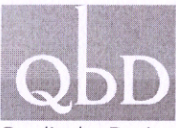


QbD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

 Quality by Design	ANALYTICAL METHOD VALIDATION PROTOCOL FOR RELATED SUBSTANCES IN RAMITHIAZIDE TABLET 10/25 MG BY HPLC METHOD		
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Standard test method code: NA	Method release date: NA
Version: 00	Supersedes Version: NA
Reference : ICH guideline	Type of validation: Validation of Non-Pharmacopoeial method
Customer Name: Generic Healthcare Pvt. Ltd.	

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Approved By	Designation	Signature	Date
	For (Generic Healthcare Pvt. Ltd.)		

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Abbreviations	
Mg	: Milligram
A.R. Grade	: Analytical Reagent Grade
μ	: Micron
mL	: Milliliter
° C	: degree Celsius
nm	: Nanometer
Min	: Minute
μL	: Microliter
G	: Gram
ppm	: Part per million
LC	: Label claim
Std	: Standard
Wt.	: Weight
RSD	: Relative Standard Deviation
HPLC	: High Performance Liquid Chromatography
Conc.	: Concentration
NMT	: Not more than
NLT	: Not Less Than
QA	: Quality Assurance

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1. OBJECTIVE

The objective of the analytical method validation for Related Substances in Ramithiazide 10/25 mg is to demonstrate, that the method is consistently yield the results which reflects the quality characteristics of the product.

2. SCOPE

The validation activity will be carried out on Ramithiazide Tablet 10/25 mg.

3. RESPONSIBILITIES

3.1.It is responsibility of the Manager Analytical, to prepare the Protocol.

3.2.It is the responsibility of the GM Analytical to review the Protocol.

3.3.It is the responsibility of the Sr. QA Manager to approve the Protocol.

4. SAFETY

Laboratory coats, safety gloves and goggles should be worn during this procedure and while handling chemicals. Normal laboratory codes should be followed and appropriate procedures should be adopted for disposal of waste.

5. STANDARD DETAILS

Standard name	Batch number/Lot no.
Ramipril working standard	*
Hydrochlorothiazide working standard	*

*Will be mentioned at the time of validation.

6. SAMPLE AND PLACEBO DETAILS

Sample name	Batch no./Lot no.
Ramithiazide 10/25 mg	GP180301
Placebo of Ramithiazide 10/25 mg	*

*Will be mentioned at the time of validation.

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7. DETAILS OF SPECIFICATIONS

Name of Components	Limit
Impurity A	NMT 2.0%
Impurity D	NMT 6.0%
Impurity E	NMT 2.0%
Single maximum unknown impurity	NMT 0.5%
Total impurities	NMT 6.0%

8. REAGENTS AND CHEMICALS

Reagent	Grade	Manufacturer
Triethylamine	AR	*
Phosphoric Acid	HPLC	*
Acetonitrile	HPLC	*
Water	MilliQ	---

*Will be mentioned at the time of validation.

Note: Equivalent reagents, chemicals and solvents may be used provided they meet the specifications.

9. INSTRUMENT DETAILS

Instruments used for the validation will be,

Instrument	Manufacturer	Instrument In-House No.	Calibration due date
HPLC	Agilent	*	*
Analytical Balance	Mettler Toledo	QbD-INST-BAL-12	*
Analytical Balance	Mettler Toledo	QbD-INST-BAL-13	*
pH meter	Lab India	QbD-INST-pH-08	*

*Will be mentioned at the time of validation.


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10. METHOD OF ANALYSIS**HPLC Chromatographic conditions**

Column	:	Inertsil ODS 3V (250 X 4.6 mm, 5 μ m), C18 or equivalent
Flow rate	:	1.0 mL/min
Column oven temperature	:	25°C
LC mode	:	Gradient
Detection wavelength	:	210 nm
Injection volume	:	30 μ L
Run time	:	30 minutes

Preparation of buffer solution:

Dissolve 12.2987 g of sodium perchlorate in water to make 1000 mL, adjust pH 2.5 with diluted phosphoric acid and mix well. Filter it through 0.45 μ membrane filter and degas.

Mobile phase A:

Use buffer solution as Mobile phase A

Mobile phase B:

Acetonitrile

Gradient program:

Time (min)	Mobile phase A (%v/v)	Mobile phase B (%v/v)
0.0	70	30
7.0	70	30
9.0	50	50
25.0	50	50
30.0	70	30

Diluent:

Water : Acetonitrile : Triethylamine (550:450:1 V/V), Mix well and adjust the pH to 3.0 with diluted phosphoric acid.

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Preparation of Ramipril standard stock solution:

Weigh accurately and transfer about 25 mg of Ramipril working standard in 25 mL of volumetric flask and add 10 mL of diluent and sonicate to dissolve and dilute to volume with diluent.

Preparation of Hydrochlorothiazide standard stock solution:

Weigh accurately and transfer about 25 mg of Hydrochlorothiazide working standard in 25 mL of volumetric flask and add 10 mL of diluent and sonicate to dissolve and dilute to volume with diluent.

Preparation of Standard solution:

Pipette out 2.0 mL of Ramipril standard stock solution and 2.5 mL of Hydrochlorothiazide standard stock solution and transfer in to 100 mL volumetric flask and dilute to volume with diluent.

Further dilute 2.0 mL of above solution to 20 mL and dilute to volume with diluent.

Placebo solution:

Transfer an accurately weighed portion of the placebo powder equivalent to 20 mg of Ramipril to a 20 mL volumetric flask. Add 12 mL of diluent, and 1 mL water sonicate for 15 minutes and dilute with diluent to make volume, mix well. Filter through 0.45µm nylon filter.

Sample solution:

Take 20 tablets, determine the average weight of tablet and finely powder. Transfer an accurately weighed portion of the powder equivalent 20 mg of Ramipril to a 20 mL volumetric flask. Add 12 mL of diluent, and 1 mL water sonicate for 15 minutes and dilute with diluent to make volume, mix well. Filter through 0.45µm nylon filter.

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Procedure:

Separately inject 30 µL of the blank solution, standard solution in six replicate, placebo solution and sample solution into the chromatography system, record the chromatograph and measure the peak response for the major peaks.

System suitability parameters:

The relative standard deviation for six replicate injections of standard solution should be not more than 5.0%.

Note: Disregard any peak due to blank and placebo.

Calculations:

Calculate the results by using the following formula

%Known impurities:

$$= \frac{AT1 \times WS \times 2 \times 2 \times 20 \times P \times \text{Average weight (mg)}}{AS \times 25 \times 100 \times 20 \times WT \times 100 \times LC} \times 100 \times RRF$$

Where,

AT1 = Area of known impurity peak obtained from sample preparation.

AS = Average area of Ramipril peak obtained from standard solution.

WS = Weight of Ramipril working standard in mg.

WT = Weight of sample in mg.

P = %Potency of Ramipril working standard on as is basis.

RRF= Relative response factor.

LC = Label claim in mg.

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%Unknown impurities:

$$= \frac{\text{AT2} \times \text{WS} \times 2 \times 2 \times 20 \times \text{P} \times \text{Average weight (mg)}}{\text{AS} \times 25 \times 100 \times 20 \times \text{WT} \times 100 \times \text{LC}} \times 100$$

Where,

AT2 = Area of unknown impurity peak obtained from sample preparation.

AS = Average area of Ramipril peak obtained from standard solution.

WS = Weight of Ramipril working standard in mg.

WT = Weight of sample in mg.

P = %Potency of Ramipril working standard on as is basis.

LC = Label claim in mg.

Total impurities: Sum of % of all known Impurities + Sum of % of all unknown Impurities.

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11. VALIDATION PARAMETERS

11.1. Specificity

- A. System suitability
- B. Specificity

11.2. Precision

- A. System precision
- B. Method precision
- C. Intermediate precision

11.3. LOD and LOQ

11.4. Linearity and Range

11.5. Accuracy

11.6. Robustness

11.7. Solution stability

11.8. Filter study

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11.1. SPECIFICITY

SPECIFICITY BY INTERFERENCE

Procedure:

Carry out procedure as per method specified in section method of analysis.

Placebo Preparation:

As per the sample preparation mentioned in the Method of Analysis.

Ramipril Impurity A stock solution:

Weigh accurately and transfer about 2.5 mg of Ramipril Impurity A in 10 mL of volumetric flask and add 5 mL of diluent and sonicate to dissolve and dilute to volume with diluent.

Ramipril Impurity E stock solution:

Weigh accurately and transfer about 2.5 mg of Ramipril Impurity E in 10 mL of volumetric flask and add 5 mL of diluent and sonicate to dissolve and dilute to volume with diluent.

Ramipril Impurity A Identification solution:

Further dilute 2.0 mL of Ramipril Impurity A stock solution to 25 mL and dilute to volume with diluent.

Ramipril Impurity E Identification solution:

Further dilute 2.0 mL of Ramipril Impurity E stock solution to 25 mL and dilute to volume with diluent.

Ramipril Impurity D Identification solution:

Weigh accurately and transfer about 3 mg of Ramipril Impurity D in 50 mL of volumetric flask and add 10 mL of diluent and sonicate to dissolve and dilute to volume with diluent.

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Spiked Sample Preparation:

Take 20 tablets, determine the average weight of tablet and finely powder. Transfer an accurately weighed portion of the powder equivalent 20 mg of Ramipril to a 20 mL volumetric flask. Add 12 mL of diluent, and 1 mL water and add 0.8 mL of each of Ramipril Impurity A standard stock solution and Ramipril Impurity E standard stock solution, sonicate for 15 minutes and dilute with diluent to make volume, mix well. Filter through 0.45µm nylon filter.

Determination:

1. Inject blank solution.
2. Inject standard solution in six replicates.
3. Inject placebo solution.
4. Inject all Impurity identification solution.
5. Inject sample solution.
6. Inject sample solution spiked with known impurities.
7. Inject bracketing standard.

System suitability parameters:

1. The relative standard deviation for six replicate injections of standard solution should be not more than 5.0%.
2. There should be no peaks in the blank and placebo chromatograms at the retention time of Ramipril, Ramipril impurity A, Ramipril impurity D and Ramipril impurity E.

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11.2. PRECISION

Precision of the method shall be established by carrying out as System precision, Method precision and Intermediate precision.

A) System Precision

Procedure:

Carry out procedure as per method specified in section method of analysis

Determination:

1. Inject blank solution.
2. Inject standard solution in six replicates.

Acceptance criteria:

The relative standard deviation for six replicate injections of standard solution should be not more than 5.0%.

B) Method precision

The precision of an analytical procedure expresses the closeness of agreement (degree of scatter) between a series of measurements obtained from multiple sampling of the same homogeneous sample under the prescribed conditions.

Procedure:

Carry out procedure as per method specified in section method of analysis.

Note: Perform method precision by spiking the known impurity at the 1% level as given below.

Ramipril Impurity A standard stock solution:

Weigh accurately and transfer about 2.5 mg of Ramipril Impurity A in 10 mL of volumetric flask and add 5 mL of diluent and sonicate to dissolve and dilute to volume with diluent.

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Ramipril Impurity E standard stock solution:

Weigh accurately and transfer about 2.5 mg of Ramipril Impurity E in 10 mL of volumetric flask and add 5 mL of diluent and sonicate to dissolve and dilute to volume with diluent.

Spiked Sample Preparation:

Take 20 tablets, determine the average weight of tablet and finely powder. Transfer an accurately weighed portion of the powder equivalent 20 mg of Ramipril to a 20 mL volumetric flask. Add 12 mL of diluent, and 1 mL water and add 0.8 mL of each of Ramipril Impurity A standard stock solution and Ramipril Impurity E standard stock solution, sonicate for 15 minutes and dilute with diluent to make volume, mix well. Filter through 0.45µm nylon filter.

Determination:

1. Inject blank solution.
2. Inject placebo solution.
3. Inject standard solution in six replicates.
4. Inject sample solution (Six sample solutions).
5. Inject spiked sample solution (Six sample solutions).
6. Inject bracketing standard.

Acceptance criteria:

1. The relative standard deviation for six replicate injections of standard solution should be not more than 5.0%.
2. The relative standard deviation for single maximum unspecified impurity and known impurities from six sample preparations should be NMT 15.0% and for total impurities should be NMT 10.0%

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C) INTERMEDIATE PRECISION

Intermediate precision of the method will be established by carrying out the analysis on different day with another analyst and another instrument.

Procedure:

Carry out procedure as per method specified in section method of analysis.

Note: Perform method precision by spiking the known impurity at the specification level as given below.

Preparation of known impurity stock solutions and spiked sample solution:

Refer as per mentioned under Method precision.

Determination:

Follow the same as per method precision.

Acceptance criteria:

1. The relative standard deviation for six replicate injections of standard solution should be not more than 5.0%.
2. Known impurity, single maximum unknown impurity and total impurities should meet the specification limits.
3. The relative standard deviation for single maximum unspecified impurity and known impurities from six sample preparations should be NMT 15.0% and for total impurities should be NMT 10.0%
4. Difference between average impurities results of two analysts,

Level of impurities, degradants (%Individually specified and total sum) (%, relative to active)	Acceptance criteria
<0.1	≤ 0.05% absolute
0.10 to 0.15	≤ 0.05% absolute
>0.15 to 0.30	≤ 0.10% absolute
>0.30 to 0.50	≤ 0.15% absolute
>0.50 to 0.80	≤ 0.20% absolute

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>0.80 to 1.0	<u>≤</u> 0.25% absolute
>1.0 to 5.0	<u>≤</u> 20% relative
>5.0	<u>≤</u> 10% relative

11.3. LIMIT OF DETECTION AND LIMIT OF QUANTITATION

LOD/LOQ establishment:

Series of Standard solution of lowest possible concentrations shall be prepared and shall be injected to establish LOD/LOQ.

Procedure:

Carry out procedure as per method specified in section method of analysis

Preparation of Ramipril standard stock solution:

Weigh accurately and transfer about 25 mg of Ramipril working standard in 25 mL of volumetric flask and add 10 mL of diluent and sonicate to dissolve and dilute to volume with diluent. Pipette out 5.0 mL of Ramipril standard stock solution and transfer in to 100 mL volumetric flask and dilute to volume with diluent.

Preparation of Ramipril standard solution:

Dilute 10.0 mL of Ramipril standard stock solution to 50 mL with diluent and mix well.

Preparation of Impurity A standard solution:

Weigh accurately and transfer about 2.5 mg of Impurity A in 10 mL of volumetric flask and add 5 mL of diluent and sonicate to dissolve and dilute to volume with diluent.

Preparation of Impurity D standard solution:

Weigh accurately and transfer about 3 mg of Impurity D in 50 mL of volumetric flask and add 35 mL of diluent and sonicate to dissolve and dilute to volume with diluent.

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Preparation of Impurity E standard solution:

Weigh accurately and transfer about 2.5 mg of Impurity E in 10 mL of volumetric flask and add 5 mL of diluent and sonicate to dissolve and dilute to volume with diluent.

Preparation of solution for determination of LOD and LOQ:

Prepare the solution for linearity as mentioned below:

Level	Volume (mL) taken from Standard solution				Volume up to mark with Diluent (mL)	Concentration (ppm)			
	Ramipril	Imp A	Imp D	Imp E		Ramipril	Imp A	Imp D	Imp E
LOD/LOQ Solution 1	0.5	0.2	2.5	0.2	25.0	0.2	2.0	6.0	2.0
LOD/LOQ Solution 2	1.0	0.4	5.0	0.4	25.0	0.4	4.0	12.0	4.0
LOD/LOQ Solution 3	1.5	0.6	7.5	0.6	25.0	0.6	6.0	18.0	6.0
LOD/LOQ Solution 4	2.0	0.8	10.0	0.8	25.0	0.8	8.0	24.0	8.0
LOD/LOQ Solution 5	2.5	1.0	12.5	1.0	25.0	1.0	10.0	30.0	10.0

Determination:

1. Inject blank solution.
2. Inject standard solution in six replicates.
3. Inject blank solution.
4. Inject LOD & LOQ solution.
5. Inject bracketing standard.

Data evaluation:

Determine the LOD and LOQ concentration.

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The limit of quantification (LOQ) and limit of detection (LOD) will be predicted for the Ramipril from the linearity using the formula.

$LOQ = 10 \times \text{residual standard deviation/slope}$

$LOD = 3.3 \times \text{residual standard deviation/slope}$

Acceptance criteria:

1. The relative standard deviation for six replicate injections of standard solution should be not more than 5.0%.
2. LOD/LOQ should be established.

LOD/LOQ Verification:

Based on the establishment of LOD/LOQ value, concentration of LOD /LOQ solution shall be prepared and shall be verified.

Procedure:

Carry out procedure as per method specified in section method of analysis

Preparation of Ramipril standard stock solution:

Weigh accurately and transfer about 25 mg of Ramipril working standard in 25 mL of volumetric flask and add 10 mL of diluent and sonicate to dissolve and dilute to volume with diluent. Pipette out 5.0 mL of Ramipril standard stock solution and transfer in to 100 mL volumetric flask and dilute to volume with diluent.

Preparation of Ramipril standard solution:

Dilute 10.0 mL of Ramipril standard stock solution to 50 mL with diluent and mix well.

Preparation of Impurity A standard solution:

Weigh accurately and transfer about 2.5 mg of Impurity A in 10 mL of volumetric flask and add 5 mL of diluent and sonicate to dissolve and dilute to volume with diluent.

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Preparation of Impurity D standard solution:

Weigh accurately and transfer about 3 mg of Impurity D in 50 mL of volumetric flask and add 35 mL of diluent and sonicate to dissolve and dilute to volume with diluent.

Preparation of Impurity E standard solution:

Weigh accurately and transfer about 2.5 mg of Impurity E in 10 mL of volumetric flask and add 5 mL of diluent and sonicate to dissolve and dilute to volume with diluent.

Note: Standard solution shall be further diluted to prepare LOD/LOQ solution of desired concentration.

Determination:

1. Inject blank solution.
2. Inject standard solution in six replicates.
3. Inject blank solution.
4. Inject LOD solution in three replicates.
5. Inject LOQ solution in six replicates.
6. Inject bracketing standard.

Acceptance criteria:

The relative standard deviation for the peak area response in standard solution should not be more than 5.0%.

Limit of detection:

The peak at LOD concentration should be consistently detected.

Limit of quantitation:

The relative standard deviation for peak area at LOQ concentration should be not more than 15.0 %.

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11.4. LINEARITY AND RANGE

The linearity of an analytical procedure is its ability (within a given range) to obtain test results which are directly proportional to the concentration (amount) of analyte in the sample.

Procedure:

Carry out procedure as per method specified in section method of analysis.

Linearity level preparations:

Preparation of Ramipril standard stock solution:

Weigh accurately and transfer about 25 mg of Ramipril working standard in 25 mL of volumetric flask and add 10 mL of diluent and sonicate to dissolve and dilute to volume with diluent. Pipette out 5.0 mL of Ramipril standard stock solution and transfer in to 100 mL volumetric flask and dilute to volume with diluent.

Preparation of Ramipril standard solution:

Dilute 10.0 mL of Ramipril standard stock solution to 25 mL with diluent and mix well.

Preparation of Impurity A standard solution:

Weigh accurately and transfer about 5 mg of Impurity A in 20 mL of volumetric flask and add 10 mL of diluent and sonicate to dissolve and dilute to volume with diluent.

Preparation of Impurity D standard solution:

Weigh accurately and transfer about 12 mg of Impurity D in 20 mL of volumetric flask and add 10 mL of diluent and sonicate to dissolve and dilute to volume with diluent.

Preparation of Impurity E standard solution:

Weigh accurately and transfer about 5 mg of Impurity E in 20 mL of volumetric flask and add 10 mL of diluent and sonicate to dissolve and dilute to volume with diluent.

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Preparation Linearity levels as follows:

Level	Volume (mL) taken from Standard solution				Volume up to mark with Diluent (mL)	Concentration (ppm)			
	Ramipril	Imp A	Imp D	Imp E		Ramipril	Imp A	Imp D	Imp E
LOQ	*	*	*	*	*	*	*	*	*
50	1.25	1.0	1.25	1.0	25.0	1.0	10.0	30.0	10.0
80	2.00	1.6	2.00	1.6	25.0	1.6	16.0	48.0	16.0
100	2.50	2.0	2.50	2.0	25.0	2.0	20.0	60.0	20.0
120	3.00	2.4	3.00	2.4	25.0	2.4	24.0	72.0	24.0
150	3.75	3.0	3.75	3.0	25.0	3.0	30.0	90.0	30.0

*Note: Will be determine at the time of validation.

Plot linearity curve with concentration of the linearity standard solution in ppm on x-axis and corresponding average peak response on y-axis. Determine the co-efficient of correlation.

Determination:

1. Inject blank solution.
2. Inject standard solution in six replicates.
3. Inject all linearity level in triplicate.
4. Inject bracketing standard.

Acceptance criteria:

1. The relative standard deviation for the peak area response in standard solution should not be more than 5.0%.
2. The correlation coefficient obtained from the graph should not be less than 0.99.

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11.5. ACCURACY (RECOVERY)

The accuracy of an analytical procedure expresses the closeness of agreement between the value, which is accepted either as conventional true value or an accepted reference value and found value.

Procedure:

Carry out procedure as per method specified in section method of analysis.

Preparation of Impurity A standard stock solution:

Weigh accurately and transfer about 5 mg of Impurity A in 25 mL of volumetric flask and add 10 mL of diluent and sonicate to dissolve and dilute to volume with diluent.

Preparation of Impurity D standard stock solution:

Weigh accurately and transfer about 15 mg of Impurity D in 25 mL of volumetric flask and add 10 mL of diluent and sonicate to dissolve and dilute to volume with diluent.

Preparation of Impurity E standard stock solution:

Weigh accurately and transfer about 5 mg of Impurity E in 25 mL of volumetric flask and add 10 mL of diluent and sonicate to dissolve and dilute to volume with diluent.

Preparation Accuracy levels as follows:

Accuracy level (%)	Weight of placebo	mL of Standard stock solution			Diluted to (mL)	Concentration (ppm)		
		Imp A	Imp D	Imp E		Imp A	Imp D	Imp E
As such	Eq. to 20 mg of Ramipril	-	-	-	-	-	-	-
LOQ		*	*	*	*	*	*	*
50		1.0	1.0	1.0	20.0	10.0	30.0	10.0
100		2.0	2.0	2.0	20.0	20.0	60.0	20.0
150		3.0	3.0	3.0	20.0	30.0	90.0	30.0

*LOQ level will be determine at the time of validation.

Prepare each level in triplicate.

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Determination:

1. Inject blank solution.
2. Inject standard solution in six replicates.
3. Inject all Accuracy levels.
4. Inject bracketing standard.

Acceptance criteria:

1. The relative standard deviation for the peak area response in standard solution should not be more than 5.0%.
2. % Recovery for LOQ level should be between 70.0% to 130% and other accuracy level should be between 80.0% to 120.0%.

11.6. ROBUSTNESS

The robustness of an analytical procedure is a measure of its capacity to remain unaffected by small, but deliberate variations in method parameters and provides an indication of its reliability during normal usage.

Procedure:

Carry out procedure as per method specified in section method of analysis.

The following parameters will be tested for robustness as:

Sr. No.	Parameter to be changed	Actual Value	+ (Increase)	- (Decrease)
1.	Buffer pH	2.5	2.6	2.4
2.	Flow Rate (mL/ min)	1.0	1.1	0.9

Acceptance criteria:

1. The relative standard deviation for the peak area response in standard solution should not be more than 5.0%.

 Quality by Design	ANALYTICAL METHOD VALIDATION PROTOCOL FOR RELATED SUBSTANCES IN RAMITHIAZIDE TABLET 10/25 MG BY HPLC METHOD		
Protocol number	QbD-PROTO-592	Page No	Page 24 of 27

2. Difference between average impurities results of Robustness data and Precision data,

Level of impurities, degradants (% Individually specified and total sum) (%, relative to active)	Acceptance criteria
<0.1	≤ 0.05% absolute
0.10 to 0.15	≤ 0.05% absolute
>0.15 to 0.30	≤ 0.10% absolute
>0.30 to 0.50	≤ 0.15% absolute
>0.50 to 0.80	≤ 0.20% absolute
>0.80 to 1.0	≤ 0.25% absolute
>1.0 to 5.0	≤ 20% relative
>5.0	≤ 10% relative

11.7. SOLUTION STABILITY

To evaluate stability of analytical solution, standard solution and sample solution will be prepared as described in the method of analysis and will be injected repeatedly up to 24 hrs from the time of preparation.

Procedure:

Carry out procedure as per method specified in section method of analysis.

Determination:

1. Inject blank solution.
2. Inject standard solution in six replicates.
3. Inject spiked sample solution.
4. Inject bracketing standard.
5. Inject standard solution (Stability interval)
6. Inject spiked sample solution (Stability interval)
7. Inject bracketing standard.

 Quality by Design	ANALYTICAL METHOD VALIDATION PROTOCOL FOR RELATED SUBSTANCES IN RAMITHIAZIDE TABLET 10/25 MG BY HPLC METHOD		
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Acceptance criteria:

1. The relative standard deviation for the peak area response in standard solution should not be more than 5.0%.
2. RSD of area response of repeatedly injected standard solution over a period of 24 hrs should be not more than 5.0%.
3. Difference between impurities results of Initial sample and repeatedly injected sample solution over a period of 24 hrs,

Level of impurities, degradants (%Individually specified and total sum) (%, relative to active)	Acceptance criteria
<0.1	≤ 0.05% absolute
0.10 to 0.15	≤ 0.05% absolute
>0.15 to 0.30	≤ 0.10% absolute
>0.30 to 0.50	≤ 0.15% absolute
>0.50 to 0.80	≤ 0.20% absolute
>0.80 to 1.0	≤ 0.25% absolute
>1.0 to 5.0	≤ 20% relative
>5.0	≤ 10% relative

11.8. FILTER STUDY

Check the filter paper interference against centrifuged sample.

Procedure:

Carry out determination as per method specified in section method of analysis.

Sample solution:

Prepare the sample solution as per the method of analysis.

Use sample solution centrifuged at 2000 rpm for 3minutes.

	ANALYTICAL METHOD VALIDATION PROTOCOL FOR RELATED SUBSTANCES IN RAMITHIAZIDE TABLET 10/25 MG BY HPLC METHOD		
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Filter this solution through 0.45 μ PVDF filter by discarding the first 5 mL filtrate and use sample filtrate after discarding 5 mL filtrate.

Filter this solution through 0.45 μ nylon filter by discarding the first 5 mL filtrate and use sample filtrate after discarding 5 mL filtrate.

Filter this solution through Whatman 41 filter by discarding the first 5 mL filtrate and use sample filtrate after discarding 5 mL filtrate.

Determination:

1. Inject blank solution.
2. Inject standard solution in six replicates.
3. Inject centrifuged sample solution.
4. Inject sample filtered through three different filters.
5. Inject bracketing standard.

Acceptance criteria:

1. The relative standard deviation for the peak area response in standard solution should not be more than 5.0%.
2. Difference for impurities between filtered solution through different filters and centrifuged sample,

Level of impurities, degradants (%Individually specified and total sum) (%, relative to active)	Acceptance criteria
<0.1	$\leq 0.05\%$ absolute
0.10 to 0.15	$\leq 0.05\%$ absolute
>0.15 to 0.30	$\leq 0.10\%$ absolute
>0.30 to 0.50	$\leq 0.15\%$ absolute
>0.50 to 0.80	$\leq 0.20\%$ absolute
>0.80 to 1.0	$\leq 0.25\%$ absolute
>1.0 to 5.0	$\leq 20\%$ relative
>5.0	$\leq 10\%$ relative


**ANALYTICAL METHOD VALIDATION PROTOCOL FOR RELATED
SUBSTANCES IN RAMITHIAZIDE TABLET 10/25 MG BY HPLC METHOD**
Protocol number

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12. DOCUMENTATION

All validation activities shall be recorded online in to the laboratory notebook. At the end of the Validation, a Protocol shall be generated. All results will be discussed, conclusions drawn and any deviations from the protocol will be documented in the Protocol.

13. REFERENCES

ICH guidelines

14. REVISION HISTORY

Version	Date	Changes	Reason for change
0		Not Applicable	New

RAW DATA OF (BATCH ANALYSIS)

RELATED SUBSTANCE METHOD VALIDATION

Product Name:	Ramipril Tablets
Label claim (mg):	5 mg And 12.5 mg
AR No.:	D1384198655
Batch No.:	GP/181243
Parameter:	Method Precision (At Such)
LNB No./ Page No.	834/001

Analysis Date: 12-Apr-19

Name	RRF
Ramipril Impurity A	1.15
Ramipril Impurity D	1.22
Ramipril Impurity E	22.09

	Weight of standard (mg)	Diluted (mL)	Concentration (nmol)	Purity (As is Basis)
Preparation of standard solution for Ramipril	25.03	25.0		
	2.0	100.0	2.00	99.64
	2.0	20.0		

Injection No.	Retention Time	Peak Area	Retention Time	Area of Bkt Standard
1	16.407	2297.079	16.721	2108.278
2	16.764	2318.205	16.834	2270.453
3	16.756	2219.142		
4	16.829	2343.709		
5	16.761	2299.695		
6	16.749	2339.516		
Average	16.778	2302.891	16.778	2299.510
SD	0.0324	45.1870	0.0408	48.1598
%RSD	0.19	1.97	0.24	1.75

System Suitability		
%RSD of Area	1.97	NMT 5.0%

	Weight of standard (mg)	Diluted (mL)	Concentration (nmol)	Purity (As is Basis)
Preparation of standard solution for Hydrochlorothiazide	25.03	25.0		
	2.5	100.0	2.50	99.86
	2.0	20.0		

Injection No.	Retention Time	Peak Area	Retention Time	Area of Bkt Standard
1	6.324	4326.284	6.274	4566.106
2	6.274	4346.335	6.304	1587.710
3	6.332	4359.288		
4	6.319	4381.489		
5	6.331	4358.918		
6	6.279	4347.931		
Average	6.310	4353.377	6.305	4409.268
SD	0.0263	18.2724	0.0255	104.7799
%RSD	0.42	0.42	0.40	2.38

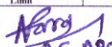
System Suitability		
%RSD of Area	0.42	NMT 5.0%

Sample solution :	Eq to 20 mg	diluted to	20.0	ml. with diluent
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Average wt. (mg):	200.39
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Sample Details	Sample wt. (mg)	Impurity name	RT	RRT	Area	%Impurity	Reported impurity	Total % Impurity
Sample 1	801.62	Unknown Impurity	13.406	0.80	264.202	0.02	BQL	2.27
		Unknown Impurity	17.669	1.06	61.888	0.01	BQL	
		Unknown Impurity	20.669	1.24	104.812	0.01	BQL	
		Unknown Impurity	21.892	1.31	1904.215	0.16	0.16	
		Ramipril Impurity E	15.326	0.92	93.855	0.18	0.18	
		Ramipril Impurity D	24.369	1.46	18232.796	1.93	1.93	
Sample 2	801.75	Ramipril	16.702	1.00	591824.845	-	-	2.26
		Unknown Impurity	13.421	0.80	278.220	0.02	BQL	
		Unknown Impurity	17.714	1.06	62.582	0.01	BQL	
		Unknown Impurity	18.721	1.12	658.827	0.06	BQL	
		Unknown Impurity	20.768	1.24	94.117	0.01	BQL	
		Unknown Impurity	22.011	1.32	1871.759	0.16	0.16	
Sample 3	801.63	Ramipril Impurity E	15.341	0.92	94.448	0.18	0.18	2.24
		Ramipril Impurity D	24.508	1.46	18215.455	1.92	1.92	
		Ramipril	16.731	1.00	595478.174	-	-	
		Unknown Impurity	13.768	0.81	211.583	0.02	BQL	
		Unknown Impurity	18.654	1.13	889.781	0.08	BQL	
		Unknown Impurity	21.761	1.31	1857.797	0.16	0.16	
Sample 4	801.87	Ramipril Impurity E	15.198	0.92	78.742	0.15	0.15	2.28
		Ramipril Impurity D	24.268	1.47	18236.939	1.93	1.93	
		Ramipril	16.564	1.00	592106.361	-	-	
		Unknown Impurity	13.371	0.81	256.811	0.02	BQL	
		Unknown Impurity	18.377	1.11	686.568	0.06	BQL	
		Unknown Impurity	20.504	1.24	85.791	0.01	BQL	
Sample 5	801.99	Unknown Impurity	21.714	1.31	1906.128	0.17	0.17	2.26
		Ramipril Impurity E	15.241	0.92	92.757	0.18	0.18	
		Ramipril Impurity D	24.234	1.46	18265.345	1.93	1.93	
		Ramipril	16.574	1.00	588175.746	-	-	
		Unknown Impurity	13.425	0.80	265.283	0.02	BQL	
		Unknown Impurity	18.698	1.12	615.429	0.05	BQL	
Sample 6	801.95	Unknown Impurity	20.735	1.24	91.768	0.01	BQL	2.26
		Unknown Impurity	21.938	1.31	1887.051	0.16	0.16	
		Ramipril Impurity E	15.351	0.92	94.625	0.18	0.18	
		Ramipril Impurity D	24.368	1.46	18141.010	1.92	1.92	
		Ramipril	16.745	1.00	595040.667	-	-	
		Unknown Impurity	13.381	0.80	267.251	0.02	BQL	
Sample 7	801.95	Unknown Impurity	18.491	1.11	680.667	0.06	BQL	2.26
		Unknown Impurity	20.574	1.24	77.702	0.01	BQL	
		Unknown Impurity	21.768	1.31	1933.563	0.17	0.17	
		Ramipril Impurity E	15.268	0.92	88.811	0.17	0.17	
		Ramipril Impurity D	24.238	1.46	18186.619	1.92	1.92	
		Ramipril	16.634	1.00	590990.730	-	-	

Sample	Ramipril Impurity E	Ramipril Impurity D	% Total Impurities
1	0.18	1.93	2.27
2	0.18	1.92	2.26
3	0.15	1.93	2.24
4	0.18	1.93	2.28
5	0.18	1.92	2.26
6	0.17	1.92	2.26
Average	0.17	1.93	2.26
SD	0.0100	0.0100	0.0100
%RSD	5.88	0.52	0.44
Limit	NMT 15 %		NMT 10 %

Done by: 
Date: 25-Apr-19Checked by: 
Date: 25-Apr-19



QbD Research & Development Lab. Pvt. Ltd.

RELATED SUBSTANCE METHOD VALIDATION

Product Name:	Ramithiazide Tablets
Label claim (mg):	10 mg And 12.5 mg
AR No:	D1304190654
Batch No.:	GP181206
Parameter:	Method Precision (As Such)
LNB No./ Page No.	834/001

Analysis Date: 13-Apr-19

Name:	RBP
Ramipril Impurity A	1.15
Ramipril Impurity D	1.22
Ramipril Impurity E	22.09

Preparation of standard solution for Ramipril	Weight of standard (mg)	Diluted (mL)	Concentration (nmol)	Purity (As is Basis)
	25.03	25.0		
	2.0	100.0	2.00	99.64
	2.0	20.0		

Ramipril				
Injection No.	Retention Time	Peak Area	Retention Time	Area of Bkt Standard
1	16.307	2797.079	16.721	2708.278
2	16.704	2218.205	16.834	2270.435
3	16.756	2219.142		
4	16.829	2343.709		
5	16.761	2299.695		
6	16.749	2139.516		
Average	16.778	2302.891	16.778	2209.510
SD	0.0324	45.3870	0.0408	48.1598
%RSD	0.19	1.97	0.24	1.75

System Suitability		
%RSD of Area	1.97	NMT 5.0%

Preparation of standard solution for Hydrochlorothiazide	Weight of standard (mg)	Diluted (mL)	Concentration (nmol)	Purity (As is Basis)
	25.03	25.0		
	2.5	100.0	2.50	99.86
	2.0	20.0		

Hydrochlorothiazide				
Injection No.	Retention Time	Peak Area	Retention Time	Area of Bkt Standard
1	6.324	4326.284	6.274	4566.106
2	6.274	4346.355	6.304	4587.710
3	6.332	4359.288		
4	6.319	4381.489		
5	6.331	4358.956		
6	6.279	4347.931		
Average	6.310	4353.377	6.305	4409.260
SD	0.0263	18.2724	0.0255	104.7799
%RSD	0.42	0.42	0.40	2.38

System Suitability		
%RSD of Area	0.42	NMT 5.0%

Sample solution :	Eq to 20 mg	diluted to	20.0	mL with Diluent
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Average wt. (mg)	199.31
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Sample Details	Sample wt. (mg)	Impurity name	RT	RRT	Area	%Impurity	Reported impurity	Total % Impurity
Sample 1	399.07	Unknown Impurity	13.427	0.81	360.813	0.03	BQL	1.52
		Unknown Impurity	17.607	1.06	24.375	0.00	BQL	
		Unknown Impurity	18.674	1.12	58.676	0.01	BQL	
		Unknown Impurity	20.374	1.23	37.183	0.00	BQL	
		Unknown Impurity	21.494	1.29	567.440	0.05	BQL	
		Ramipril Impurity E	15.277	0.92	75.883	0.15	0.15	
		Ramipril Impurity D	24.280	1.46	12094.137	1.37	1.37	
		Ramipril	16.664	1.00	585052.335	-	-	
Sample 2	398.95	Unknown Impurity	13.444	0.81	390.551	0.03	BQL	1.50
		Unknown Impurity	17.591	1.06	21.528	0.00	BQL	
		Unknown Impurity	18.661	1.12	77.198	0.01	BQL	
		Unknown Impurity	20.581	1.24	38.776	0.00	BQL	
		Unknown Impurity	21.531	1.29	528.313	0.05	BQL	
		Ramipril Impurity E	15.274	0.92	73.993	0.14	0.14	
		Ramipril Impurity D	24.298	1.46	12831.945	1.36	1.36	
		Ramipril	16.661	1.00	584266.799	-	-	
Sample 3	398.87	Unknown Impurity	13.436	0.80	404.532	0.04	BQL	1.50
		Unknown Impurity	18.683	1.12	63.299	0.01	BQL	
		Unknown Impurity	20.639	1.24	28.738	0.00	BQL	
		Unknown Impurity	21.586	1.29	569.747	0.05	BQL	
		Ramipril Impurity E	15.306	0.92	77.823	0.15	0.15	
		Ramipril Impurity D	24.356	1.46	12825.271	1.35	1.35	
		Ramipril	16.706	1.00	584246.825	-	-	
		Unknown Impurity	13.416	0.81	374.025	0.03	BQL	1.51
Sample 4	398.94	Unknown Impurity	17.606	1.06	26.494	0.00	BQL	
		Unknown Impurity	18.643	1.12	76.286	0.01	BQL	
		Unknown Impurity	20.606	1.24	37.573	0.00	BQL	
		Unknown Impurity	21.550	1.29	571.400	0.05	BQL	
		Ramipril Impurity E	15.260	0.92	71.359	0.14	0.14	
		Ramipril Impurity D	24.373	1.46	12992.193	1.37	1.37	
		Ramipril	16.643	1.00	590629.985	-	-	
		Unknown Impurity	13.411	0.81	382.131	0.03	BQL	1.51
Sample 5	398.92	Unknown Impurity	17.588	1.06	24.427	0.00	BQL	
		Unknown Impurity	18.648	1.12	58.459	0.01	BQL	
		Unknown Impurity	20.541	1.23	37.527	0.00	BQL	
		Unknown Impurity	21.454	1.29	538.793	0.05	BQL	
		Ramipril Impurity E	15.268	0.92	75.923	0.15	0.15	
		Ramipril Impurity D	24.268	1.46	12835.568	1.36	1.36	
		Ramipril	16.641	1.00	585669.493	-	-	
		Unknown Impurity	13.413	0.81	381.961	0.03	BQL	1.49
Sample 6	398.89	Unknown Impurity	17.557	1.06	25.275	0.00	BQL	
		Unknown Impurity	18.597	1.12	66.922	0.01	BQL	
		Unknown Impurity	20.520	1.23	28.915	0.00	BQL	
		Unknown Impurity	21.387	1.29	574.034	0.05	BQL	
		Ramipril Impurity E	15.270	0.92	75.711	0.14	0.14	
		Ramipril Impurity D	24.200	1.46	12754.276	1.35	1.35	
		Ramipril	16.627	1.00	580982.641	-	-	

Sample	Ramipril Impurity E	Ramipril Impurity D	% Total Impurities
1	0.15	1.37	1.52
2	0.14	1.36	1.50
3	0.15	1.35	1.50
4	0.14	1.37	1.51
5	0.15	1.36	1.51
6	0.14	1.35	1.49
Average	0.15	1.36	1.51
SD	0.0100	0.0100	0.0100
%RSD	6.67	0.74	0.66
Limit	NMT 15 %		NMT 10 %

Done by: *ABD*
Date: 25-APR-19Checked by: *Baw*
Date: 25-APR-19

Name HPLC-04_Ramithiazide Tablet_RS_Met
Data Vault XVault
Path chrom://qbd-pc-15/XVault/QbD-INST-HPLC-04/93/HPLC-04_13-Apr-19_A.seq/HPLC-04_Ramithiazide Tablet_RS_Met.instmeth
Comment Ramithiazide Tablet
Description New instrument method created
Run time 30.000 [min]
Instrument QbD-INST-HPLC-04 on qbd-pc-15
Created 13-Apr-19 16:53:21 +05:30 Rahul Kanase
Last Update 13-Apr-19 16:53:21 +05:30 Rahul Kanase

⑧
13-Apr-19

13-Apr-19

Stage	Time min	Command	Value	Comment
Instrument Setup	initial			
Inject Preparation	0.000	Wait	LCSystem.Read y	
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.AcqO n LCSystem.QuatPump_SolventRatioB.AcqO n LCSystem.QuatPump_SolventRatioC.AcqO n LCSystem.QuatPump_SolventRatioD.AcqO n LCSystem.TCC_Left_Temperature.AcqOn LCSystem.TCC_Right_Temperature.AcqOn LCSystem.VWD_Board_Temperature.Acq On LCSystem.VWD_OpticalUnit_Temp.AcqOn LCSystem.VWD_Reference_Intensity.AcqO n LCSystem.VWD_Sample_Intensity.AcqOn LCSystem.VWD_UVLamp_AnodeVoltage.A cqOn LCSystem.VWD_Signal_A.AcqOn		
Run			Duration = 30.000 [min]	
Stop Run	0.000			
	30.000	LCSystem.ALS_Temperature.AcqOff LCSystem.QuatPump_Dir_PistonA.AcqOff LCSystem.QuatPump_Flow.AcqOff LCSystem.QuatPump_Pressure.AcqOff LCSystem.QuatPump_SolventRatioA.AcqO ff		

(8)
13-Apr-19

for
13-Apr-19

LCSystem.QuatPump_SolventRatioB.AcqOff
LCSystem.QuatPump_SolventRatioC.AcqOff
LCSystem.QuatPump_SolventRatioD.AcqOff
LCSystem.TCC_Left_Temperature.AcqOff
LCSystem.TCC_Right_Temperature.AcqOff

LCSystem.VWD_Board_Temperature.AcqOff
LCSystem.VWD_OpticalUnit_Temp.AcqOff

LCSystem.VWD_Reference_Intensity.AcqOff
LCSystem.VWD_Sample_Intensity.AcqOff
LCSystem.VWD_UVLamp_AnodeVoltage.AcqOff
LCSystem.VWD_Signal_A.AcqOff

End

(8)
13-Apr-19

Sm
13-Apr-19

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	30.00 [min]
Section Post Time (PostTime)	
Posttime Mode	Off
Solvent Composition (SolventComposition)	
0	
Channel	A
Name 1	
Used	Yes
Percent	70.0 [%]
1	
Channel	B
Name 1	
Used	Yes
Percent	30.0 [%]
2	
Channel	C
Name 1	
Used	No
3	
Channel	D
Name 1	
Used	No
Timetable (Timetable)	
0	
Time	7.00 [min]
A	70.0 [%]
B	30.0 [%]
C	0.0 [%]
D	0.0 [%]
Flow	1.000 [mL/min]
Pressure	400.00 [bar]
1	

(B)
(3 Apr 19)

Sm
13 Apr 19

Time	9.00 [min]
A	50.0 [%]
B	50.0 [%]
C	0.0 [%]
D	0.0 [%]
Flow	1.000 [mL/min]
Pressure	400.00 [bar]
2	
Time	25.00 [min]
A	50.0 [%]
B	50.0 [%]
C	0.0 [%]
D	0.0 [%]
Flow	1.000 [mL/min]
Pressure	400.00 [bar]
3	
Time	30.00 [min]
A	70.0 [%]
B	30.0 [%]
C	0.0 [%]
D	0.0 [%]
Flow	1.000 [mL/min]
Pressure	400.00 [bar]
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	30.00 [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	Thermostat Control Set Value
Thermostat Temperature	25 [°C]
Section Stop Time (StopTime)	
Stoptime Mode	As pump/No limit
Section Post Time (PostTime)	

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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 On	Yes
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 (G1314F - VWD: VWD.0)	
Signal Peakwidth	> 0.1 min (2 s resp. time) (5 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)	
Section Signal (Signals_Signal)	
Use Signal	Yes
Signal ID	Signal A
Signal Wavelength	210 [nm]

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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)	

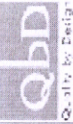
13-Apr-19

13-Apr-19

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

13 APR 19

Rahul Kanase



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Instrument ID : QbD-INST-HPLC-04

Sequence Name : HPLC-04_13-Apr-19_A

Data Vault : QbD_2019_R1

Sequence Path :

Seq. Created By : Rahul Kanase

Seq. Last Updated By :

Seq. Created On : 13-04-2019 16:59:53

Seq. Last Updated On

13-04-2019 17:33:20

Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq

Inj No.	Injection Name	Injection Type	Volume µL	Vial No.	Status	Injection Time	Instrument Method	Processing Method	Level	AR_NO	BATCH_NO	COLUMN_NO
1	Blank	Unknown	30.00	Vial:1	Idle	n.a	-04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
2	Placebo Solution	Unknown	30.00	Vial:2	Idle	n.a	-04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
3	Blank	Unknown	30.00	Vial:1	Idle	n.a	-04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
4	Standard solution 1	Unknown	30.00	Vial:3	Idle	n.a	-04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
5	Standard solution 2	Unknown	30.00	Vial:3	Idle	n.a	-04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
6	Standard solution 3	Unknown	30.00	Vial:3	Idle	n.a	-04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
7	Standard solution 4	Unknown	30.00	Vial:3	Idle	n.a	-04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
8	Standard solution 5	Unknown	30.00	Vial:3	Idle	n.a	-04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
9	Standard solution 6	Unknown	30.00	Vial:3	Idle	n.a	-04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
10	Sample Solution 1	Unknown	30.00	Vial:3	Idle	n.a	-04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
11	Sample Solution 2	Unknown	30.00	Vial:4	Idle	n.a	-04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
12	Sample Solution 3	Unknown	30.00	Vial:5	Idle	n.a	-04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
13	Sample Solution 4	Unknown	30.00	Vial:6	Idle	n.a	-04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
14	Sample Solution 5	Unknown	30.00	Vial:7	Idle	n.a	-04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
15	Sample Solution 6	Unknown	30.00	Vial:8	Idle	n.a	-04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
16	Blank	Unknown	30.00	Vial:9	Idle	n.a	-04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
17	Standard solution_Bkt	Unknown	30.00	Vial:1	Idle	n.a	-04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
18	Sample Solution 1	Unknown	30.00	Vial:3	Idle	n.a	-04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
19	Sample Solution 2	Unknown	30.00	Vial:10	Idle	n.a	-04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190655	GP181203	QbD/LC/COL/128
20	Sample Solution 3	Unknown	30.00	Vial:11	Idle	n.a	-04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190655	GP181203	QbD/LC/COL/128
21	Sample Solution 4	Unknown	30.00	Vial:12	Idle	n.a	-04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190655	GP181203	QbD/LC/COL/128
22	Sample Solution 5	Unknown	30.00	Vial:13	Idle	n.a	-04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190655	GP181203	QbD/LC/COL/128
23	Sample Solution 6	Unknown	30.00	Vial:14	Idle	n.a	-04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190655	GP181203	QbD/LC/COL/128
24	Blank	Unknown	30.00	Vial:15	Idle	n.a	-04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190655	GP181206	QbD/LC/COL/128
25	Standard solution_Bkt	Unknown	30.00	Vial:3	Idle	n.a	-04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128

13-Apr-19

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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Instrument ID :

QBD-INST-HPLC-04

Sequence Name :

HPLC-04_13-Apr-19_A

Data Vault :

QBD_2019_R1

Sequence Path :

Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq

Seq. Created By : Rahul Kanase

Seq. Last Updated By :

Rahul Kanase

Seq. Created On : 13-04-2019 16:59:53

Seq. Last Updated On

13-04-2019 18:07:55

Inj No.	Injection Name	Injection Type	Volume µL	Vial No.	Status	Injection Time	Instrument Method	Processing Method	Level	AR_NO	BATCH_NO	COLUMN_NO
1	Blank	Unknown	30.00	Vial 1	Interrupted	13-04-2019 17:38:54	04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
2	Blank	Unknown	30.00	Vial 1	Idle	n.a.	04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
3	Placebo Solution(10mg/12.5mg)	Unknown	30.00	Vial 2	Idle	n.a.	04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
4	Blank	Unknown	30.00	Vial 1	Idle	n.a.	04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
5	Placebo Solution(5mg/12.5mg)	Unknown	30.00	Vial 3	Idle	n.a.	04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190655	GP181203	QbD/LC/COL/128
6	Blank	Unknown	30.00	Vial 1	Idle	n.a.	04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
7	Standard solution 1	Unknown	30.00	Vial 4	Idle	n.a.	04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
8	Standard solution 2	Unknown	30.00	Vial 4	Idle	n.a.	04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
9	Standard solution 3	Unknown	30.00	Vial 4	Idle	n.a.	04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
10	Standard solution 4	Unknown	30.00	Vial 4	Idle	n.a.	04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
11	Standard solution 5	Unknown	30.00	Vial 4	Idle	n.a.	04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
12	Standard solution 6	Unknown	30.00	Vial 4	Idle	n.a.	04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
13	Sample Solution 1 (10mg/12.5mg)	Unknown	30.00	Vial 5	Idle	n.a.	04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
14	Sample Solution 2 (10mg/12.5mg)	Unknown	30.00	Vial 6	Idle	n.a.	04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
15	Sample Solution 3 (10mg/12.5mg)	Unknown	30.00	Vial 7	Idle	n.a.	04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
16	Sample Solution 4 (10mg/12.5mg)	Unknown	30.00	Vial 8	Idle	n.a.	04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
17	Sample Solution 5 (10mg/12.5mg)	Unknown	30.00	Vial 9	Idle	n.a.	04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
18	Sample Solution 6 (10mg/12.5mg)	Unknown	30.00	Vial 10	Idle	n.a.	04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
19	Blank	Unknown	30.00	Vial 1	Idle	n.a.	04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
20	Standard solution_Bkt	Unknown	30.00	Vial 4	Idle	n.a.	04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
21	Sample Solution 1 (5mg/12.5mg)	Unknown	30.00	Vial 11	Idle	n.a.	04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190655	GP181203	QbD/LC/COL/128
22	Sample Solution 2 (5mg/12.5mg)	Unknown	30.00	Vial 12	Idle	n.a.	04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190655	GP181203	QbD/LC/COL/128
23	Sample Solution 3 (5mg/12.5mg)	Unknown	30.00	Vial 13	Idle	n.a.	04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190655	GP181203	QbD/LC/COL/128
24	Sample Solution 4 (5mg/12.5mg)	Unknown	30.00	Vial 14	Idle	n.a.	04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190655	GP181203	QbD/LC/COL/128
25	Sample Solution 5 (5mg/12.5mg)	Unknown	30.00	Vial 15	Idle	n.a.	04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190655	GP181203	QbD/LC/COL/128
26	Sample Solution 6 (5mg/12.5mg)	Unknown	30.00	Vial 16	Idle	n.a.	04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190655	GP181203	QbD/LC/COL/128
27	Blank	Unknown	30.00	Vial 1	Idle	n.a.	04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128
28	Standard solution_Bkt	Unknown	30.00	Vial 4	Idle	n.a.	04_Ramithiazide Tablet_R	Ramithiazide Tablet		D1304190654	GP181206	QbD/LC/COL/128

QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Instrument ID :	QbD-INST-HPLC-04	Seq. Created By :	Rahul Kanase	Seq. Last Updated By :	Rahul Kanase
Sequence Name :	HPLC-04_13-Apr-19_A	Seq. Created On :	13-04-2019 16:59:53	Seq. Last Updated On :	13-04-2019 18:07:55
Data Vault :	QbD_2019_R1				
Sequence Path :	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq				

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Page No. 2 of 2 Printed Time 13-Apr-2019 18:12

Electronically Signed Document

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QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Instrument ID : QbD-INST-HPLC-04
Sequence Name : HPLC-04_13-Apr-19_A
Data Vault : QbD_2019_R1
Sequence Path : Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq

Seq. Created By : Rahul Kanase
Seq. Created On : 13-04-2019 16:59:53

Inj No.	Injection Name	Injection Type	Volume μ L	Vial No.	Status	Injection Time	Instrument Method	Processing Method	Level
1	Blank	Unknown	30.00	Vial:1	Interrupted	13-04-2019 17:38:54	04_Ramithiazide Tablet_R	Ramithiazide Tablet	
2	Blank	Unknown	30.00	Vial:1	Interrupted	13-04-2019 18:16:48	04_Ramithiazide Tablet_R	Ramithiazide Tablet	
3	Blank	Unknown	30.00	Vial:1	Finished	13-04-2019 18:58:05	04_Ramithiazide Tablet_R	Ramithiazide Tablet	
4	Blank	Unknown	30.00	Vial:1	Finished	13-04-2019 19:30:32	04_Ramithiazide Tablet_R	Ramithiazide Tablet	
5	Placebo Solution(10mg/12.5mg)	Unknown	30.00	Vial:2	Finished	13-04-2019 20:02:14	04_Ramithiazide Tablet_R	Ramithiazide Tablets_PR	
6	Blank	Unknown	30.00	Vial:1	Finished	13-04-2019 20:33:56	04_Ramithiazide Tablet_R	Ramithiazide Tablet	
7	Placebo Solution(5mg/12.5mg)	Unknown	30.00	Vial:3	Finished	13-04-2019 21:05:38	04_Ramithiazide Tablet_R	Ramithiazide Tablets_PR1	
8	Blank	Unknown	30.00	Vial:1	Finished	13-04-2019 21:37:20	04_Ramithiazide Tablet_R	Ramithiazide Tablet	
9	Standard solution 1	Unknown	30.00	Vial:4	Finished	13-04-2019 22:09:02	04_Ramithiazide Tablet_R	Ramithiazide Tablet	
10	Standard solution 2	Unknown	30.00	Vial:4	Finished	13-04-2019 22:40:43	04_Ramithiazide Tablet_R	Ramithiazide Tablet	
11	Standard solution 3	Unknown	30.00	Vial:4	Finished	13-04-2019 23:12:24	04_Ramithiazide Tablet_R	Ramithiazide Tablet	
12	Standard solution 4	Unknown	30.00	Vial:4	Finished	13-04-2019 23:44:06	04_Ramithiazide Tablet_R	Ramithiazide Tablet	
13	Standard solution 5	Unknown	30.00	Vial:4	Finished	14-04-2019 00:15:49	04_Ramithiazide Tablet_R	Ramithiazide Tablet	
14	Standard solution 6	Unknown	30.00	Vial:4	Finished	14-04-2019 00:47:31	04_Ramithiazide Tablet_R	Ramithiazide Tablet	
15	Sample Solution 1 (10mg/12.5mg)	Unknown	30.00	Vial:5	Finished	14-04-2019 01:19:11	04_Ramithiazide Tablet_R	Ramithiazide Tablets_PR	
16	Sample Solution 2 (10mg/12.5mg)	Unknown	30.00	Vial:6	Finished	14-04-2019 01:50:50	04_Ramithiazide Tablet_R	Ramithiazide Tablets_PR	
17	Sample Solution 3 (10mg/12.5mg)	Unknown	30.00	Vial:7	Finished	14-04-2019 02:22:30	04_Ramithiazide Tablet_R	Ramithiazide Tablets_PR	
18	Sample Solution 4 (10mg/12.5mg)	Unknown	30.00	Vial:8	Finished	14-04-2019 02:54:09	04_Ramithiazide Tablet_R	Ramithiazide Tablets_PR	
19	Sample Solution 5 (10mg/12.5mg)	Unknown	30.00	Vial:9	Finished	14-04-2019 03:25:52	04_Ramithiazide Tablet_R	Ramithiazide Tablets_PR	
20	Sample Solution 6 (10mg/12.5mg)	Unknown	30.00	Vial:10	Finished	14-04-2019 03:57:37	04_Ramithiazide Tablet_R	Ramithiazide Tablets_PR	
21	Blank	Unknown	30.00	Vial:1	Finished	14-04-2019 04:29:18	04_Ramithiazide Tablet_R	Ramithiazide Tablet	
22	Standard solution_Bkt	Unknown	30.00	Vial:4	Finished	14-04-2019 05:01:00	04_Ramithiazide Tablet_R	Ramithiazide Tablet	
23	Sample Solution 1 (5mg/12.5mg)	Unknown	30.00	Vial:11	Finished	14-04-2019 05:32:46	04_Ramithiazide Tablet_R	Ramithiazide Tablets_PR1	
24	Sample Solution 2 (5mg/12.5mg)	Unknown	30.00	Vial:12	Finished	14-04-2019 06:04:26	04_Ramithiazide Tablet_R	Ramithiazide Tablets_PR1	
25	Sample Solution 3 (5mg/12.5mg)	Unknown	30.00	Vial:13	Finished	14-04-2019 06:36:05	04_Ramithiazide Tablet_R	Ramithiazide Tablets_PR1	
26	Sample Solution 4 (5mg/12.5mg)	Unknown	30.00	Vial:14	Finished	14-04-2019 07:07:46	04_Ramithiazide Tablet_R	Ramithiazide Tablets_PR1	
27	Sample Solution 5 (5mg/12.5mg)	Unknown	30.00	Vial:15	Finished	14-04-2019 07:39:25	04_Ramithiazide Tablet_R	Ramithiazide Tablets_PR1	
28	Sample Solution 6 (5mg/12.5mg)	Unknown	30.00	Vial:16	Finished	14-04-2019 08:11:05	04_Ramithiazide Tablet_R	Ramithiazide Tablets_PR1	
29	Blank	Unknown	30.00	Vial:1	Finished	14-04-2019 08:42:50	04_Ramithiazide Tablet_R	Ramithiazide Tablet	
30	Standard solution_Bkt	Unknown	30.00	Vial:4	Finished	14-04-2019 09:14:32	04_Ramithiazide Tablet_R	Ramithiazide Tablet	

Seq. Last Updated By : Ankita Parab
Seq. Last Updated On 23-04-2019 17:49:43

AR_NO	BATCH_NO	COLUMN_NO
D1304190654	GP181206	QbD/LC/COL/128
D1304190654	GP181206	QbD/LC/COL/128
D1304190654	GP181206	QbD/LC/COL/128
D1304190654	GP181206	QbD/LC/COL/128
D1304190654	GP181206	QbD/LC/COL/128
D1304190654	GP181206	QbD/LC/COL/128
D1304190655	GP181203	QbD/LC/COL/128
D1304190654	GP181206	QbD/LC/COL/128
D1304190654	GP181206	QbD/LC/COL/128
D1304190654	GP181206	QbD/LC/COL/128
D1304190654	GP181206	QbD/LC/COL/128
D1304190654	GP181206	QbD/LC/COL/128
D1304190654	GP181206	QbD/LC/COL/128
D1304190654	GP181206	QbD/LC/COL/128
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D1304190654	GP181206	QbD/LC/COL/128
D1304190654	GP181206	QbD/LC/COL/128
D1304190654	GP181206	QbD/LC/COL/128
D1304190654	GP181206	QbD/LC/COL/128
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D1304190654	GP181206	QbD/LC/COL/128
D1304190655	GP181203	QbD/LC/COL/128
D1304190655	GP181203	QbD/LC/COL/128
D1304190655	GP181203	QbD/LC/COL/128
D1304190655	GP181203	QbD/LC/COL/128
D1304190655	GP181203	QbD/LC/COL/128
D1304190655	GP181203	QbD/LC/COL/128
D1304190655	GP181203	QbD/LC/COL/128
D1304190654	GP181206	QbD/LC/COL/128
D1304190654	GP181206	QbD/LC/COL/128



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Sequence Path	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		
Sequence Name	HPLC-04_13-Apr-19_A	Instrument ID :	QbD-INST-HPLC-04
Data Vault	QbD_2019_R1	Seq. Created By :	Rahul Kanase
		Seq. Created On :	13-04-2019 16:59:53

Inj No.	Injection Name	Injection Type	Volume µL	Vial No.	Status	Injection Time	Instrument Method	Processing Method	Processing Method Last Updated on
1	Blank	Unknown	30	Vial:1	Interrupted	13-04-2019 17:38:54	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablet	18-04-2019 07:54:13
2	Blank	Unknown	30	Vial:1	Interrupted	13-04-2019 18:16:48	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablet	18-04-2019 07:54:13
3	Blank	Unknown	30	Vial:1	Finished	13-04-2019 18:58:05	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablet	18-04-2019 07:54:13
4	Blank	Unknown	30	Vial:1	Finished	13-04-2019 19:30:32	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablet	18-04-2019 07:54:13
5	Placebo Solution(10mg/12.5mg)	Unknown	30	Vial:2	Finished	13-04-2019 20:02:14	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablets_PR	18-04-2019 07:51:19
6	Blank	Unknown	30	Vial:1	Finished	13-04-2019 20:33:56	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablet	18-04-2019 07:54:13
7	Placebo Solution(5mg/12.5mg)	Unknown	30	Vial:3	Finished	13-04-2019 21:05:38	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablets_PR1	23-04-2019 17:49:43
8	Blank	Unknown	30	Vial:1	Finished	13-04-2019 21:37:20	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablet	18-04-2019 07:54:13
9	Standard solution 1	Unknown	30	Vial:4	Finished	13-04-2019 22:09:02	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablet	18-04-2019 07:54:13
10	Standard solution 2	Unknown	30	Vial:4	Finished	13-04-2019 22:40:43	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablet	18-04-2019 07:54:13
11	Standard solution 3	Unknown	30	Vial:4	Finished	13-04-2019 23:12:24	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablet	18-04-2019 07:54:13
12	Standard solution 4	Unknown	30	Vial:4	Finished	13-04-2019 23:44:06	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablet	18-04-2019 07:54:13
13	Standard solution 5	Unknown	30	Vial:4	Finished	14-04-2019 00:15:49	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablet	18-04-2019 07:54:13
14	Standard solution 6	Unknown	30	Vial:4	Finished	14-04-2019 00:47:31	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablet	18-04-2019 07:54:13
15	Sample Solution 1 (10mg/12.5mg)	Unknown	30	Vial:5	Finished	14-04-2019 01:19:11	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablets_PR	18-04-2019 07:51:19
16	Sample Solution 2 (10mg/12.5mg)	Unknown	30	Vial:6	Finished	14-04-2019 01:50:50	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablets_PR	18-04-2019 07:51:19
17	Sample Solution 3 (10mg/12.5mg)	Unknown	30	Vial:7	Finished	14-04-2019 02:22:30	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablets_PR	18-04-2019 07:51:19
18	Sample Solution 4 (10mg/12.5mg)	Unknown	30	Vial:8	Finished	14-04-2019 02:54:09	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablets_PR	18-04-2019 07:51:19
19	Sample Solution 5 (10mg/12.5mg)	Unknown	30	Vial:9	Finished	14-04-2019 03:25:52	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablets_PR	18-04-2019 07:51:19
20	Sample Solution 6 (10mg/12.5mg)	Unknown	30	Vial:10	Finished	14-04-2019 03:57:37	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablets_PR	18-04-2019 07:51:19
21	Blank	Unknown	30	Vial:1	Finished	14-04-2019 04:29:18	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablet	18-04-2019 07:54:13
22	Standard solution_Bkt	Unknown	30	Vial:4	Finished	14-04-2019 05:01:00	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablet	18-04-2019 07:54:13
23	Sample Solution 1 (5mg/12.5mg)	Unknown	30	Vial:11	Finished	14-04-2019 05:32:46	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablets_PR1	23-04-2019 17:49:43
24	Sample Solution 2 (5mg/12.5mg)	Unknown	30	Vial:12	Finished	14-04-2019 06:04:26	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablets_PR1	23-04-2019 17:49:43
25	Sample Solution 3 (5mg/12.5mg)	Unknown	30	Vial:13	Finished	14-04-2019 06:36:05	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablets_PR1	23-04-2019 17:49:43
26	Sample Solution 4 (5mg/12.5mg)	Unknown	30	Vial:14	Finished	14-04-2019 07:07:46	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablets_PR1	23-04-2019 17:49:43
27	Sample Solution 5 (5mg/12.5mg)	Unknown	30	Vial:15	Finished	14-04-2019 07:39:25	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablets_PR1	23-04-2019 17:49:43
28	Sample Solution 6 (5mg/12.5mg)	Unknown	30	Vial:16	Finished	14-04-2019 08:11:05	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablets_PR1	23-04-2019 17:49:43
29	Blank	Unknown	30	Vial:1	Finished	14-04-2019 08:42:50	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablet	18-04-2019 07:54:13
30	Standard solution_Bkt	Unknown	30	Vial:4	Finished	14-04-2019 09:14:32	C-04_Ramithiazide Tablet_RS	Ramithiazide Tablet	18-04-2019 07:54:13

Sequence Version : 4
 Seq. Last Updated By : Ankita Parab
 Seq. Last Updated On : 23-04-2019 17:49:43

Proc. Meth Version	Proc. Meth Version Date & Time	Lock Status	Manually Integrated ?
1	13-04-2019 16:59		n.a.
1	13-04-2019 16:59		FALSE
1	13-04-2019 16:59		FALSE
1	13-04-2019 16:59		FALSE
1	17-04-2019 15:14		FALSE
1	13-04-2019 16:59		FALSE
3	23-04-2019 17:49		FALSE
1	13-04-2019 16:59		FALSE
1	13-04-2019 16:59		FALSE
1	13-04-2019 16:59		FALSE
1	13-04-2019 16:59		FALSE
1	13-04-2019 16:59		FALSE
1	13-04-2019 16:59		FALSE
1	13-04-2019 16:59		FALSE
1	13-04-2019 16:59		FALSE
1	17-04-2019 15:14		FALSE
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1	17-04-2019 15:14		FALSE
1	17-04-2019 15:14		FALSE
1	13-04-2019 16:59		FALSE
1	13-04-2019 16:59		FALSE
3	23-04-2019 17:49		FALSE
3	23-04-2019 17:49		FALSE
3	23-04-2019 17:49		FALSE
3	23-04-2019 17:49		FALSE
3	23-04-2019 17:49		FALSE
3	23-04-2019 17:49		FALSE
1	13-04-2019 16:59		FALSE
1	13-04-2019 16:59		FALSE



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Processing Method

Processing Method Name :	Ramithiazide Tablet		
Processing Method Path :	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		
Processing Method Created By :	Rahul Kanase	Processing Method Last Updated By :	Rahul Kanase
Processing Method Created On :	13-04-2019 16:57:06	Processing Method Last Updated On :	18-04-2019 07:54:13

Detection Alogrithm	Chromeleon 6	Version	1
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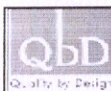
Detection Parameter

Ret. Time min	Param. Name	Param. Value	Inj. Type	Channel
0.000	Minimum Area	1000.0000 [Signal*min]	Any	All Channels
0.000	Inhibit Integration	On	Any	All Channels
4.196	Inhibit Integration	Off	Any	All Channels
9.218	Inhibit Integration	On	Any	All Channels
15.000	Minimum Area	1000.0000 [Signal*min]	Any	All Channels
15.995	Inhibit Integration	Off	Any	All Channels
18.454	Inhibit Integration	On	Any	All Channels

Peak Table

No.	Peak Name	Ret. Time
1	Placebo 1	2.541
2	Placebo 2	3.000
3	Hydrochlorothiazide	6.304
4	Unknown	11.357
5	Placebo 3	12.604
6	Unknown	13.427
7	Unknown	15.277
8	Placebo 4	15.657
9	Ramipril	16.807
10	Unknown	17.607
11	Unknown	18.674
12	Unknown	20.574
13	Unknown	21.494
14	Unknown	24.280
15	Placebo 4	27.104

QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.**Processing Method**



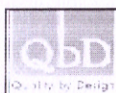
QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181206
Sample Name :-	Blank	AR. No. :-	D1304190654
Sample Number :-	1	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:1	Processing Method :-	Ramithiazide Tablet
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Rahul Kanase
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	18-04-2019 07:54:13
Injection Date & Time :-	13-04-2019 17:38:54	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		

Channel VWD_Signal_A is not available for injection #1 - Blank.

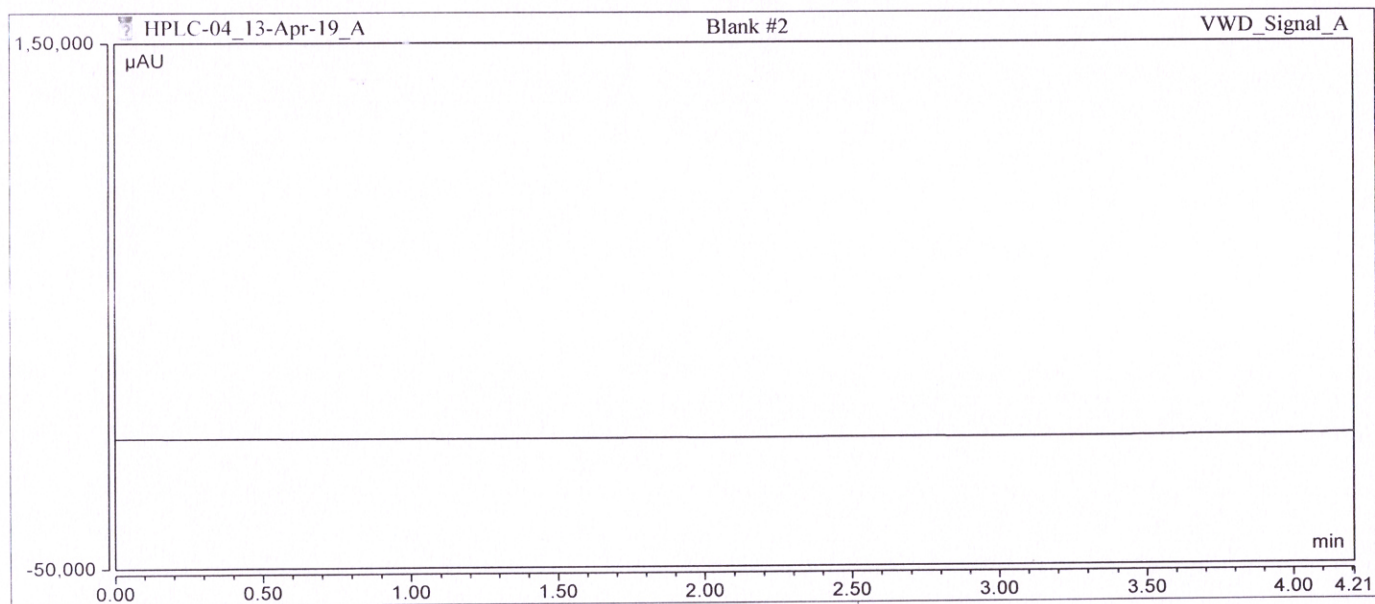
Peak No.	Peak Name	Ret. Time min	Area n.a.	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
n.a.	Placebo 1	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
n.a.	Placebo 2	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
n.a.	Hydrochlorothiazide	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
n.a.	Placebo 3	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
n.a.	Ramipril	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

INVALID



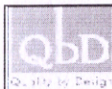
QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181206
Sample Name :-	Blank	AR. No. :-	D1304190654
Sample Number :-	2	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:1	Processing Method :-	Ramithiazide Tablet
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Rahul Kanase
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	18-04-2019 07:54:13
Injection Date & Time :-	13-04-2019 18:16:48	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		



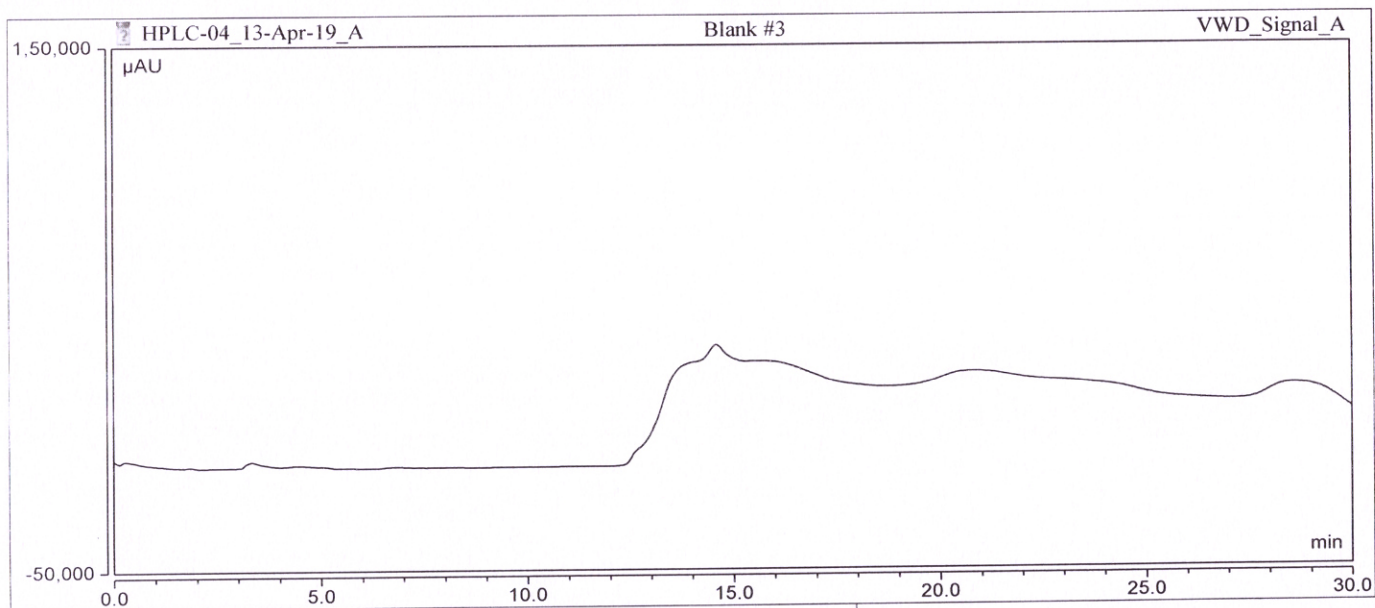
Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
n.a.	Placebo 1	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 2	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Hydrochlorothiazide	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 3	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Ramipril	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.

INVALID



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181206
Sample Name :-	Blank	AR. No. :-	D1304190654
Sample Number :-	3	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:1	Processing Method :-	Ramithiazide Tablet
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Rahul Kanase
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	18-04-2019 07:54:13
Injection Date & Time :-	13-04-2019 18:58:05	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		

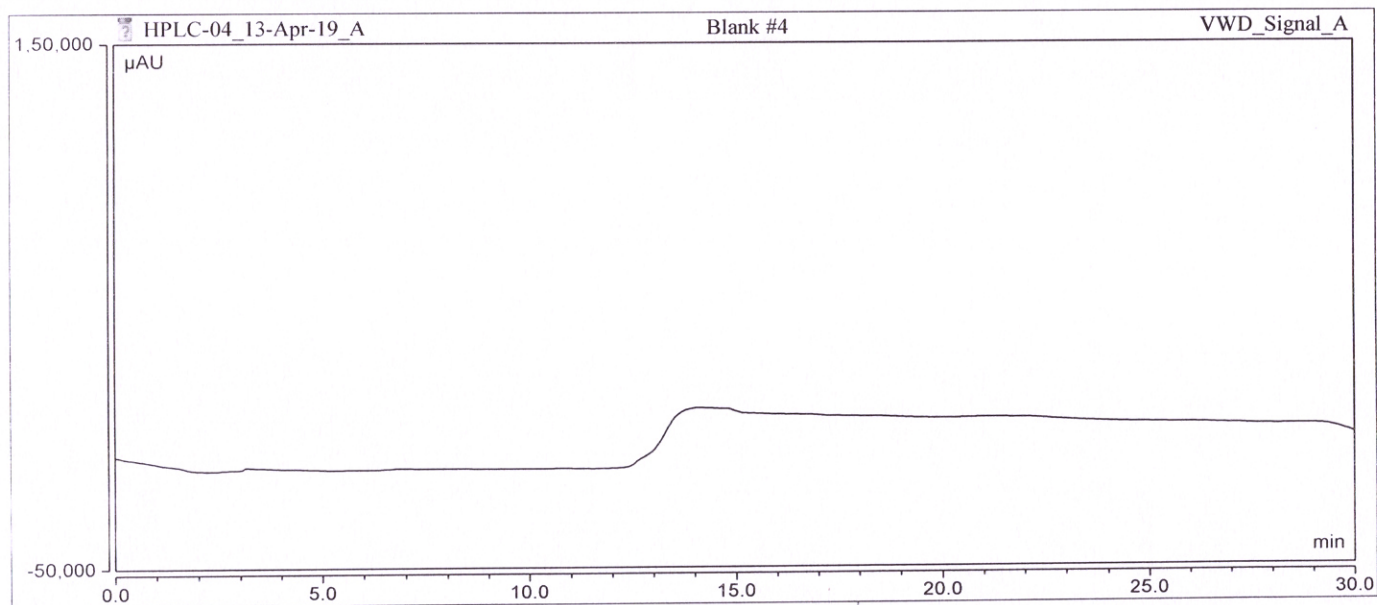


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
n.a.	Placebo 1	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 2	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Hydrochlorothiazide	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 3	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Ramipril	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.

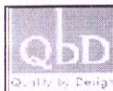


QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181206
Sample Name :-	Blank	AR. No. :-	D1304190654
Sample Number :-	4	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:1	Processing Method :-	Ramithiazide Tablet
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Rahul Kanase
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	18-04-2019 07:54:13
Injection Date & Time :-	13-04-2019 19:30:32	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		

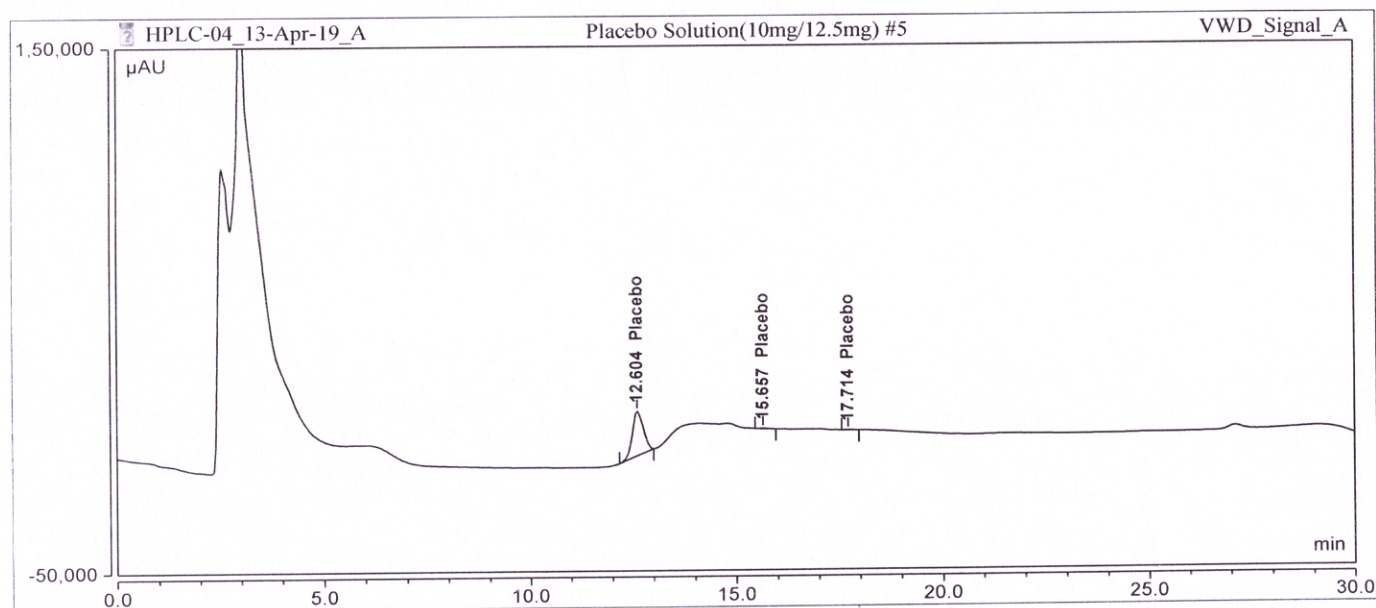


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
n.a.	Placebo 1	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 2	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Hydrochlorothiazide	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 3	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Ramipril	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181206
Sample Name :-	Placebo Solution(10mg/12.5mg)	AR. No. :-	D1304190654
Sample Number :-	5	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:2	Processing Method :-	Ramithiazide Tablets_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Rahul Kanase
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	18-04-2019 07:51:19
Injection Date & Time :-	13-04-2019 20:02:14	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		

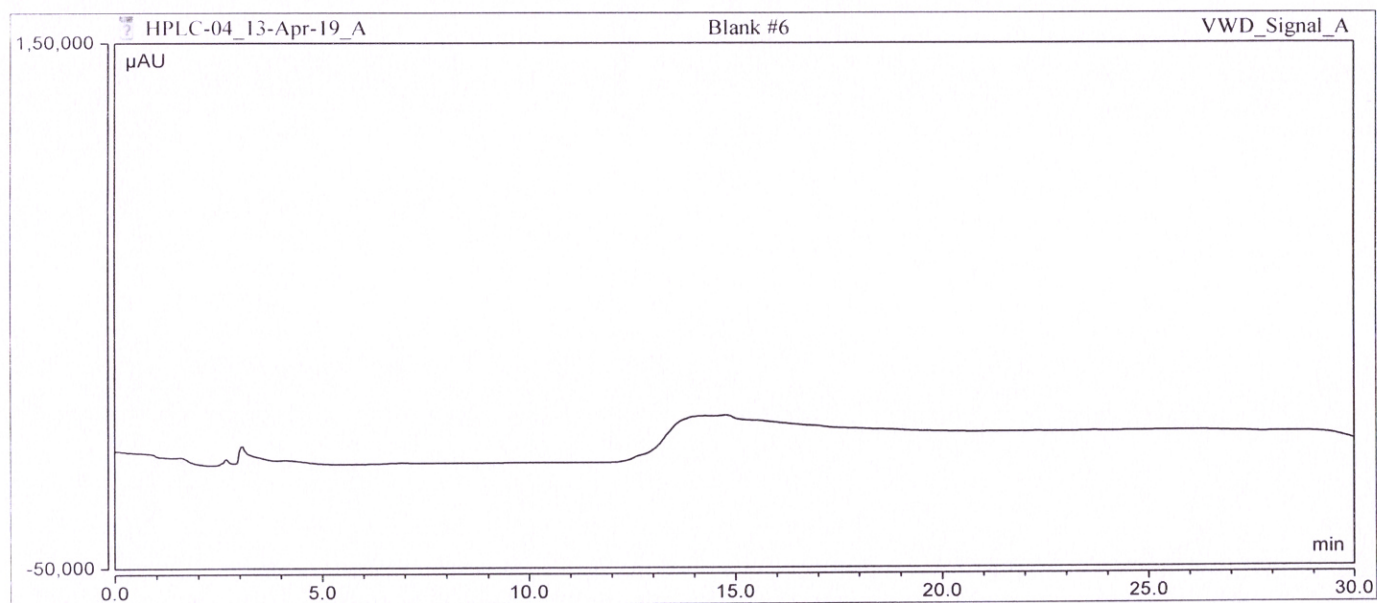


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
n.a.	Hydrochlorothiazide	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
1	Placebo	12.604	5260.626	98.95	1.07	10274	FALSE	n.a.
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Impurity E	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
2	Placebo	15.657	35.370	0.67	1.31	30542	FALSE	7.14
n.a.	Ramipril	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
3	Placebo	17.714	20.375	0.38	1.43	33249	FALSE	5.51
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Impurity D	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181206
Sample Name :-	Blank	AR. No. :-	D1304190654
Sample Number :-	6	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:1	Processing Method :-	Ramithiazide Tablet
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Rahul Kanase
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	18-04-2019 07:54:13
Injection Date & Time :-	13-04-2019 20:33:56	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		

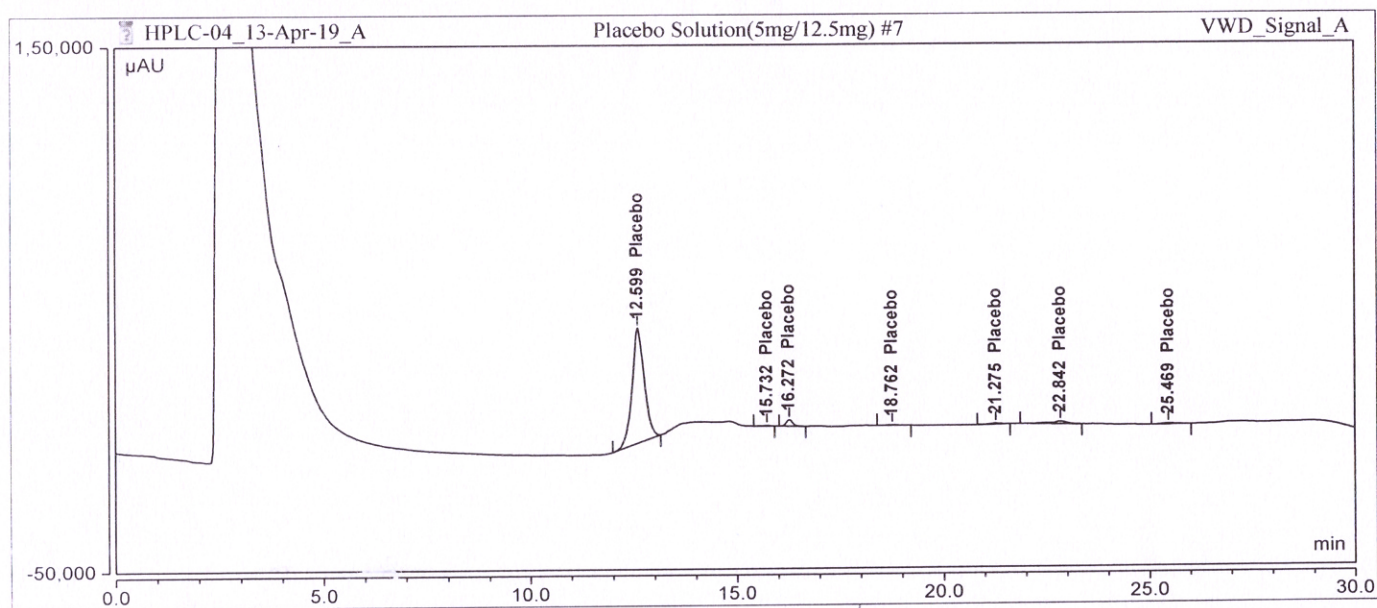


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
n.a.	Placebo 1	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 2	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Hydrochlorothiazide	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 3	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Ramipril	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181203
Sample Name :-	Placebo Solution(5mg/12.5mg)	AR. No. :-	D1304190655
Sample Number :-	7	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:3	Processing Method :-	Ramithiazide Tablets_PR1
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Ankita Parab
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	23-04-2019 17:49:43
Injection Date & Time :-	13-04-2019 21:05:38	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		

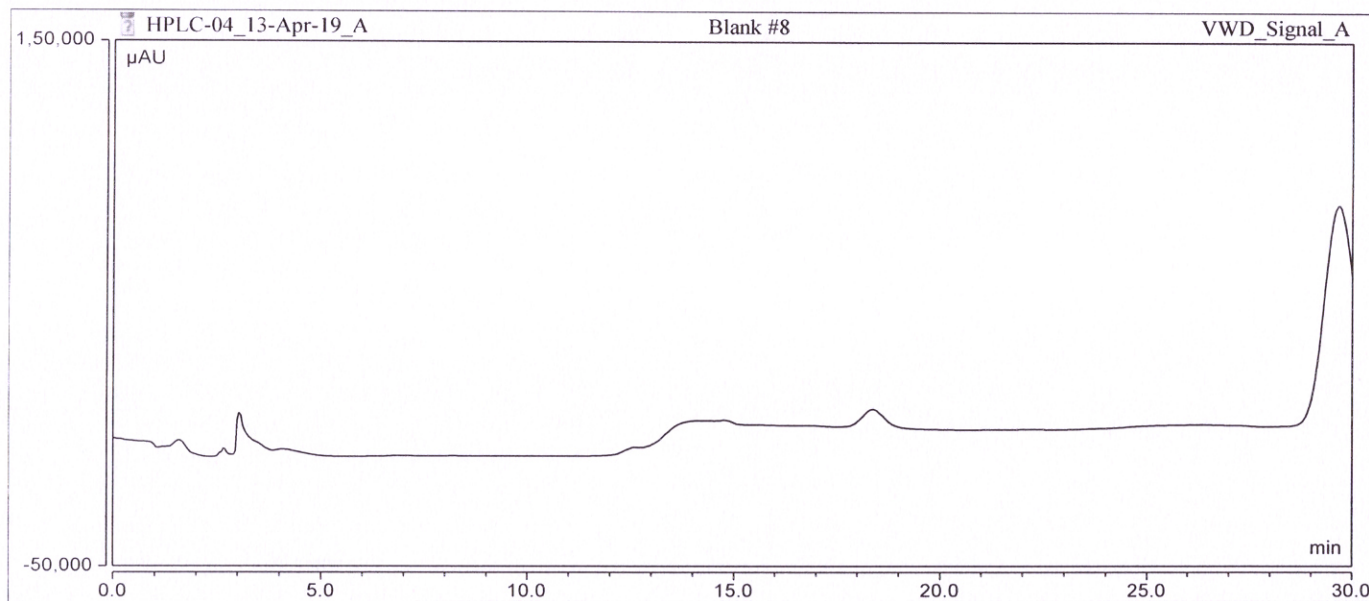


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
n.a.	Hydrochlorothiazide	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
1	Placebo	12.599	14941.661	92.02	1.06	8965	FALSE	n.a.
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Impurity E	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
2	Placebo	15.732	62.925	0.39	0.80	40890	FALSE	7.43
3	Placebo	16.272	457.214	2.82	1.17	51938	FALSE	1.81
n.a.	Ramipril	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
4	Placebo	18.762	65.470	0.40	1.21	31030	FALSE	7.00
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
5	Placebo	21.275	113.155	0.70	0.91	32026	FALSE	5.58
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
6	Placebo	22.842	463.219	2.85	0.71	27446	FALSE	3.05
n.a.	Impurity D	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
7	Placebo	25.469	133.748	0.82	1.18	14081	FALSE	3.73



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181206
Sample Name :-	Blank	AR. No. :-	D1304190654
Sample Number :-	8	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:1	Processing Method :-	Ramithiazide Tablet
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Rahul Kanase
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	18-04-2019 07:54:13
Injection Date & Time :-	13-04-2019 21:37:20	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		

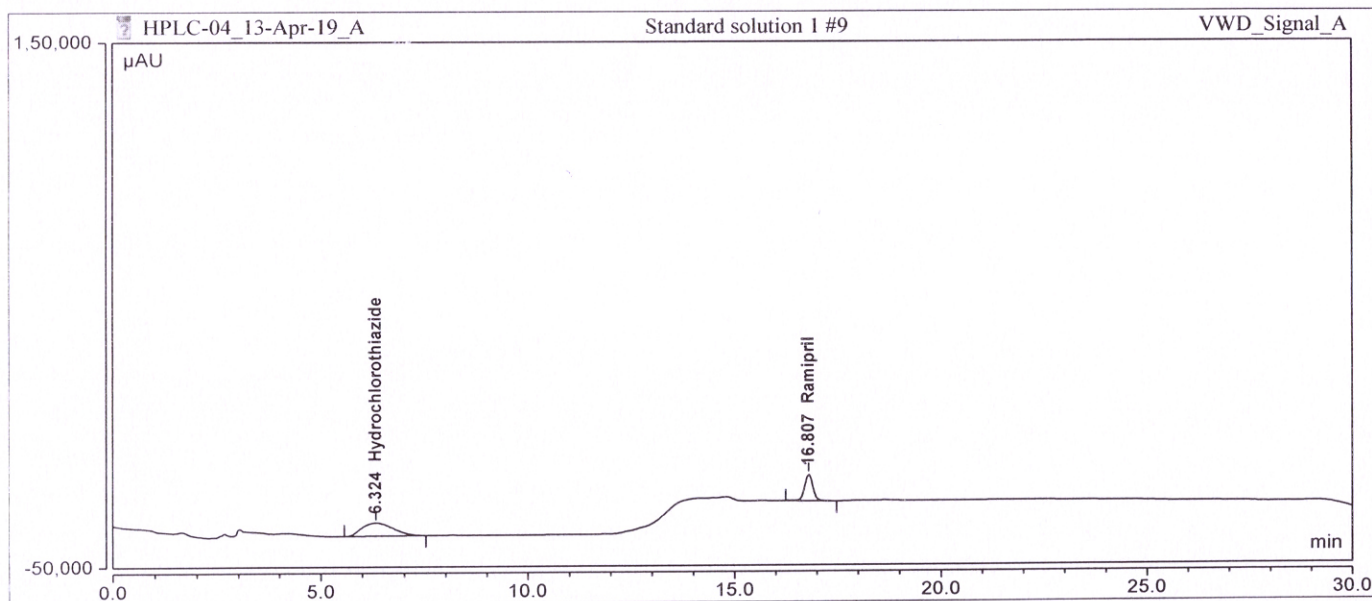


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
n.a.	Placebo 1	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 2	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Hydrochlorothiazide	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 3	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Ramipril	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181206
Sample Name :-	Standard solution 1	AR. No. :-	D1304190654
Sample Number :-	9	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:4	Processing Method :-	Ramithiazide Tablet
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Rahul Kanase
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	18-04-2019 07:54:13
Injection Date & Time :-	13-04-2019 22:09:02	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		

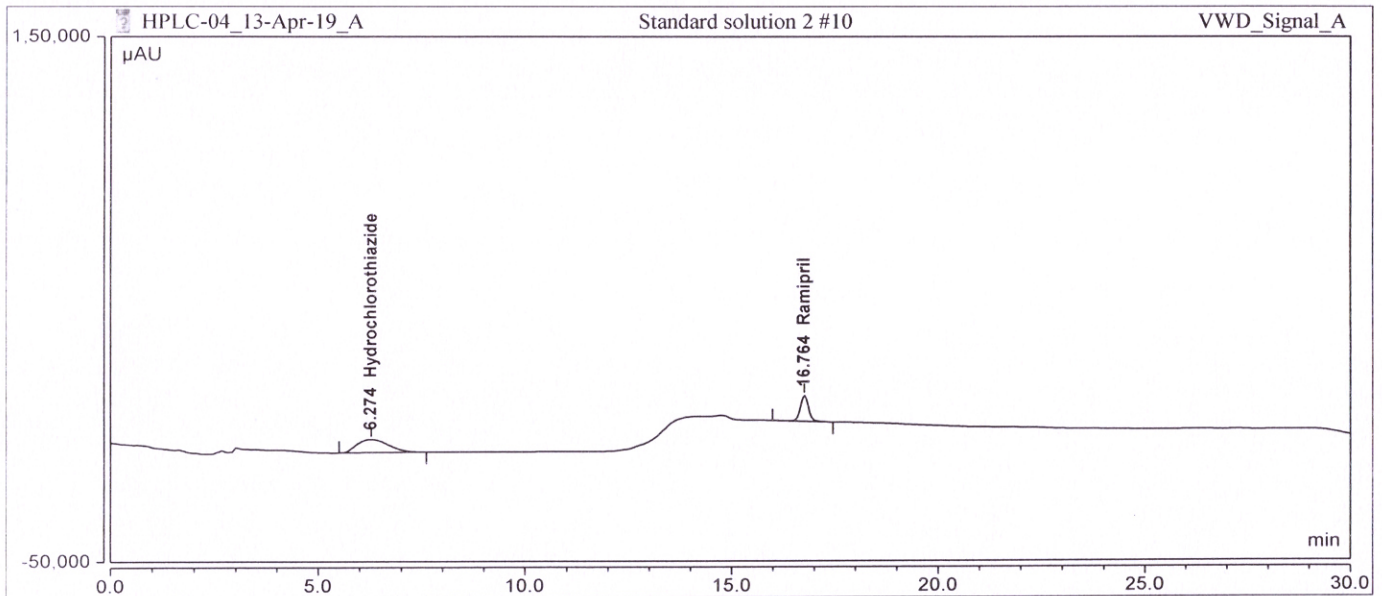


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
n.a.	Placebo 1	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 2	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
1	Hydrochlorothiazide	6.324	4326.284	65.32	1.25	334	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 3	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
2	Ramipril	16.807	2297.079	34.68	1.03	35894	FALSE	12.06
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181206
Sample Name :-	Standard solution 2	AR. No. :-	D1304190654
Sample Number :-	10	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:4	Processing Method :-	Ramithiazide Tablet
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Rahul Kanase
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	18-04-2019 07:54:13
Injection Date & Time :-	13-04-2019 22:40:43	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		

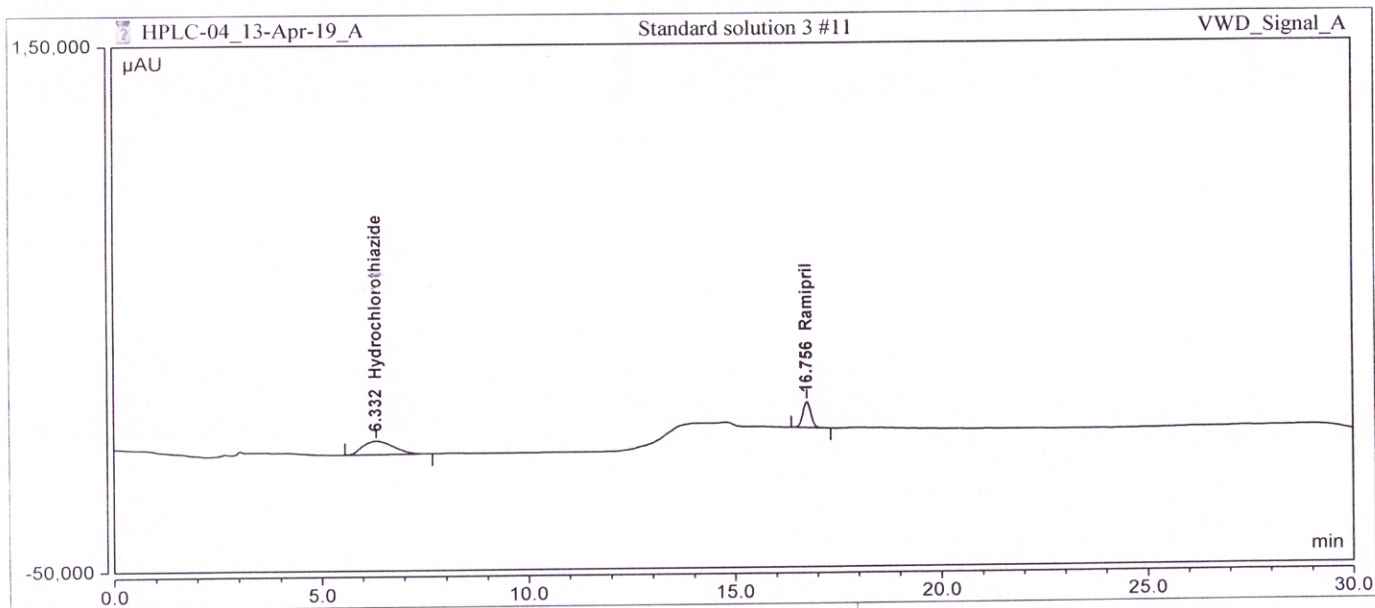


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
n.a.	Placebo 1	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 2	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
1	Hydrochlorothiazide	6.274	4346.335	65.22	1.26	322	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 3	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
2	Ramipril	16.764	2318.205	34.78	1.06	35410	FALSE	11.95
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.

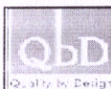


QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181206
Sample Name :-	Standard solution 3	AR. No. :-	D1304190654
Sample Number :-	11	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:4	Processing Method :-	Ramithiazide Tablet
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Rahul Kanase
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	18-04-2019 07:54:13
Injection Date & Time :-	13-04-2019 23:12:24	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		

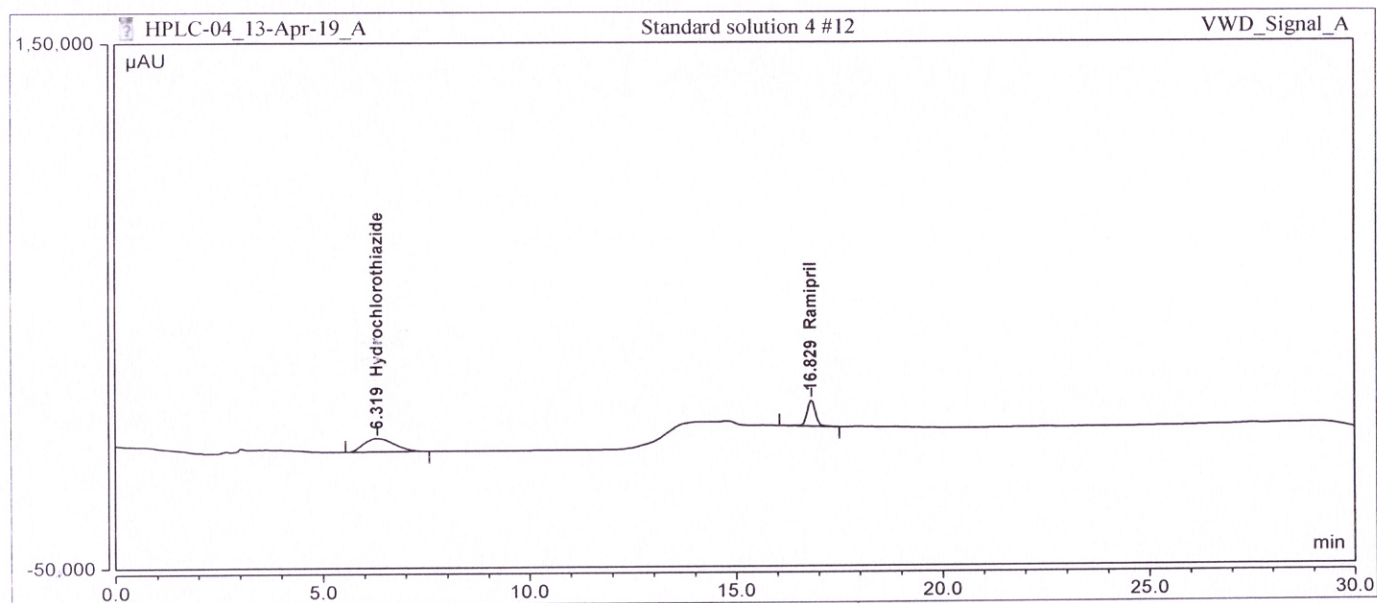


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
n.a.	Placebo 1	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 2	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
1	Hydrochlorothiazide	6.332	4359.288	66.27	1.27	338	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 3	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
2	Ramipril	16.756	2219.142	33.73	1.03	36691	FALSE	12.07
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181206
Sample Name :-	Standard solution 4	AR. No. :-	D1304190654
Sample Number :-	12	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:4	Processing Method :-	Ramithiazide Tablet
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Rahul Kanase
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	18-04-2019 07:54:13
Injection Date & Time :-	13-04-2019 23:44:06	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		

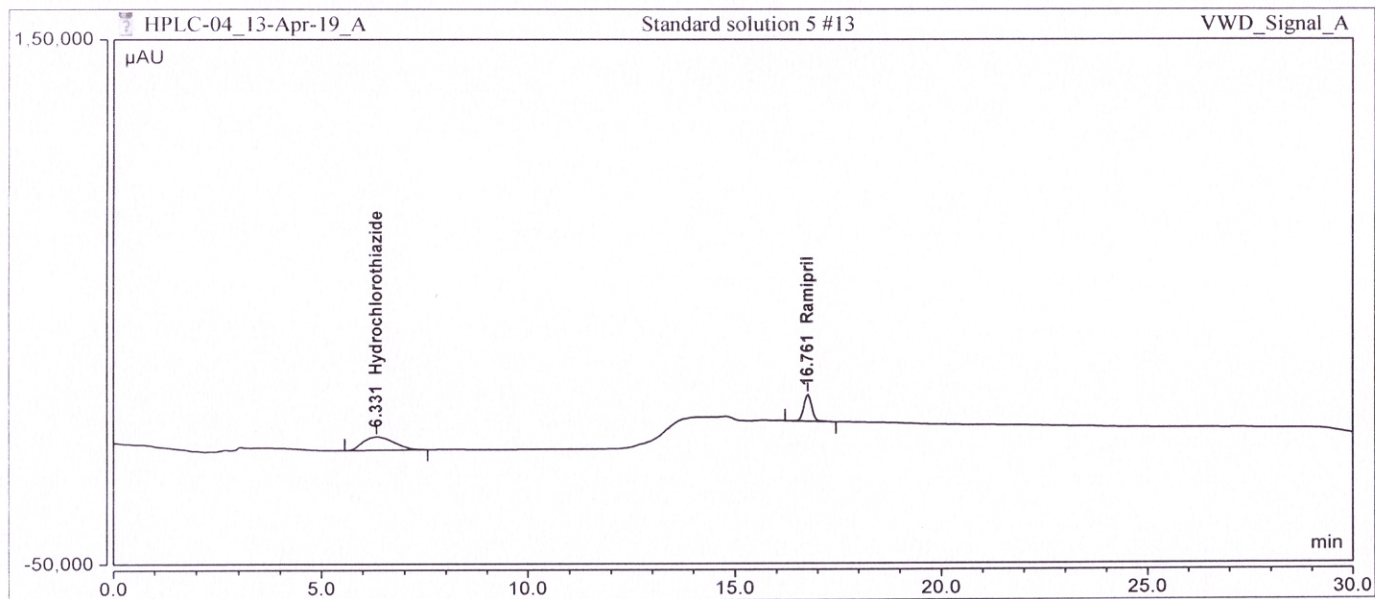


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
n.a.	Placebo 1	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 2	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
1	Hydrochlorothiazide	6.319	4381.489	65.15	1.26	336	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 3	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
2	Ramipril	16.829	2343.709	34.85	1.03	35195	FALSE	12.09
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.

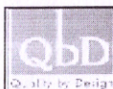


QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181206
Sample Name :-	Standard solution 5	AR. No. :-	D1304190654
Sample Number :-	13	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:4	Processing Method :-	Ramithiazide Tablet
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Rahul Kanase
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	18-04-2019 07:54:13
Injection Date & Time :-	14-04-2019 00:15:49	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		

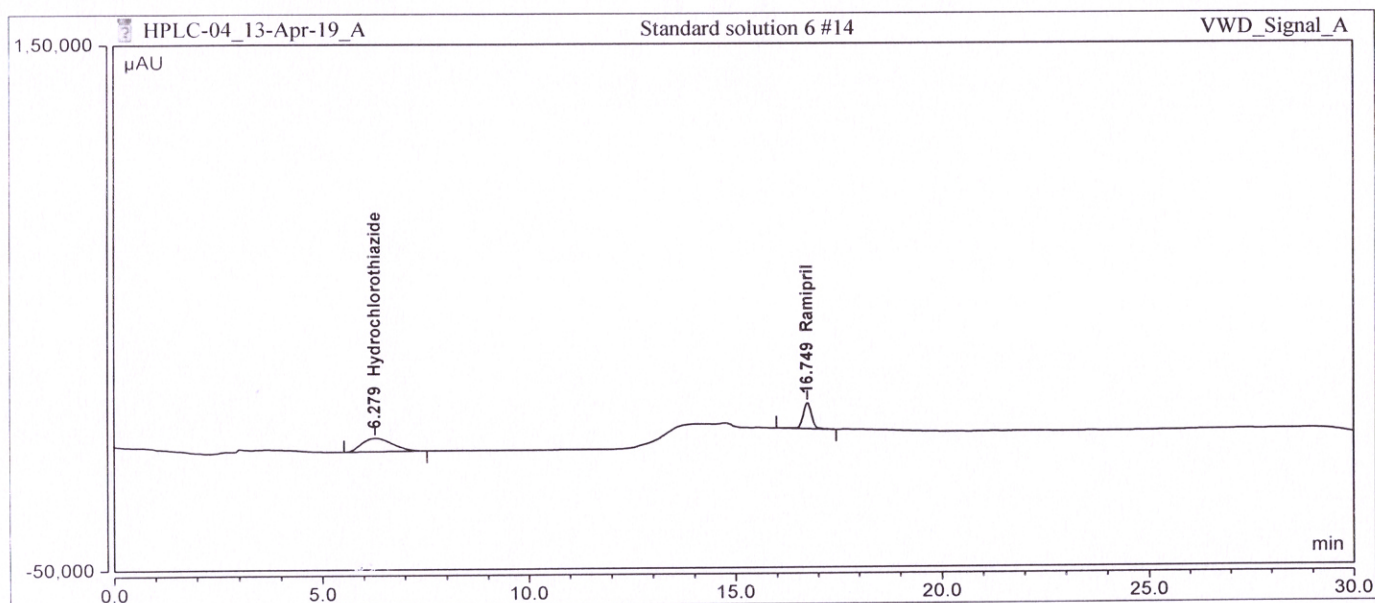


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
n.a.	Placebo 1	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 2	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
1	Hydrochlorothiazide	6.331	4358.936	65.46	1.28	334	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 3	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
2	Ramipril	16.761	2299.695	34.54	1.05	36556	FALSE	12.02
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.

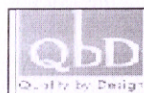


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Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181206
Sample Name :-	Standard solution 6	AR. No. :-	D1304190654
Sample Number :-	14	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:4	Processing Method :-	Ramithiazide Tablet
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Rahul Kanase
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	18-04-2019 07:54:13
Injection Date & Time :-	14-04-2019 00:47:31	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		



Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
n.a.	Placebo 1	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 2	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
1	Hydrochlorothiazide	6.279	4347.931	65.02	1.29	333	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 3	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
2	Ramipril	16.749	2339.516	34.98	1.02	35461	FALSE	12.09
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.



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Processing Method

Processing Method Name :	Ramithiazide Tablets_PR		
Processing Method Path :	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		
Processing Method Created By :	Satish Dodtale	Processing Method Last Updated By :	Rahul Kanase
Processing Method Created On :	17-04-2019 15:14:17	Processing Method Last Updated On :	18-04-2019 07:51:19

Detection Alogrithm	Chromeleon 6	Version	1
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Detection Parameter

Ret. Time min	Param. Name	Param. Value	Inj. Type	Channel
0.000	Minimum Area	16.0000 [Signal*min]	Any	All Channels
0.000	Valley To Valley	On	Any	All Channels
0.000	Inhibit Integration	On	Any	All Channels
0.000	Minimum Height	20.000 [Signal]	Any	All Channels
0.000	Minimum Height	0.000 [Signal]	Any	All Channels
0.000	Fronting Sensitivity Factor	Off	Any	All Channels
5.000	Inhibit Integration	Off	Any	All Channels
5.000	Minimum Height	10.000 [Signal]	Any	All Channels
7.500	Minimum Height	0.000 [Signal]	Any	All Channels
13.000	Inhibit Integration	On	Any	All Channels
13.000	Inhibit Integration	Off	Any	All Channels
13.700	Inhibit Integration	On	Any	All Channels
15.000	Inhibit Integration	Off	Any	All Channels
15.000	Minimum Area	5.0000 [Signal*min]	Any	All Channels
17.000	Minimum Area	16.0000 [Signal*min]	Any	All Channels
18.000	Fronting Sensitivity Factor	1.200	Any	All Channels
18.262	Tailing Sensitivity Factor	1.000	Any	All Channels
19.743	Tailing Sensitivity Factor	Off	Any	All Channels
19.986	Fronting Sensitivity Factor	Off	Any	All Channels
22.000	Minimum Area	18.0000 [Signal*min]	Any	All Channels
26.418	Inhibit Integration	On	Any	All Channels

Peak Table

No.	Peak Name	Ret. Time
1	Hydrochlorothiazide	6.304
2	Placebo	12.604
3	Unknown Impurity	13.413
4	Impurity E	15.270
5	Placebo	15.570
6	Ramipril	16.664
7	Unknown Impurity	17.557
8	Placebo	17.714
9	Unknown Impurity	18.597
10	Unknown Impurity	20.520
11	Unknown Impurity	21.380
12	Impurity D	24.200

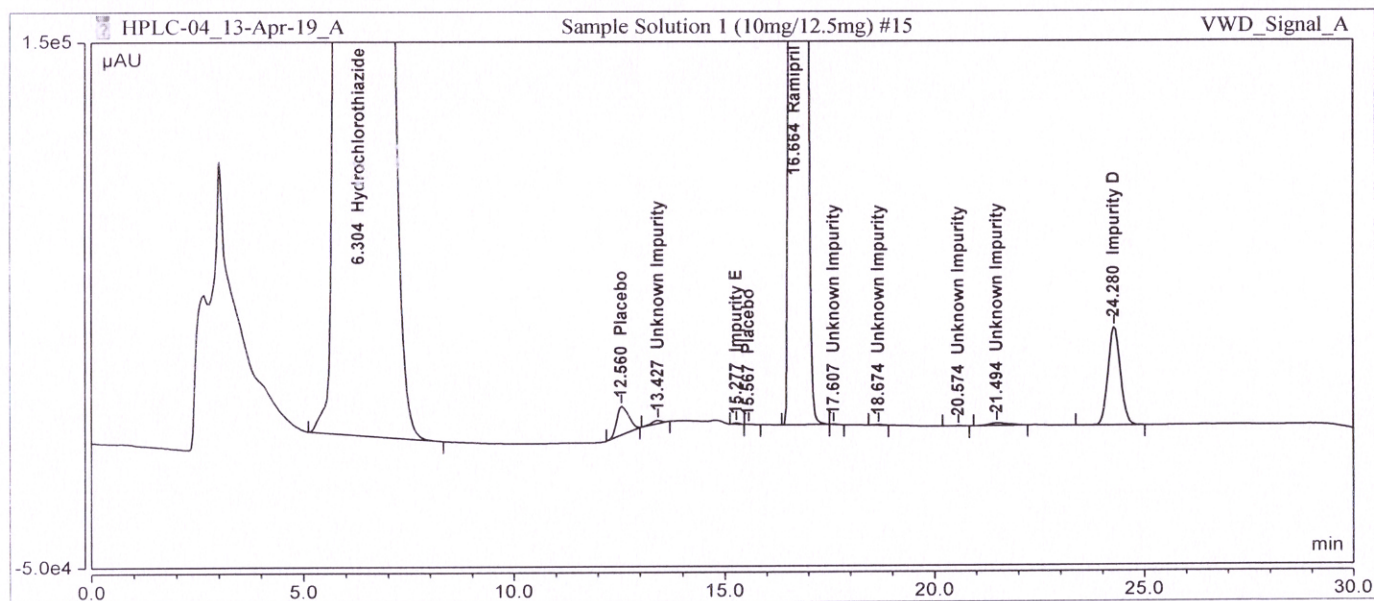
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Processing Method



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Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181206
Sample Name :-	Sample Solution 1 (10mg/12.5mg)	AR. No. :-	D1304190654
Sample Number :-	15	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:5	Processing Method :-	Ramithiazide Tablets_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Rahul Kanase
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	18-04-2019 07:51:19
Injection Date & Time :-	14-04-2019 01:19:11	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		

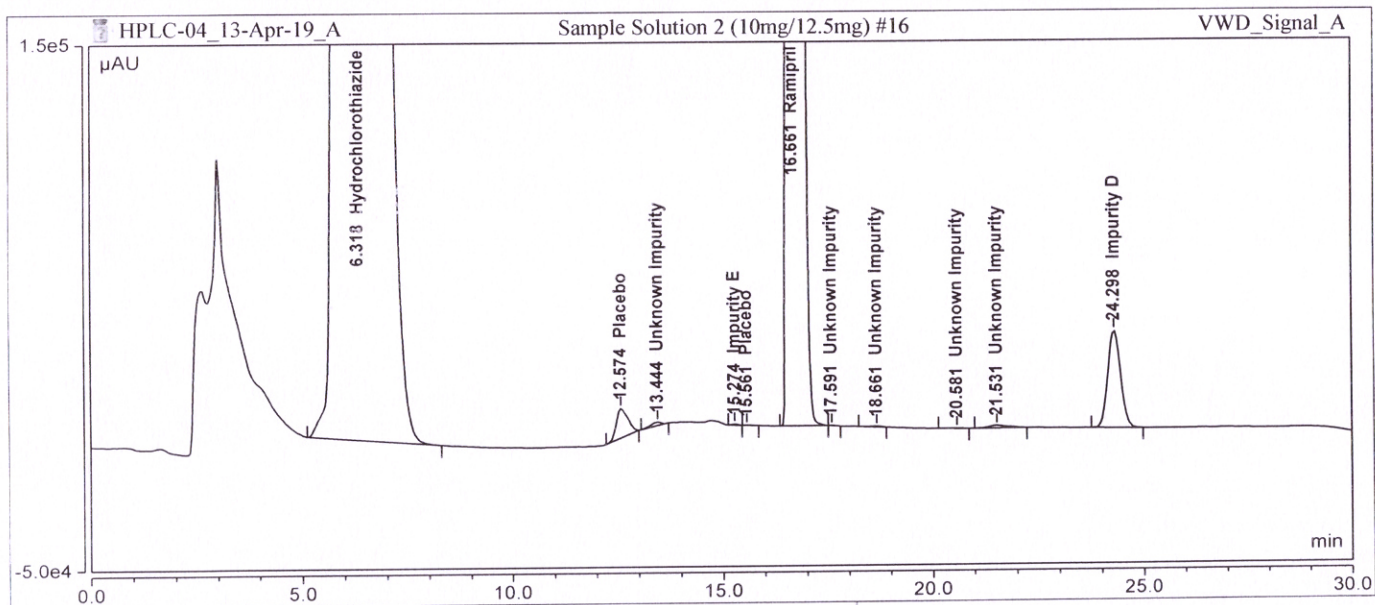


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	6.304	1795715.963	74.87	1.23	311	FALSE	n.a.
2	Placebo	12.560	3544.869	0.15	1.25	8930	FALSE	6.38
3	Unknown Impurity	13.427	360.813	0.02	0.83	16382	FALSE	1.82
4	Impurity E	15.277	75.883	0.00	1.07	53602	FALSE	5.41
5	Placebo	15.567	15.838	0.00	1.87	14777	FALSE	0.75
6	Ramipril	16.664	585052.335	24.39	1.65	19580	FALSE	2.22
7	Unknown Impurity	17.607	24.373	0.00	1.56	86575	FALSE	2.64
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
8	Unknown Impurity	18.674	58.676	0.00	0.97	38135	FALSE	3.43
9	Unknown Impurity	20.574	37.183	0.00	0.82	32223	FALSE	4.52
10	Unknown Impurity	21.494	567.440	0.02	1.26	10793	FALSE	1.43
11	Impurity D	24.280	12954.137	0.54	1.07	31829	FALSE	4.06



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Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181206
Sample Name :-	Sample Solution 2 (10mg/12.5mg)	AR. No. :-	D1304190654
Sample Number :-	16	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:6	Processing Method :-	Ramithiazide Tablets_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Rahul Kanase
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	18-04-2019 07:51:19
Injection Date & Time :-	14-04-2019 01:50:50	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		

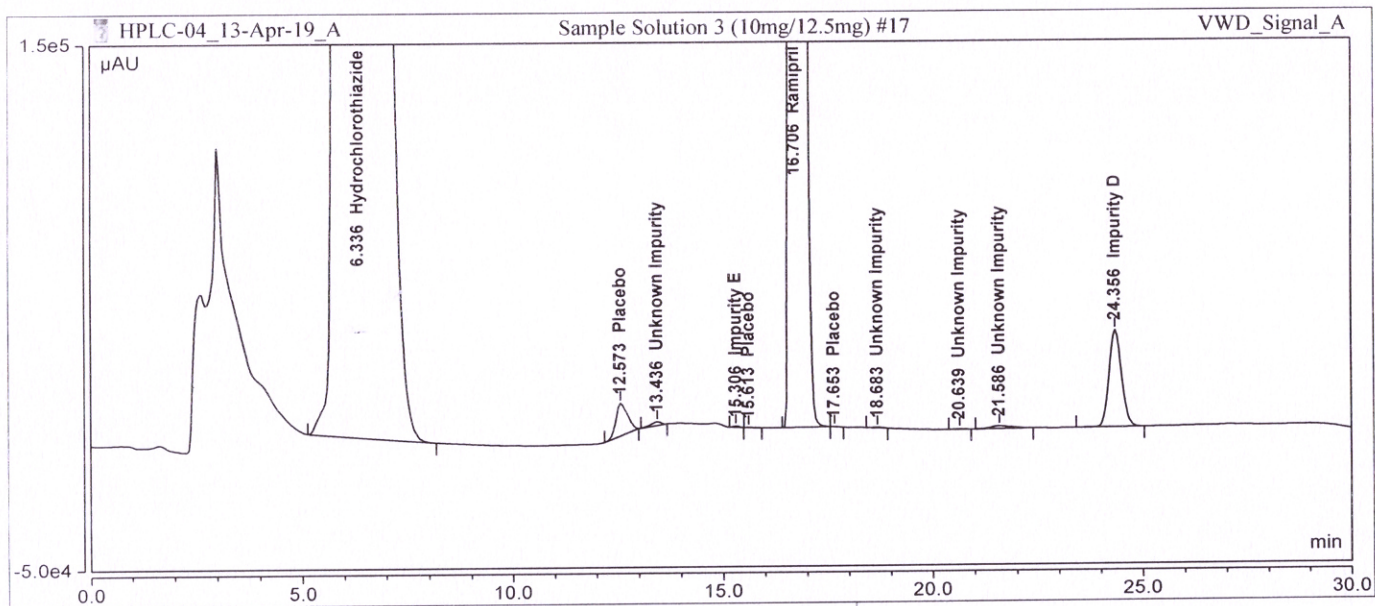


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	6.318	1799916.072	74.94	1.22	304	FALSE	n.a.
2	Placebo	12.574	3571.225	0.15	1.24	8104	FALSE	6.23
3	Unknown Impurity	13.444	390.551	0.02	0.75	17334	FALSE	1.80
4	Impurity E	15.274	73.993	0.00	1.07	56829	FALSE	5.51
5	Placebo	15.561	19.206	0.00	1.96	45143	FALSE	1.04
6	Ramipril	16.661	584266.799	24.33	1.65	19595	FALSE	2.86
7	Unknown Impurity	17.591	21.528	0.00	1.75	90524	FALSE	2.62
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
8	Unknown Impurity	18.661	77.198	0.00	0.86	27029	FALSE	3.11
9	Unknown Impurity	20.581	38.776	0.00	0.83	25174	FALSE	3.95
10	Unknown Impurity	21.531	528.313	0.02	1.27	12794	FALSE	1.48
11	Impurity D	24.298	12831.945	0.53	1.08	31756	FALSE	4.23



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Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181206
Sample Name :-	Sample Solution 3 (10mg/12.5mg)	AR. No. :-	D1304190654
Sample Number :-	17	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:7	Processing Method :-	Ramithiazide Tablets_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Rahul Kanase
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	18-04-2019 07:51:19
Injection Date & Time :-	14-04-2019 02:22:30	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		

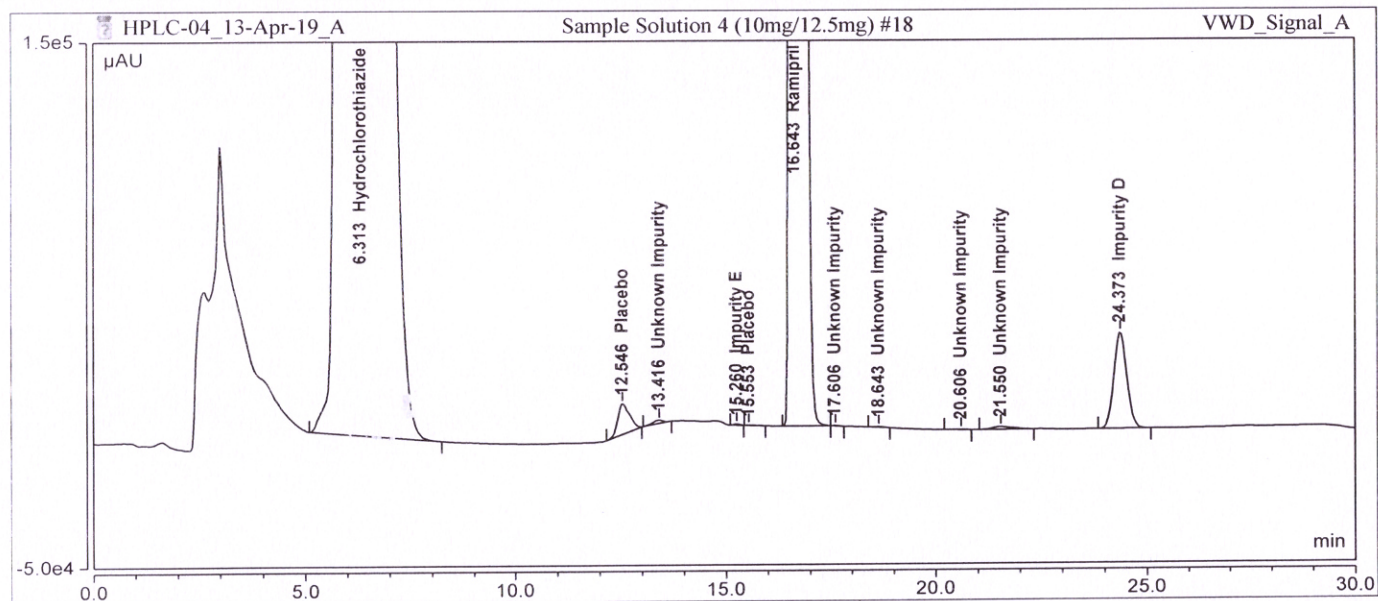


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	6.336	1791376.816	74.84	1.22	307	FALSE	n.a.
2	Placebo	12.573	3958.694	0.17	1.20	8241	FALSE	6.23
3	Unknown Impurity	13.436	404.532	0.02	0.77	16707	FALSE	1.78
4	Impurity E	15.306	77.823	0.00	1.10	52187	FALSE	5.47
5	Placebo	15.613	22.283	0.00	1.72	41487	FALSE	1.07
6	Ramipril	16.706	584246.825	24.41	1.65	19686	FALSE	2.79
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
7	Placebo	17.653	27.885	0.00	1.50	79638	FALSE	2.61
8	Unknown Impurity	18.683	63.299	0.00	1.01	32391	FALSE	3.10
9	Unknown Impurity	20.639	28.738	0.00	1.03	42686	FALSE	4.80
10	Unknown Impurity	21.586	569.747	0.02	1.25	10245	FALSE	1.51
11	Impurity D	24.356	12825.271	0.54	1.08	31604	FALSE	3.95



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Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181206
Sample Name :-	Sample Solution 4 (10mg/12.5mg)	AR. No. :-	D1304190654
Sample Number :-	18	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:8	Processing Method :-	Ramithiazide Tablets_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Rahul Kanase
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	18-04-2019 07:51:19
Injection Date & Time :-	14-04-2019 02:54:09	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		

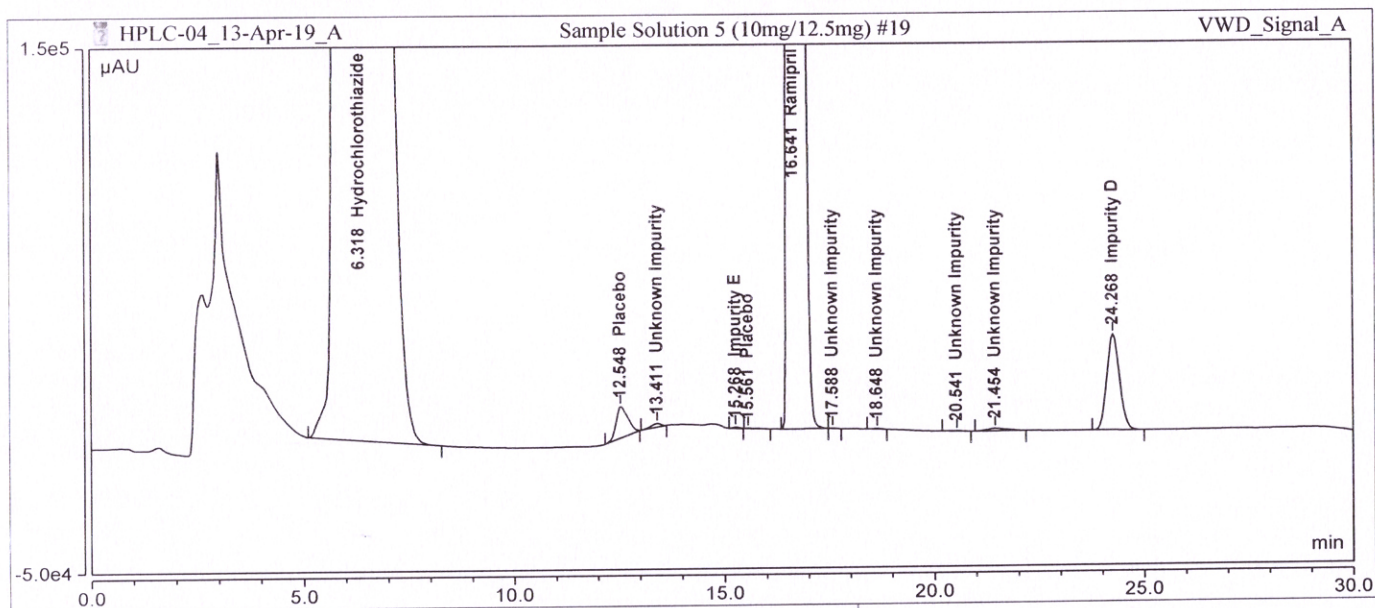


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	6.313	1820403.812	74.95	1.20	297	FALSE	n.a.
2	Placebo	12.546	3772.001	0.16	1.23	8624	FALSE	6.22
3	Unknown Impurity	13.416	374.025	0.02	0.77	17370	FALSE	1.84
4	Impurity E	15.260	71.359	0.00	1.05	54053	FALSE	5.50
5	Placebo	15.553	26.234	0.00	2.35	39832	FALSE	1.02
6	Ramipril	16.643	590629.985	24.32	1.65	19180	FALSE	2.75
7	Unknown Impurity	17.606	26.494	0.00	1.38	76519	FALSE	2.62
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
8	Unknown Impurity	18.643	76.286	0.00	1.06	28643	FALSE	2.98
9	Unknown Impurity	20.606	37.573	0.00	0.81	31358	FALSE	4.33
10	Unknown Impurity	21.550	571.400	0.02	1.27	9460	FALSE	1.40
11	Impurity D	24.373	12992.193	0.53	1.08	30269	FALSE	3.90



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Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181206
Sample Name :-	Sample Solution 5 (10mg/12.5mg)	AR. No. :-	D1304190654
Sample Number :-	19	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:9	Processing Method :-	Ramithiazide Tablets_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Rahul Kanase
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	18-04-2019 07:51:19
Injection Date & Time :-	14-04-2019 03:25:52	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		

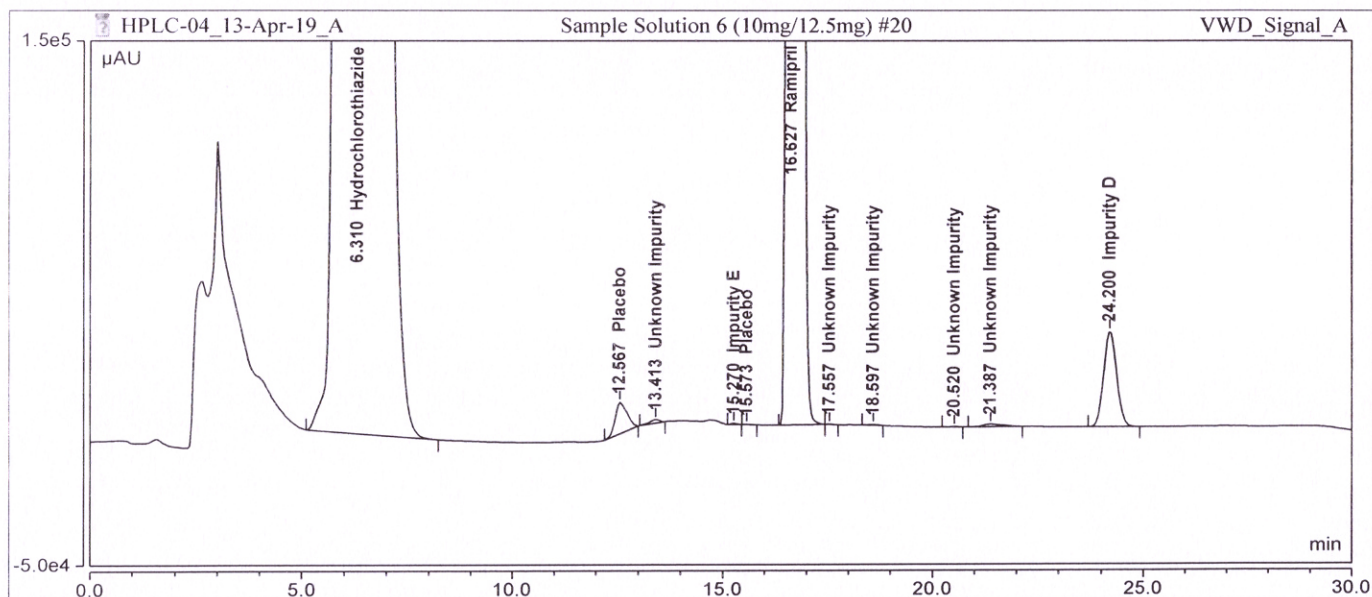


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	6.318	1804730.352	74.94	1.21	301	FALSE	n.a.
2	Placebo	12.548	3874.205	0.16	1.23	8380	FALSE	6.22
3	Unknown Impurity	13.411	382.131	0.02	0.76	16959	FALSE	1.80
4	Impurity E	15.268	75.923	0.00	1.09	53675	FALSE	5.50
5	Placebo	15.561	36.721	0.00	3.39	19547	FALSE	0.83
6	Ramipril	16.641	585669.493	24.32	1.63	19413	FALSE	2.34
7	Unknown Impurity	17.588	24.427	0.00	1.39	86217	FALSE	2.64
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
8	Unknown Impurity	18.648	58.459	0.00	0.99	41366	FALSE	3.50
9	Unknown Impurity	20.541	37.527	0.00	0.93	35464	FALSE	4.72
10	Unknown Impurity	21.454	538.793	0.02	1.33	9973	FALSE	1.41
11	Impurity D	24.268	12835.568	0.53	1.09	30719	FALSE	3.98



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181206
Sample Name :-	Sample Solution 6 (10mg/12.5mg)	AR. No. :-	D1304190654
Sample Number :-	20	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:10	Processing Method :-	Ramithiazide Tablets_PR
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Rahul Kanase
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	18-04-2019 07:51:19
Injection Date & Time :-	14-04-2019 03:57:37	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		

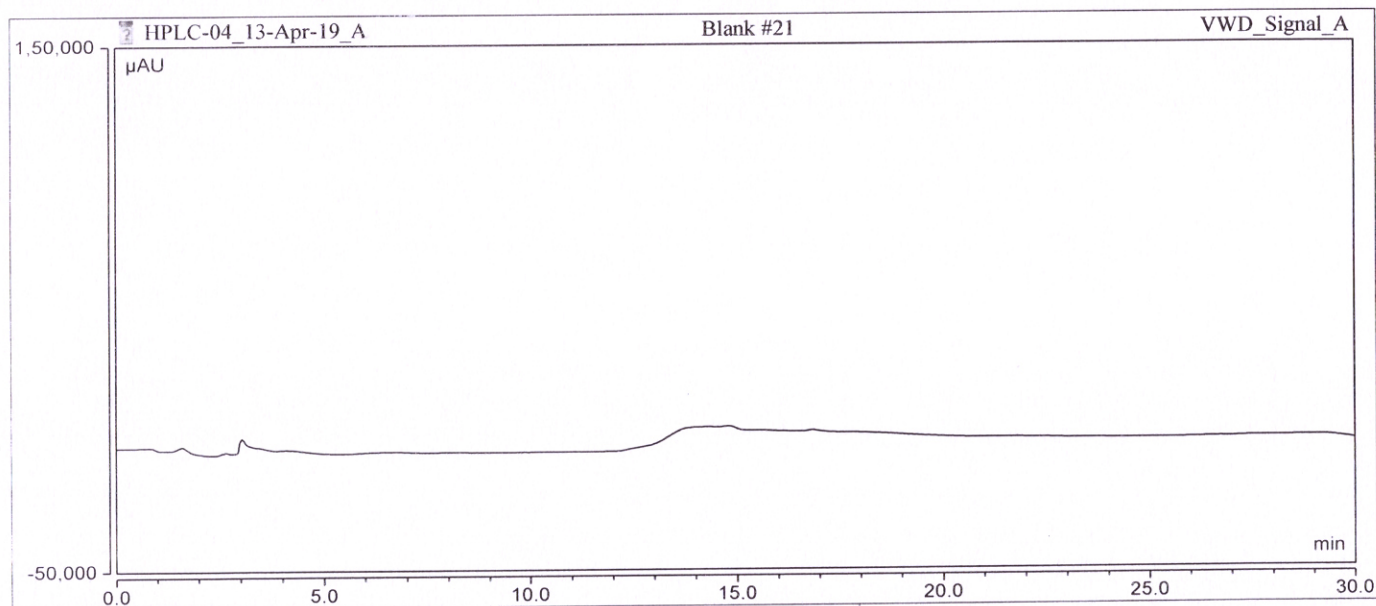


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	6.310	1794056.307	74.98	1.21	306	FALSE	n.a.
2	Placebo	12.567	3775.671	0.16	1.23	8293	FALSE	6.28
3	Unknown Impurity	13.413	381.961	0.02	0.76	16861	FALSE	1.75
4	Impurity E	15.270	75.711	0.00	1.07	55155	FALSE	5.52
5	Placebo	15.573	18.731	0.00	1.54	33343	FALSE	1.01
6	Ramipril	16.627	580982.641	24.28	1.63	19716	FALSE	2.59
7	Unknown Impurity	17.557	25.275	0.00	1.40	84664	FALSE	2.60
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
8	Unknown Impurity	18.597	66.922	0.00	0.95	35646	FALSE	3.27
9	Unknown Impurity	20.520	28.915	0.00	0.84	49436	FALSE	5.04
10	Unknown Impurity	21.387	574.034	0.02	1.30	9115	FALSE	1.37
11	Impurity D	24.200	12754.276	0.53	1.09	30575	FALSE	3.88



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Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181206
Sample Name :-	Blank	AR. No. :-	D1304190654
Sample Number :-	21	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:1	Processing Method :-	Ramithiazide Tablet
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Rahul Kanase
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	18-04-2019 07:54:13
Injection Date & Time :-	14-04-2019 04:29:18	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		

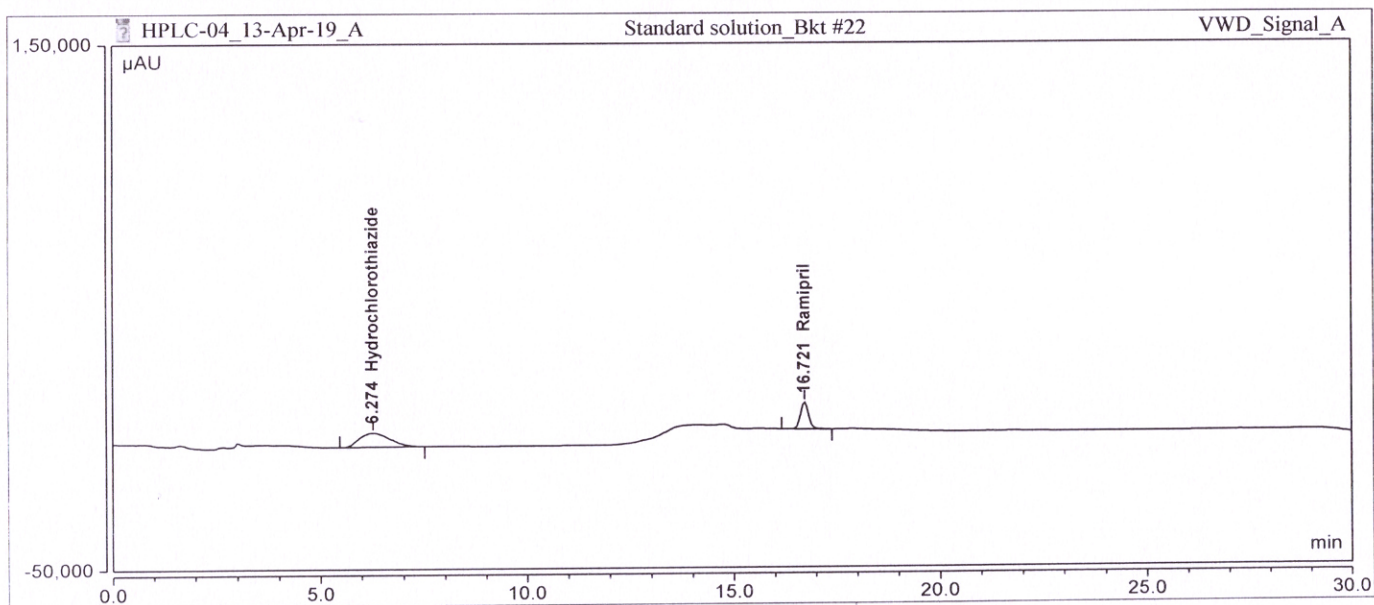


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
n.a.	Placebo 1	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 2	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Hydrochlorothiazide	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 3	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Ramipril	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.



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Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181206
Sample Name :-	Standard solution_Bkt	AR. No. :-	D1304190654
Sample Number :-	22	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:4	Processing Method :-	Ramithiazide Tablet
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Rahul Kanase
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	18-04-2019 07:54:13
Injection Date & Time :-	14-04-2019 05:01:00	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		



Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
n.a.	Placebo 1	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 2	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
1	Hydrochlorothiazide	6.274	4566.106	66.42	1.26	334	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 3	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
2	Ramipril	16.721	2308.278	33.58	1.05	36121	FALSE	12.12
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.



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Processing Method

Processing Method Name :	Ramithiazide Tablets_PR1		
Processing Method Path :	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		
Processing Method Created By :	Satish Dodtale	Processing Method Last Updated By :	Ankita Parab
Processing Method Created On :	17-04-2019 15:15:13	Processing Method Last Updated On :	23-04-2019 17:49:43

Detection Alogrithm	Chromeleon 6	Version	3
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Detection Parameter

Ret. Time min	Param. Name	Param. Value	Inj. Type	Channel
0.000	Minimum Area	10.0000 [Signal*min]	Any	All Channels
0.000	Inhibit Integration	On	Any	All Channels
5.000	Inhibit Integration	Off	Any	All Channels
9.000	Inhibit Integration	On	Any	All Channels
11.956	Inhibit Integration	Off	Any	All Channels
13.144	Inhibit Integration	On	Any	All Channels
13.144	Inhibit Integration	Off	Any	All Channels
14.000	Inhibit Integration	On	Any	All Channels
15.000	Inhibit Integration	Off	Any	All Channels
16.000	Minimum Area	60.0000 [Signal*min]	Any	All Channels
27.000	Inhibit Integration	On	Any	All Channels

Peak Table

No.	Peak Name	Ret. Time
1	Hydrochlorothiazide	6.310
2	Placebo	12.570
3	Unknown Impurity	13.413
4	Impurity E	15.270
5	Placebo	15.730
6	Placebo	16.270
7	Ramipril	16.620
8	Unknown Impurity	17.557
9	Unknown Impurity	18.597
10	Unknown Impurity	18.720
11	Placebo	18.760
12	Unknown Impurity	20.520
13	Placebo	21.270
14	Unknown Impurity	21.760
15	Unknown Impurity	21.890
16	Unknown Impurity	22.010
17	Placebo	22.840
18	Impurity D	24.500
19	Placebo	25.460

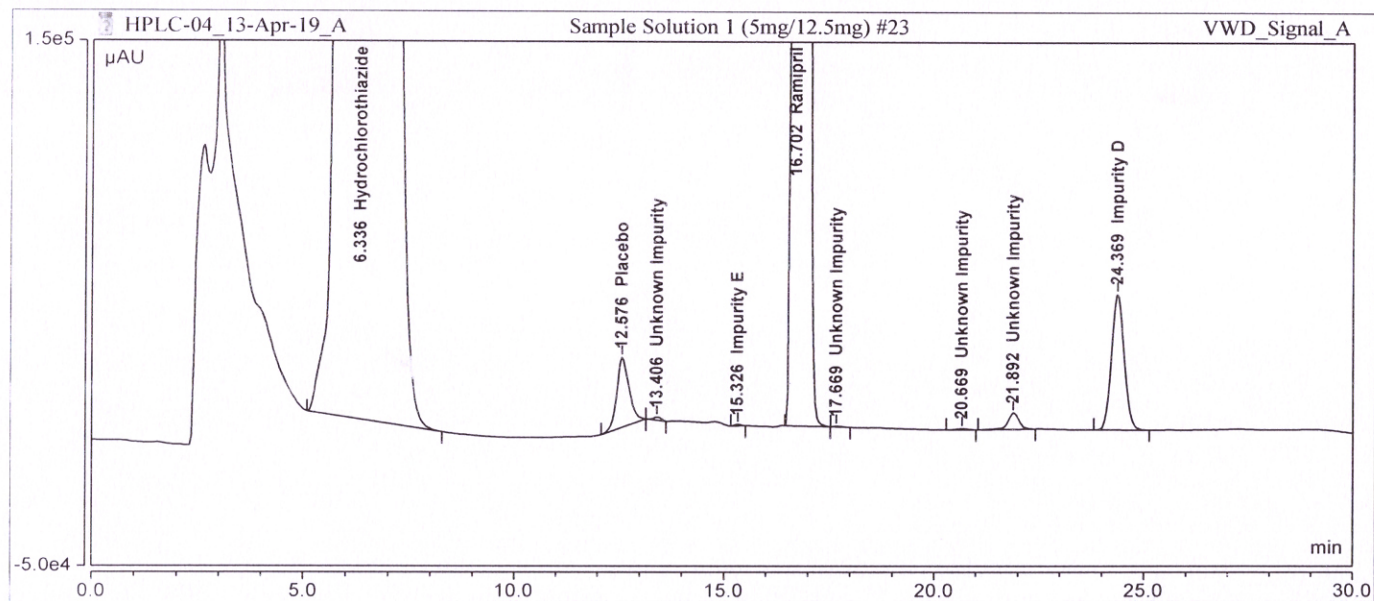
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Processing Method

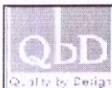


QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181203
Sample Name :-	Sample Solution 1 (5mg/12.5mg)	AR. No. :-	D1304190655
Sample Number :-	23	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:11	Processing Method :-	Ramithiazide Tablets_PR1
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Ankita Parab
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	23-04-2019 17:49:43
Injection Date & Time :-	14-04-2019 05:32:46	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		

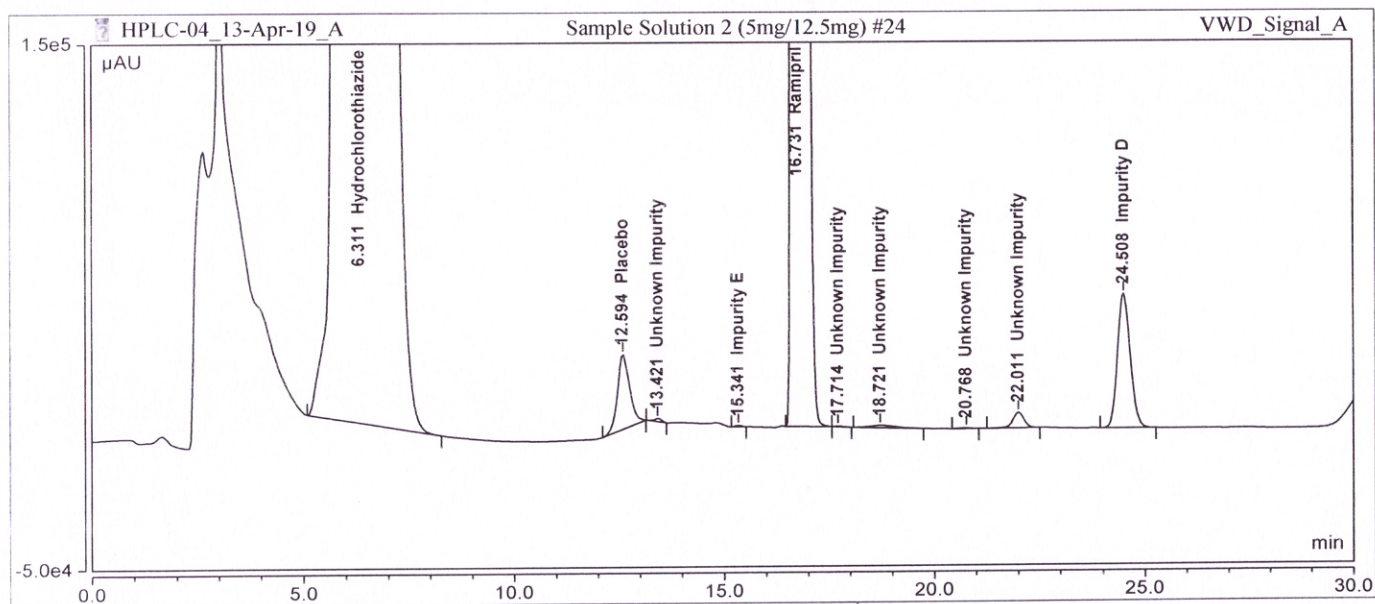


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	6.336	2703086.808	81.31	1.21	268	FALSE	n.a.
2	Placebo	12.576	9027.944	0.27	1.20	8922	FALSE	6.00
3	Unknown Impurity	13.406	264.202	0.01	0.97	25111	FALSE	1.91
4	Impurity E	15.326	93.855	0.00	1.04	53226	FALSE	6.36
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
5	Ramipril	16.702	591824.845	17.80	1.65	19289	FALSE	3.69
6	Unknown Impurity	17.669	61.888	0.00	1.76	47287	FALSE	2.40
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
7	Unknown Impurity	20.669	104.812	0.00	0.97	29633	FALSE	7.45
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
8	Unknown Impurity	21.892	1904.215	0.06	0.93	36457	FALSE	2.61
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
9	Impurity D	24.369	18232.796	0.55	1.09	30681	FALSE	4.88
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.



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Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181203
Sample Name :-	Sample Solution 2 (5mg/12.5mg)	AR. No. :-	D1304190655
Sample Number :-	24	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:12	Processing Method :-	Ramithiazide Tablets_PR1
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Ankita Parab
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	23-04-2019 17:49:43
Injection Date & Time :-	14-04-2019 06:04:26	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		

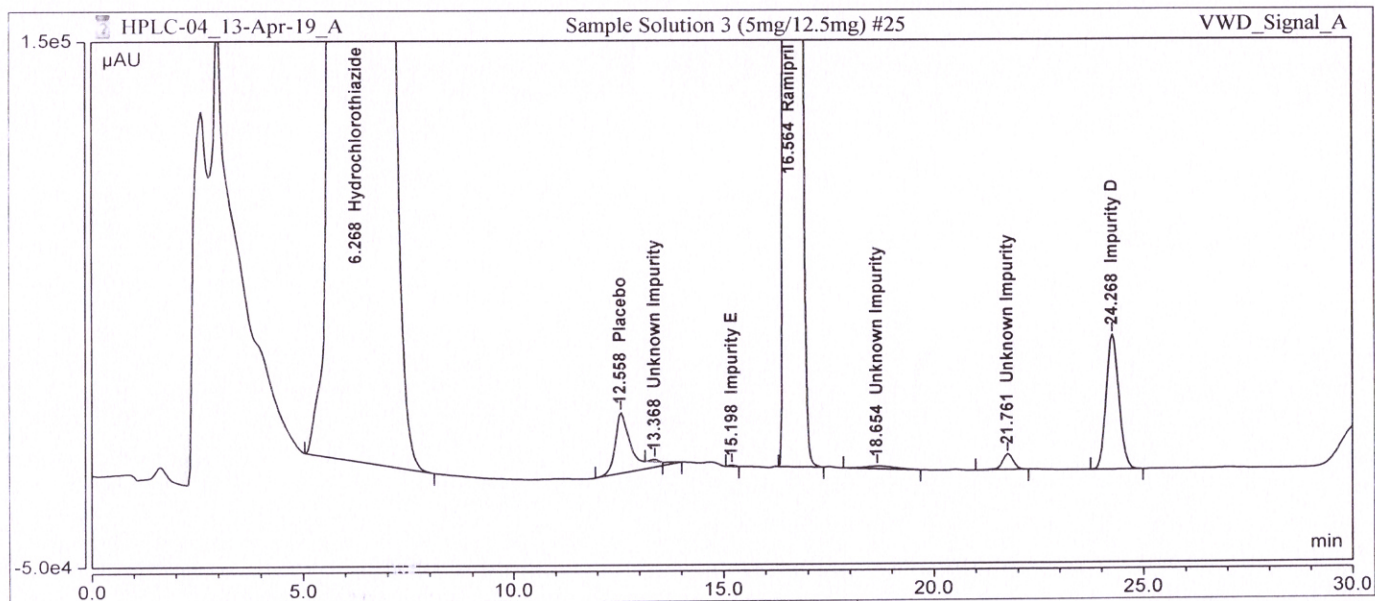


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	6.311	2679292.556	81.05	1.25	271	FALSE	n.a.
2	Placebo	12.594	9562.330	0.29	1.16	9299	FALSE	6.11
3	Unknown Impurity	13.421	278.220	0.01	0.96	26090	FALSE	1.93
4	Impurity E	15.341	94.448	0.00	1.05	53414	FALSE	6.42
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
5	Ramipril	16.731	595478.174	18.01	1.68	19006	FALSE	3.70
6	Unknown Impurity	17.714	62.582	0.00	1.57	48968	FALSE	2.44
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
7	Unknown Impurity	18.721	658.827	0.02	1.25	4351	FALSE	1.38
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
8	Unknown Impurity	20.768	94.117	0.00	0.95	31364	FALSE	2.55
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
9	Unknown Impurity	22.011	1871.759	0.06	0.94	35043	FALSE	2.65
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
10	Impurity D	24.508	18215.455	0.55	1.09	30470	FALSE	4.84
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.

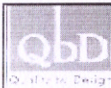


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Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181203
Sample Name :-	Sample Solution 3 (5mg/12.5mg)	AR. No. :-	D1304190655
Sample Number :-	25	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:13	Processing Method :-	Ramithiazide Tablets_PR1
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Ankita Parab
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	23-04-2019 17:49:43
Injection Date & Time :-	14-04-2019 06:36:05	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		

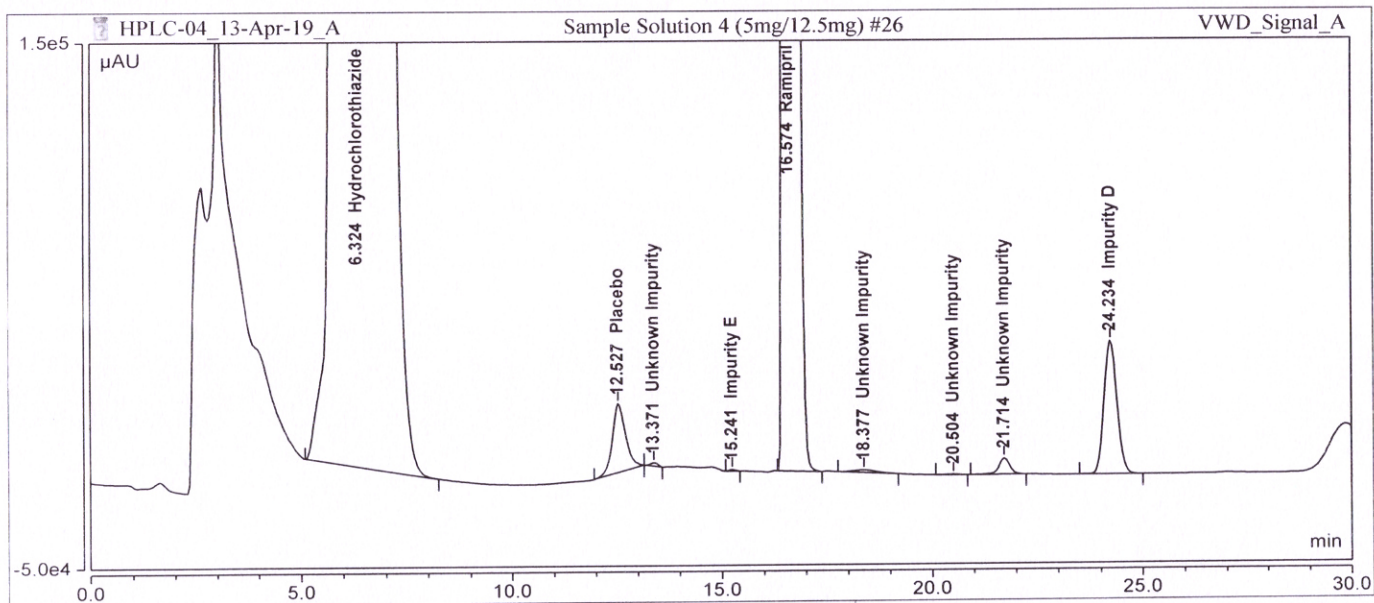


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	6.268	2689861.570	81.18	1.21	265	FALSE	n.a.
2	Placebo	12.558	10408.413	0.31	1.92	6570	FALSE	5.82
3	Unknown Impurity	13.368	211.583	0.01	n.a.	n.a.	FALSE	n.a.
4	Impurity E	15.198	78.742	0.00	1.08	54027	FALSE	5.99
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
5	Ramipril	16.564	592106.361	17.87	1.65	18942	FALSE	3.68
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
6	Unknown Impurity	18.654	889.781	0.03	1.14	2975	FALSE	2.26
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
7	Unknown Impurity	21.761	1857.797	0.06	0.97	34677	FALSE	3.39
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
8	Impurity D	24.268	18236.939	0.55	1.09	29969	FALSE	4.88
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.



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Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181203
Sample Name :-	Sample Solution 4 (5mg/12.5mg)	AR. No. :-	D1304190655
Sample Number :-	26	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:14	Processing Method :-	Ramithiazide Tablets_PR1
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Ankita Parab
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	23-04-2019 17:49:43
Injection Date & Time :-	14-04-2019 07:07:46	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		

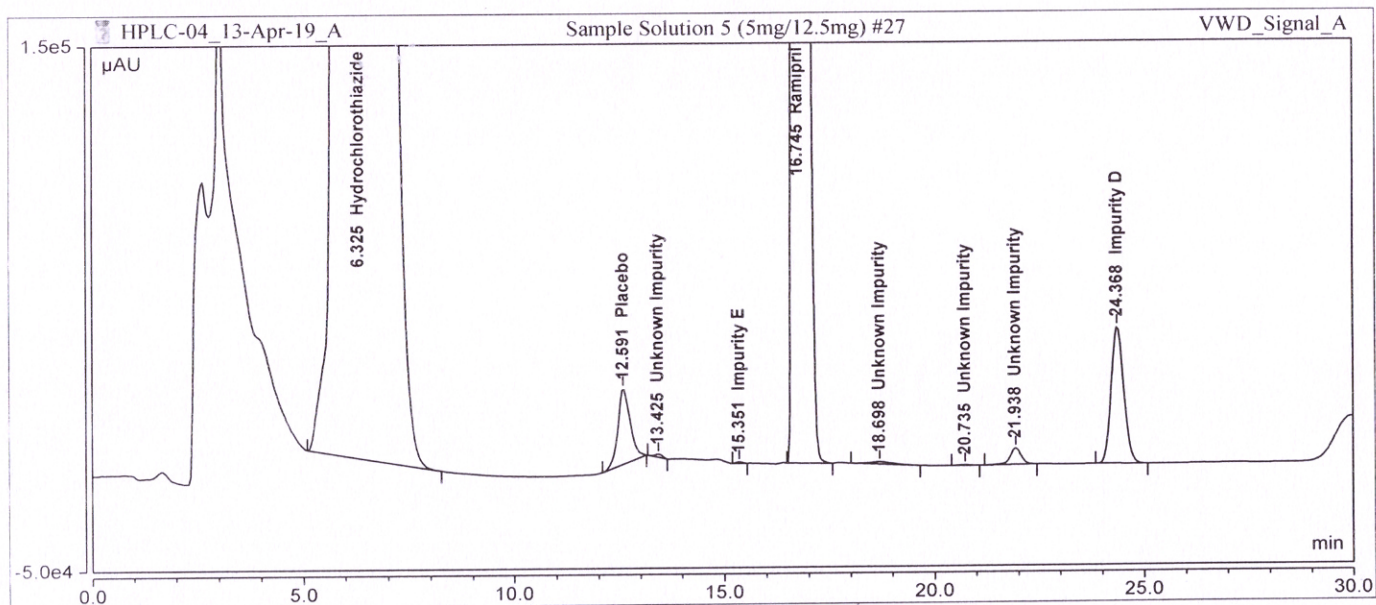


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	6.324	2688016.987	81.28	1.23	272	FALSE	n.a.
2	Placebo	12.527	9567.464	0.29	1.15	7920	FALSE	5.91
3	Unknown Impurity	13.371	256.811	0.01	1.00	27175	FALSE	1.90
4	Impurity E	15.241	92.757	0.00	1.05	54380	FALSE	6.38
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
5	Ramipril	16.574	588175.746	17.79	1.65	19347	FALSE	3.61
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
6	Unknown Impurity	18.377	686.568	0.02	1.18	5189	FALSE	2.41
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
7	Unknown Impurity	20.504	85.791	0.00	0.89	30053	FALSE	2.85
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
8	Unknown Impurity	21.714	1906.128	0.06	0.94	34595	FALSE	2.57
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
9	Impurity D	24.234	18265.345	0.55	1.09	29335	FALSE	4.88
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.



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Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181203
Sample Name :-	Sample Solution 5 (5mg/12.5mg)	AR. No. :-	D1304190655
Sample Number :-	27	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:15	Processing Method :-	Ramithiazide Tablets_PR1
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Ankita Parab
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	23-04-2019 17:49:43
Injection Date & Time :-	14-04-2019 07:39:25	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		

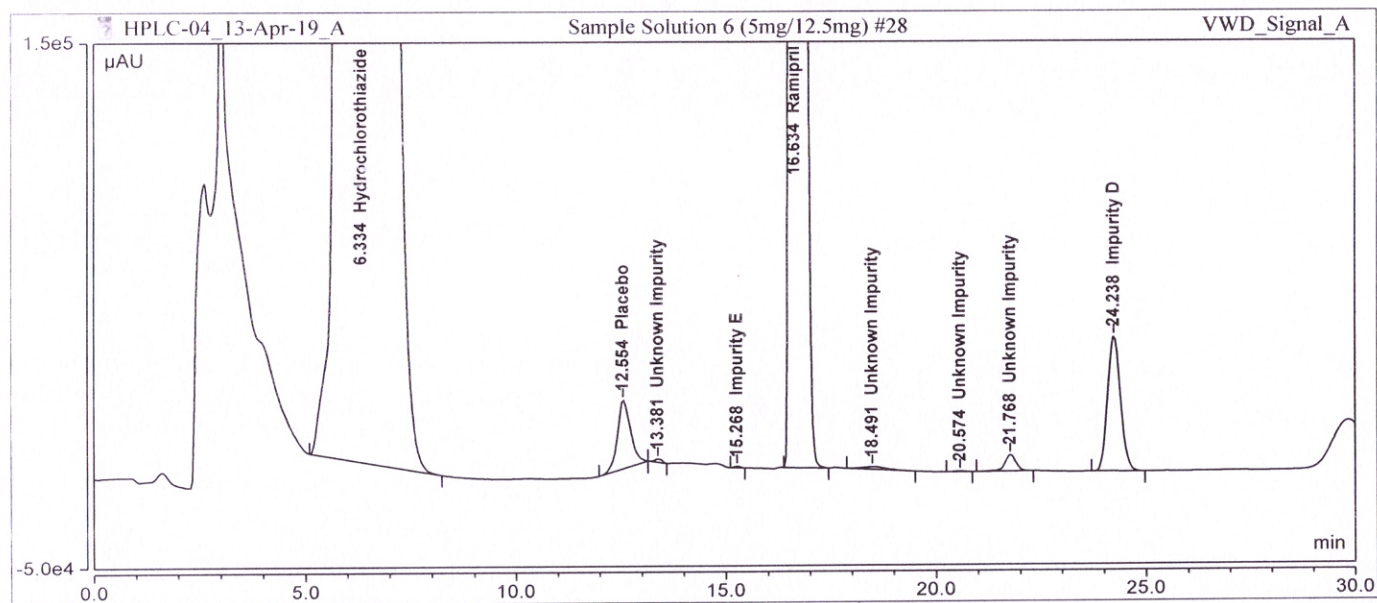


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	6.325	2680378.573	81.07	1.23	275	FALSE	n.a.
2	Placebo	12.591	9822.421	0.30	1.15	9028	FALSE	6.09
3	Unknown Impurity	13.425	265.283	0.01	1.03	26753	FALSE	1.94
4	Impurity E	15.351	94.625	0.00	1.02	50658	FALSE	6.41
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
5	Ramipril	16.745	595040.667	18.00	1.66	19095	FALSE	3.68
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
6	Unknown Impurity	18.698	615.429	0.02	1.18	5041	FALSE	2.54
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
7	Unknown Impurity	20.735	91.768	0.00	0.95	34885	FALSE	2.72
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
8	Unknown Impurity	21.938	1887.051	0.06	0.94	36915	FALSE	2.67
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
9	Impurity D	24.368	18141.010	0.55	1.10	31269	FALSE	4.82
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.



QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181203
Sample Name :-	Sample Solution 6 (5mg/12.5mg)	AR. No. :-	D1304190655
Sample Number :-	28	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:16	Processing Method :-	Ramithiazide Tablets_PR1
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Ankita Parab
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	23-04-2019 17:49:43
Injection Date & Time :-	14-04-2019 08:11:05	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		

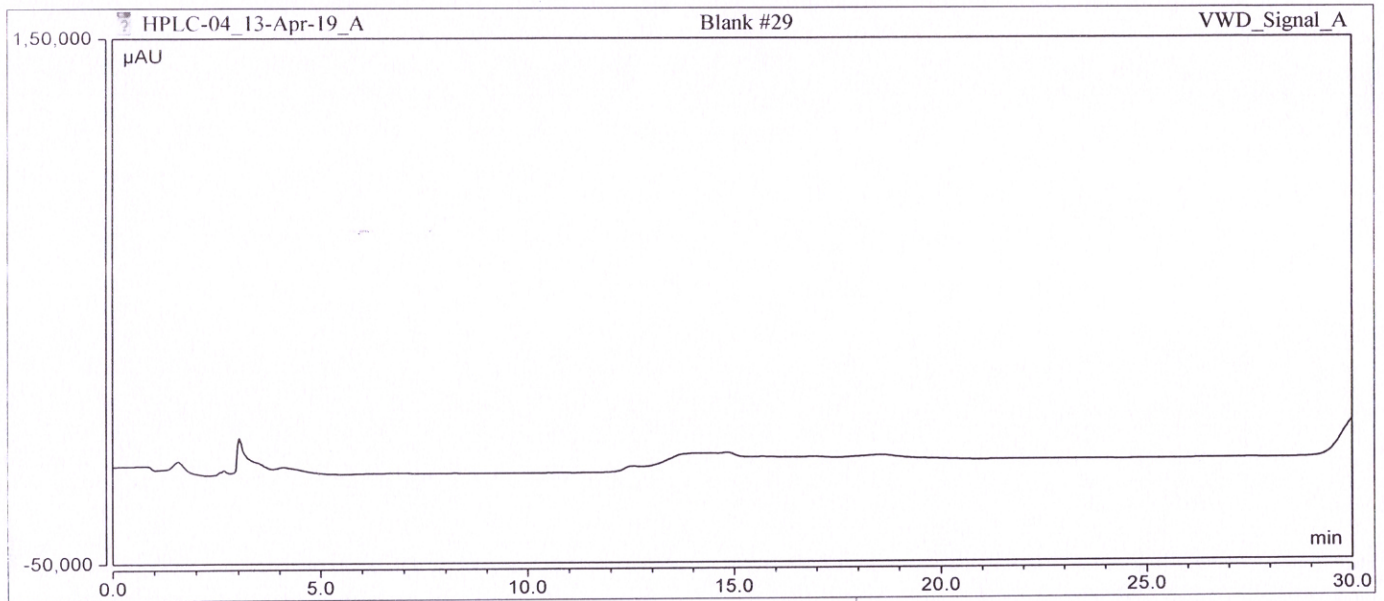


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
1	Hydrochlorothiazide	6.334	2689048.748	81.22	1.21	272	FALSE	n.a.
2	Placebo	12.554	9488.927	0.29	1.15	8038	FALSE	5.94
3	Unknown Impurity	13.381	267.251	0.01	1.02	26933	FALSE	1.87
4	Impurity E	15.268	88.811	0.00	1.05	52696	FALSE	6.37
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
5	Ramipril	16.634	590990.730	17.85	1.66	19225	FALSE	3.66
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
6	Unknown Impurity	18.491	680.667	0.02	1.32	4479	FALSE	2.34
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
7	Unknown Impurity	20.574	77.702	0.00	0.92	31345	FALSE	2.65
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
8	Unknown Impurity	21.768	1933.565	0.06	0.90	35965	FALSE	2.58
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown Impurity	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
9	Impurity D	24.238	18186.619	0.55	1.10	30007	FALSE	4.85
n.a.	Placebo	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.



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Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181206
Sample Name :-	Blank	AR. No. :-	D1304190654
Sample Number :-	29	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:1	Processing Method :-	Ramithiazide Tablet
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Rahul Kanase
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	18-04-2019 07:54:13
Injection Date & Time :-	14-04-2019 08:42:50	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		

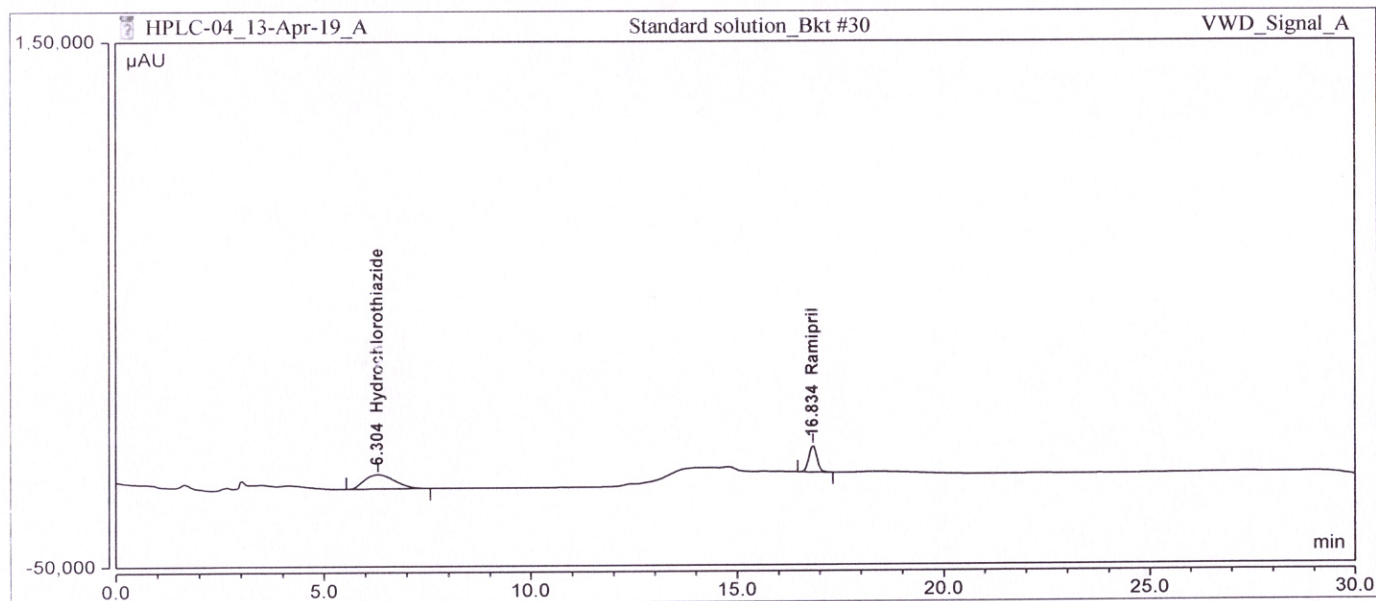


Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
n.a.	Placebo 1	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 2	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Hydrochlorothiazide	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 3	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Ramipril	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.



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Product Name :-	Ramithiazide Tablet	Batch No. :-	GP181206
Sample Name :-	Standard solution_Bkt	AR. No. :-	D1304190654
Sample Number :-	30	Instrument Method :-	HPLC-04_Ramithiazide Tablet_RS_M
Sample Type :-	Unknown	Instrument Method Created By :-	Rahul Kanase
Injection Volume :-	30.00 µL	Instrument Method Created On :-	13-04-2019 16:53:22
Vial Position :-	Vial:4	Processing Method :-	Ramithiazide Tablet
Column No. :-	QbD/LC/COL/128	Processing Method Last Updated By :-	Rahul Kanase
Instrument ID. :-	QbD-INST-HPLC-04	Processing Method Last Updated On :-	18-04-2019 07:54:13
Injection Date & Time :-	14-04-2019 09:14:32	Experiment Name:-	Precision
Analyst :-	Ankita Parab	Wavelength:-	n.a.
Sequence Path :-	Method Validation\Generic Healthcare\Ramithiazide Tablet\Related substances\HPLC-04_13-Apr-19_A.seq		



Peak No.	Peak Name	Ret. Time min	Area µAU*min	Area %	Asymmetry (EP/USP)	Plates (USP)	Manipulated	Resolution (USP)
n.a.	Placebo 1	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 2	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
1	Hydrochlorothiazide	6.304	4587.710	66.89	1.28	349	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 3	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
2	Ramipril	16.834	2270.453	33.11	1.04	35192	FALSE	12.33
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Unknown	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.
n.a.	Placebo 4	n.a.	n.a.	n.a.	n.a.	n.a.	FALSE	n.a.