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HPLC Method Development and Validation for Sitagliptin and Ertugliflozin in Bulk and Dosage Forms

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KEYWORDS

Ertugliflozin, sitagliptin, HPLC, Simultaneous estimation.

ABSTRACT:

A novel and robust analytical method has been developed and validated for the simultaneous estimation of Sitagliptin and Ertugliflozin in bulk and dosage forms using high-performance liquid chromatography (HPLC) (1).The method employs a UV detector for detection at a wavelength of 212 nm. The chromatographic separation was achieved using an Agilent Poroshell C18 column (150 mm × 4.6 mm i.d., 5 µm particle size) with a mobile phase composed of Acetonitrile and water in a 60:40 ratio. The flow rate was set to 1.0 ml/min, and the column oven was maintained at 35°C to ensure optimal separation (2). The injection volume was 20 µL, and the analysis was carried out at a wavelength of 212 nm, ensuring precise quantification of both Sitagliptin and Ertugliflozin in the pharmaceutical dosage form and bulk drug substance. The developed method demonstrates excellent resolution and sensitivity, making it suitable for routine analysis in quality control laboratories (3, 4). Method validation was performed according to ICH guidelines, evaluating parameters such as linearity, precision, accuracy, and specificity, limit of detection (LOD), limit of quantification (LOQ), robustness, and system suitability. The method proved to be reliable, accurate, and precise, offering a suitable solution for the simultaneous analysis of Sitagliptin and Ertugliflozin in both bulk and dosage forms. This validated analytical method is expected to be highly effective in ensuring the quality and consistency of pharmaceutical formulations containing Sitagliptin and Ertugliflozin (5).

INTRODUCTION:

The molecular name for ertugliflozin is 5-[4-chloro-3-[(4-ethoxyphenyl) methyl] (1S,2S,3S,4R,5S) [phenyl] -1 (hydroxymethyl) Octane-2,3,4 triol; -6, 8-dioxabicyclo (3,2,1); (2S) A selective inhibitor of sodium-dependent glucose cotransporters (SGLT), more especially type 2 diabetes, is 5-oxopyrrolidine-2-carboxylic acid (Fediuk et al., 2020). A novel medication that inhibits dipeptidyl peptidase-4 (DPP 4) and has the molecular designation (R) 3-(Trifluoromethyl)-3-Amino-1 4,3 A) Pyrazin-7(8h)-yl)-4-(2,4,5-Trifluorophenyl -5,6-Dihydro-(1,2,4)TriazoloButan-1. Sitagliptin is one. Sitagliptin inhibits the breakdown of the incretin GLP-1 by the protease dipeptidyl peptidase-4 (DPP-4). By inhibiting DPP-4, elevated or sustained GLP-1 levels can improve the pancreas' capacity to release insulin (6). Sitagliptin increases the synthesis of insulin while decreasing the overproduction of glucose in the liver. Sitagliptin only works when blood sugar levels are elevated in order to counteract lower insulin levels caused by beta-cell dysfunction and the liver's uncontrolled production of glucose.

Ertugliflozin and sitagliptin were given together as a dosage to treat type 2 diabetes (7, 8). A few verified analytical methods for quantifying sitagliptin and ertugliflozin using the HPLC method have been described. It was discovered that there was no commercially viable technique for the simultaneous estimate of sitagliptin and ertugliflozin in tablet and bulk dosage forms in the literature. The current study aims to create and validate the cost-effective RP-HPLC method for the simultaneous measurement of sitagliptin

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and ertugliflozin in tablet and bulk medication dosage forms (9).

EXPERIMENTAL WORK:

APPARATUS:

The HPLC was LC Waters (Waters, Milford, MA, USA), Electronic Weighing Balance (LC-GC India), pH Meter (Elico, Model LI 612), Ultrasonic bath (Enertech), Thermostatic oven (Thermolab), Micropipettes (Genie), Data Processing software (Empower 2), Photodiode array detector (Waters, model 2998), Autosampler (Waters, model 717 plus).

REAGENTS & CHEMICALS:

All the chemicals and reagents in this experiment were of analytical grade. Water was double distilled and filtered with a membrane filter. Methanol – HPLC grade (Merck, India), methanol and Acetonitrile (SD fine chem, India) were used to prepare mobile phase. Pharmaceutical grade standard drugs viz., Ertugliflozin and Sitagliptin were kindly gifted by Ajanta Pharma Ltd, Mumbai, India. The combined tablet formulation contains 15 mg of Ertugliflozin and 100mg of Sitagliptin (Steglujan, Natco).

PRELIMINARY CHARACTERIZATION OF DRUG

1 Color, odour and appearance

Sitagliptin and Ertugliflozin was evaluated for parameters like color; odour & appearance are shown in result**.**

2. Factor Calculation:

Sitagliptin phosphate factor calculations

Molecular weight of Sitagliptin phosphate: 523.32

Molecular weight of Sitagliptin: 407.314

$$Factor = \frac{Molecular\ weight\ of\ \text{Sitagliptin}}{Molecular\ weight\ of\ \text{Sitagliptin phosphate}}$$

$$Factor = \frac{407.314}{523.32}$$

Factor = 0.778

Ertugliflozin L-pyroglutamic acid factor calculations

Molecular weight of Ertugliflozin L-pyroglutamic acid: 566

Molecular weight of Ertugliflozin: 436.89

$$Factor = \frac{Molecular\ weight\ of\ \text{Ertugliflozin}}{Molecular\ weight\ of\ \text{Ertugliflozin L–pyroglutamic acid}}$$

$$Factor = \frac{436.89}{566}$$

Factor = 0.772

Determination of solubility

The solubility was determined in Water & Methanol at a concentration of 3 mg/mL as follows and is given in results**.**

Water:

Sitagliptin: Weighed approx 38.56 mg of Sitagliptin phosphate (Equivalent to 30 mg of Sitagliptin) and sonicated for 5-10 minutes to dissolve in 10 ml of Water.

Ertugliflozin: Weighed approx 38.86 mg of Ertugliflozin L-pyroglutamic acid (Equivalent to 30 mg of Ertugliflozin) and sonicated for 5-10 minutes to dissolve in 10 ml of Water.

Methanol:

Sitagliptin: Weighed approx 38.56 mg of Sitagliptin phosphate (Equivalent to 30 mg of Sitagliptin) and sonicated for 5-10 minutes to dissolve in 10 ml of Methanol.

Ertugliflozin: Weighed approx 38.86 mg of Ertugliflozin L-pyroglutamic acid (Equivalent to 30 mg of Ertugliflozin) and sonicated for 5-10 minutes to dissolve in 10 ml of Methanol.

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Selection of analytical wavelength

1. Selection of solvent

Methanol was selected as the solvent for dissolving Sitagliptin and Ertugliflozin.

2. Preparation of standard stock solutions

Sitagliptin: In order to prepare stock solution, weighed accurately 25.71 mg Sitagliptin phosphate (Equivalent to 20 mg of Sitagliptin) and transferred into 20 ml volumetric flask, added 15 ml of methanol and sonicated to dissolve the standard completely and diluted up to the mark with methanol (1000 PPM).

Further diluted 0.4 mL to 20 mL with methanol. (20 PPM)

Ertugliflozin: In order to prepare stock solution, weighed accurately 25.91 mg Ertugliflozin L-pyroglutamic acid (Equivalent to 20 mg of Ertugliflozin) and transferred into 20 ml volumetric flask, added 15 ml of methanol and sonicated to dissolve the standard completely and diluted up to the mark with methanol (1000 PPM).

Further diluted 0.4 mL to 20 mL with methanol. (20 PPM)

Selection of analytical wavelength

Methanol as a blank and Sitagliptin and Ertugliflozin standard solution (20 PPM each) was scanned from 400 nm to 200 nm. Absorption maxima were determined for both drugs. Sitagliptin and Ertugliflozin showed Q-point at 212 nm shown in results.

METHOD DEVELOPMENT BY RP – HPLC:

Sitagliptin: In order to prepare stock solution, weighed accurately 12.85 mg Sitagliptin phosphate (Equivalent to 10 mg of Sitagliptin) and transferred into 20 ml volumetric flask, added 15 ml of methanol and sonicated to dissolve the standard completely and diluted up to the mark with methanol (500 PPM).

Further diluted 2 mL to 10 mL with Mobile phase (100 PPM). It was prepared in mobile phase of each trial and injected in development trials.

Ertugliflozin: In order to prepare stock solution, weighed accurately 12.95 mg Ertugliflozin L-pyroglutamic acid (Equivalent to 10 mg of Ertugliflozin) and transferred into 20 ml volumetric flask, added 15 ml of methanol and sonicated to dissolve the standard completely and diluted up to the mark with methanol (500 PPM).

Further diluted 2 mL to 10 mL with Mobile phase (100 PPM). It was prepared in mobile phase of each trial and injected in development trials.

Selection of analytical wavelength for HPLC method development: Analytical wavelength for the examination was selected from the Q-point from the spectrophotometric analysis and it was 212 nm**.**

Preparation of System suitability stock solutions:

Sitagliptin: Weighed 25.71 mg Sitagliptin phosphate (Equivalent to 20 mg of Sitagliptin) and transferred in 20 mL volumetric flask, added 15 mL of methanol, sonicated to dissolve it, made volume up to the mark with methanol. (1000 PPM)

Ertugliflozin: Weighed 12.95 mg Ertugliflozin L-pyroglutamic acid (Equivalent to 10 mg of Ertugliflozin) and transferred in 20 mL volumetric flask, added 15 mL of methanol, sonicated to dissolve it, made volume up to the mark with methanol. (500 PPM)

System suitability standard mixture solution:

Pipette out 2.0 mL of Sitagliptin standard stock solution and 0.6 mL of Ertugliflozin standard stock solution and transferred in 20 mL volumetric flask, made volume up to the mark with mobile phase.

(Sitagliptin = 100 ppm)

(Ertugliflozin = 15 ppm)

100 PPM of Sitagliptin and 15 PPM of Ertugliflozin are the working concentration.

Marketed formulation contains Ertugliflozin (15 mg) and Sitagliptin (100 mg) in the ratio of 1:6.67; hence concentration is selected in this ratio.

System suitability is a Pharmacopoeial requirement and is used to verify, whether the chromatographic system is adequate for analysis to be done. The tests were performed by collecting data from five replicate injection of standard drug solution and the results are recorded.

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Acceptance criteria

1. RSD should not be more than 2.0 % for five replicate injections of standard.

2. USP Tailing Factor/ Asymmetry Factor is not more than 2.0.

3. The column efficiency as determined for Plate Count should be more than 2000.

VALIDATION OF RP-HPLC METHOD

The developed method for estimation of Ertugliflozin and Sitagliptin was validated as per ICH guidelines for following parameters.

1) FILTRATION STUDY:

Filtration study of an analytical procedure checks the interference of extraneous components from filter, deposition on filter bed and compatibility of filter with sample.

This study was conducted with Test sample solution. (Steglujan Tablet solution)

Filtration study carried out with unfiltered (Centrifuged at 3000 RPM for 5 minutes) and filtered test solution. During filtration activity 0.45 µm PVDF and 0.45 µm Nylon syringe filters used by discarding 5 mL of aliquot sample.

2) SPECIFICITY:

Specificity is the ability to access unequivocally the analytes in the presence of components which may be expected to be present.

Following solution shall be prepared and injected to prove the specificity nature of the method.

I. Blank (Mobile phase)

II. Placebo

Analyzing marketed test sample contains excipients (additives) which are totally

Unknown. So Placebo prepared at lab level by using formula as follows:

Total 10 gm of placebo prepared:

Sr. No.	Ingredients	Role	Qty (mg)
1	Lactose	Filler	80
2	Starch	Binder	5
3	Magnesium stearate	Lubricant	5
4	Talc	Glidant	5
5	crospovidone	Disintegrants	5
Total			100 mg

Placebo Sample solution preparation:

Weighed 337.64 mg of placebo material (Which is equivalent to 100 mg of Sitagliptin and 15 mg of Ertugliflozin) and transferred to clean and dried 100 mL of volumetric flask. Added 70 mL of methanol, sonicated for 15 minutes with intermittent shaking. After 15 minutes allow to cool the solution to room temperature and made volume up to the mark with methanol. Filtered the solution through suitable 0.45 µ syringe filter discarding 3-5 mL of initial filtrate. Further dilute 2.0 ml of filtered stock solution to 20 ml with mobile phase, injected the resultant solution and chromatograms were recorded.

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3) LINEARITY AND RANGE :

Preparation of linearity solution

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 analytes in the sample.

5 levels of Linearity was performed from 10% to 150% of working concentration

Linearity stock solutions:

Sitagliptin: Weighed 64.27 mg Sitagliptin phosphate (Equivalent to 50 mg of Sitagliptin) and transferred in 50 mL volumetric flask, added 35 mL of methanol, sonicated to dissolve it completely, made volume up to the mark with methanol. (1000 PPM)

Ertugliflozin: Weighed 19.43 mg Ertugliflozin L-pyroglutamic acid (Equivalent to 15 mg of Ertugliflozin) and transferred in 100 mL volumetric flask, added 70 mL of methanol, sonicated to dissolve it completely, made volume up to the mark with methanol. (150 PPM)

Linearity levels prepared as follows:

Level	Sitagliptin Stock solution (mL)	Ertugliflozin Stock solution (mL)	Diluted to with Mobile phase	Sitagliptin Conc (µg/mL)	Ertugliflozin Conc (µg/mL)
10%	0.2	0.2	20	10.0	1.50
50%	1.0	1.0	20	50.0	7.50
100%	2.0	2.0	20	100.0	15.00
125%	2.5	2.5	20	125.0	18.75
150%	3.0	3.0	20	150.0	22.50

Determination

Each level injected in triplicate and mean area calculated. Calibration curve was plotted graphically as a function of analytes concentration in µg/mL on X-axis Vs mean area on y-Axis as given in results.

Acceptance criteria

Correlation Coefficient: NLT 0.98

Intercept: To be report

Slope: To be report

4) Limit of Detection (LOD) and Limit of Quantitation (LOQ):

Detection limit:

The detection limit of an individual analytical procedure is the lowest amount of analytes in a sample which can be detected but not necessarily quantitated as an exact value.

Quantitation limit:

The quantitation limit of an individual analytical procedure is the lowest amount of analytes in a sample which can be quantitatively determined with suitable precision and accuracy.

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As per ICH Q2R1 guidelines LOD and LOQ was determined by using the approach Based on the Calibration Curve in which residual standard deviation of a regression line was calculated and determined the LOD and LOQ by using following formula:

LOD = 3.3 σ / S

LOQ = 10 σ / S

Where,

σ = residual standard deviation of a regression line

S = Slope of regression line

5) ACCURACY (% RECOVERY):

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

Accuracy will be conducted in the range from 50 % to 150 % of working concentration. Solution of each accuracy level was prepared in triplicate. Calculated % Recovery for each sample, Mean % recovery for each level and overall recovery and also calculated % RSD for each level and % RSD for overall recovery.

Accuracy levels details:

Refer Following table for each sample:

Level (%)	Sitagliptin Phosphate API (mg)	Ertugliflozin L-pyroglutamic acid API (mg)	Wt of Placebo (mg)	Diluted to (mL)	Volume taken (mL)	Diluted to (mL)	Sitagliptin Added Conc (µg/mL)	Ertugliflozin Added Conc (µg/mL)
50	64.30	9.90	337.7	100	2.00	20	50.03	7.64
	64.60	9.80	337.9	100	2.00	20	50.26	7.57
	64.40	9.80	337.5	100	2.00	20	50.10	7.57
100	128.7	19.7	337.8	100	2.00	20	100.13	15.21
	128.9	19.6	337.4	100	2.00	20	100.28	15.13
	128.8	19.5	337.9	100	2.00	20	100.21	15.05
150	192.90	29.40	337.7	100	2.00	20	150.08	22.70
	193.20	29.20	338.1	100	2.00	20	150.31	22.54
	193.10	29.30	337.6	100	2.00	20	150.23	22.62

Procedure for preparation of Accuracy sample solution:

Take clean and dried 9 volumetric flasks of 100 mL. Weighed aprrox 337.64 mg of placebo and transferred in each 100 mL volumetric flask. Weighed Sitagliptin phosphate and Ertugliflozin L-pyroglutamic acid API as per accuracy level and transferred in same 100 ml volumetric flask. Added 70 mL of methanol and sonicated it for 15 minutes with intermittent shaking. Made the volume up to the mark with methanol. Filter the solution through 0.45 µ Nylon filter syringe filter discarding 3-5 mL of filtrate. Further dilute 2.0 ml of filtrate to 20 ml with mobile phase.

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Acceptance criteria

1. % Recovery for each sample and Mean recovery and overall recovery should be in the range of 98-102%.

2. The Relative Standard Deviation should not be more than 2.0%.

6) PRECISION:

Precision of an analytical procedure expresses the closeness of agreement between a series of measurements obtained from multiple sampling of the same homogeneous test under the prescribed conditions. Precision is of two types, Repeatability and Intermediate precision. It is performed on tablet test sample.

I.Repeatability:

Preparation of sample solution (6 Samples prepared):

Weighed 20 tablets transferred in mortar pestle and crushed to fine powder. Mixed the contents with butter paper uniformly. Weighed the powder material equivalent to 100 mg of Sitagliptin and 15 mg of Ertugliflozin (485.6 mg of powder material). Transfer it in a clean and dried 100 mL of volumetric flask; added 70 ml of methanol sonicated it for 15 minutes with intermittent shaking. Made the volume up to the mark with methanol. Filter the solution through suitable 0.45 µ syringe filter discarding 3-5 mL of filtrate. Further diluted 2.0 ml of filtrate to 20 ml with mobile phase. (100 PPM of Sitagliptin and 15 PPM of Ertugliflozin)

Six samples prepared.

Precision (Repeatability) Sample details are as follows:

Sample No.	Test powder material (mg)	Diluted to (mL)	Volume taken (mL)	Diluted to (mL)
1	486.2	100	2	20
2	485.8	100	2	20
3	485.6	100	2	20
4	486.1	100	2	20
5	485.3	100	2	20
6	485.5	100	2	20

Acceptance criteria:

% Assay: 90-110% for each sample and mean assay value

% RSD for % assay value of 6 samples: NMT 2%

II.Intermediate precision

It is performed by doing analysis on another day to check reproducibility of results. Samples prepared in same manner as that of Repeatability parameter (6 Samples prepared).

Intermediate Precision Sample details are as follows:

Sample No.	Test powder material (mg)	Diluted to (mL)	Volume taken (mL)	Diluted to (mL)
1	485.7	100	2	20
2	485.3	100	2	20
3	485.9	100	2	20

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4	485.7	100	2	20
5	486.1	100	2	20
6	485.5	100	2	20

Acceptance criteria:

% Assay: 90-110% for each sample and mean assay value

% RSD for % assay of 6 samples of Intermediate precision**:** NMT 2

% RSD for Total 12 samples: NMT 2% for test results (6 of Repeatability and 6 of Intermediate precision)

7) 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.

Determination: Standard solution was injected under different chromatographic conditions as shown below. a) Changes in flow rate by ±10%. (± 0.1ml/min) b) Change in column oven temperature. (± 2ºC). c) Change in wavelength (± 3 nm)

RESULT AND DISCUSSION

PRELIMINARY CHARACTERIZATION AND IDENTIFICATION OF DRUG

1. Color, odour and appearance

Color, odour and appearance of Drug

Sr. No	Name	Colour, odour and appearance of drug
1	Sitagliptin Phosphate	White, odourless and Crystalline powder
2	Ertugliflozin L-pyroglutamic acid	White, odourless and Crystalline powder

2. Solubility study

Solubility study of Sitagliptin and Ertugliflozin in Water

Sr. No.	Name of Drug	Observation	Conclusion	Summary
1	Sitagliptin	No Drug Particles seen after sonication	Drug was found soluble in water.	Ertugliflozin not soluble in water hence water cannot used as solvent
2	Ertugliflozin	Particles seen after sonication	Drug was not found soluble in water.	

Solubility study of Sitagliptin and Ertugliflozin in Methanol

Sr. No.	Name of Drug	Observation	Conclusion	Summary
1	Sitagliptin	No Drug Particles	Drug was found soluble	Both Drugs was found soluble

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		seen after sonication	in Methanol.	in Methanol.
2	Ertugliflozin	No Drug Particles seen after sonication	Drug was found soluble in Methanol.	

Selection of solvent

Methanol was selected as the solvent for dissolving Sitagliptin and Ertugliflozin.

Selection of analytical wavelength

1) Blank Methanol:

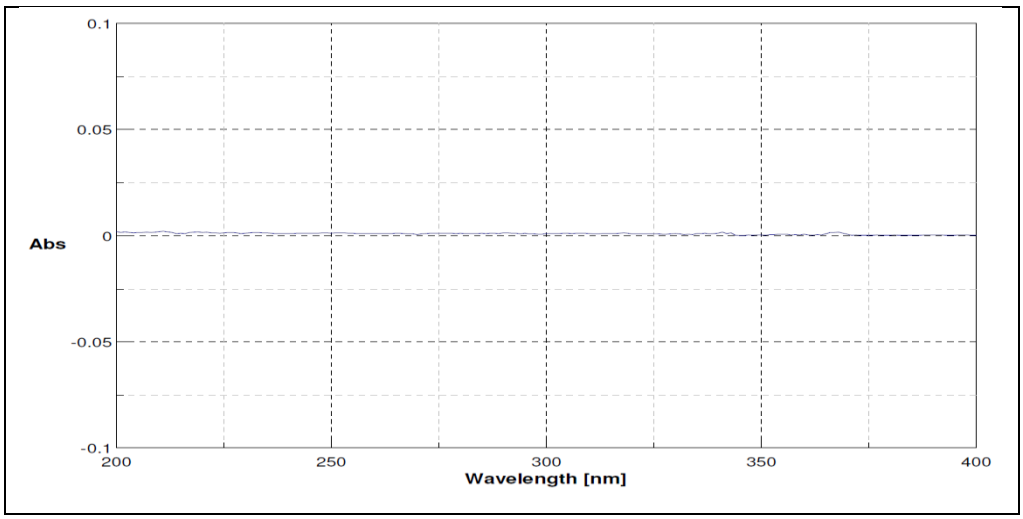

Fig. No. 1 UV spectrum of Methanol as a blank

2) Sitagliptin STD solution: (20 PPM)

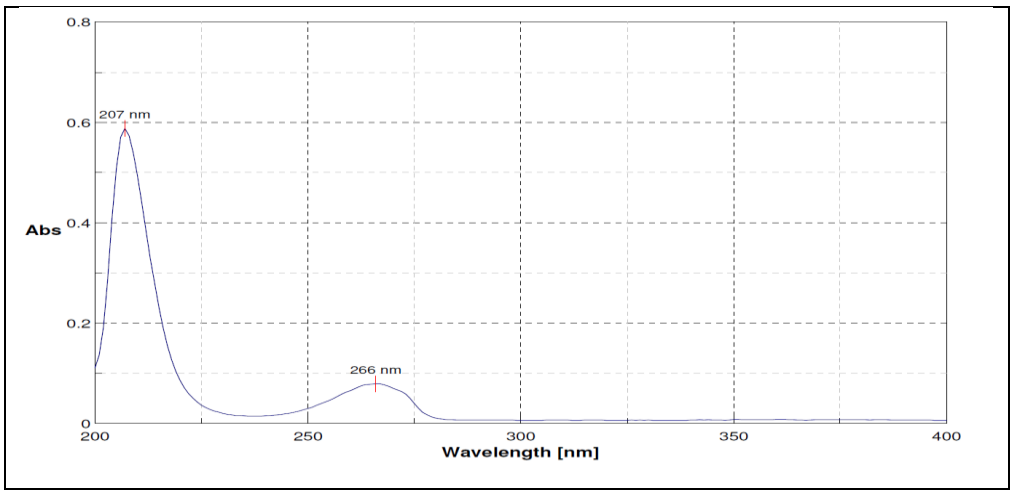

Fig. No. 2 UV spectrum of Sitagliptin

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3) Ertugliflozin STD solution: (20 PPM)

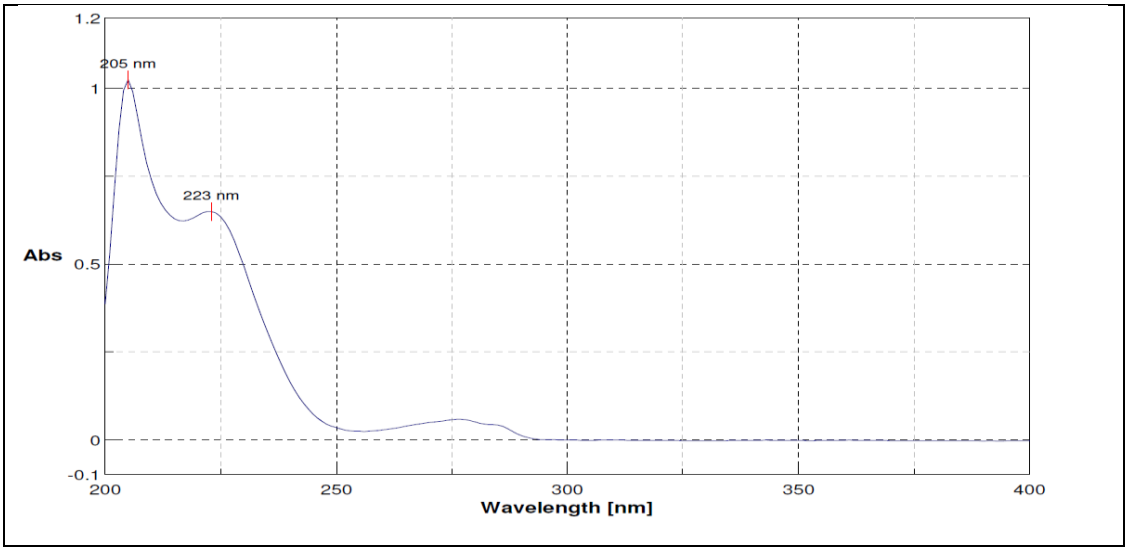

Fig. No. 3 UV spectrum of Ertugliflozin

4) Overlay plot: (Each 20 PPM)

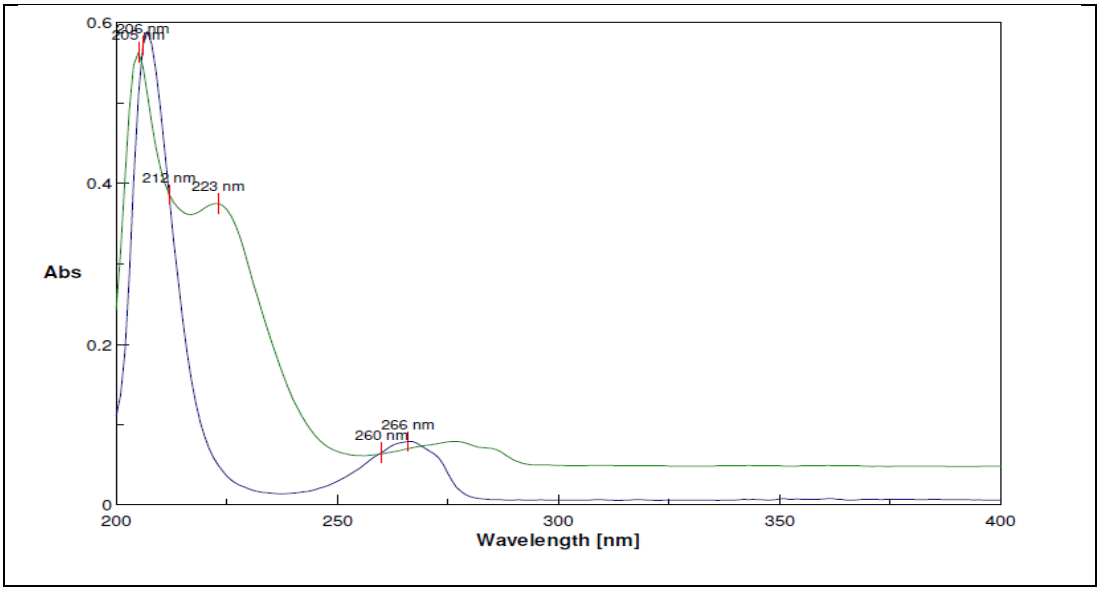

Fig. No. 4 Overlay UV spectrum of Sitagliptin & Ertugliflozin

Observation: Both standard solutions were scanned between 200 nm to 400 nm. Q-absorption point was determined for both drugs. It is shown in **Figure No.4**. 212 nm found as Q-absorption point.

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Method Development by RP – HPLC

Chromatogram:

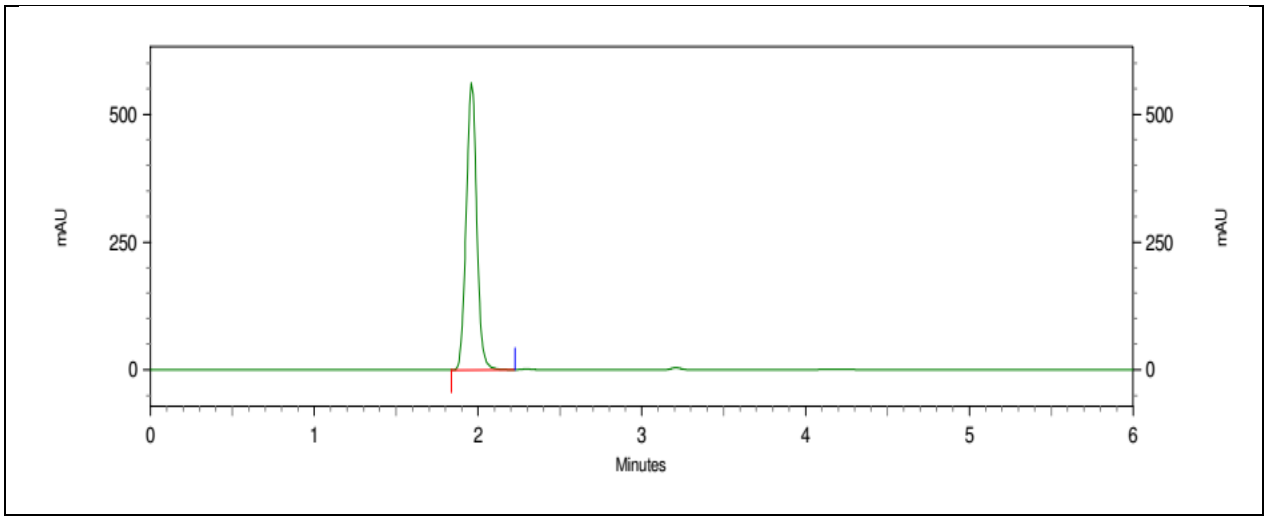

Fig. No. 5 Typical chromatogram of Sitagliptin

Chromatogram:

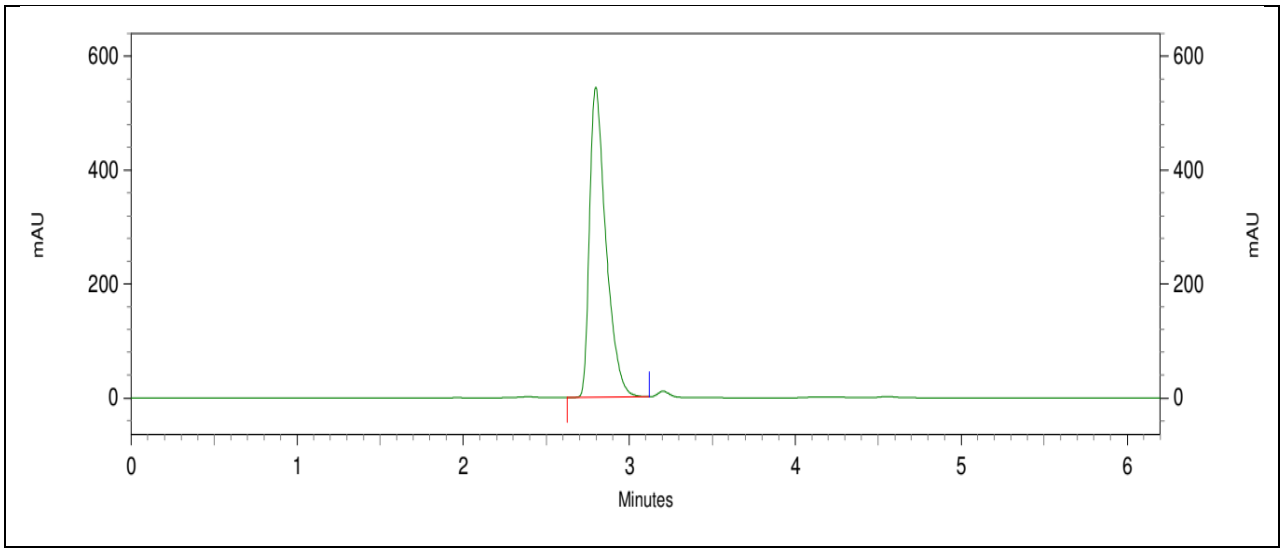

Fig. No. 6 Typical chromatogram of Ertugliflozin

Observation: Both drugs eluted with good chromatography.

Conclusion: Method Accepted.

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Mixture (Sitagliptin 100 PPM & Ertugliflozin 100 PPM).

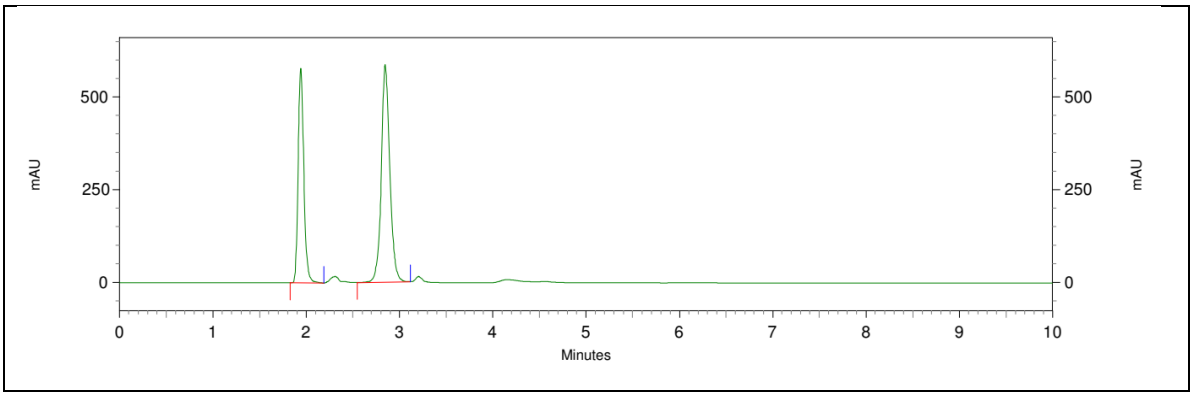

Fig. No. 7 Typical chromatogram of Mixture (Sitagliptin and Ertugliflozin)

Observation: Both drugs eluted with good chromatography with good resolution.

Conclusion: From the observations of trials first to four, it was concluded that chromatographic conditions in trial four gives better peak, good retention time, good tailing factor, Theoretical plates and good resolution therefore chromatographic conditions in trial four was subjected for method validation

Optimized Chromatographic Conditions

Parameter	**Description**
Mode	Isocratic
Detector	UV Detector
Column Name	Agilent Poroshell C18**,** 150 mm X 4.6mm ID, 5 µm
Column Oven temp	35ºC
Injection Volume	20 µl
Wavelength	212 nm
Mobile Phase	Acetonitrile : 0.1% TFAA in water (60:40)
Flow Rate	1.0 ml/min
Diluents	Mobile phase
Run time	6 Minutes

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System suitability test

Results for System Suitability Test of Sitagliptin:

Sr No.	Standard solution	Area	Asymmetry	Theoretical plates
1	Standard_1	35842173	1.12	5645
2	Standard_2	35420540	1.11	5671
3	Standard_3	35860253	1.12	5658
4	Standard_4	35711049	1.12	5662
5	Standard_5	35671005	1.11	5654
Mean		**35701004**	**1.12**	**5658**
STD Dev		**176741.21469**		
% RSD		**0.50**		

Results for System Suitability Test of Ertugliflozin:

Sr No.	Standard solution	Area	Asymmetry	Theoretical plates
1	Standard_1	6845032	1.35	6632
2	Standard_2	6834692	1.35	6647
3	Standard_3	6856024	1.36	6621
4	Standard_4	6828145	1.35	6653
5	Standard_5	6882691	1.34	6649
Mean		**6849317**	**1.35**	**6640**
STD Dev		**21443.60720**		
% RSD		**0.31**		

System Suitability Acceptance Criteria:

1. Relative standard deviation of the area of analytes peaks in standard chromatograms should not be more than 2.0 %.

2. Theoretical plates of analytes peak in standard chromatograms should not be less than 2000.

3. Tailing Factor (Asymmetry) of analytes peaks in Standard Chromatograms should be less than 2.0

Data interpretation: It was observed from the data tabulated above; the method complies with system suitability parameters. Hence, it can be concluded that the chromatographic method is adequate for intended analysis.

VALIDATION OF RP-HPLC METHOD

1) FILTRATION STUDY:

Filtration study of an analytical procedure checks the interference of extraneous components from filter,

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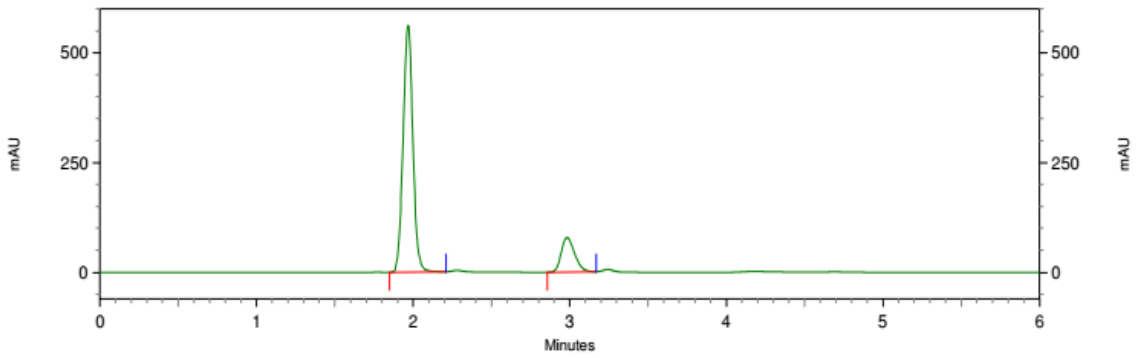
deposition on filter bed and compatibility of filter with sample. Performed on tablet test sample.

Results of Filter study for Steglujan Tablet:

Drug	Sample description	Area	% Absolute difference
Sitagliptin	**Unfiltered**	35392503	NA
	0.45 µ PVDF filter	35109047	0.80
	0.45 µ Nylon filter	35260391	0.37
Ertugliflozin	**Unfiltered**	6789201	NA
	0.45 µ PVDF filter	6725692	0.94
	0.45 µ Nylon filter	6742008	0.70

Chromatograms:

Sample Name: SAMPLE SOLUTION_UNFILTERED



VWD: Signal A, 212 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical plates (USP)
Sitagliptin	1.96	35392503	1.13	5687
Ertugliflozin	2.97	6789201	1.37	6671
Totals		42181704		

Fig. No. 8 Typical chromatogram of unfiltered sample.

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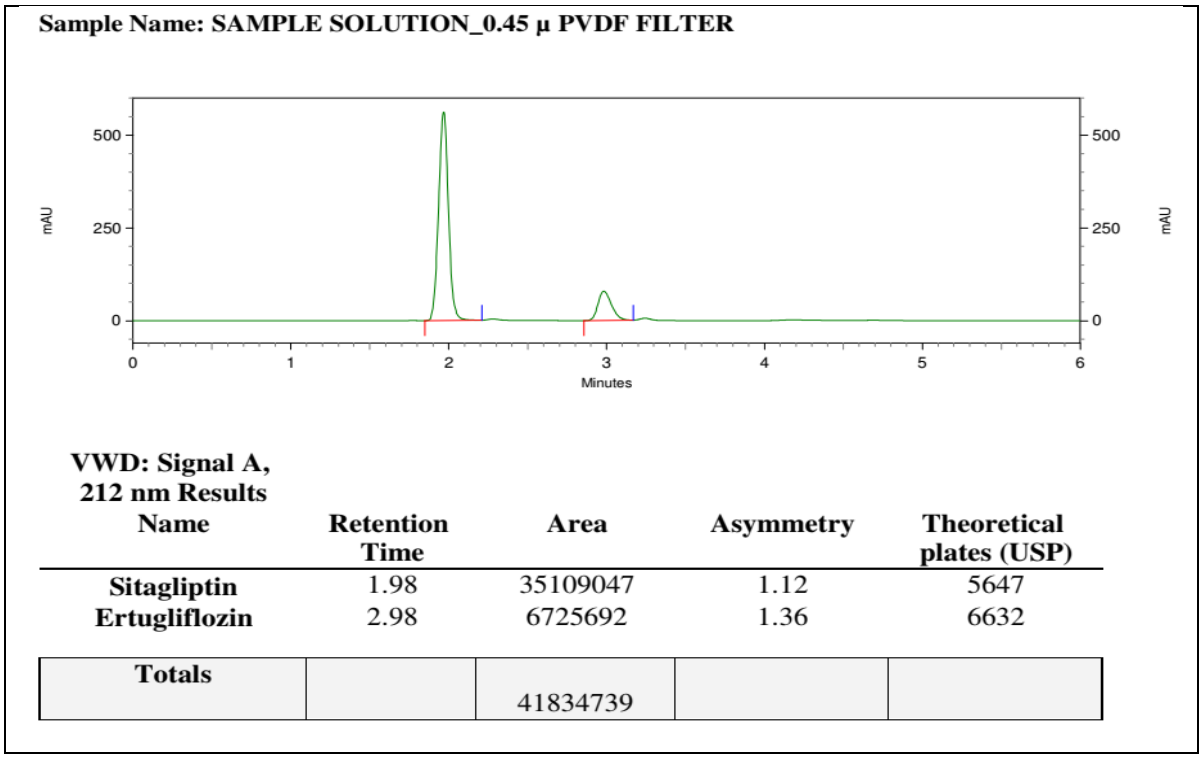
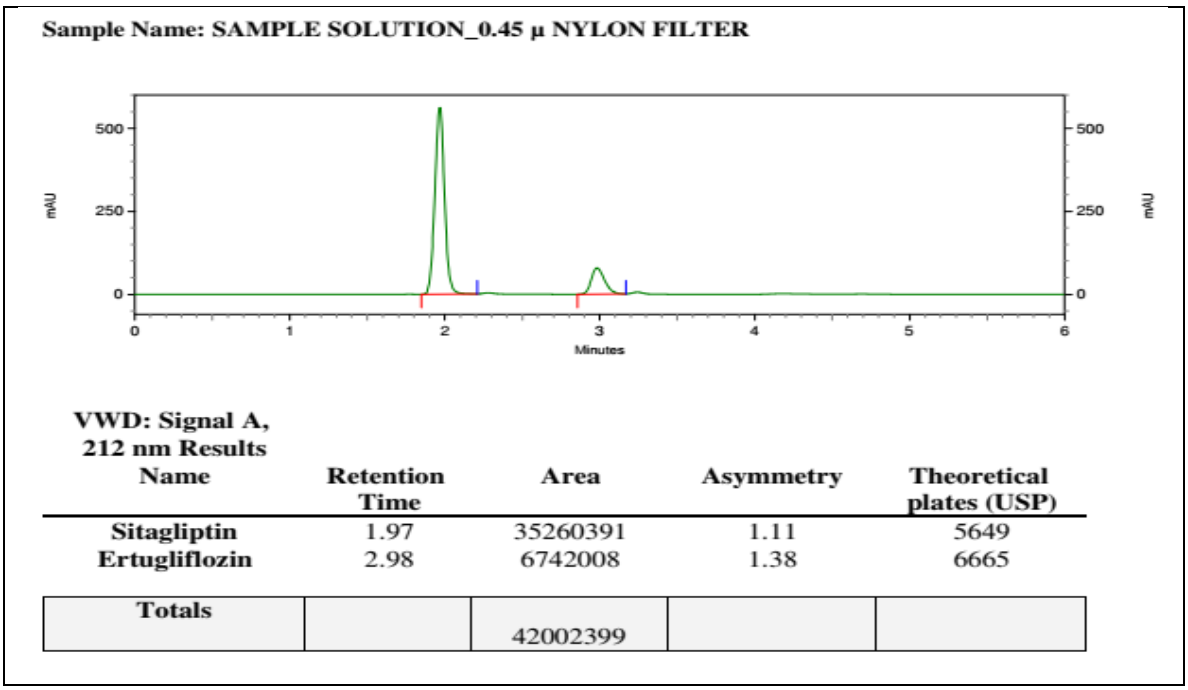


VWD: Signal A, 212 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical plates (USP)
Sitagliptin	1.98	35109047	1.12	5647
Ertugliflozin	2.98	6725692	1.36	6632
Totals		41834739		

Fig. No. 9 Typical chromatogram of sample filtered through 0.45µ PVDF filter.



VWD: Signal A, 212 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical plates (USP)
Sitagliptin	1.97	35260391	1.11	5649
Ertugliflozin	2.98	6742008	1.38	6665
Totals		42002399		

Fig. No. 10 Typical chromatogram of sample filtered through 0.45µ Nylon filter.

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Acceptance criteria: % Absolute difference of filtered samples NMT 2.0 w.r.t. Unfiltered sample.

Data interpretation: Both filters PVDF and Nylon passes the criteria for filter study; hence both filters can be used. We used Nylon filter because it showed less absolute difference as compare to PVDF filter for both drugs.

2) SPECIFICITY: Specificity is the ability to access unequivocally the analytes in the presence of components which may be expected to be present.

Blank and placebo solutions prepared and injected to check interference at R.T. of Sitagliptin and Ertugliflozin.

Results of Specificity.

Description	Observation
Blank	No interference at R.T. of Sitagliptin & Ertugliflozin due to blank
Placebo	No interference at R.T. of Sitagliptin & Ertugliflozin due to placebo

Chromatograms:

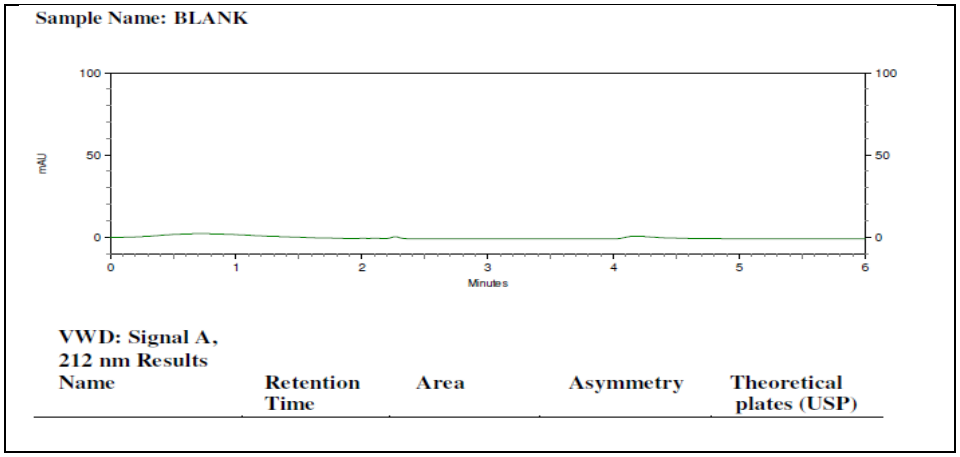

Fig. No. 11 Typical chromatogram of Blank solution.

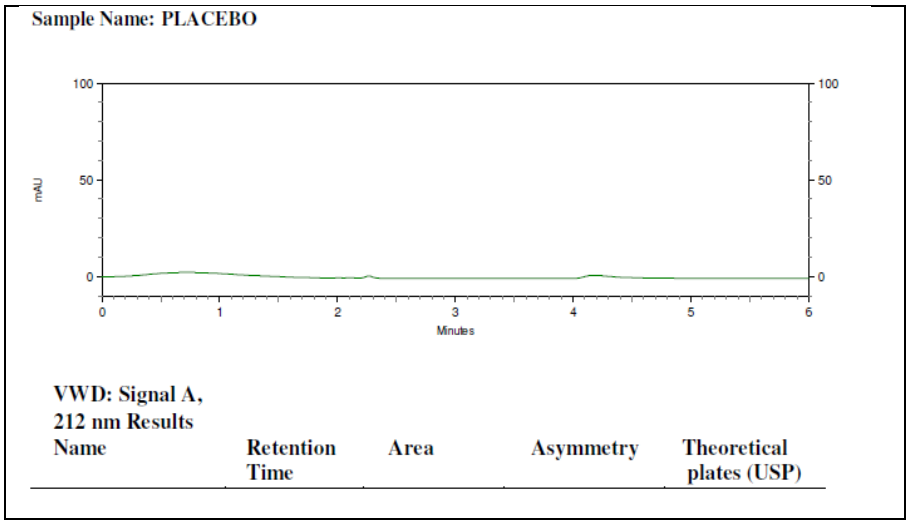

Fig. No. 12 Typical chromatogram of Placebo solution.

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Acceptance criteria:

Blank: There should be no Interference at R.T. of Sitagliptin and Ertugliflozin

Placebo: There should be no Interference at R.T. of Sitagliptin and Ertugliflozin

Data interpretation: Blank and placebo was not having interference at R.T. of Sitagliptin and Ertugliflozin. Hence developed chromatographic method passed the criteria for specificity.

3) LINEARITY AND RANGE:

Linearity of an analytical method is its ability to elicit test results that are proportional to the concentration of analytes in samples within a given range.

Linearity Data for Sitagliptin:

Level	Conc (µg/mL)	Area	Mean	% RSD
10%	10	3492830	3491936	0.157
		3486052		
		3496925		
50%	50	17411035	17397467	0.184
		17420460		
		17360907		
100%	100	35622070	35573846	0.164
		35509214		
		35590253		
125%	125	44421538	44336123	0.187
		44256351		
		44330480		
150%	150	53563005	53554215	0.204
		53659014		
		53440625		

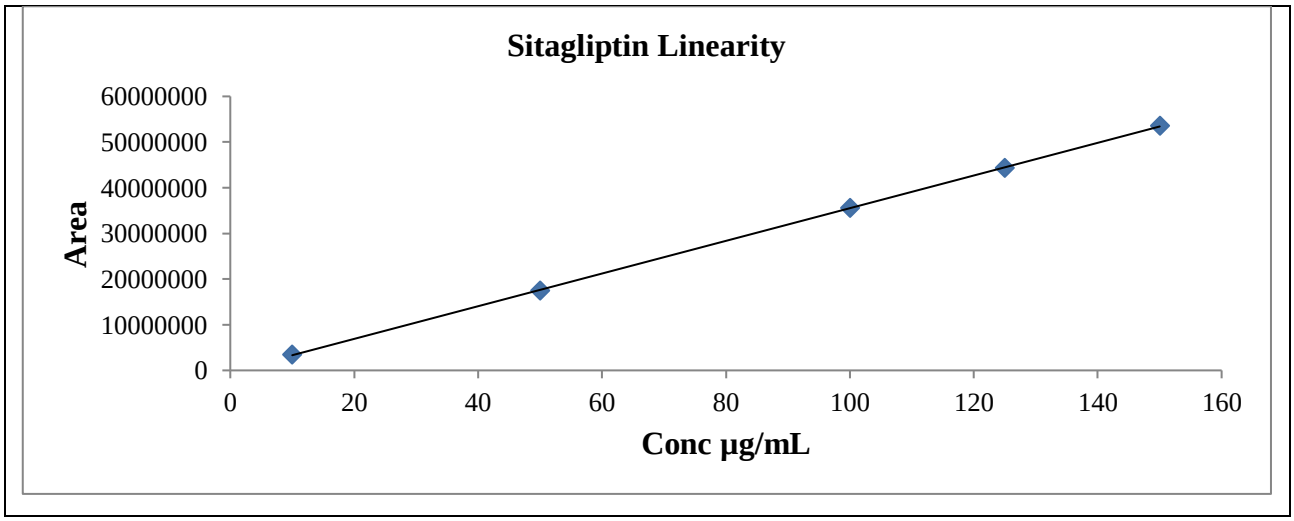

Fig. No. 13 Calibration curve of Sitagliptin

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Data of linearity of Sitagliptin:

Sr no.	Parameter	Result value	Acceptance criteria
1	Beer's linearity range	10.0 – 150.0 µg/mL	NA
2	Correlation coefficient (R^2)	0.99996	NLT 0.98
3	Intercept	-257541.278	To be report
4	Slope	357779.627	To be report
5	% RSD for area at each level	NA	NMT 2.0

The respective linear equation for Sitagliptin was

Y = M X + C

Y = 357779.627 x + -257541.278

Where, x = concentration of Analytes in µg/mL

Y = is area of peak.

M = Slope

C= Intercept

Linearity Data for Ertugliflozin:

Level	Conc (µg/mL)	Area	Mean	% RSD
10%	1.50	677409 675869 678701	677326	0.209
50%	7.50	3461037 3449691 3459200	3456643	0.176
100%	15.00	6862129 6854792 6876910	6864610	0.164
125%	18.75	8529047 8548281 8547183	8541504	0.126
150%	22.50	10303107 10313603 10336920	10317877	0.168

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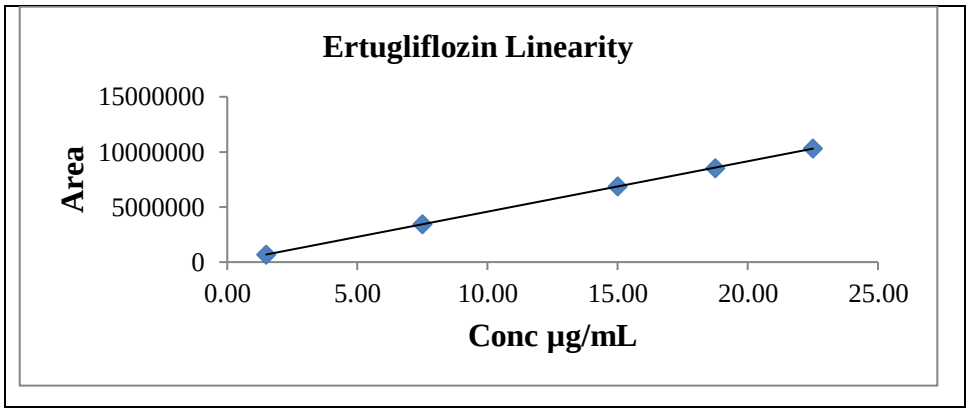

Fig. No. 14 Calibration curve of Ertugliflozin

Data of linearity of Ertugliflozin:

Sr no.	Parameter	Result value	Acceptance criteria
1	Beer's linearity range	1.50 - 22.50 µg/mL	NA
2	Correlation coefficient (R^2)	0.99998	NLT 0.98
3	Intercept	1869.230	To be report
4	Slope	457450.021	To be report
5	% RSD for area at each level	NA	NMT 2.0

The respective linear equation for Ertugliflozin was

Y = M X + C

Y = 457450.021 x + 1869.230

Where, x = concentration of Analytes in µg/mL

Y = is area of peak.

M = Slope

C= Intercept

Chromatograms:

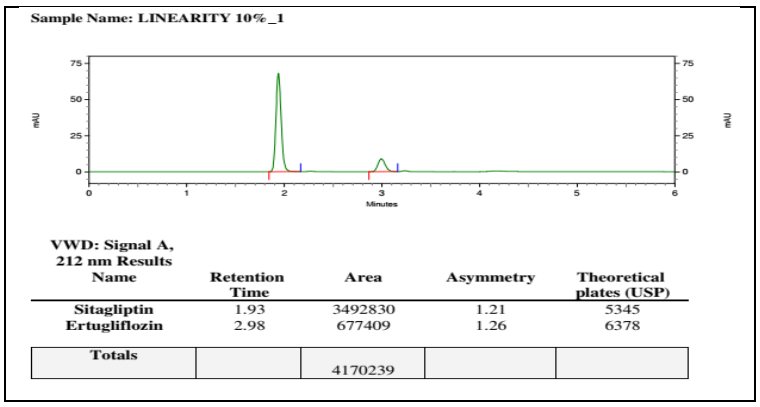

Fig. No. 15 Typical chromatogram of Linearity 10%.

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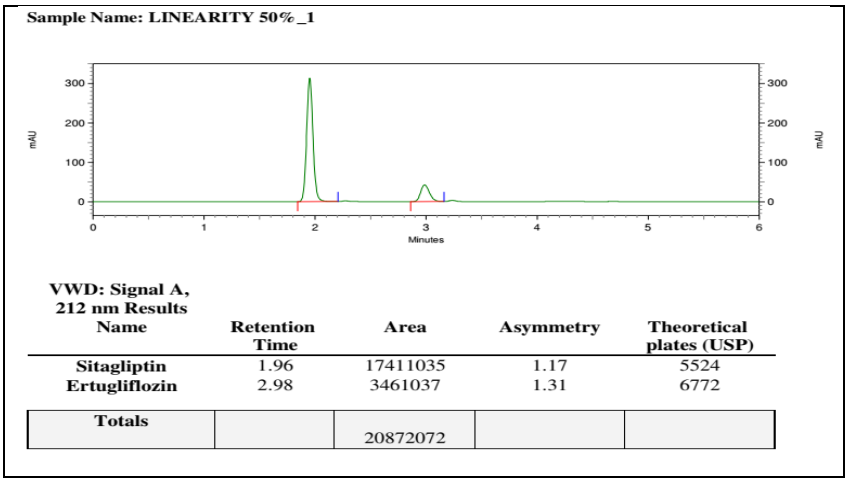
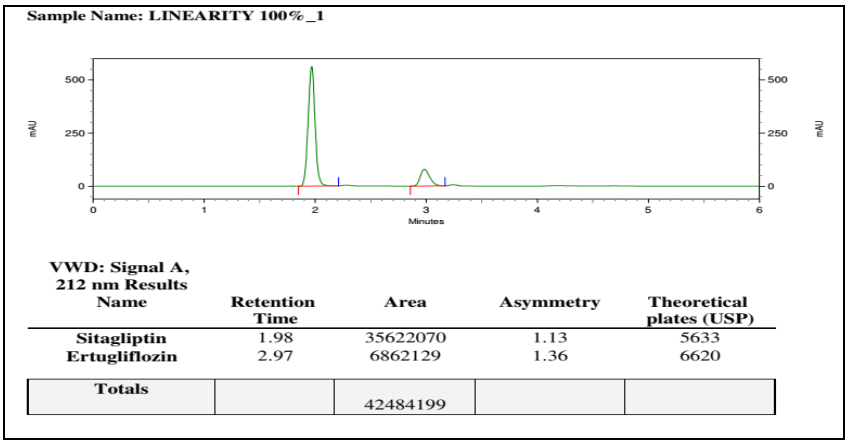


VWD: Signal A, 212 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical plates (USP)
Sitagliptin	1.96	17411035	1.17	5524
Ertugliflozin	2.98	3461037	1.31	6772
Totals		20872072		

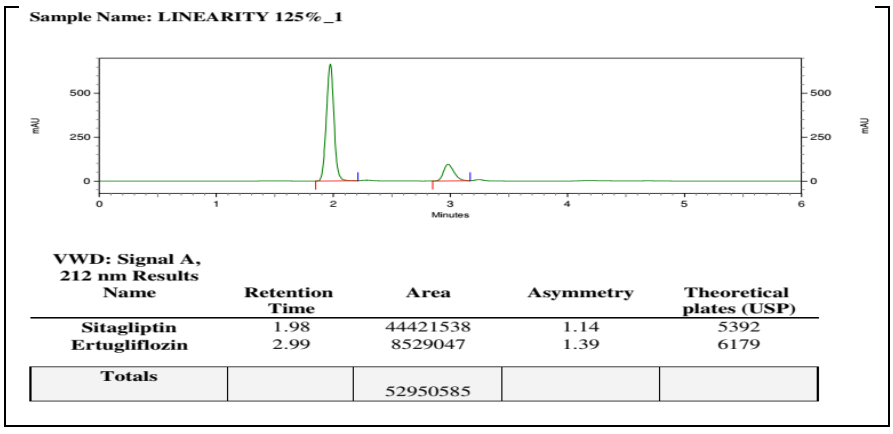
Fig. No. 16 Typical chromatogram of Linearity 50%.



VWD: Signal A, 212 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical plates (USP)
Sitagliptin	1.98	35622070	1.13	5633
Ertugliflozin	2.97	6862129	1.36	6620
Totals		42484199		

Fig. No. 17 Typical chromatogram of Linearity 100%.



VWD: Signal A, 212 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical plates (USP)
Sitagliptin	1.98	44421538	1.14	5392
Ertugliflozin	2.99	8529047	1.39	6179
Totals		52950585		

Fig. No. 18 Typical chromatogram of Linearity 125%.

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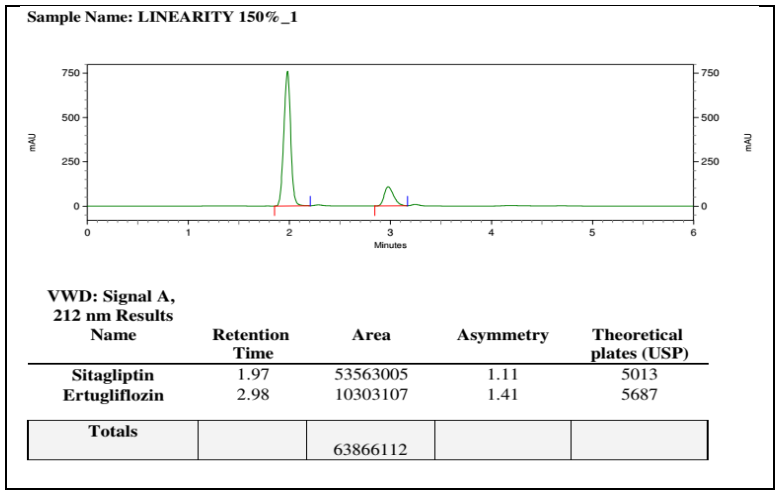

VWD: Signal A, 212 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical plates (USP)
Sitagliptin	1.97	53563005	1.11	5013
Ertugliflozin	2.98	10303107	1.41	5687
Totals		63866112		

Fig. No. 19 Typical chromatogram of Linearity 150%.

Conclusion: From the calibration curve it was concluded that the Sitagliptin and Ertugliflozin shows linear response in the proposed range. The Regression value was found well within the limit.

4) Limit of Detection (LOD) and Limit of Quantitation (LOQ):

A) LOD and LOQ for Sitagliptin:

σ = 176451.21 (Residual standard deviation of a regression line)

s = 357779.627 (Slope)

Detection limit (LOD):

LOD = 3.3 σ / S

LOD = 3.3 x 176451.21 / 357779.627

LOD = 1.628 µg/mL

Quantitations limit (LOQ):

LOQ = 10 σ / S

LOQ = 10 x 176451.21 / 357779.627

LOQ = 4.932 µg/mL

B) LOD and LOQ for Ertugliflozin:

σ = 25709.7975 (Residual standard deviation of a regression line)

s = 457450.021 (Slope)

Detection limit (LOD):

LOD = 3.3 σ / S

LOD = 3.3 x 25709.7975 / 457450.021

LOD = 0.185 µg/mL

Quantitations limit (LOQ):

LOQ = 10 σ / S

LOQ = 10 x 25709.7975 / 457450.021

LOQ = 0.562 µg/mL

Result Summary of LOD and LOQ:

Drug	LOD (µg/mL)	LOQ (µg/mL)
Sitagliptin	1.628	4.932
Ertugliflozin	0.185	0.562

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5) ACCURACY (RECOVERY):

The accuracy of an analytical method is the closeness of test results obtained by that method to the true value. The accuracy of an analytical method is determined by applying the method to analyzed samples to which known amounts of analytes have been added.

Result and statistical data of Accuracy of Sitagliptin:

Level (%)	Area	Sitagliptin Recovered conc (µg/mL)	Sitagliptin Added conc (µg/mL)	% Recovery	Mean % Recovery	% RSD
50	17650253	49.44	50.03	98.84	99.77	0.890
	18050251	50.57	50.26	100.61		
	17860492	50.03	50.10	99.86		
100	35991723	100.83	100.13	100.70	100.41	0.849
	35600472	99.73	100.28	99.45		
	36158402	101.29	100.21	101.08		
150	53431251	149.68	150.08	99.74	99.73	0.802
	53081253	148.70	150.31	98.93		
	53912421	151.03	150.23	100.53		

Overall Recovery of Sitagliptin: 99.97 %

% RSD for Overall Recovery Sitagliptin: 0.805

Result and statistical data of Accuracy of Ertugliflozin:

Level (%)	Area	Ertugliflozin Recovered conc (µg/mL)	Ertugliflozin Added Conc (µg/mL)	% Recovery	Mean % Recovery	% RSD
50	3475025	7.61	7.64	99.55	99.80	1.242
	3495217	7.65	7.57	101.15		
	3411025	7.47	7.57	98.71		
100	6895025	15.10	15.21	99.26	99.29	0.590
	6822692	14.94	15.13	98.72		
	6868014	15.04	15.05	99.89		
150	10425012	22.82	22.70	100.56	99.57	0.948

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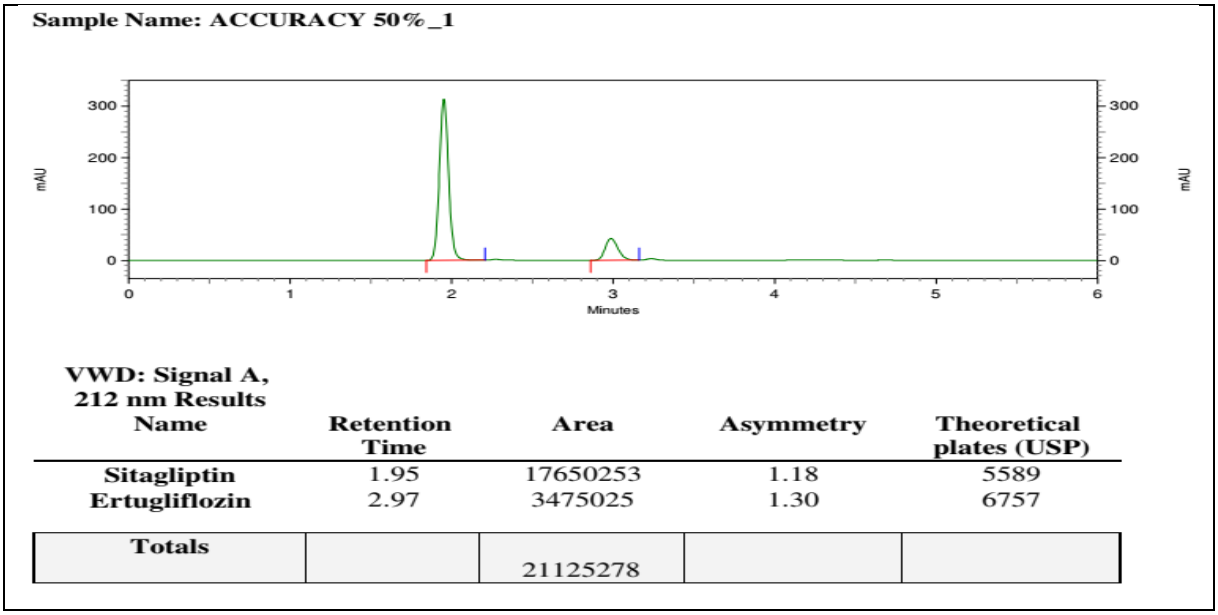
	10241975	22.42	22.54	99.48		
	10194713	22.32	22.62	98.68		

Overall Recovery of Ertugliflozin: 99.56%

% RSD for Overall Recovery Ertugliflozin: 0.865

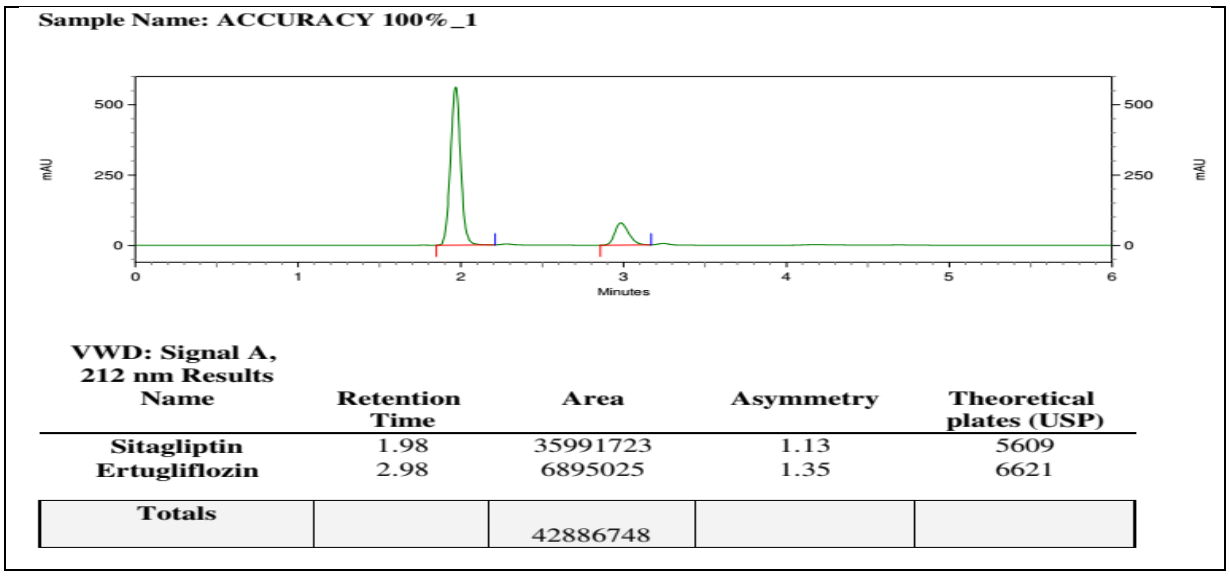
Chromatograms:



VWD: Signal A, 212 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical plates (USP)
Sitagliptin	1.95	17650253	1.18	5589
Ertugliflozin	2.97	3475025	1.30	6757
Totals		21125278		

Fig. No. 20 Typical chromatogram of Accuracy 50%.



VWD: Signal A, 212 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical plates (USP)
Sitagliptin	1.98	35991723	1.13	5609
Ertugliflozin	2.98	6895025	1.35	6621
Totals		42886748		

Fig. No. 21 Typical chromatogram of Accuracy 100%.

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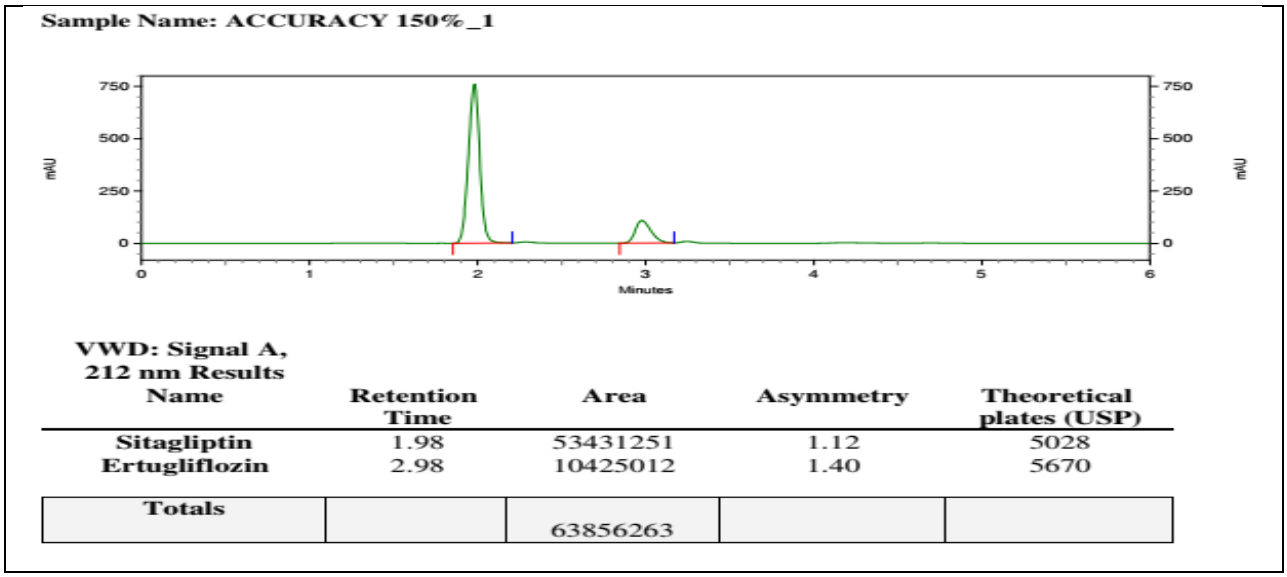

VWD: Signal A, 212 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical plates (USP)
Sitagliptin	1.98	53431251	1.12	5028
Ertugliflozin	2.98	10425012	1.40	5670
Totals		63856263		

Fig. No. 22 Typical chromatogram of Accuracy 150%.

Acceptance criteria:

% Recovery for each level and overall recovery: 98.0 to 102.0%

% RSD for each level and overall recovery: NMT 2.0

Data interpretation: Recovery of analytical procedure was found well within acceptance criteria at all 3 levels. % Recovery not gets hampered by changed in analytes concentration.

6) PRECISION

Precision of an analytical method is the degree of agreement among individual test results when the procedure is applied repeatedly to multiple samplings of a homogenous sample. Precision of an analytical method is usually expressed as standard deviation or relative standard deviation. Precision was performed on Test sample.

Result for Sitagliptin of Intra- day and Inter- Day Precision of test sample assay:

	Sample	**Test Sample (mg)**	**Area**	**% Assay**
Repeatability	Sample 1	486.2	35202145	98.49
	Sample 2	485.8	34781935	97.40
	Sample 3	485.6	34893041	97.75
	Sample 4	486.1	35479106	99.29
	Sample 5	485.3	35796100	100.34
	Sample 6	485.5	35294034	98.89
	Mean			**98.69**
	STD DEV			**1.0695**
	% RSD			**1.084**

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Intermediate precision (Inter-Day)	Sample 1	485.7	35742014	100.11
	Sample 2	485.3	35090728	98.36
	Sample 3	485.9	36099930	101.07
	Sample 4	485.7	35140301	98.42
	Sample 5	486.1	35478568	99.29
	Sample 6	485.5	34848593	97.64
	Mean			**99.15**
	STD DEV			**1.2670**
	% RSD			**1.278**
Repeatability Plus Inter-day	**Mean**			**98.921**
	STD DEV			**1.1428**
	% RSD			**1.155**

Result for Ertugliflozin of Intra- day and Inter- Day Precision of test sample assay:

	Sample	**Test Sample (mg)**	**Area**	**% Assay**
Repeatability	Sample 1	486.2	6705605	97.76
	Sample 2	485.8	6756925	98.58
	Sample 3	485.6	6791540	99.13
	Sample 4	486.1	6849218	99.87
	Sample 5	485.3	6741932	98.47
	Sample 6	485.5	6710210	97.96
	Mean			**98.63**
	STD DEV			**0.777765**
	% RSD			**0.789**
Intermediate precision (Inter-Day)	Sample 1	485.7	6744859	98.43
	Sample 2	485.3	6632563	96.87
	Sample 3	485.9	6846040	99.86
	Sample 4	485.7	6721034	98.08
	Sample 5	486.1	6833050	99.63
	Sample 6	485.5	6701309	97.83
	Mean			**98.45**

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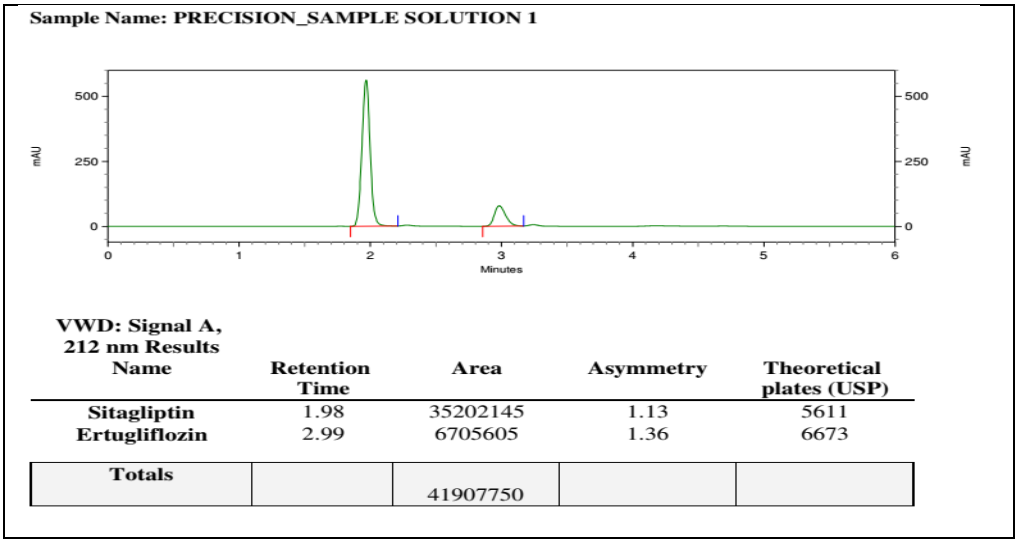
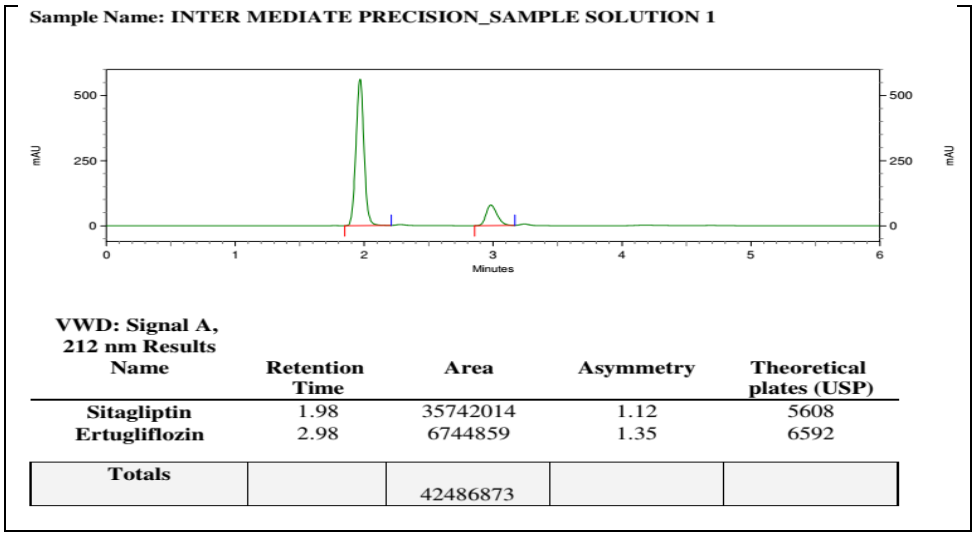
	STD DEV	**1.132675**
	% RSD	**1.151**
Repeatability Plus Inter-day	**Mean**	**98.540**
	STD DEV	**0.93093**
	% RSD	**0.945**

Chromatograms:



Name	Retention Time	Area	Asymmetry	Theoretical plates (USP)
Sitagliptin	1.98	35202145	1.13	5611
Ertugliflozin	2.99	6705605	1.36	6673
Totals		41907750		

Fig. No. 23 Typical chromatogram of Repeatability precision (Sample 1).



Name	Retention Time	Area	Asymmetry	Theoretical plates (USP)
Sitagliptin	1.98	35742014	1.12	5608
Ertugliflozin	2.98	6744859	1.35	6592
Totals		42486873		

Fig. No. 24 Typical chromatogram of Inter-day precision (Sample 1).

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Acceptance criteria:

% Assay: % Assay value for each sample (Individual sample) and mean assay value for precision (6 sample), mean assay value intermediate precision (6 sample), and mean assay value for precision plus intermediate precision sample (12 samples): 90-110%

% RSD: % RSD for precision study samples (6 sample), Intermediate precision study samples (6 samples) and precision plus intermediate precision sample (12 samples): NMT 2.0

Data interpretation: % Assay and% RSD was found well within acceptance limit and hence method is precise (Reproducible).

7) ROBUSTNESS:

The robustness of an analytical method 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.

Following changes made under Robustness:

- Change in Wavelength
- Change in flow rate
- Change in column oven temperature

Result of Robustness study:

A) Sitagliptin

Change in Parameter	R.T.	Standard area	Asymmetry	Theoretical plates
Wavelength by +3 NM (215 NM)	1.98	19503691	1.12	5786
Wavelength by -3 NM (209 NM)	1.98	51391070	1.14	5728
Flow rate by +10% (1.10 mL/min)	1.80	31250638	1.11	5523
Flow rate by -10% (0.90 mL/min)	2.21	39081250	1.13	5906
Column oven temp by +2ºC (37 ºC)	1.99	35497063	1.14	5762
Column oven temp by -2ºC (33 ºC)	1.98	35269910	1.12	5628

B) Ertugliflozin

Change in Parameter	R.T.	Standard area	Asymmetry	Theoretical plates
Wavelength by +3 NM (215 NM)	2.98	7329480	1.38	6706
Wavelength by -3 NM (209 NM)	2.98	6402035	1.37	6665
Flow rate by +10% (1.10 mL/min)	2.72	6140256	1.32	6396
Flow rate by -10% (0.90 mL/min)	3.32	7780690	1.37	7012
Column oven temp by +2ºC (32 ºC)	2.97	6823917	1.35	6596
Column oven temp by -2ºC (28 ºC)	2.98	6815071	1.38	6737

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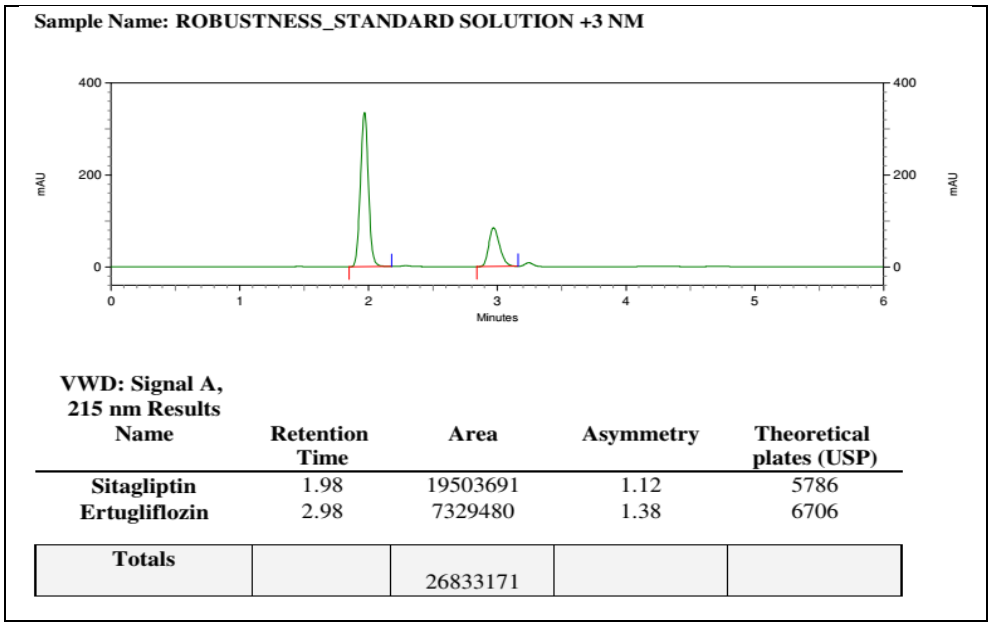
Chromatograms:

A. Change in Wavelength by +3 NM:

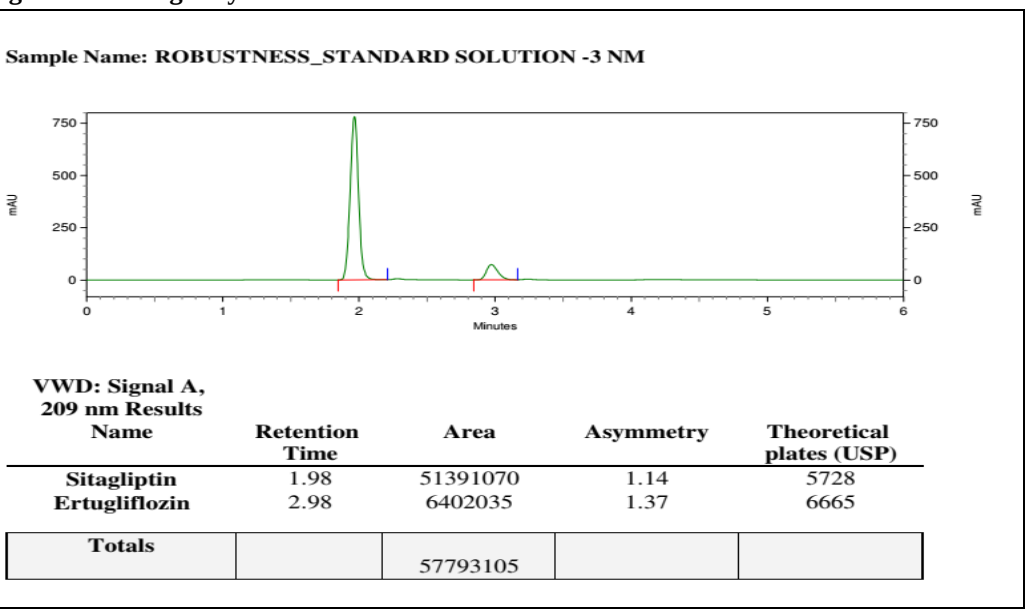


VWD: Signal A, 215 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical plates (USP)
Sitagliptin	1.98	19503691	1.12	5786
Ertugliflozin	2.98	7329480	1.38	6706
Totals		26833171		

Fig. No. 25 Typical chromatogram of Standard +3 NM.

B. Change in Wavelength by -3 NM:



VWD: Signal A, 209 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical plates (USP)
Sitagliptin	1.98	51391070	1.14	5728
Ertugliflozin	2.98	6402035	1.37	6665
Totals		57793105		

Fig. No. 26 Typical chromatogram of Standard -3 NM.

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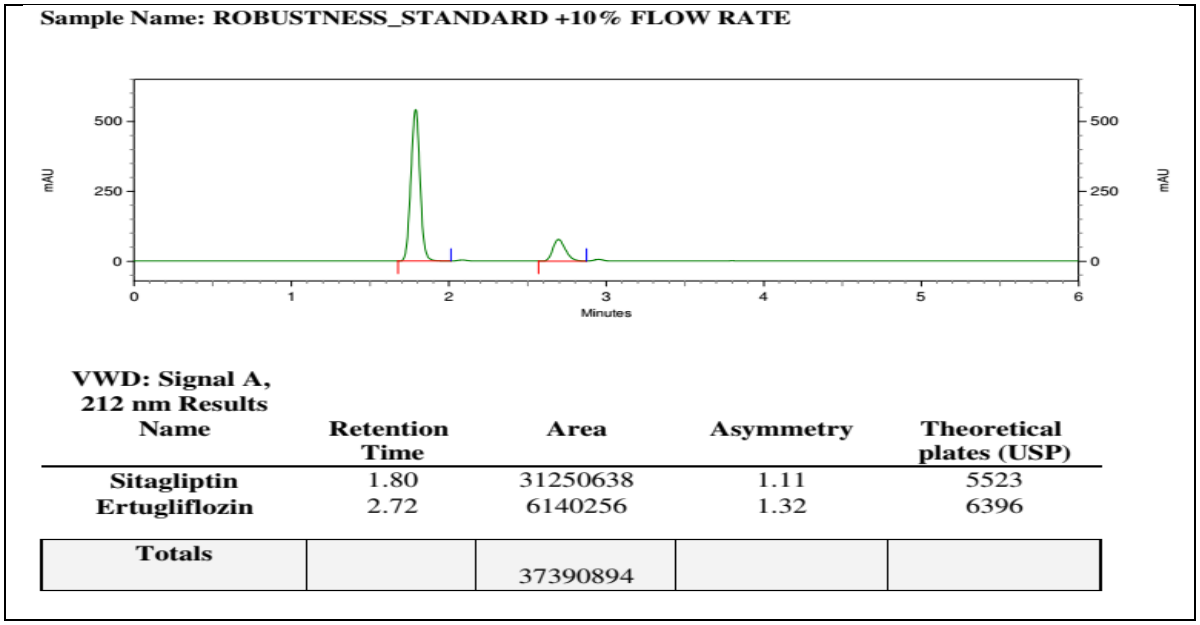
C. Change in Flow rate by + 10%

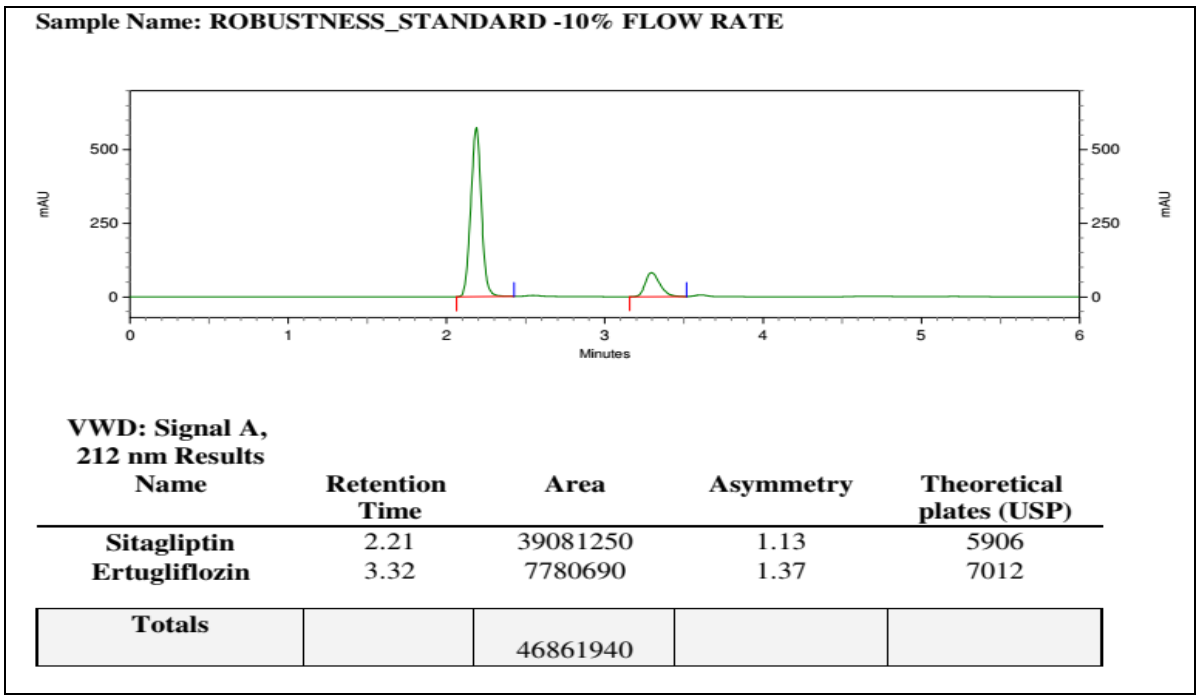


VWD: Signal A, 212 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical plates (USP)
Sitagliptin	1.80	31250638	1.11	5523
Ertugliflozin	2.72	6140256	1.32	6396
Totals		37390894		

Fig. No. 27 Typical chromatogram of Standard +10 F.R. %.

D. Change in Flow rate by - 10%



VWD: Signal A, 212 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical plates (USP)
Sitagliptin	2.21	39081250	1.13	5906
Ertugliflozin	3.32	7780690	1.37	7012
Totals		46861940		

Fig. No. 28 Typical chromatogram of Standard -10 F.R.%.

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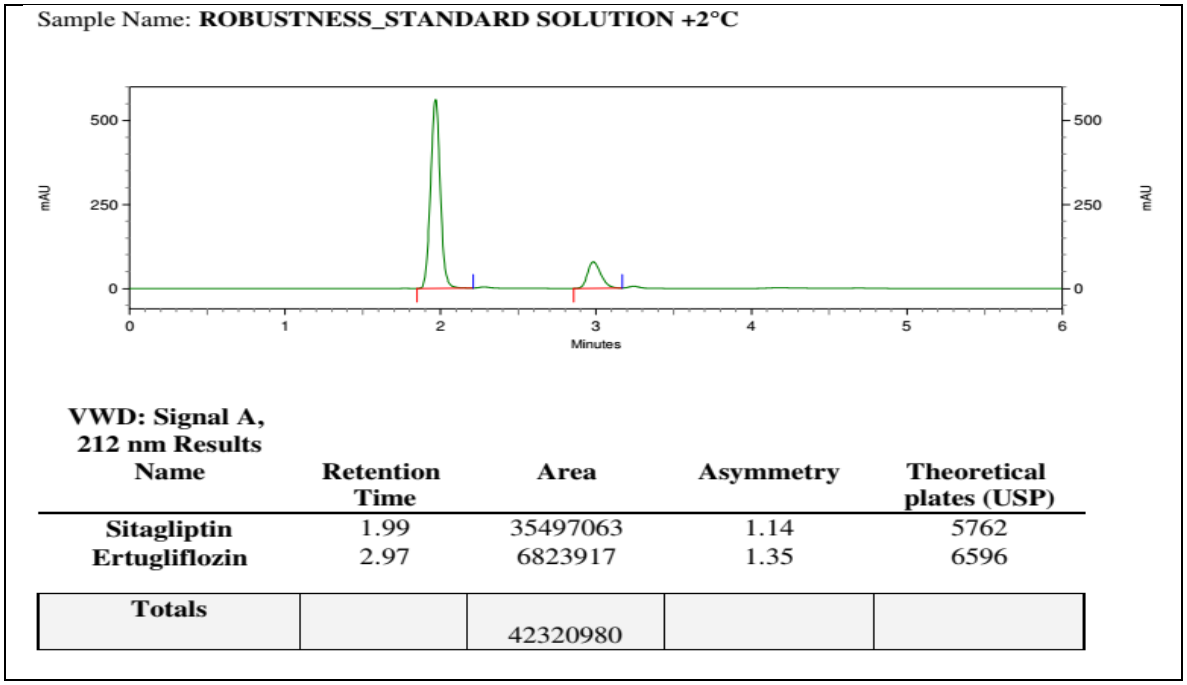
E. Change in Column Oven temperature by +2°C:

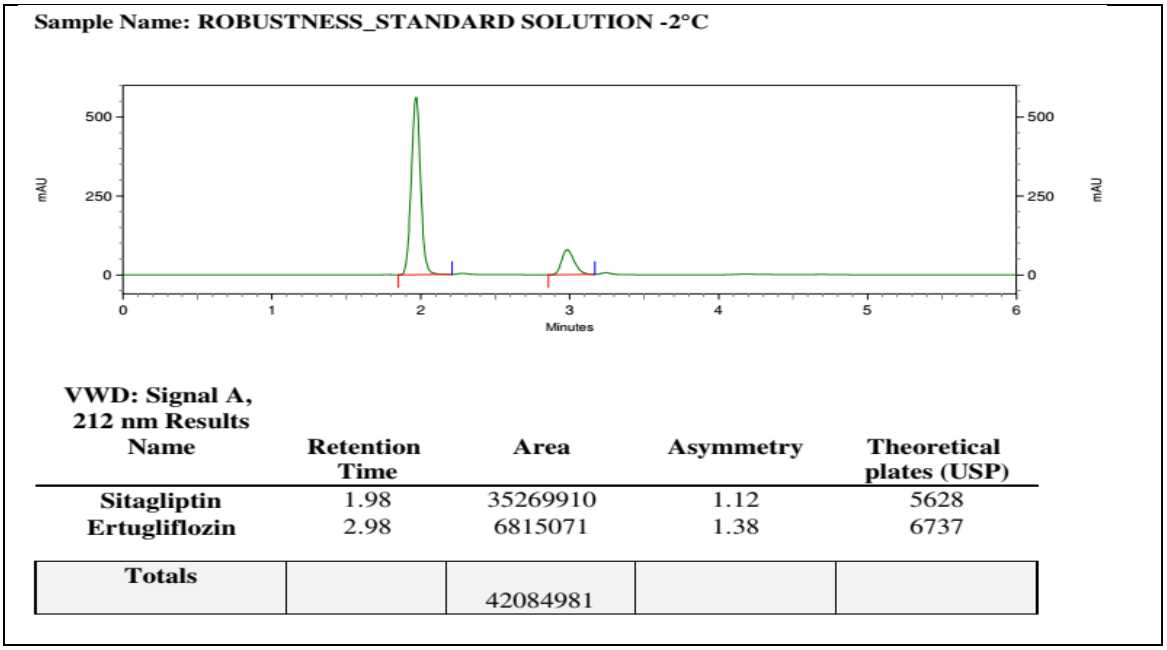


VWD: Signal A, 212 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical plates (USP)
Sitagliptin	1.99	35497063	1.14	5762
Ertugliflozin	2.97	6823917	1.35	6596
Totals		42320980		

Fig. No. 29 Typical chromatogram of Standard +2°C C.O.T.

F. Change in Column Oven temperature by -2°C:



VWD: Signal A, 212 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical plates (USP)
Sitagliptin	1.98	35269910	1.12	5628
Ertugliflozin	2.98	6815071	1.38	6737
Totals		42084981		

Fig. No. 30 Typical chromatogram of Standard -2ºC C.O.T.

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Acceptance criteria:

Chromatography (System suitability) acceptance criteria should not get failed.

Data interpretation: From the above results, it was concluded that the system suitability test result was found well within the limits and analytical method was robust.

CONCLUSION:

During validation, the developed HPLC technique was discovered to be straightforward, accurate, sensitive, and precise for the simultaneous measurement of sitagliptin and ertugliflozin. Both in its unadulterated state and in its medicinal dose forms. Therefore, this approach is simple and practical to use for routine quality control examination of pharmaceutical dosage forms of ertugliflozin and sitagliptin in their pure forms.

REFERENCES:

1. Sonawane A. (2022), Analytical Method Development and Validation For Simultaneous Estimation of Sitagliptin and Ertugliflozin in Bulk and Dosage Form; World Journal of Pharmacy and Pharmaceutical Sciences, Volume 11, Issue 9, 1102-1111.
2. Rani Ch. and Pravalika*M. (2021), Analytical Method Development And Validation For Simultaneous Estimation Of Ertugliflozin And Sitagliptin In Pharmaceutical Dosage Form By Rp-Hplc; European Journal of Biomedical and Pharmaceutical sciences, Volume 8, Issue 10, 261-267.
3. Bamniya J., Manocha N., Choudhary S., Dubey P.K (2023); Analytical Method Development by HPLC to Evaluate the Stress Degradation Stability Profile of Ertugliflozin; International Journal of Pharmaceutical Sciences and Medicine (IJPSM), Vol.8 Issue. 6, June- 2023, pg. 139-153.
4. Mankar*S. D., Sagar P., Bhawar S., Siddheshwar S. and Dighe S. (2023); Development and validation of RP-HPLC method for simultaneous estimation of Ertugliflozin and Sitagliptin in bulk drug and tablet dosage form; International Journal of Experimental Research and Review, Vol. 32: 288-296 (2023).
5. China Babu D.*, Chetty C. M. and Mastanamma S.k. (2018); Oriental Journal of Chemistry; Vol. 34, No. (5): Pg. 2554-2561.
6. Patil*M., Thakur A., Jain A. (2024); Stability Indicating Method Development and Validation, Stress Degradation Studies for Empagliflozin and Sitagliptin Phosphate by Using RP-HPLC; International Journal of Pharmaceutical Sciences, Vol 2, Issue 12, 2017-2037.
7. Shelke S., Singh N. (2022); Development and Validation of HPLC Method for Determination of Ertugliflozin Impurity Profile; Journal of Population Therapeutics and Clinical Pharmacology, Vol. 29 No.04 JPTCP (4326 – 4352).
8. Kulkarni * D., Sakhare R., Joshi A., Shendge S. and Hangargekar P. (2023); Development and Validation of Stability Indicating Rp-Hplc Method for Ertugliflozin and Sitagliptin by Qbd Approach; International Journal of Pharmaceutical Sciences and Research, Vol. 14(8): 3852-3867.
9. Suneetha A., Mounika V., Sajid S. M., Development and Validation of Stability indicating RP-HPLC Method for the simultaneous Estimation of Sitagliptin and Ertugliflozin in bulk and Tablet Dosage Forms. Asian J. Pharm. Ana, 2020; 10(2): 81-85.