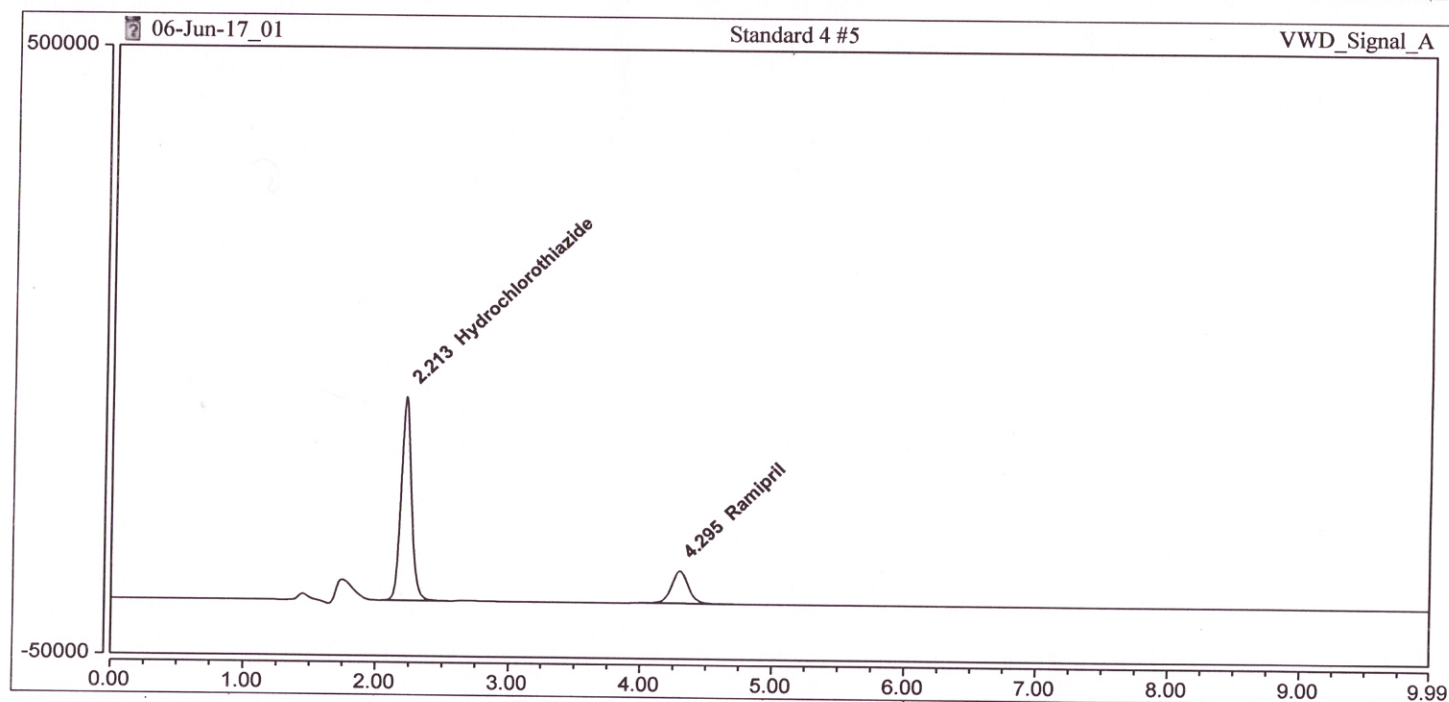
Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.213	16265.507	78.76	1.21	4330	n.a.
2	Ramipril	4.300	4387.098	21.24	1.03	5779	11.60

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07-Jun-17



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Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	Standard 4	AR. No. :-	D010620172169-71
Sample Number :-	5	Instrument Method :-	Ramithiazide Dissolution HPLC-
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmere
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:2	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmere
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 15:25:01	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



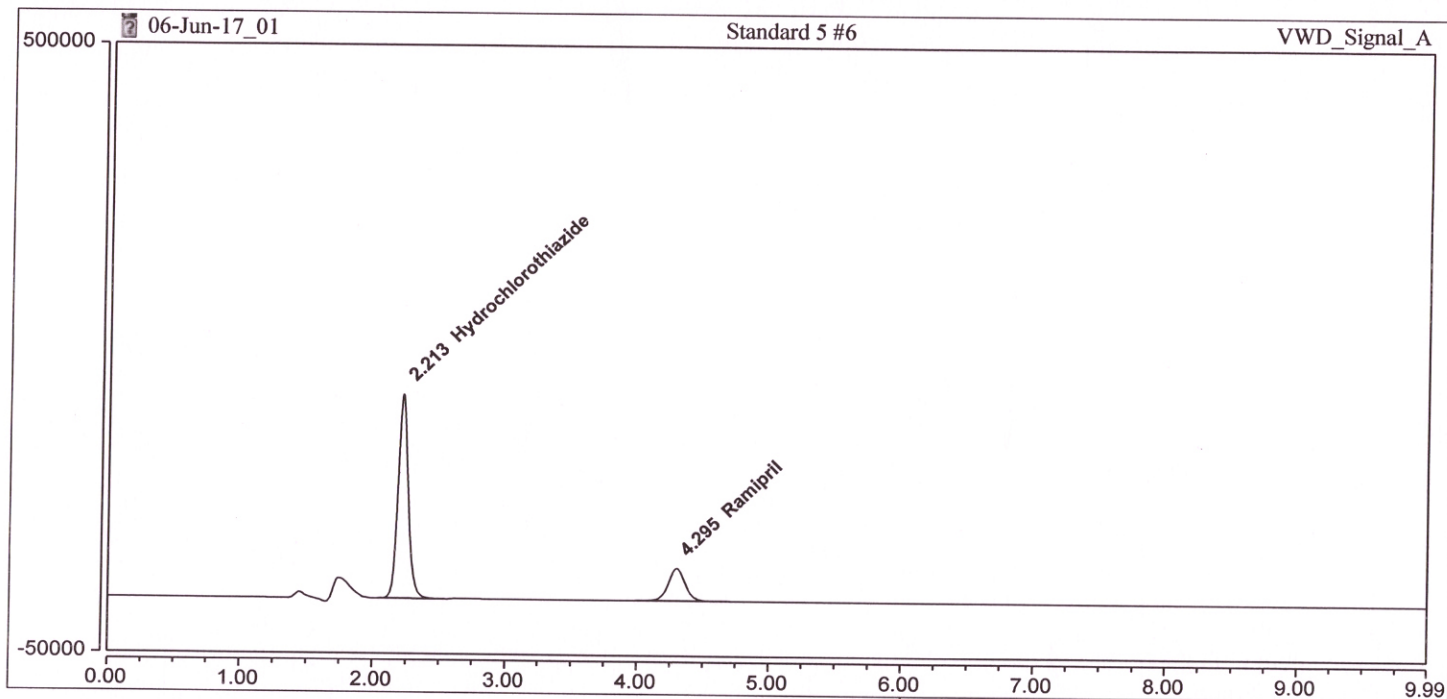
Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.213	16273.524	78.78	1.19	4332	n.a.
2	Ramipril	4.295	4383.716	21.22	1.05	5772	11.58

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07-Jun-17



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	Standard 5	AR. No. :-	D010620172169-71
Sample Number :-	6	Instrument Method :-	Ramithiazide Dissolution HPLC-
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmere
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:2	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmere
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 15:36:36	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



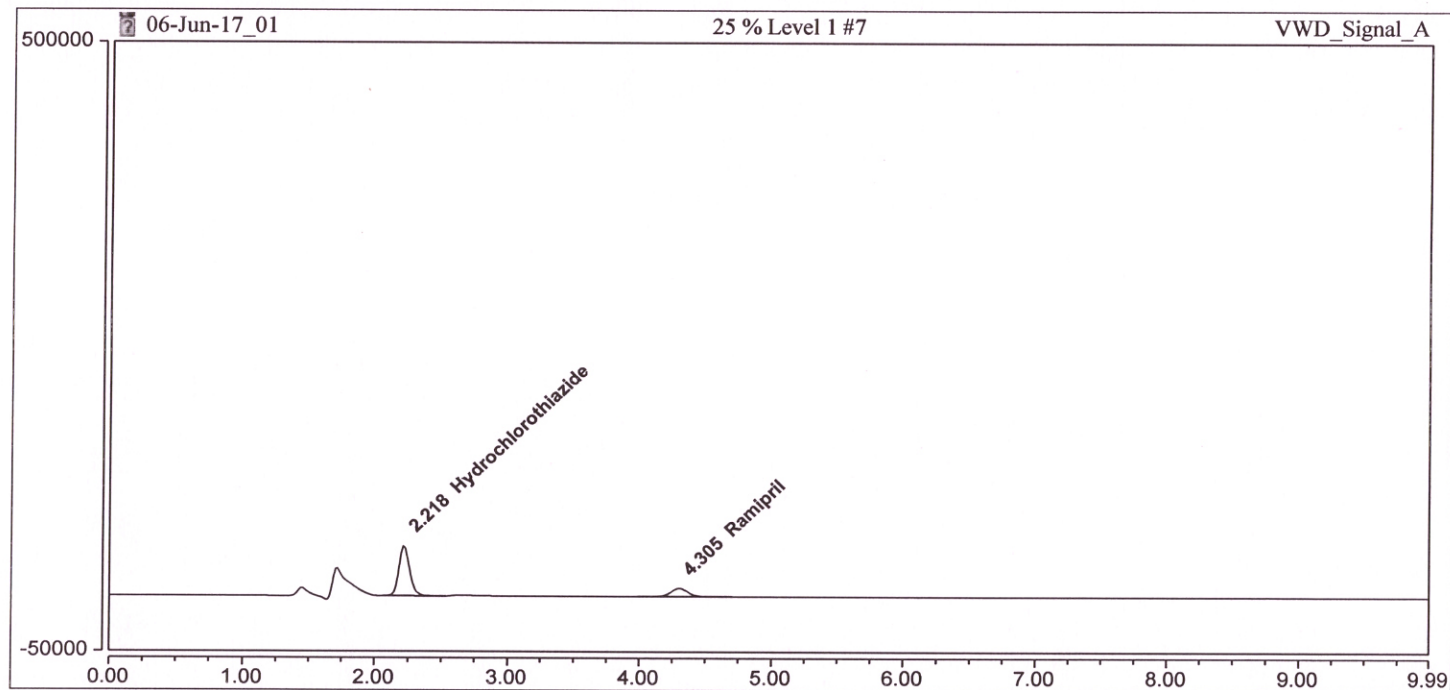
Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.213	16318.812	78.79	1.21	4339	n.a.
2	Ramipril	4.295	4394.023	21.21	1.05	5779	11.59

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07-Jun-17



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	25 % Level 1	AR. No. :-	D010620172169-71
Sample Number :-	7	Instrument Method :-	Ramithiazide Dissolution HPLC-
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmere
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:3	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmere
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 15:48:15	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



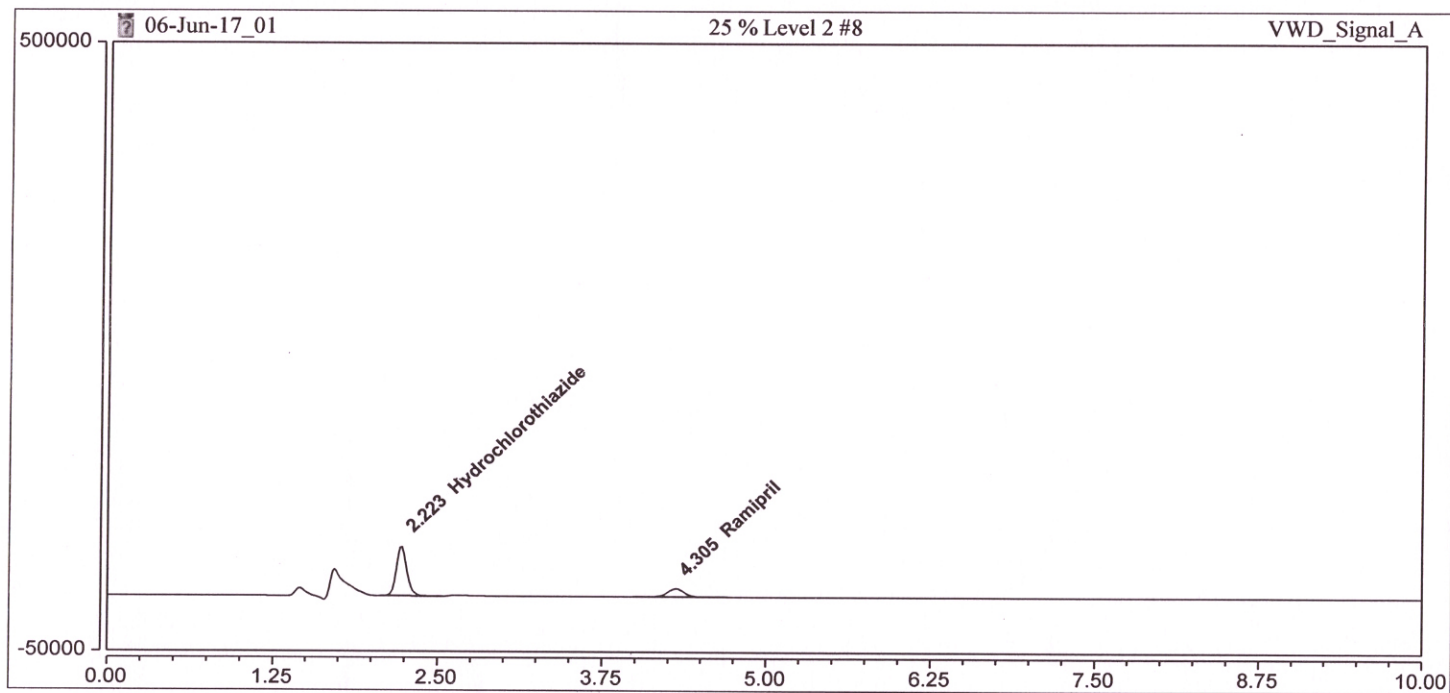
Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.218	4108.377	78.79	1.16	4042	n.a.
2	Ramipril	4.305	1106.260	21.21	1.02	5681	11.37

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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	25 % Level 2	AR. No. :-	D010620172169-71
Sample Number :-	8	Instrument Method :-	Ramithiazide Dissolution HPLC-
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmure
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:3	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmure
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 15:59:52	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



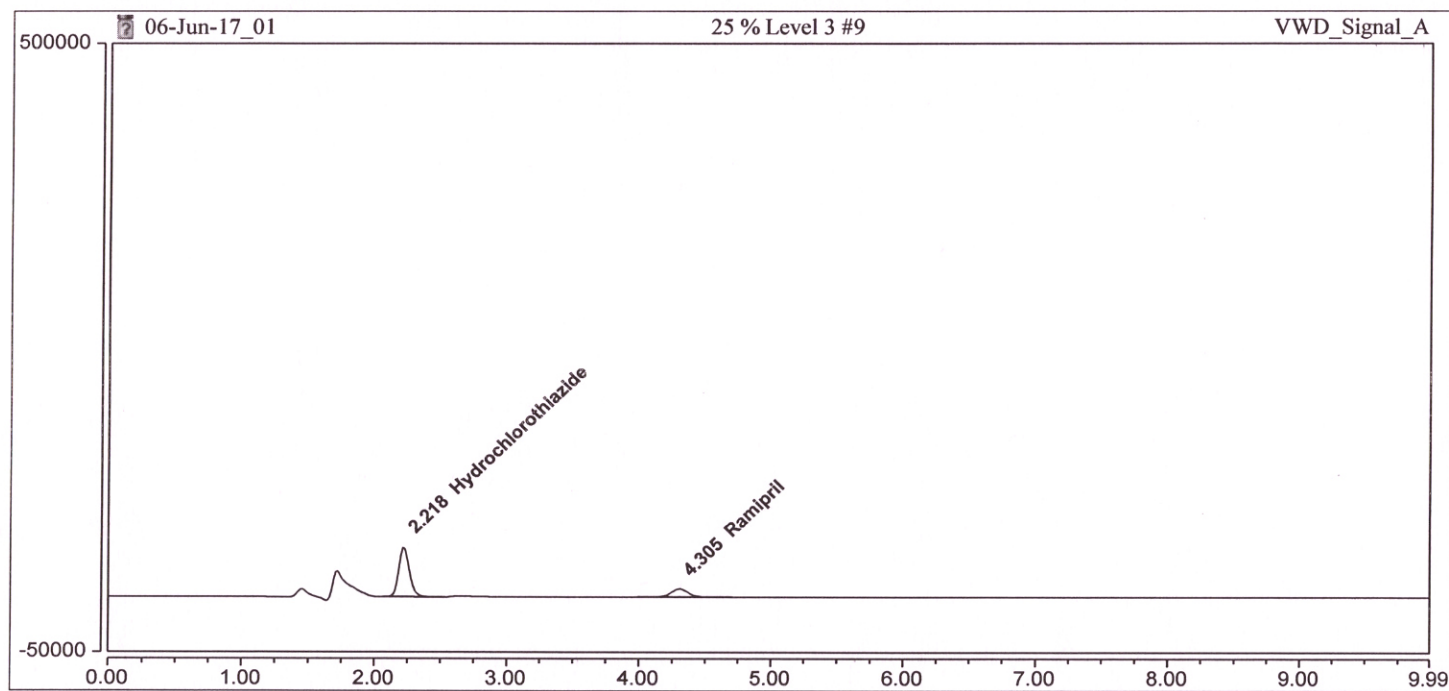
Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.223	4098.371	78.78	1.16	4065	n.a.
2	Ramipril	4.305	1104.019	21.22	1.05	5681	11.35

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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	25 % Level 3	AR. No. :-	D010620172169-71
Sample Number :-	9	Instrument Method :-	Ramithiazide Dissolution HPLC-3
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmure
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:3	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmure
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 16:11:30	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



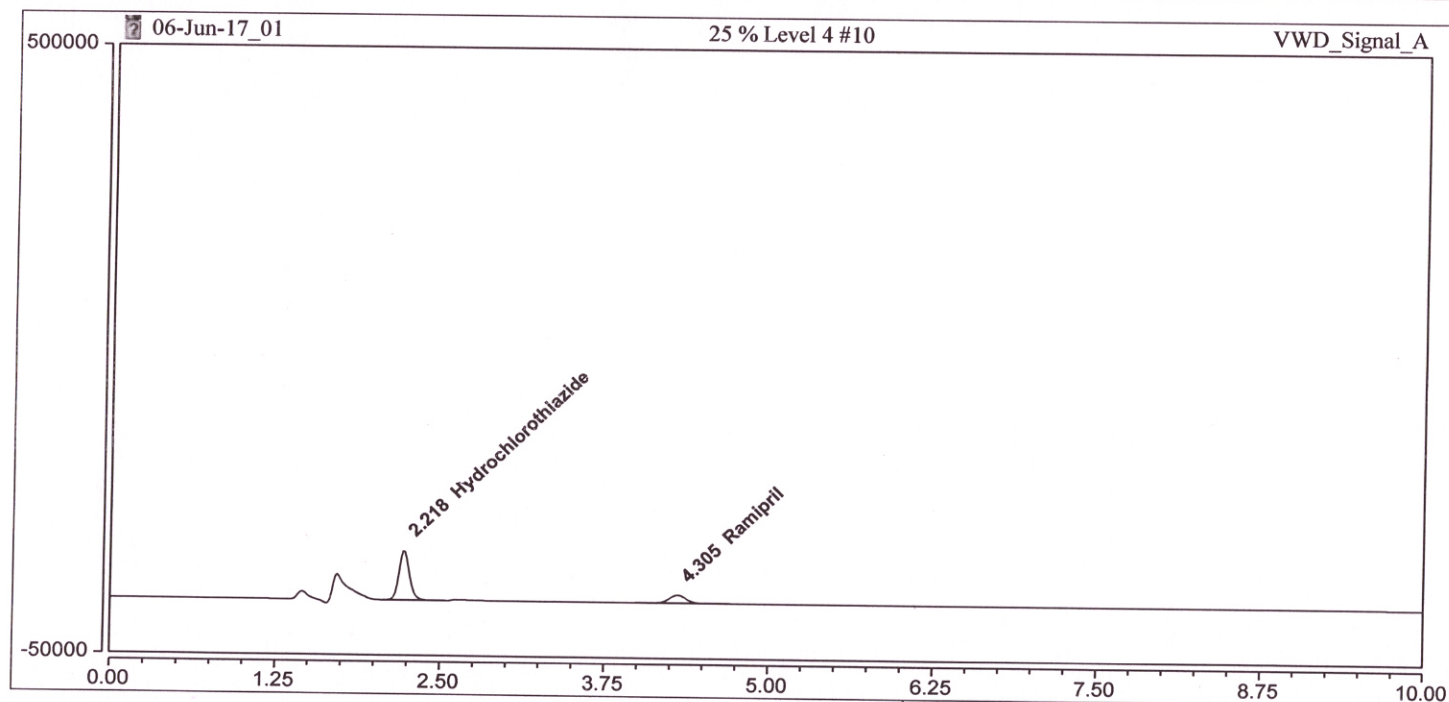
Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.218	4103.076	78.79	1.20	4056	n.a.
2	Ramipril	4.305	1104.517	21.21	1.03	5701	11.39

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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	25 % Level 4	AR. No. :-	D010620172169-71
Sample Number :-	10	Instrument Method :-	Ramithiazide Dissolution HPLC-
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmere
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:3	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmere
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 16:23:07	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		

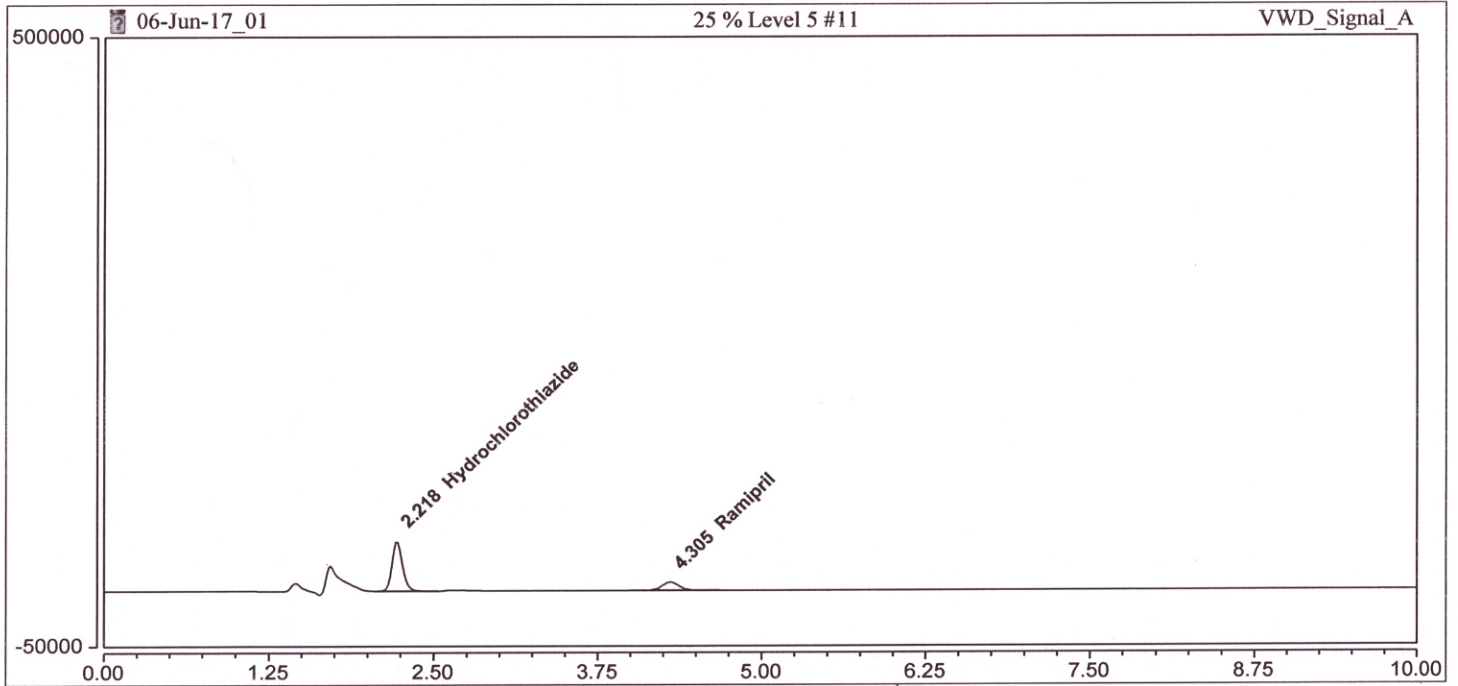


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.218	4102.985	78.75	1.22	4058	n.a.
2	Ramipril	4.305	1106.878	21.25	1.03	5714	11.40



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	25 % Level 5	AR. No. :-	D010620172169-71
Sample Number :-	11	Instrument Method :-	Ramithiazide Dissolution HPLC-5
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmere
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:3	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmere
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 16:34:47	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



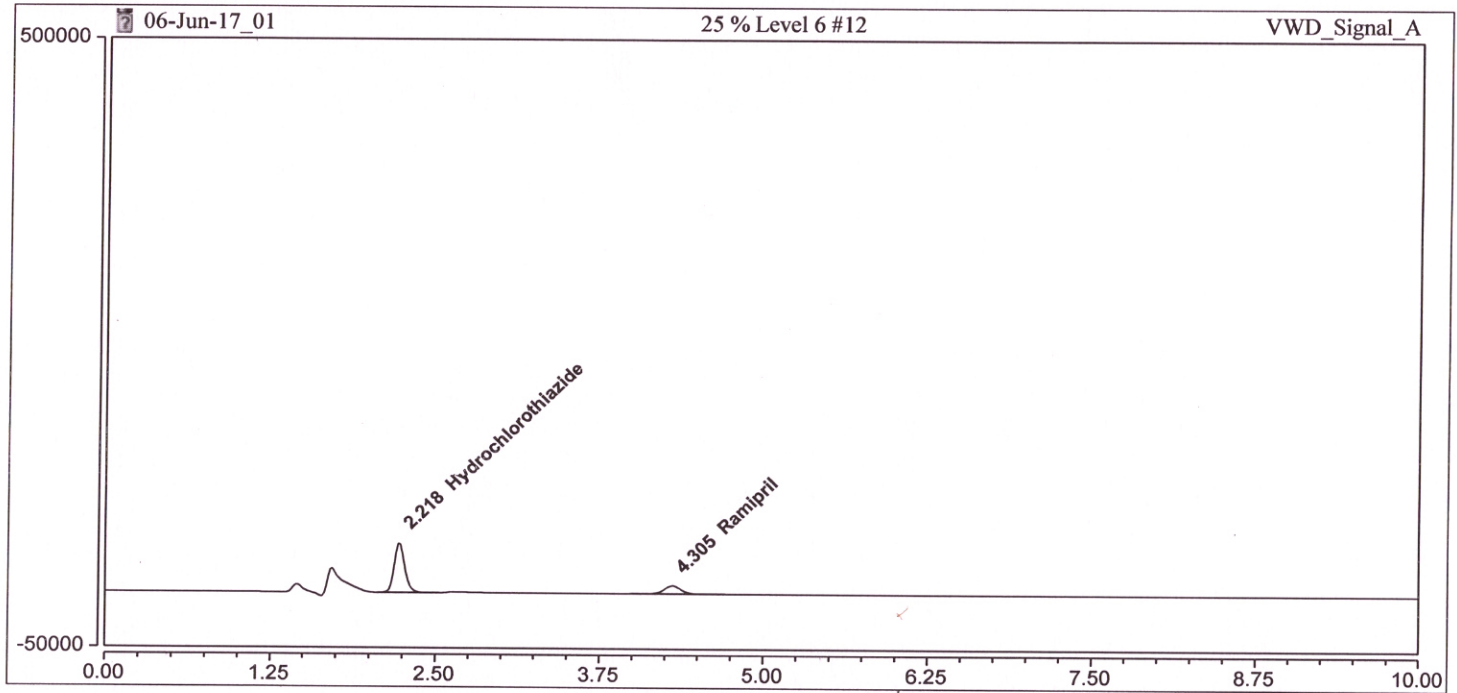
Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.218	4103.983	78.80	1.21	4048	n.a.
2	Ramipril	4.305	1103.886	21.20	1.03	5714	11.40

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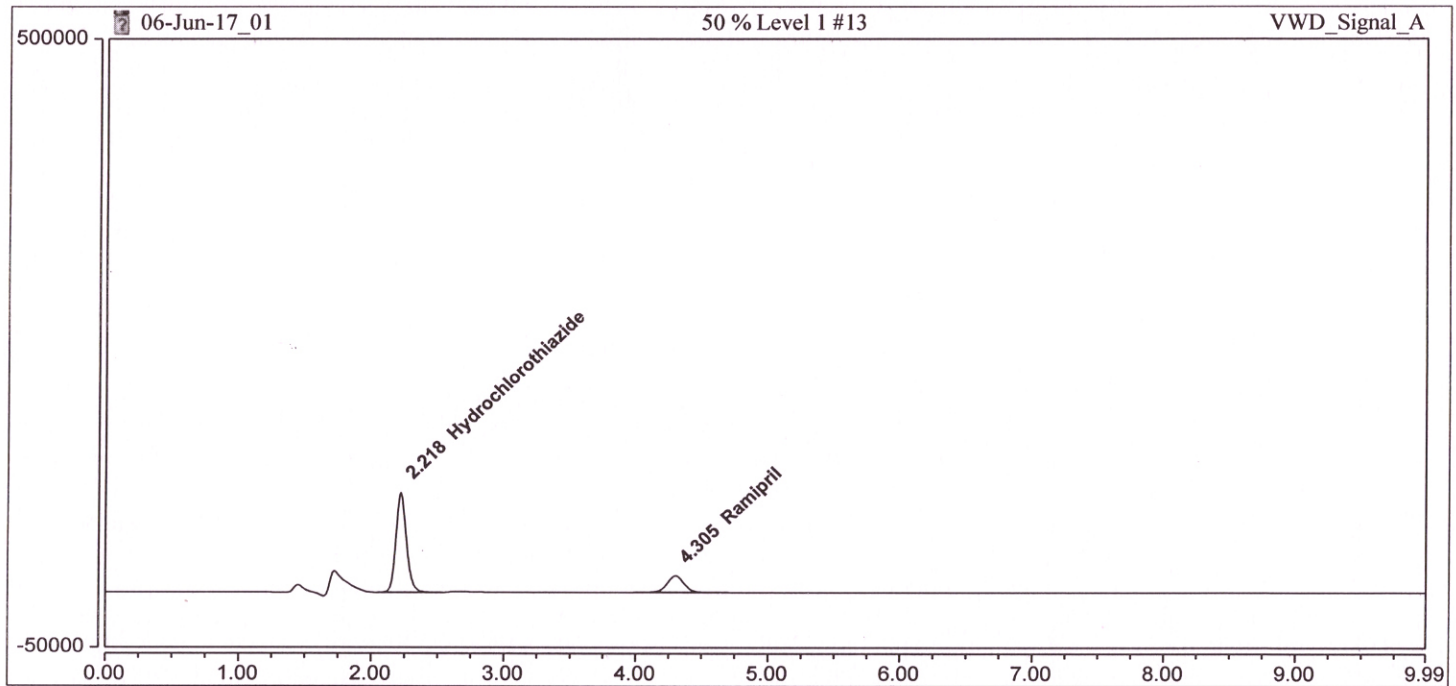
Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	25 % Level 6	AR. No. :-	D010620172169-71
Sample Number :-	12	Instrument Method :-	Ramithiazide Dissolution HPLC-
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmere
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:3	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmere
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 16:46:26	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.218	4100.051	78.77	1.21	4053	n.a.
2	Ramipril	4.305	1105.076	21.23	1.03	5699	11.39

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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.			
Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	50 % Level 1	AR. No. :-	D010620172169-71
Sample Number :-	13	Instrument Method :-	Ramithiazide Dissolution HPLC-
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmere
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:4	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmere
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 16:58:00	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



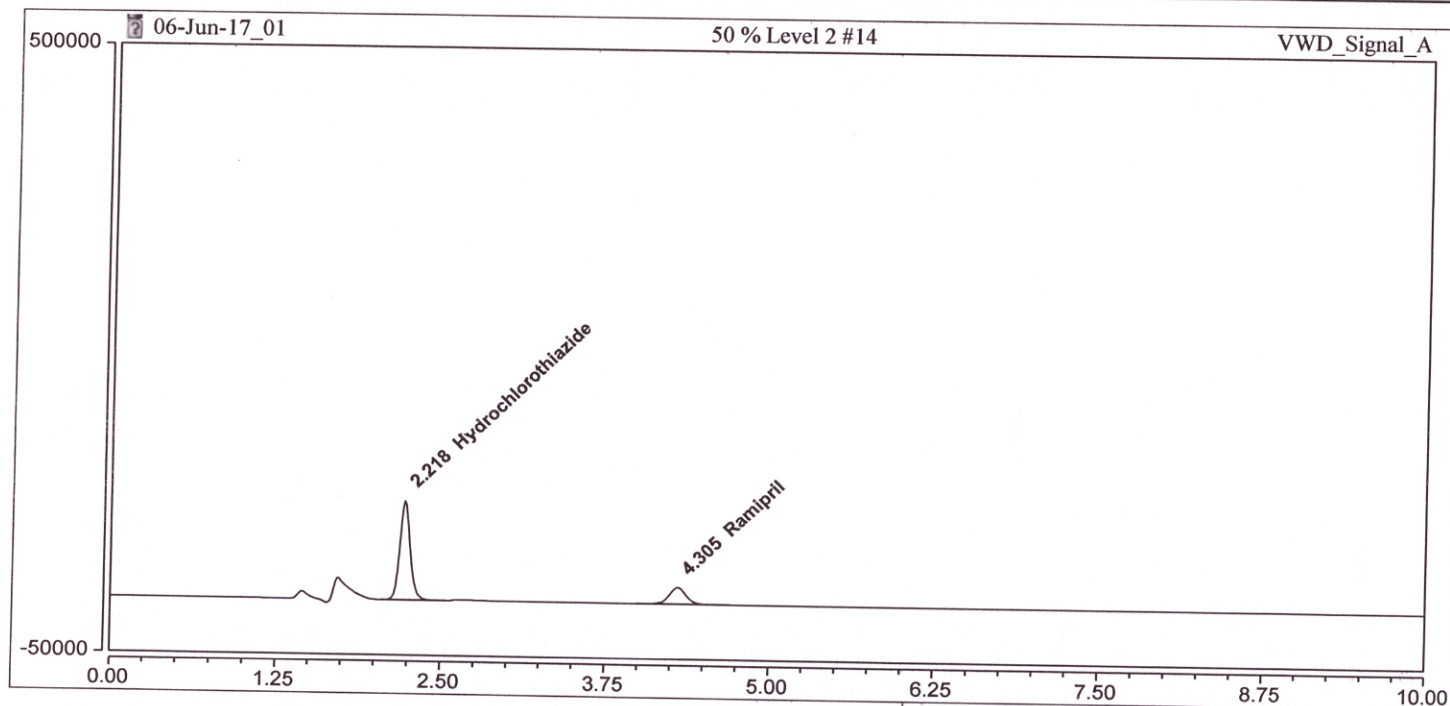
Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.218	8111.711	78.34	1.19	4176	n.a.
2	Ramipril	4.305	2242.621	21.66	1.02	5748	11.48

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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	50 % Level 2	AR. No. :-	D010620172169-71
Sample Number :-	14	Instrument Method :-	Ramithiazide Dissolution HPLC-
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmere
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:4	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmere
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 17:09:40	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



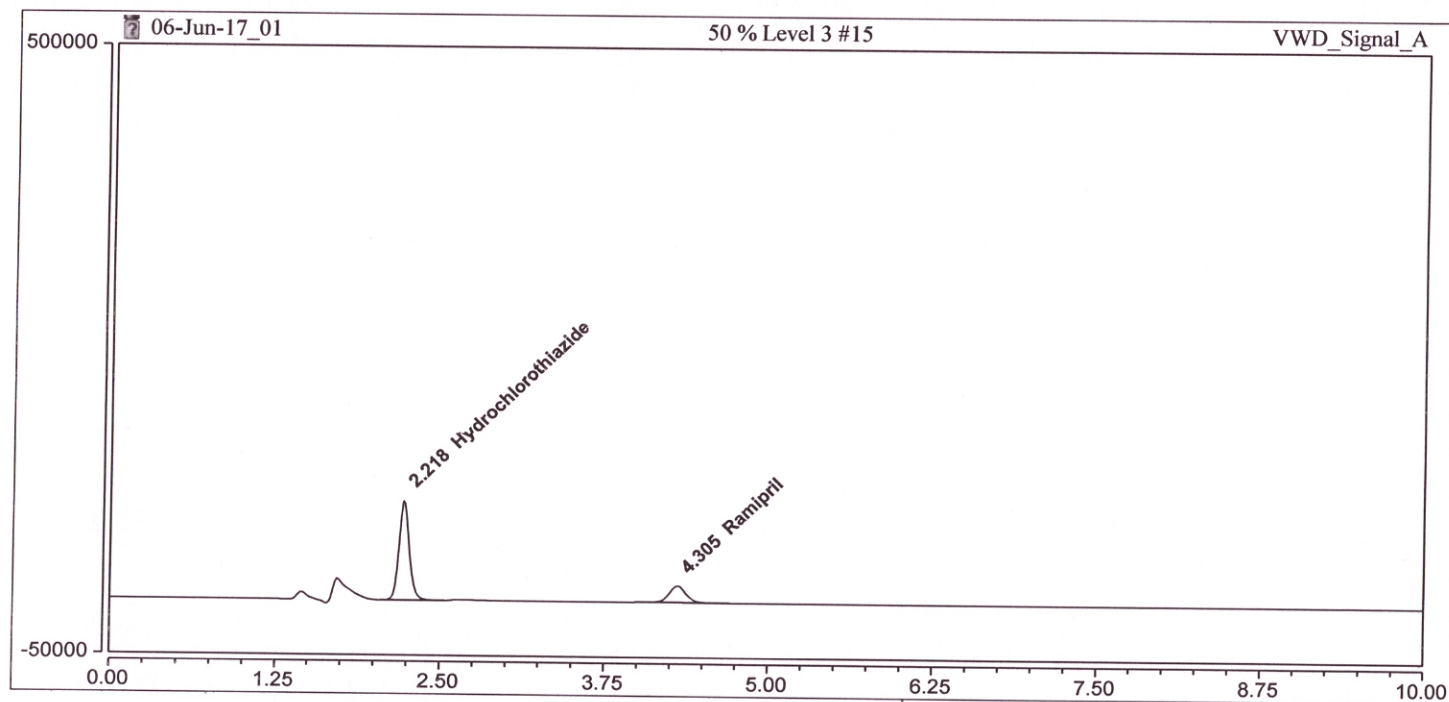
Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.218	8058.520	78.29	1.21	4173	n.a.
2	Ramipril	4.305	2235.066	21.71	1.03	5747	11.48

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Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	50 % Level 3	AR. No. :-	D010620172169-71
Sample Number :-	15	Instrument Method :-	Ramithiazide Dissolution HPLC-1
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmere
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:4	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmere
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 17:21:13	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



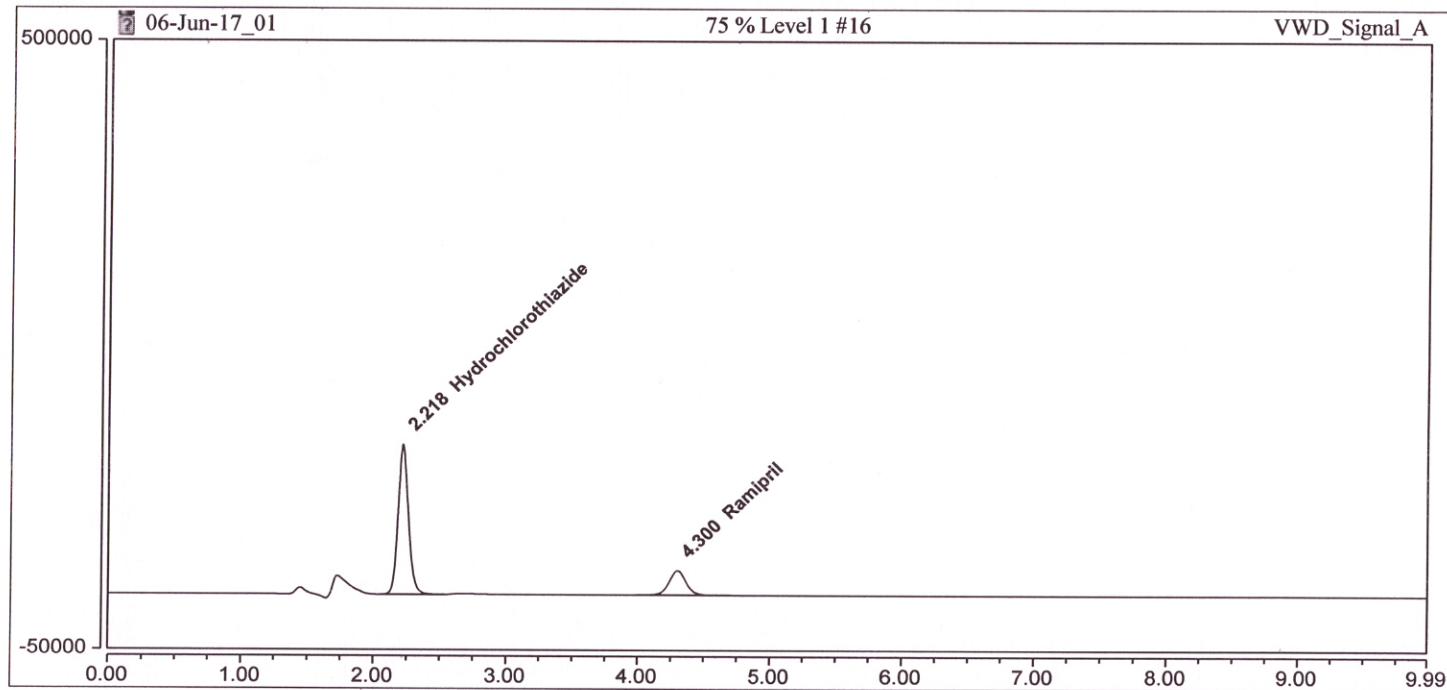
Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.218	8057.730	78.27	1.22	4159	n.a.
2	Ramipril	4.305	2237.525	21.73	1.05	5731	11.47

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07-Jun-17



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	75 % Level 1	AR. No. :-	D010620172169-71
Sample Number :-	16	Instrument Method :-	Ramithiazide Dissolution HPLC-
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmere
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:5	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmere
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 17:32:46	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



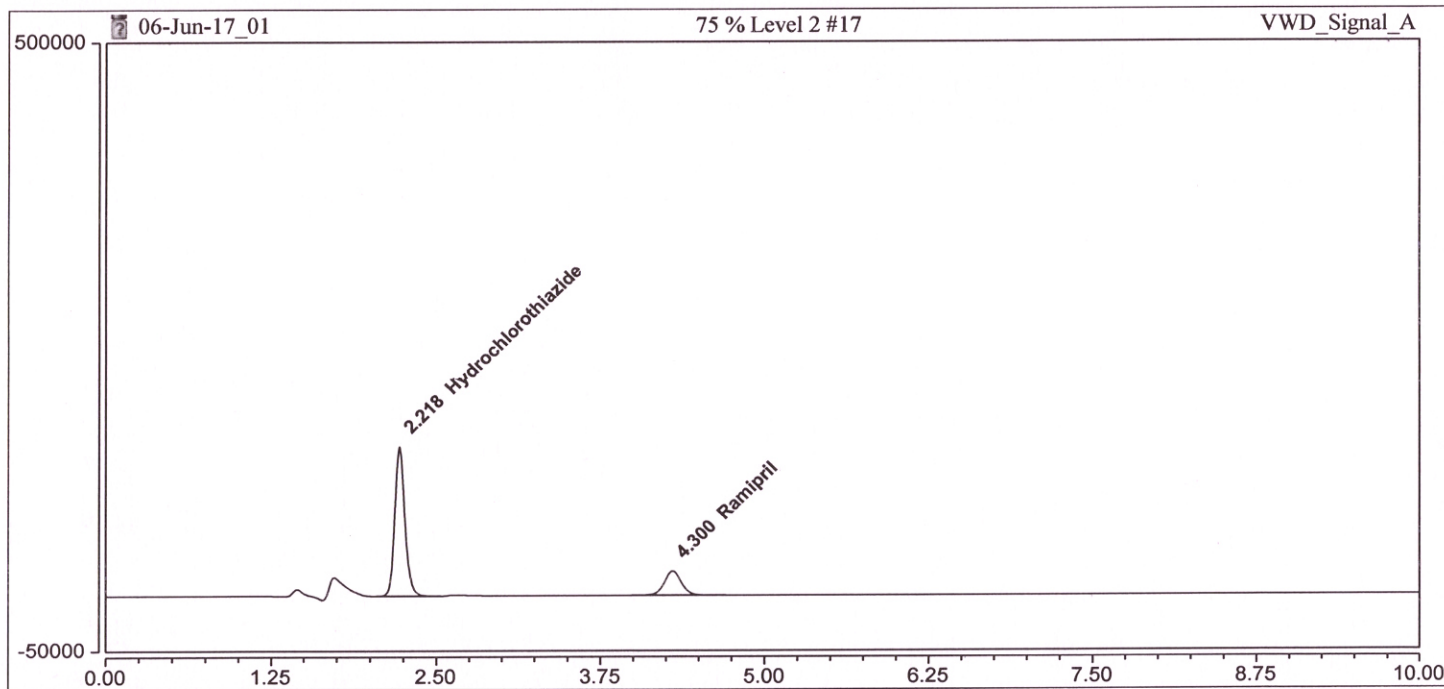
Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.218	12097.737	78.63	1.16	4262	n.a.
2	Ramipril	4.300	3288.544	21.37	1.04	5780	11.53

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07-Jun-17



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	75 % Level 2	AR. No. :-	D010620172169-71
Sample Number :-	17	Instrument Method :-	Ramithiazide Dissolution HPLC-5
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmere
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:5	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmere
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 17:44:20	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



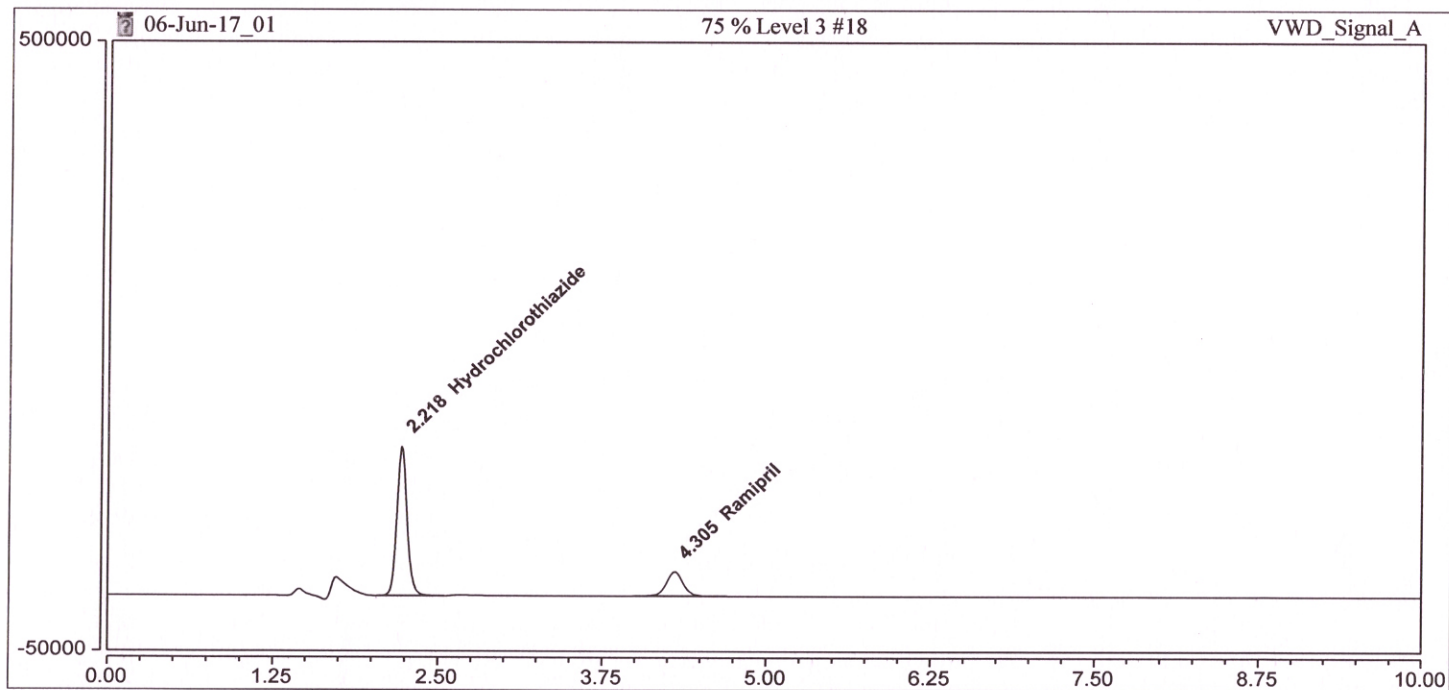
Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.218	12006.775	78.56	1.18	4265	n.a.
2	Ramipril	4.300	3276.074	21.44	1.04	5765	11.52

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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	75 % Level 3	AR. No. :-	D010620172169-71
Sample Number :-	18	Instrument Method :-	Ramithiazide Dissolution HPLC-5
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmere
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:5	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmere
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 17:55:51	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



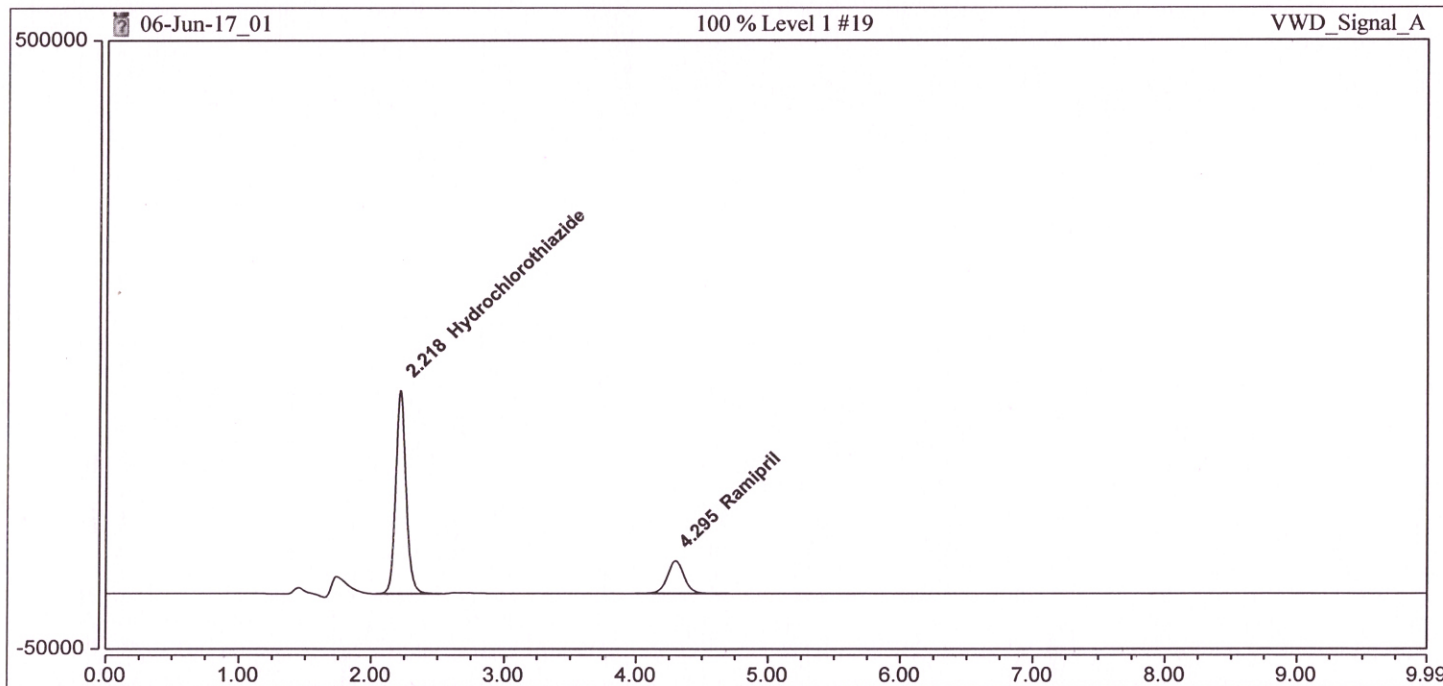
Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.218	12006.473	78.57	1.22	4264	n.a.
2	Ramipril	4.305	3273.948	21.43	1.03	5785	11.55

SPD
07-Jun-17



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	100 % Level 1	AR. No. :-	D010620172169-71
Sample Number :-	19	Instrument Method :-	Ramithiazide Dissolution HPLC-
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmere
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:6	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmere
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 18:07:28	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



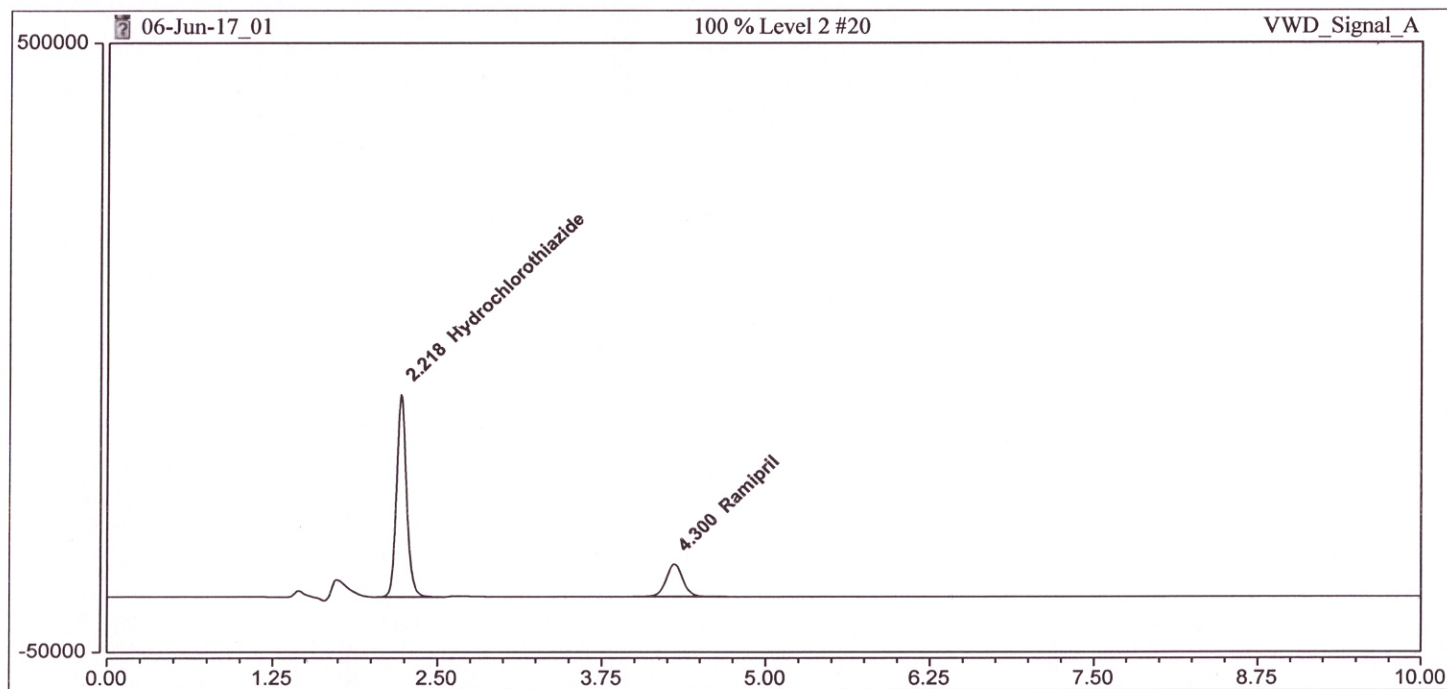
Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.218	16233.327	78.69	1.15	4358	n.a.
2	Ramipril	4.295	4396.359	21.31	1.05	5842	11.60

SPB
07 Jun-17



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	100 % Level 2	AR. No. :-	D010620172169-71
Sample Number :-	20	Instrument Method :-	Ramithiazide Dissolution HPLC-
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmere
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:6	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmere
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 18:19:05	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



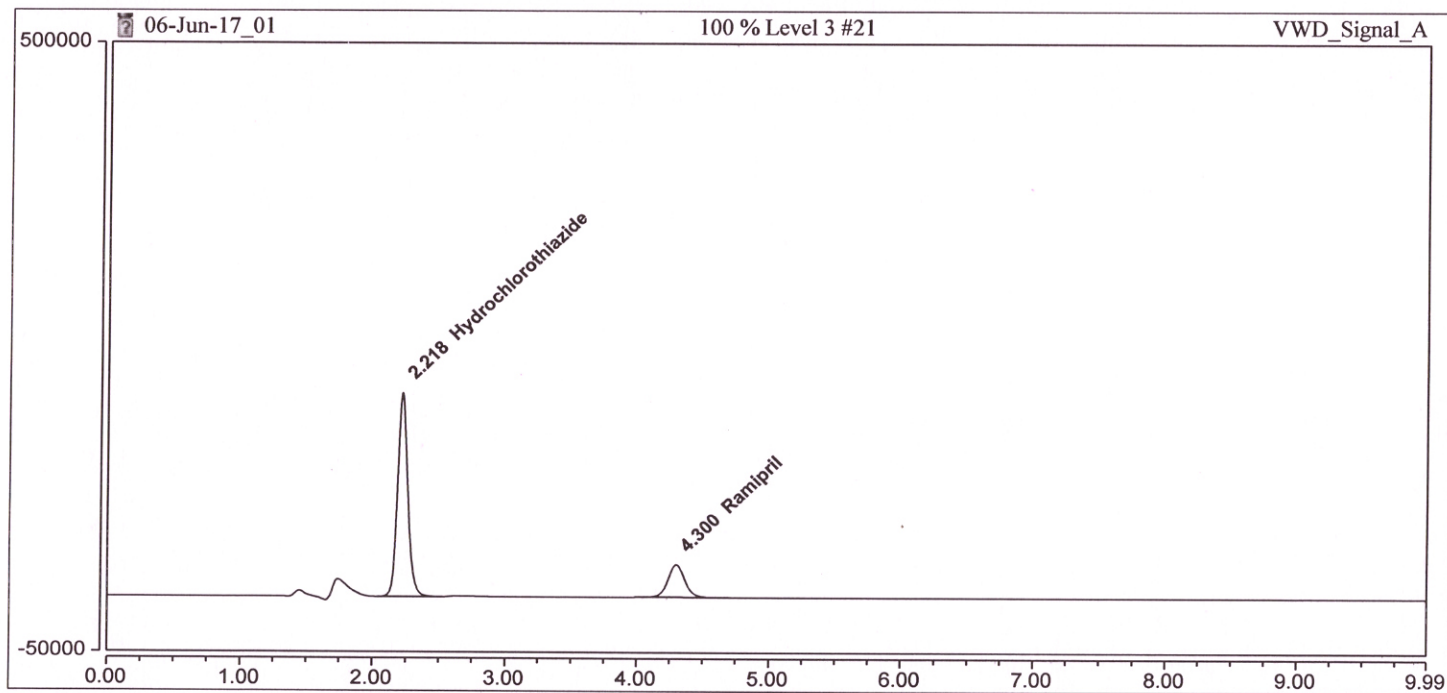
Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.218	16166.768	78.68	1.20	4351	n.a.
2	Ramipril	4.300	4380.366	21.32	1.04	5815	11.60

SKP
07-Jun-17



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	100 % Level 3	AR. No. :-	D010620172169-71
Sample Number :-	21	Instrument Method :-	Ramithiazide Dissolution HPLC-5
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmere
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:6	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmere
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 18:30:35	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



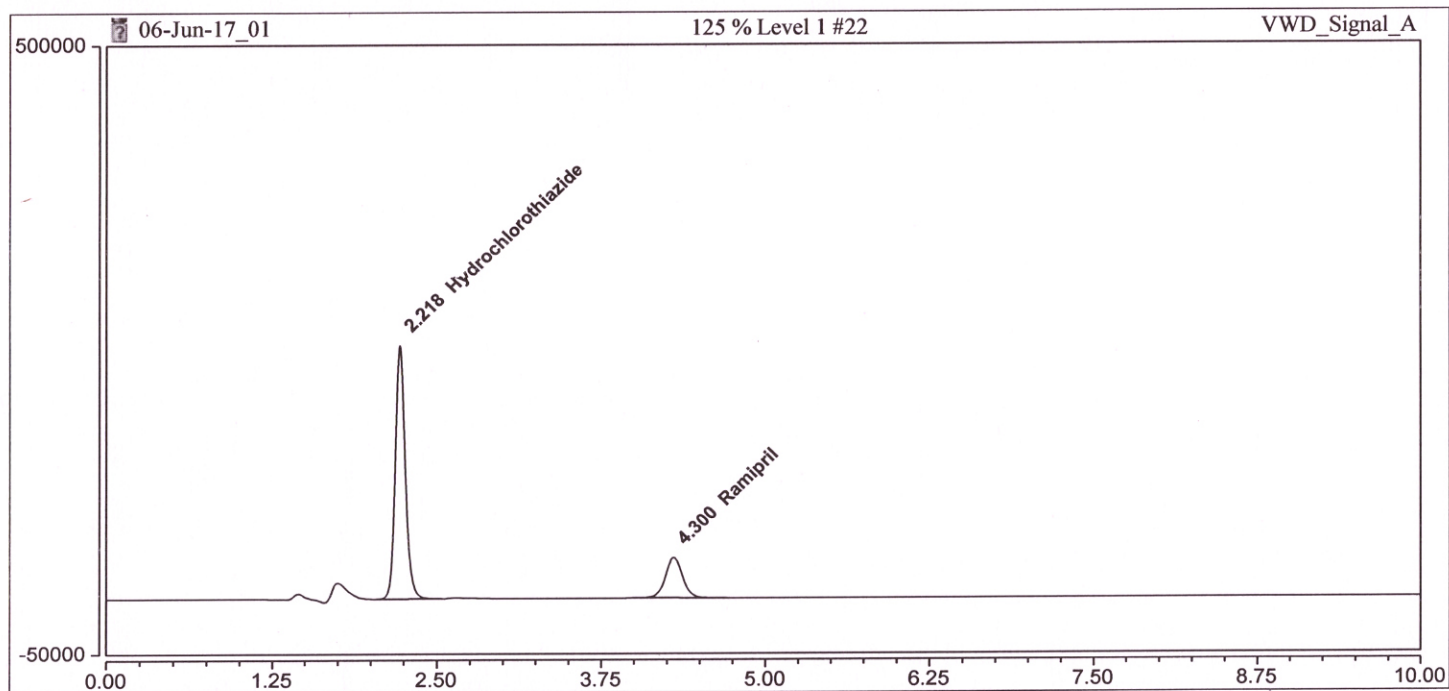
Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.218	16259.276	78.69	1.17	4348	n.a.
2	Ramipril	4.300	4402.936	21.31	1.04	5801	11.59

SKP
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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	125 % Level 1	AR. No. :-	D010620172169-71
Sample Number :-	22	Instrument Method :-	Ramithiazide Dissolution HPLC-
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmere
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:7	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmere
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 18:42:12	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



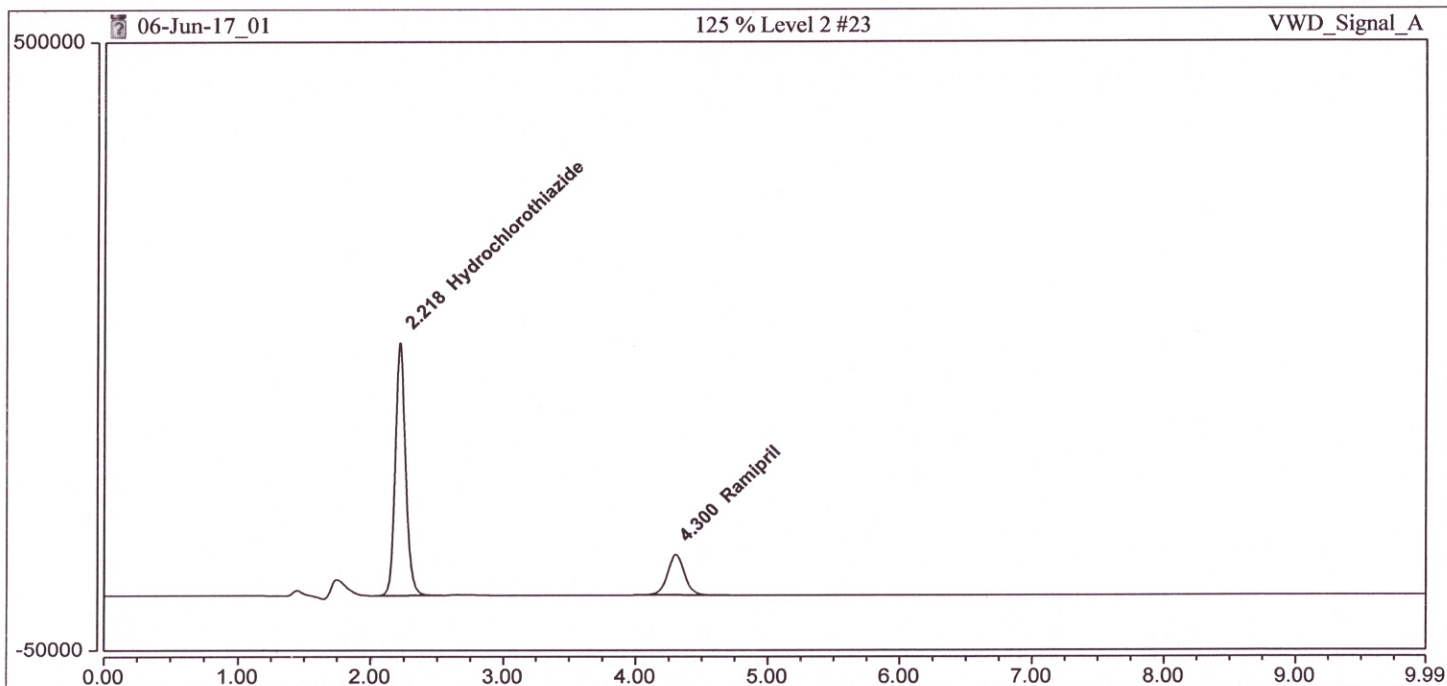
Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.218	20081.864	78.64	1.18	4425	n.a.
2	Ramipril	4.300	5455.809	21.36	1.05	5829	11.64

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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	125 % Level 2	AR. No. :-	D010620172169-71
Sample Number :-	23	Instrument Method :-	Ramithiazide Dissolution HPLC-
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmere
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:7	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmere
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 18:53:49	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



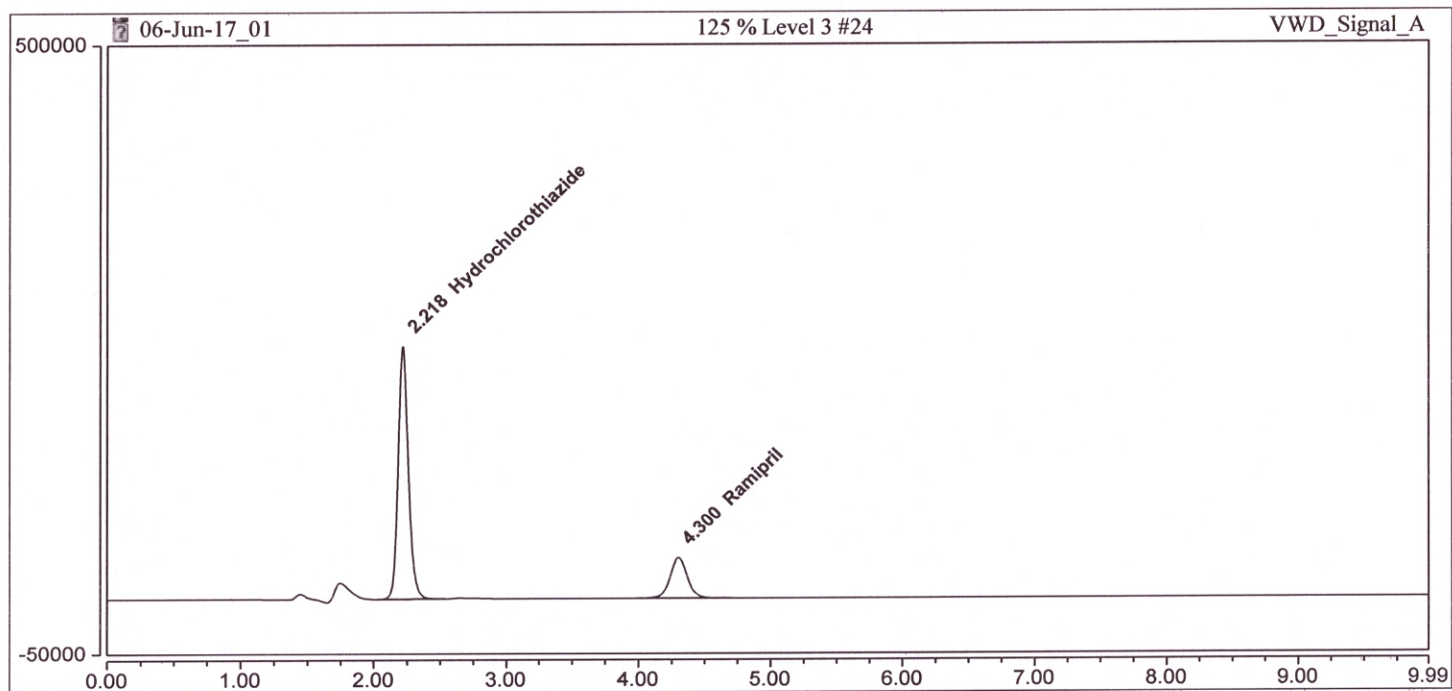
Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.218	20099.317	78.63	1.15	4410	n.a.
2	Ramipril	4.300	5461.386	21.37	1.05	5829	11.63

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Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	125 % Level 3	AR. No. :-	D010620172169-71
Sample Number :-	24	Instrument Method :-	Ramithiazide Dissolution HPLC-
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmure
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:7	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmure
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 19:05:29	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



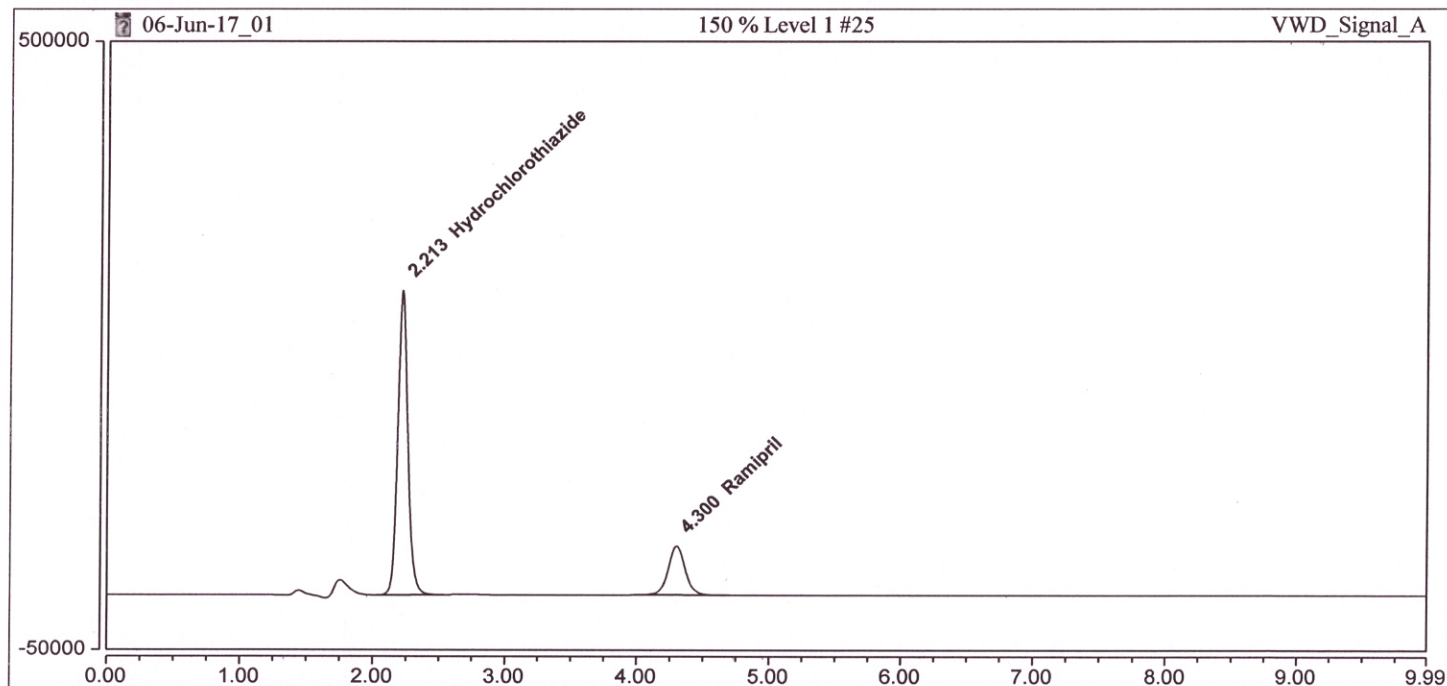
Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.218	20074.587	78.62	1.16	4414	n.a.
2	Ramipril	4.300	5458.646	21.38	1.05	5832	11.64

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Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	150 % Level 1	AR. No. :-	D010620172169-71
Sample Number :-	25	Instrument Method :-	Ramithiazide Dissolution HPLC-3
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmere
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:8	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmere
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 19:17:02	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



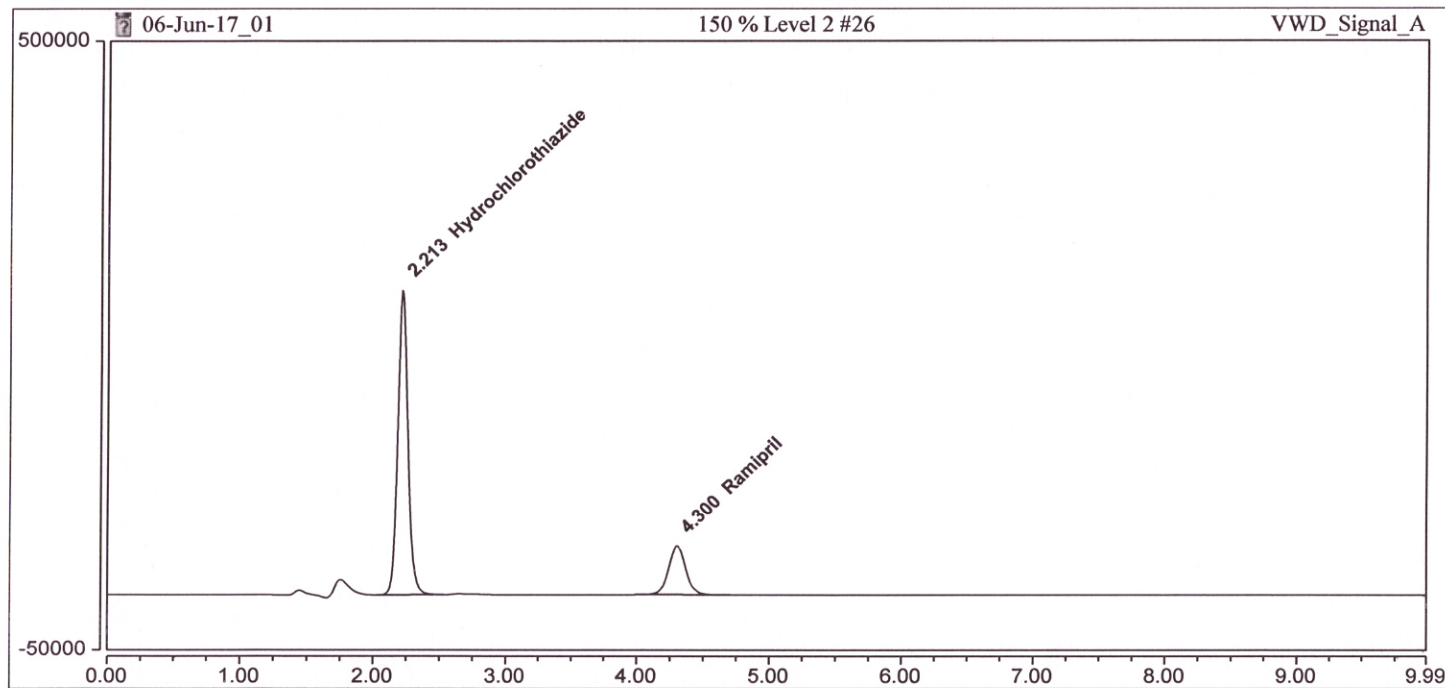
Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.213	24021.387	78.59	1.21	4454	n.a.
2	Ramipril	4.300	6544.987	21.41	1.04	5848	11.70

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Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	150 % Level 2	AR. No. :-	D010620172169-71
Sample Number :-	26	Instrument Method :-	Ramithiazide Dissolution HPLC-
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmere
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:8	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmere
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 19:28:37	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



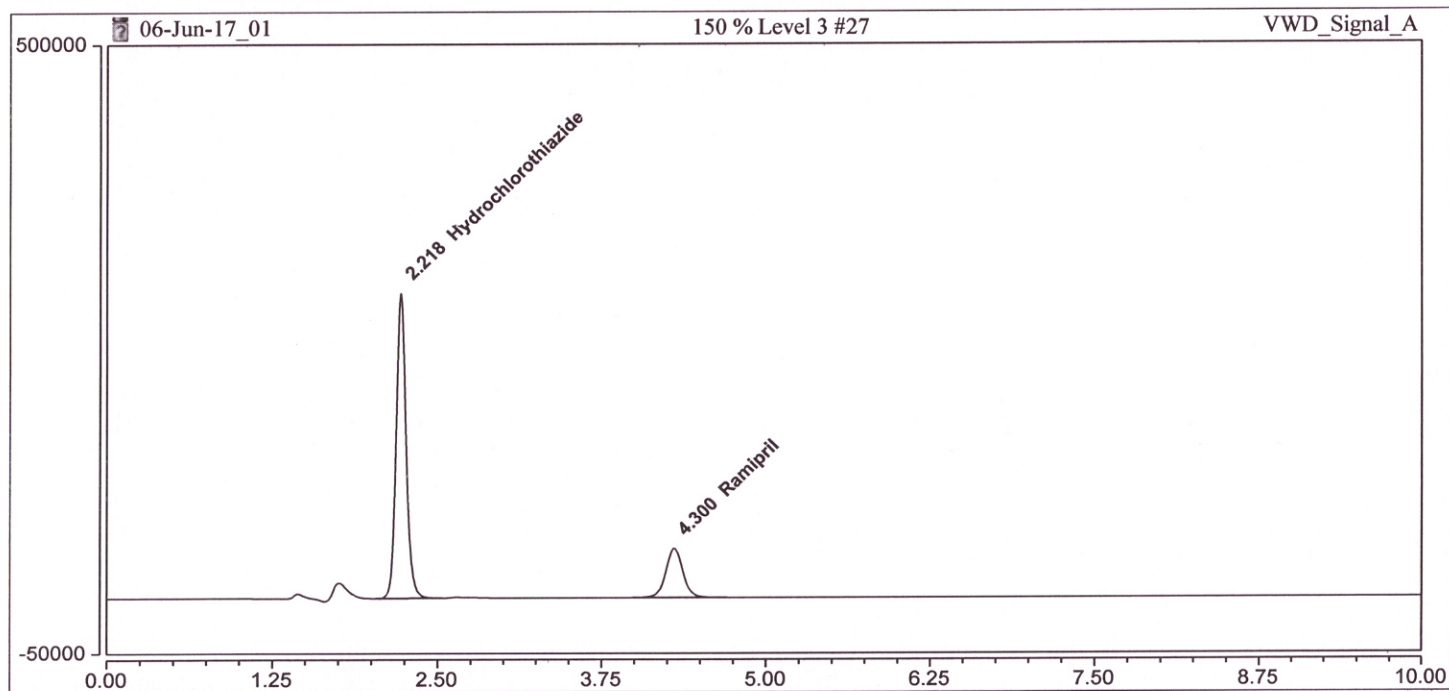
Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.213	24088.856	78.57	1.22	4446	n.a.
2	Ramipril	4.300	6568.676	21.43	1.05	5835	11.69

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Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	150 % Level 3	AR. No. :-	D010620172169-71
Sample Number :-	27	Instrument Method :-	Ramithiazide Dissolution HPLC-
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmere
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:8	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmere
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 19:40:20	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



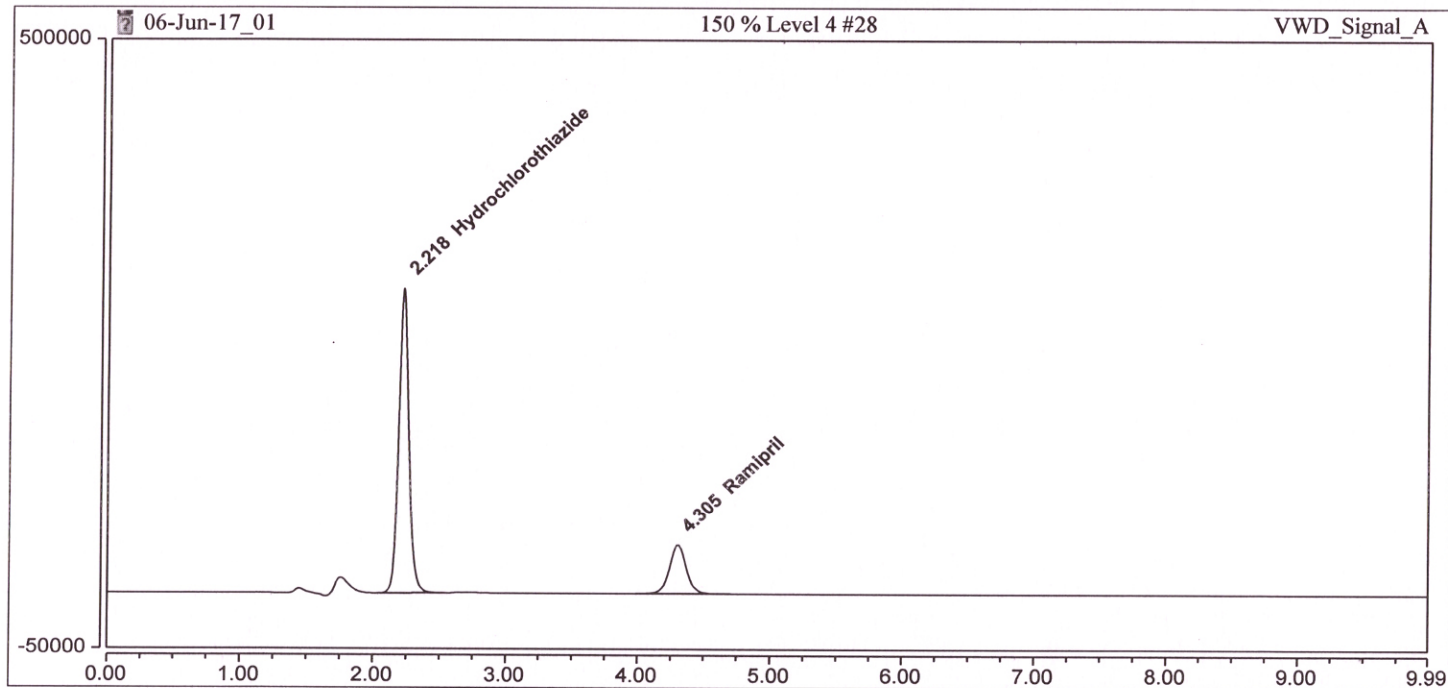
Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.218	24087.047	78.57	1.17	4464	n.a.
2	Ramipril	4.300	6568.118	21.43	1.05	5839	11.67

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Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	150 % Level 4	AR. No. :-	D010620172169-71
Sample Number :-	28	Instrument Method :-	Ramithiazide Dissolution HPLC-
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmure
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:8	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmure
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 19:51:54	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



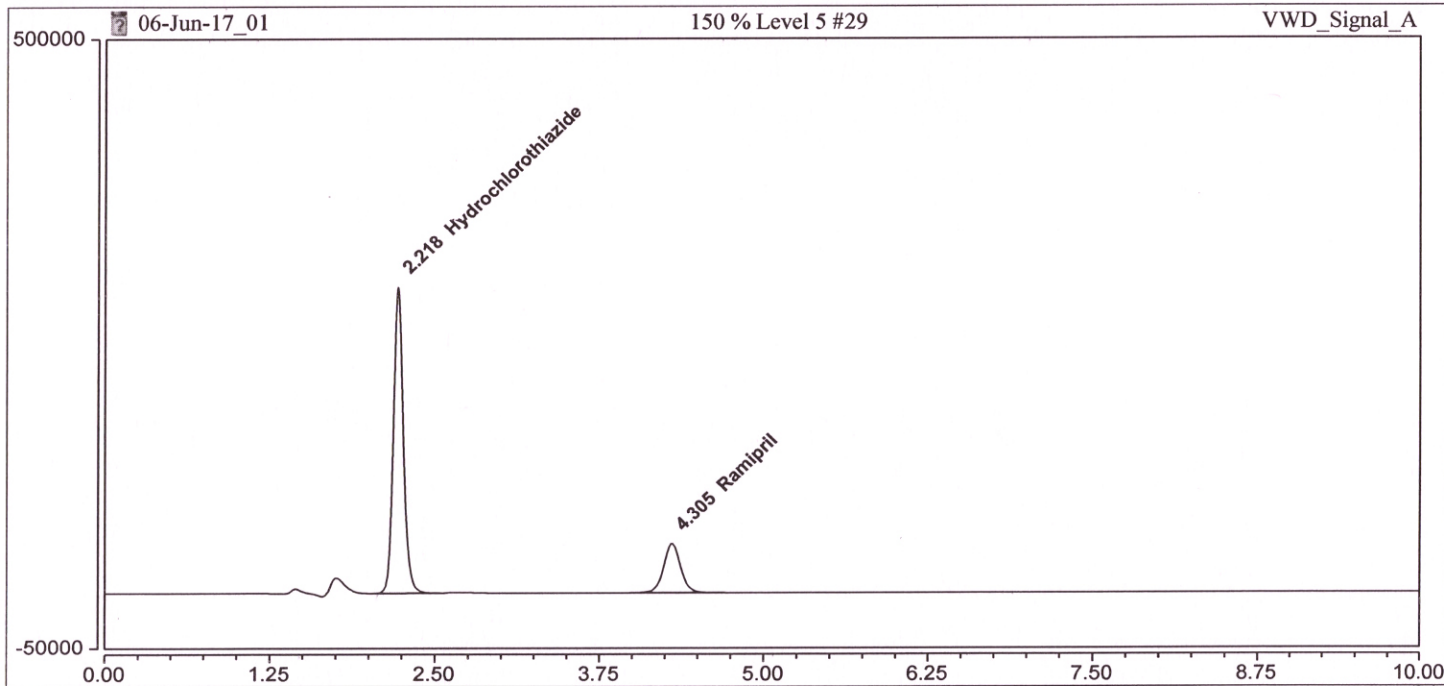
Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.218	24109.205	78.60	1.17	4469	n.a.
2	Ramipril	4.305	6565.379	21.40	1.03	5849	11.69

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Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	150 % Level 5	AR. No. :-	D010620172169-71
Sample Number :-	29	Instrument Method :-	Ramithiazide Dissolution HPLC-5
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmere
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:8	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmere
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 20:03:28	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



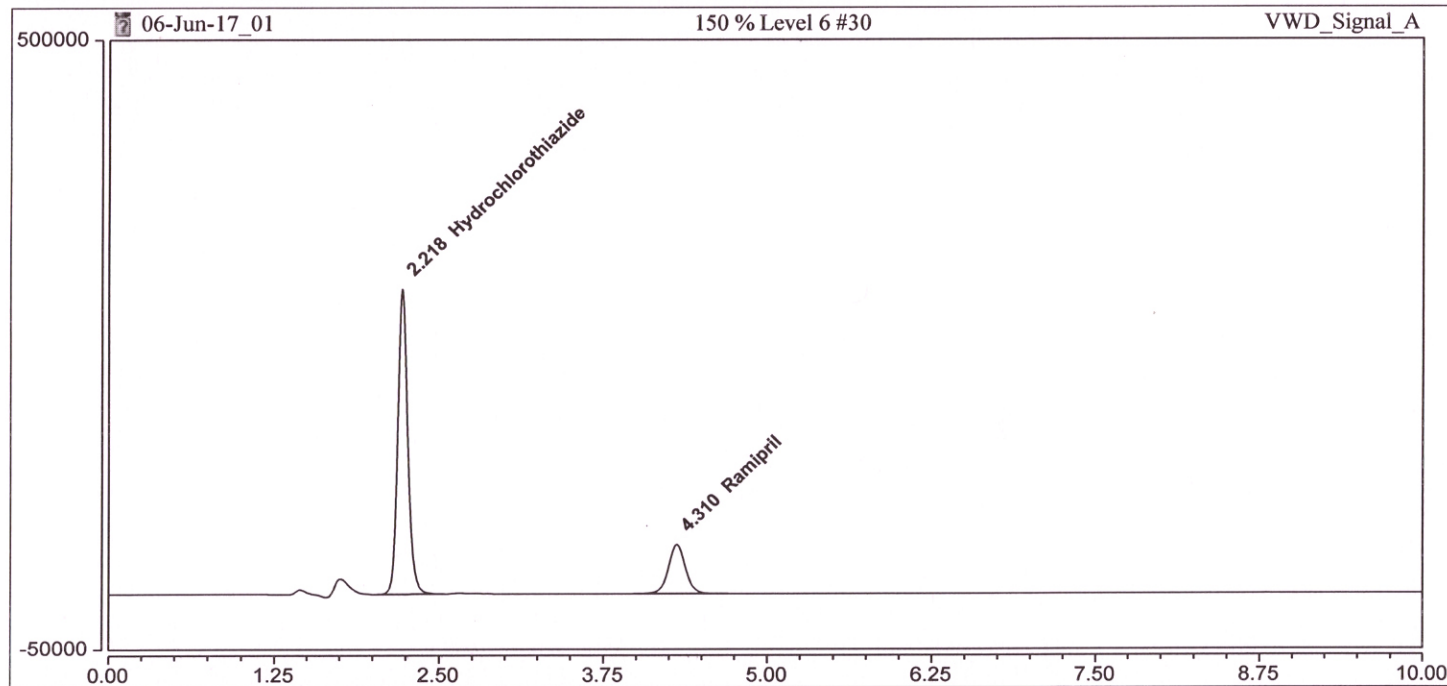
Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.218	24129.946	78.57	1.18	4473	n.a.
2	Ramipril	4.305	6580.626	21.43	1.04	5854	11.70

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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	150 % Level 6	AR. No. :-	D010620172169-71
Sample Number :-	30	Instrument Method :-	Ramithiazide Dissolution HPLC-
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmere
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:8	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmere
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 20:15:06	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



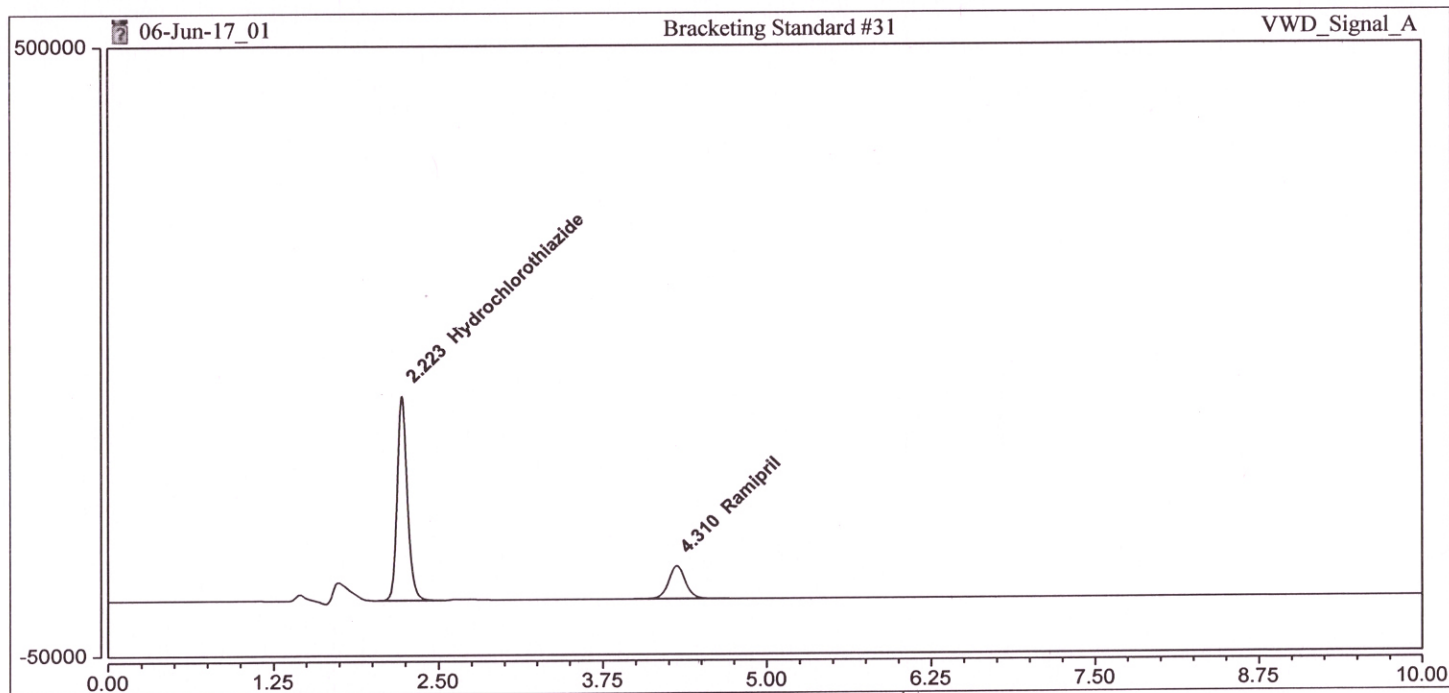
Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.218	24112.861	78.59	1.22	4464	n.a.
2	Ramipril	4.310	6569.096	21.41	1.03	5862	11.72

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Product Name :-	Ramithiazide	Batch No. :-	n.a.
Sample Name :-	Bracketing Standard	AR. No. :-	D010620172169-71
Sample Number :-	31	Instrument Method :-	Ramithiazide Dissolution HPLC-
Sample Type :-	Unknown	Instrument Method Created By :-	Santosh K Padmere
Injection Volume :-	10.00 µL	Instrument Method Created On :-	06-06-2017 14:25:56
Vial Position :-	Vial:2	Processing Method :-	Ramithiazide Dissolution PR
Column No. :-	QbD-LC-COL-29	Processing Method Last Updated By :-	Santosh K Padmere
Instrument ID. :-	QbD-INST-HPLC-59	Processing Method Last Updated On :-	06-06-2017 16:30:39
Injection Date & Time :-	06-06-2017 20:26:45	Experiment Name:-	Linearity
Sequence Path :-	Method Validation\Generic Health Care\Ramithiazide Tablets\Dissolution\06-Jun-17_01.seq		



Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (EP)	Resolution (EP)
1	Hydrochlorothiazide	2.223	16333.793	78.72	1.16	4363	n.a.
2	Ramipril	4.310	4416.093	21.28	1.04	5824	11.61

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