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Analytical Method Development and Validation for Estimation of Fexuprazan Hydrochloride in Bulk and Its Tablet Dosage Form by RP-HPLC Method

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ABSTRACT:
A simple, rapid, and reliable reversed-phase high-performance liquid chromatography (RP-HPLC) method was developed and validated for the quantitative estimation of Fexuprazan Hydrochloride in bulk drug and tablet dosage form. Chromatographic separation was achieved using a C18 column (250 × 4.6 mm, 5 µm) with an isocratic mobile phase consisting of dimethyl sulfoxide (DMSO) and potassium dihydrogen orthophosphate buffer (80:20 % v/v, pH 4). The flow rate was maintained at 1.0 ml/min, with UV detection at 224 nm and an injection volume of 20 µl. Fexuprazan Hydrochloride was eluted at a retention time of approximately 2.7 minutes with good peak symmetry. The method was validated in accordance with ICH Q2 guidelines for specificity, system suitability, linearity, precision, accuracy, robustness, limit of detection (LOD), and limit of quantification (LOQ). The method exhibited linearity over the concentration range of 10–50 µg/ml with a correlation coefficient of 0.993. Precision studies showed %RSD values below 2%, confirming excellent repeatability and reproducibility. Accuracy studies demonstrated satisfactory recovery ranging from 99.6% to 100.3%. Robustness studies indicated that minor variations in chromatographic conditions did not significantly affect the analytical performance. The validated RP-HPLC method is precise, accurate, economical, and suitable for routine quality control analysis of Fexuprazan Hydrochloride in pharmaceutical formulations.

Keywords: Fexuprazan Hydrochloride, RP-HPLC, Method Development, Method Validation, Pharmaceutical Analysis, Quality Control.

I. INTRODUCTION:

High-performance liquid chromatography (or High pressure liquid chromatography. HPLC) is a form of column chromatography used frequently in biochemistry and analytical chemistry to separate, identify, and quantify compounds. There are different modes of separation in HPLC. They are normal phase mode, reversed phase mode, reversed phase ion pair chromatography, affinity chromatography, Ion exchange chromatography and size exclusion chromatography (gel permeation or gel filtration chromatography).

Normal phase uses a polar stationary phase and a non-polar mobile phase. The polar analytes are retained for longer time and takes more time to elute because of its higher affinity towards stationary phase whereas the non-polar compounds travel faster and are eluted first because of its lower affinity towards stationary phase. Use of more polar solvents in the mobile phase will decrease the retention time of the analytes, whereas more hydrophobic solvents tend to increase retention times.

Reversed phase uses a non-polar hydrophobic packing with octyl or octa decyl functional group bonded to silica gel as stationary phase and an aqueous, moderately polar solvent as mobile phase. With the stationary phases, retention time is longer for molecules which are more non-polar, while polar molecules elute more readily. Reverse phase mode is the most popular mode for analytical and preparative separation of compounds of interest in, chemical biological, pharmaceutical, food and biomedical sciences. Most of the drugs in pharmaceuticals are polar in nature. The different columns used are octa decyl silane (ODS) or C18, C8, C4, etc., (In the order of increasing polarity of the stationary phase).

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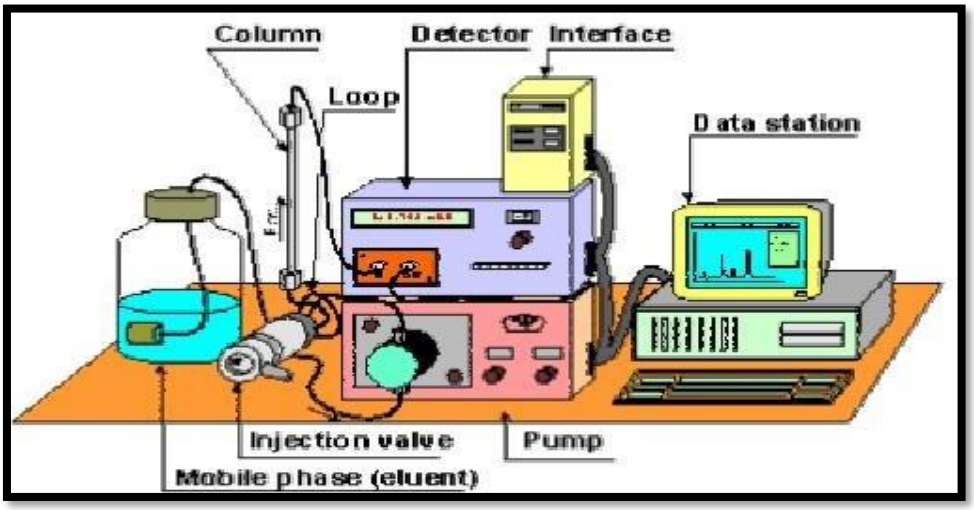
Fig: 1 Complete picture of HPLC System



II. DRUG PROFILE:

- **Drug Name:** Fexuprazan Hydrochloride.
- **Chemical Name:** 1-(5-(2, 4-Difluorophenyl)-1-((3-fluorophenyl)sulfonyl)-4-methoxy-1H-pyrrol-3yl)-N-methylmethanamine hydrochloride.
- **Molecular Formula:** $C_{19}H_{17}F_3N_2O_3S.HCl$
- **Molecular Weight:** 446.87g/mol.
- **Strength:** 40 mg
- **Description:** Each film coated tablet contains Fexuprazan hydrochloride 40 mg. Fexuprazan is a novel drug classified as a potassium-competitive acid blocker (PCAB).
- **Color:** Pale green to light green film coated tablet.
- **Solubility:** It is highly soluble in DMSO and is poorly soluble in water.
- **Selection Of Solvent:** DMSO and Buffer is used as solvent. (6.8 gm of Potassium dihydrogen orthophosphate dissolved in 1000 ml of water).
- **Melting Point:** 174-180°C.
- **Boiling Point:** 497.9 ± 55.0 °C.
- **Bioavailability:** Oral ~38 to 44 **%** (absolute). IV = 100%.
- **Elimination Half Life:** (T1/2) = ~8 to 10 hours.
- **Generic Name:** Fexuprazan Hydrochloride Tablets.
- **Pharmacological Properties:** Fexuprazan Hydrochloride is a potassium competitive acid blocker.
- **Mechanism Of Action:** Fexuprazan hydrochloride has a mechanism of action to inhibit gastric acid secretion by controlling H+/K+-ATPase in parietal cells of stomach in a Co-dependent's and reversible manner. Fexuprazan hydrochloride directly inhibits the proton pump without undergoing acid induced activity.
- **Target Enzyme:** H+/K+-ATPase (proton pump).

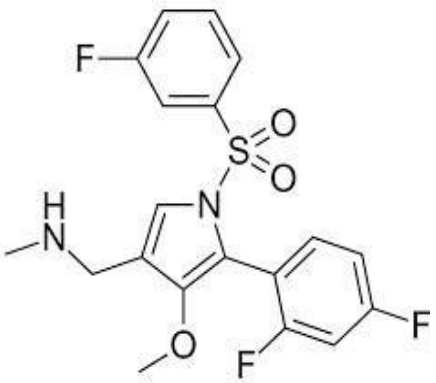


Fig: 2 Structure of Fexuprazan Hydrochloride

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III. MATERIALS AND METHODS:

3.1 METHOD DEVELOPMENT:

Preparation of Mobile Phase: Required weight (6.8 gm) of buffer with molarity 0.5M was taken and is dissolved in 1000 ml of water. Sonicate the solution for 10 min and adjust the pH to 4 using ortho-phosphoric acid and filter the solution using vacuum filter and add it to reagent bottle. To this solution add DMSO. Mix well and sonicate the mixture for 20 min.

Diluent: DMSO and Buffer in the ratio of 80:20%v/v.

Preparation of standard stock solution: Standard stock solution was prepared by dissolving accurately weighed 100 mg pure drug in 100ml of diluents. This will become 1000 mcg / ml solution, which was taken as stock solution.

Preparation of stock solution: A stock solution of Fexuprazan Hydrochloride was prepared by accurately weighing 25 mg of drug, transferring to 50 ml volumetric flask, dissolving in 25 ml of mobile phase and sonicated for 5min. Appropriate aliquot of this solution was further diluted to 50 ml with mobile phase to Obtain final standard solution of 100 µg / ml of Fexuprazan Hydrochloride and the resultant solution was filtered through Whatman Filter paper.

Selection of chromatographic method: A RP C18:250x4.6mm 5µm column equilibrated with mobile phase DMSO: Potassium dihydrogen Orthophosphate (80:20%v/v, pH4) was used. Mobile phase flow rate was maintained at1.0 ml / min. Detection wavelength 224 nm was selected by scanning standard drug over a wide range of wavelength 200 nm to 400 nm in U.V Spectroscopy. The sample was injected through 20 µl fixed loop, and the total run time was adjusted for 6 mins.

S. No	Column used	Mobile phase	Isocratic/ Gradient	Inj. Vol.	Observation	Result
1.	C18:250x4.6mm. 5µm	DMSO: Buffer (50:50)	Isocratic	20µl	The theoretical plates are not with in the limit	Method Rejected
2.	C18:250x4.6mm. 5µm	DMSO: Buffer (60:40)	Isocratic	20µl	The theoretical plates are not with in the limit	Method Rejected
3.	C18:250x4.6mm. 5µm	DMSO : Buffer (70:30)	Isocratic	20µl	The tailing factor and, theoretical plates are not with the limit	Method Rejected
4.	C18:250x4.6mm. 5µm	DMSO : Buffer (80:20)	Isocratic	20µl	The tailing factor and, theoretical plates are within the limit	Method Accepted

Table: 1 Method Development For RP-HPLC Analysis Of Fexuprazan

MOBILE PHASE	DMSO: Buffer
COLUMN	C18:250x4.6mm.5µm
FLOWRATE	1.0
COLUMN TEMPERATURE	Ambient

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WAVE LENGTH	224
INJECTION VOLUME	20µl

Table: 2 Chromatographic system

ANALYSIS

Sample Name: Fexuprazan **Sample ID: std0001**

File: 00014.RAW **Date: 2026-01-08**

Chromatogram

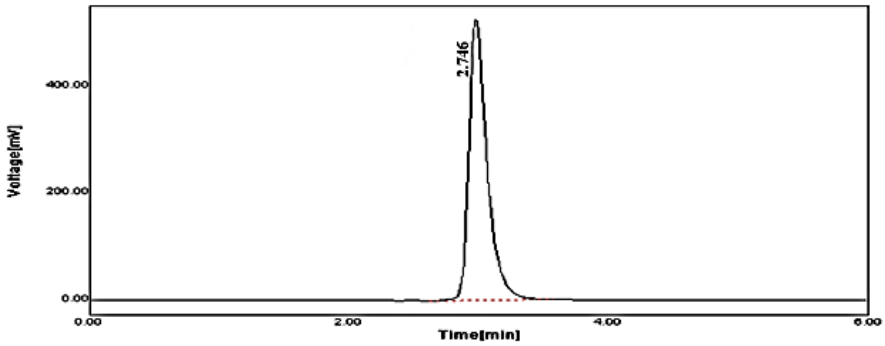

Fig: 3 Analysis Report

S.No.	Name	RT [min]	Peak Area	Theoretical Plate	Tailing factor
1	Fexuprazan	2.746	26576551	5819	1.12

Table: 3 Analysis Report

ANALYSIS

Sample Name: Fexuprazan **Sample ID: spl0011**

File: 00022.TAB **Date: 2026-01-08**

Chromatogram

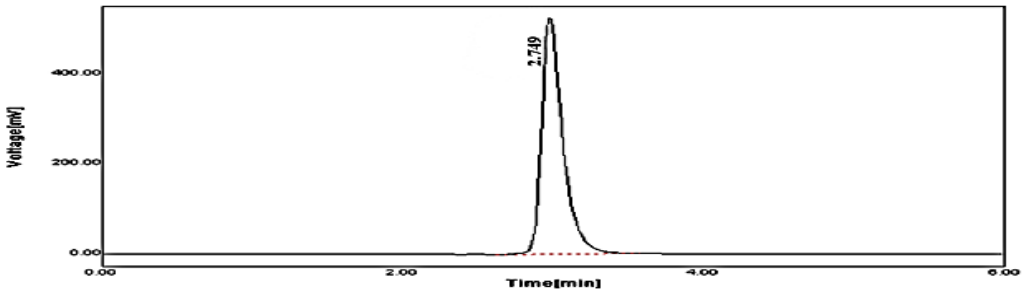

Fig: 4 Analysis Report

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S.No.	Name	RT [min]	Peak Area	Theoretical Plate	Tailing factor
1	Fexuprazan	2.749	26666495	5831	1.12

Table: 4 Analysis Report

3.2 VALIDATION PARAMETERS:

Specificity and selectivity: The successful and interference-free detection of Fexuprazan Hydrochloride in the sample served as validation of the method's specificity and selectivity. While the blank, which was merely the diluents, showed no reaction or interference, the chromatogram of the Fexuprazan Hydrochloride reference standard produced a positive result. Figure 1 displays the Chromatogram corresponding to the standard.

Evaluation of system suitability: System suitability studies were carried out to confirm the HPLC system's reliability. To quantify column efficiency, plate count, and tailing factor, injections of 40µg/ml were made six times. The outcomes showed consistency by verifying that the system met the predetermined standards and stayed within the given parameters.

Precision: System Precision (Injection repeatability) was measured by using six replicates of the same band containing 100 mg of pure Fexuprazan Hydrochloride and % RSD of the replicate injections was Calculated. The precision of the method was determined by spotting six replicates of the sample solution of Fexuprazan Hydrochloride such that each band containing 100 mg of Fexuprazan Hydrochloride and % RSD of the replicate injections was calculated. Both the system precision and method precision were subjected to intra-day and inter-day variation.

Linearity: Appropriate aliquots of standard Fexuprazan Hydrochloride stock solutions (100 µg / ml) were taken in different 10 ml volumetric flask and resultant solution was diluted up to the mark with mobile phase to obtain final concentration of 10-50 µg / ml. These solutions were injected into chromatographic system. The chromatograms were obtained and peak area was determined for each concentration of drug solution.

Accuracy: The accuracy of the method was determined by use of standard additions at three different levels, i.e. multiple-level recovery studies. Sample stock solution of Fexuprazan Hydrochloride was prepared, 80%, 100% and120% of the standard drug solution was added to the solution, and the recovery [%] was determined. Values were found to be within the limits.

Robustness: Robustness is a measure of capacity of a method to remain unaffected by small but deliberate variations in the method conditions, and is indications of the reliability of the method. A method is robust, if it is unaffected by small changes in operating conditions. To determine the robustness of this method, the experimental conditions were deliberately altered at three different levels and retention time and chromatographic response were evaluated. One factor at a time was changed to study the effect. Variation of mobile phase ratio (80 :20 % v / v).

Validation: After acceptable chromatographic conditions were established, the method was validated Following the ICH Q2 requirements. Additionally, the stability of reagents and solvents was investigated as well.

Limit of Detection (LOD) and Limit of Quantification (LOQ): Limit of detection and Limit of Quantification is determined by the analysis of samples with known concentrations of analyte and by establishing the minimum level at which the analyte can be reliably detected. The Limit of detection and Limit of Quantification was found to be 40mg for Fexuprazan Hydrochloride the results of LOD and LOQ were shown in formula.

$$LOD = (3.3 * \sigma) / S$$

$$LOQ = (10 * \sigma) / S$$

IV. RESULTS AND DISCUSSION:

4.1 METHOD DEVELOPMENT AND OPTIMIZATION:

Mobile phase: Several columns were used during technique development to achieve excellent

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Fexuprazan Hydrochloride separation, including Inertsil ODS 3V and Water symmetry C18, with dimensions of 250 × 4.6 mm and 150 × 4.6 mm a particle size of 5 µm. The peak should occur when the medication either fully ionizes or unionizes because the pH of the mobile phase greatly influences the peak. The pKa of Fexuprazan Hydrochloride was taken into consideration when evaluating different mobile phase solutions: DMSO and Buffer were both tested as organic solvents for the mobile phase. To decrease the drug's retention time (RT) and enhance peak form, the composition of the mobile phase was changed. Chromatographic data software was used to calculate system suitability characteristics, such as tailing factor at 10% peak width (Tf10%), theoretical plate count, and percent relative standard deviation (%RSD) of areas of six replicates of the standard solution in order to determine the best approach. Short run times, minimal organic solvent usage, an asymmetry factor near 1.0, and a maximum theoretical plate count were all taken into account. Based on the results, Potassium dihydrogen ortho-phosphate Buffer and DMSO (20:80% v/v) was finalized as the optimized mobile phase for the estimation of Fexuprazan Hydrochloride.

Effect of column: Several columns, including C4 and C18, were tested for the Fexuprazan Hydrochloride elution. A peak form that was adequate could not be achieved when the C4 column was tested. The high affinity of Fexuprazan Hydrochloride for the stationary phase may account for the larger peak of Fexuprazan Hydrochloride with tailing in the C4 column even at greater organic ratio in the mobile phase. Less retention time and an excellent peak shape were displayed by the C18 column. When contrasted with the C18 column using water symmetry column chemistry displayed superior peak form and peak separation.

Effect of flow rate: When the flow rate was adjusted from 1 ml/min to 1.1ml/min, there was no discernible change in the form of the Fexuprazan Hydrochloride peak. Thus, a 1.0 ml/min flow rate was maintained.

Column oven temperature: The temperature of the column oven had no discernible effect on peak shape. Peak form altered only slightly when the temperature was raised from 25° to 40°. Because a greater temperature could shorten the column's lifespan, the column oven temperature was maintained at 25°.

4.2 SPECIFICITY:

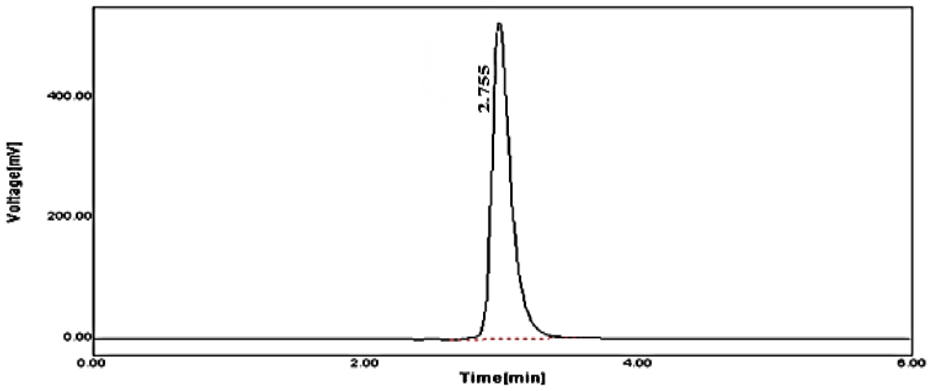

Fig: 5 Displays The Chromatogram Corresponding To The Standard

4.3 SYSTEM SUITABILITY PARAMETERS:

By computing the percentage RSD (relative standard deviation) based on six consecutive injections of the reference solution, the accuracy of the HPLC system was assessed. To be considered acceptable, the Relative Standard Deviation (RSD) may not be greater than 2%. The RSD of the standard solution was within the allowed range, indicating precision within the specified criterion, demonstrating the procedure's dependability for precisely quantifying Fexuprazan Hydrochloride in samples. Table 5 presents the findings. With a retention time (RT) of 2.896 minutes, Fexuprazan Hydrochloride demonstrated quick identification and successful separation. The HPLC technique for Fexuprazan Hydrochloride measurement was adjusted to select the right wavelength, fine-tune parameters, and mobile phase composition with care

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in order to provide quick analysis and good resolution. Strict analytical requirements are satisfied by the accurate and effective measurement of Fexuprazan Hydrochloride provided by this comprehensive optimization.

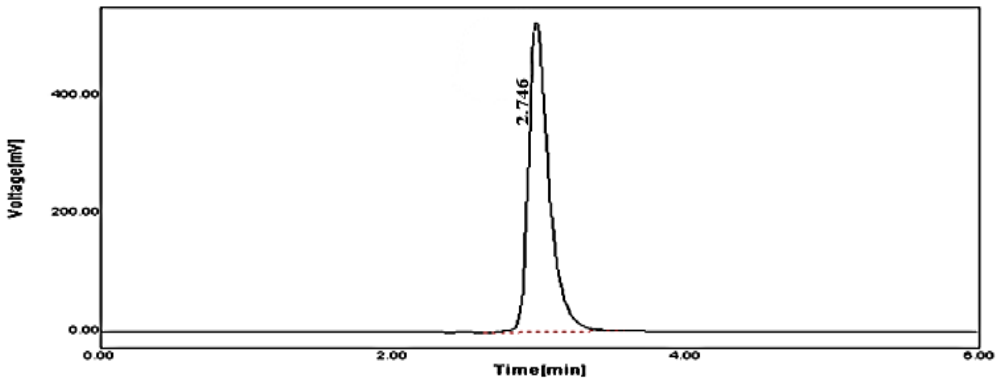

Fig: 6 System Suitability

S. No	Parameter	Fexuprazan Hydrochloride	Acceptance Criteria
1	Retention time	2.746	-----
2	Theoretical plates	5819	NMT 2000
3	Tailing factor	1.12	NMT 2.0
4	Linearity concentration	10-50 µg/ml	-----
5	Regression data: Slope	11696	-----
6	Regression data: Intercept	26030	-----
7	Regression data: Correlation Coefficient	0.993	-----

Table: 5 System Suitability

4.4 INTERDAY PRECISION:

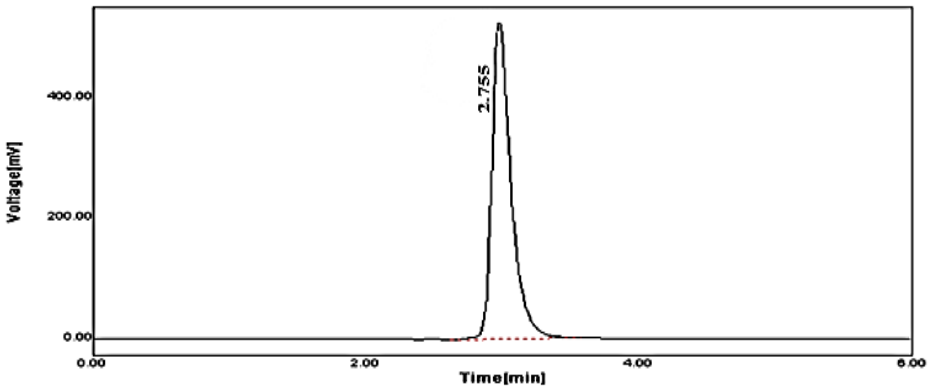

Fig: 7 Interday Precision Graph Of Fexuprazan

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S. No	Concentration (µg/ml)	Retention time (min)	Interday Precision(Area)
1	40	2.755	2237555.25
2	40	2.755	2266743.52
3	40	2.756	2256608.41
4	40	2.755	2234011.28
5	40	2.757	2268042.25
6	40	2.755	2244111.18
Mean		**2.755**	**2701414.378**
Std.Dev		**0.0007637**	**13456.05953**
%RSD		**0.027**	**0.498**

Table: 6 Interday Precision Graph Of Fexuprazan

4.5 INTRADAY PRECISION:

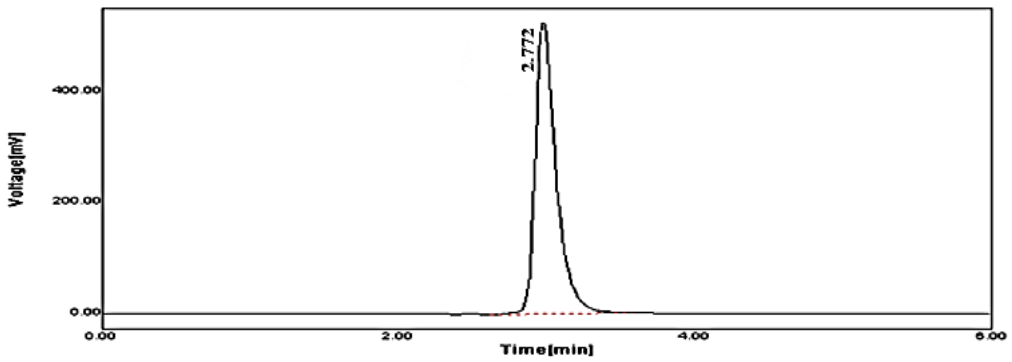

Fig: 8 Intraday Precision

S. No	Concentration (µg/ml)	Retention time (min)	Intraday Precision(Area)
1	40	2.772	2242555.25
2	40	2.773	2258743.52
3	40	2.772	2265608.41
4	40	2.772	2231102.28
5	40	2.774	2277843.25
6	40	2.771	2283221.18
Mean		**2.7723**	**2259845.648**
Std.Dev		**0.0009428**	**18393.35184**
%RSD		**0.034**	**0.8139**

Table: 7 Intraday Precision Graph Of Fexuprazan

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4.6 LINEARITY:

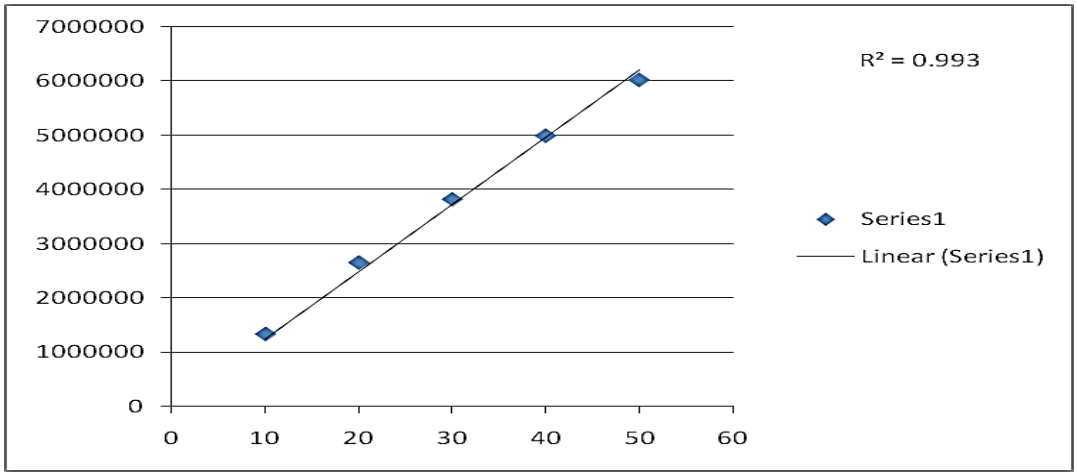

Fig: 9 Linearity

S. No	Concentration(µg/ml)	Retention time (min)	Peak area(mv)
1	10	2.759	1344206
2	20	2.771	2657655
3	30	2.775	3825225
4	40	2.772	4995206
5	50	2.779	6023521
Slope			**11696**
Standard deviation			**16555.54**
Correlation coefficient			**0.993**

Table: 8 Linearity Data of Fexuprazan By RP-HPLC Method

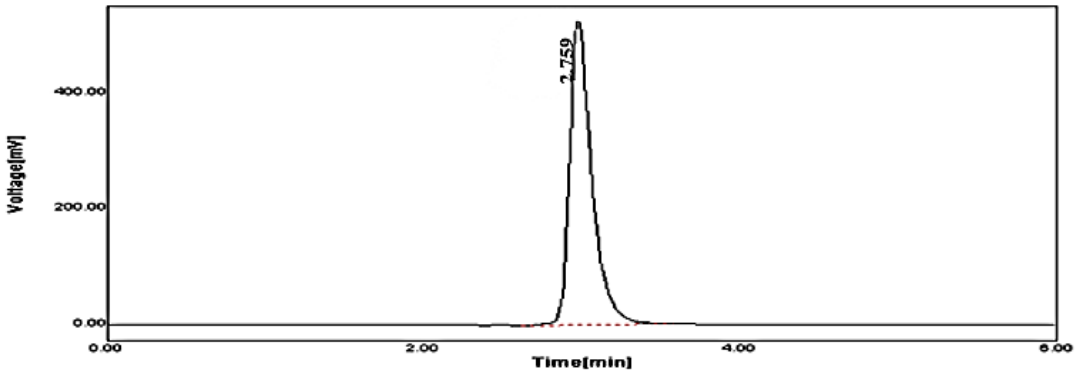

Fig: 10 Linearity Graph Of Fexuprazan at 10 µg /ml

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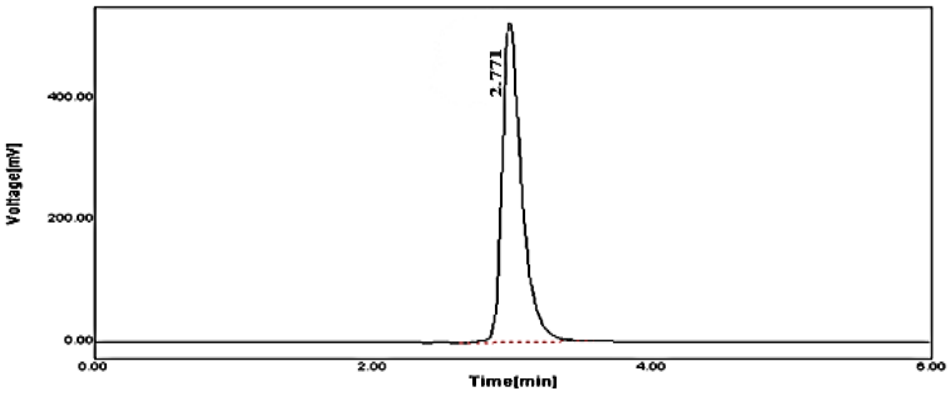

Fig: 11 Linearity Graph of Fexuprazan at 20 µg /ml

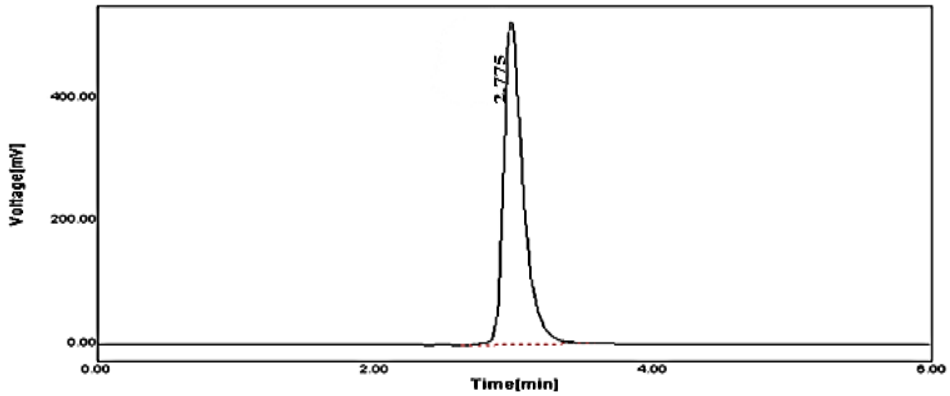

Fig: 12 Linearity Graph of Fexuprazan at 30 µg /ml

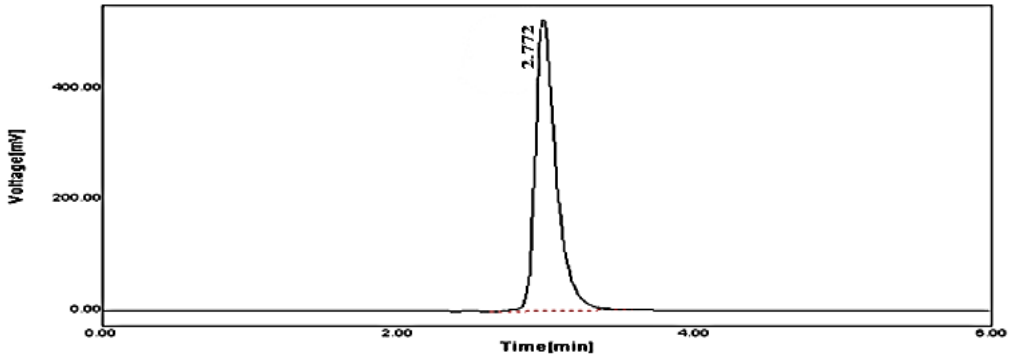

Fig: 13 Linearity Graph of Fexuprazan at 40 µg /ml

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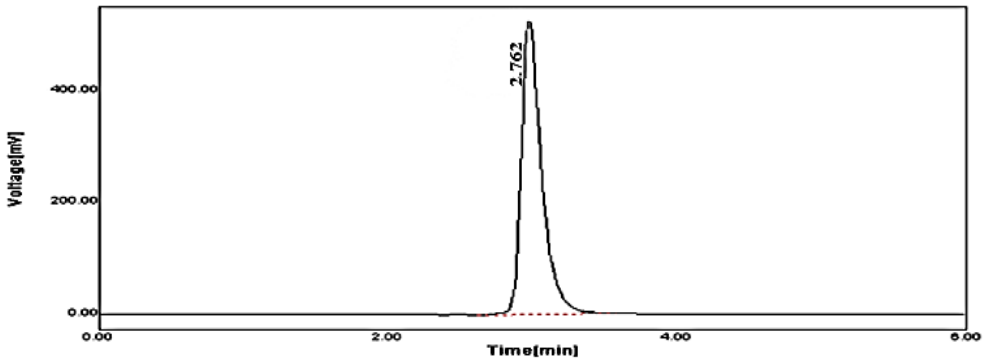

Fig: 14 Linearity Graph Of Fexuprazan at 50 µg /ml

4.7 ACCURACY:

Brand used	Label claim	% accuracy	Recovery ± SD*(%)
Fexuclue	40	80	99.6
		100	100.3
		120	99.87

Table: 9 Accuracy Results For Fexuprazan

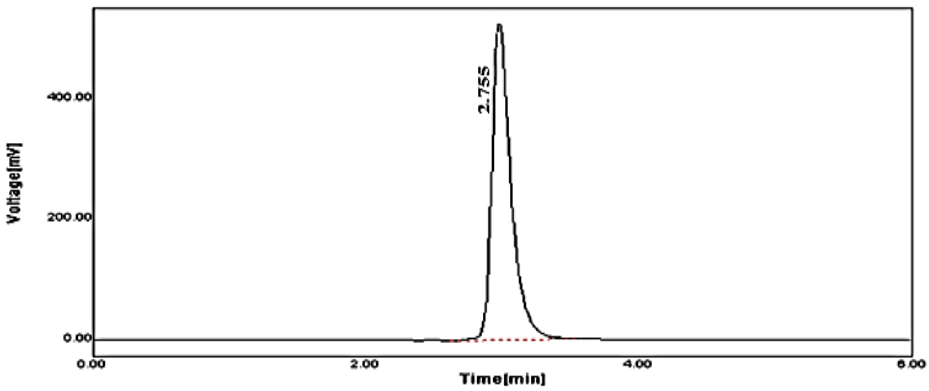

Fig: 15 Accuracy Graph of Fexuprazan at 80%

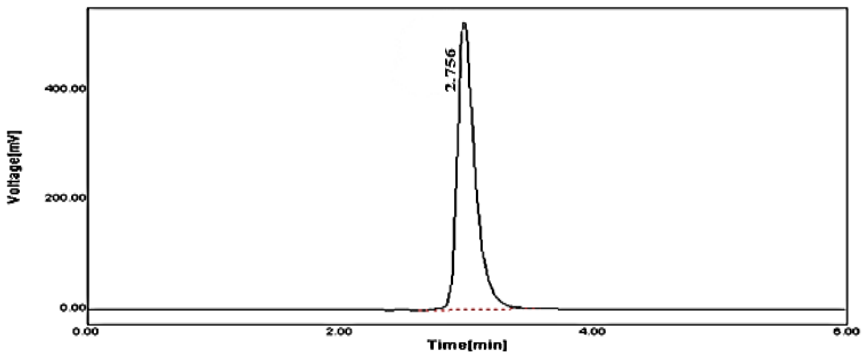

Fig: 16 Accuracy Graph of Fexuprazan at 100%

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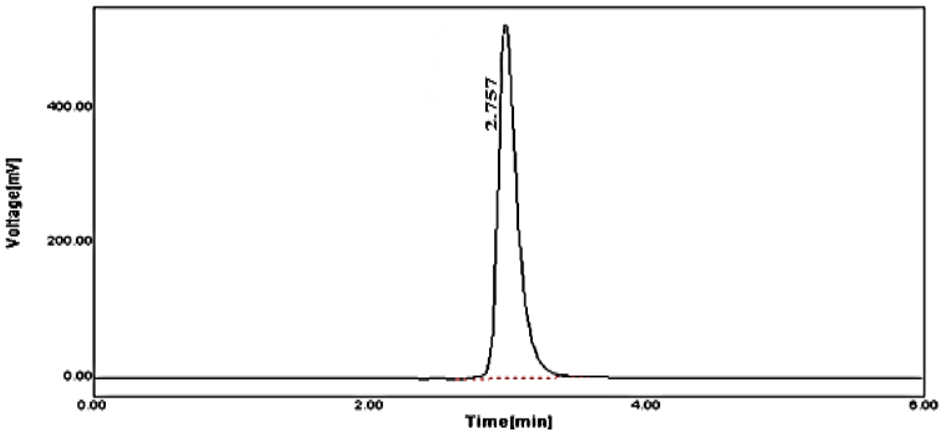

Fig: 17 Accuracy Graph of Fexuprazan at 120%

4.8 ROBUTNESS:

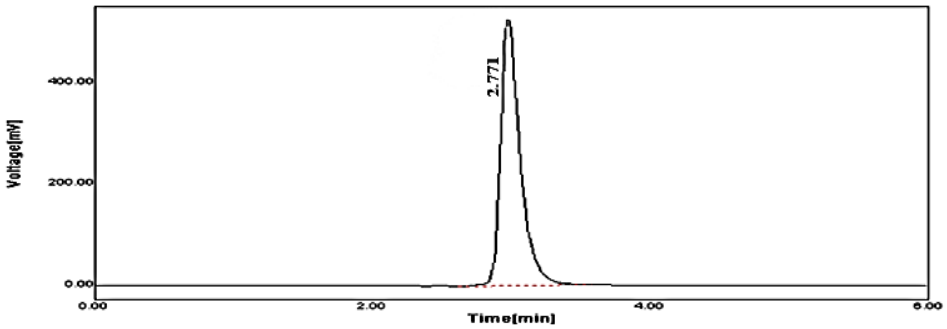

Fig: 18 Robustness Graph Of Fexuprazan At 0.9 ml Flow Rate

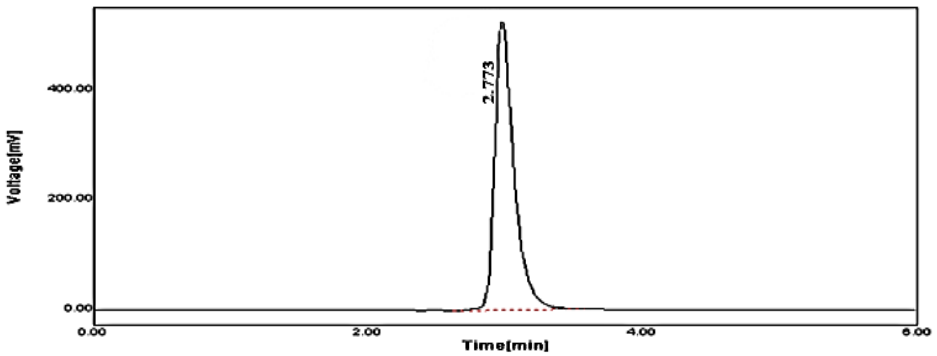

Fig: 19 Robustness Graph Of Fexuprazan At 1.1 ml Flow Rate

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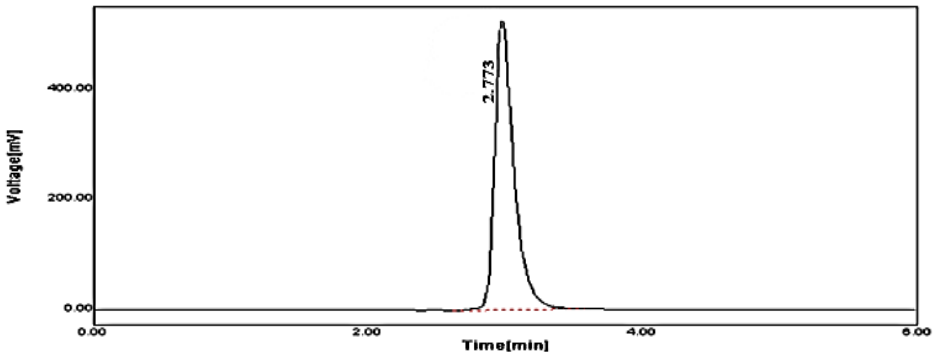

Fig: 20 Robustness Graph of Fexuprazan At 3.9 ml pH

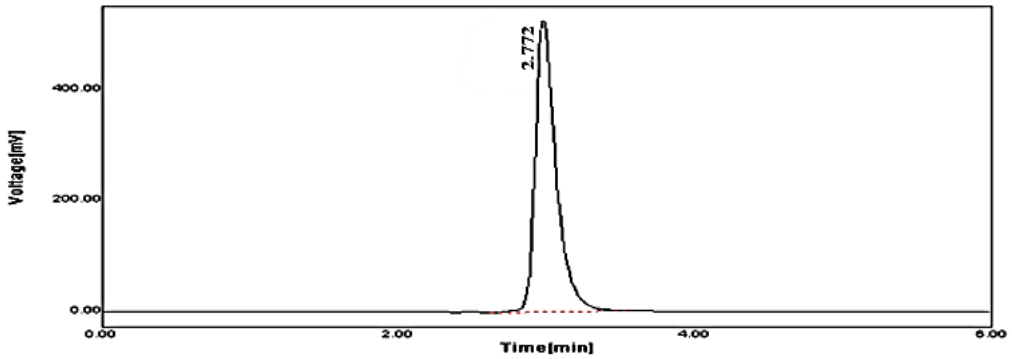

Fig: 21 Robustness Graph Of Fexuprazan At 4.1 ml pH

S. No	Parameters	Retention Time	Area	%RSD
Change in Flow rate				
1	0.9 ml	2.771	2283211.18	1.05
2	1.1 ml	2.773	2258724.52	1.11
Change in pH				
1	3.9	2.773	2239721.02	1.09
2	4.1	2.772	2256204.18	1.06

Table: 10 Robustness Studies of Fexuprazan

V. DISCUSSION:

A simple, rapid, and reliable RP-HPLC method was successfully developed and optimized for the estimation of Fexuprazan Hydrochloride. During method development, various chromatographic conditions were systematically evaluated to achieve optimal separation, peak symmetry, and reduced analysis time. The selection of mobile phase played a crucial role, as the ionization behaviour of Fexuprazan Hydrochloride is highly dependent on pH. Considering the pKa of the drug, different organic solvents and buffer combinations were examined. Among the tested systems, a mobile phase consisting of DMSO and potassium dihydrogen orthophosphate buffer in the ratio of (80:20%v/v) provided the best chromatographic performance, yielding sharp, symmetrical peaks with minimal tailing and reduced retention time.

The effect of column chemistry was also investigated using different stationary phases. The C4 column showed poor peak symmetry and tailing, possibly due to stronger interactions between the drug and the stationary phase. In contrast, the C18

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column, particularly the Waters Symmetry C18 column, demonstrated superior peak shape, better resolution, and reduced retention time, making it suitable for routine analysis.

Flow rate variation studies revealed that minor changes (±0.1 ml/min) did not significantly affect peak shape or retention time, indicating method robustness. Similarly, column oven temperature showed negligible influence on chromatographic behaviour within the studied range. Therefore, a flow rate of 1.0 ml/min and a column temperature of 25°C were selected to ensure method stability and prolong column life.

System suitability parameters confirmed the adequacy of the developed method. Theoretical plate count exceeded the minimum acceptance criteria, tailing factor was well within limits, and %RSD values were less than 2%, demonstrating excellent system precision. The retention time of approximately 2.7–2.9 minutes indicates rapid analysis, making the method time-efficient.

Precision studies, including Interday and Intraday precision, showed very low %RSD values (<1%), confirming the repeatability and reproducibility of the method. Linearity was established over a concentration range of 10–50 µg/ml with a correlation coefficient (r^2 = 0.993), indicating a strong linear relationship between concentration and peak area. Accuracy studies further validated the method, with percentage recovery values ranging from 99.6% to 100.3%, demonstrating the absence of interference from excipients.

Robustness testing confirmed that small, deliberate variations in flow rate and pH did not significantly impact retention time, peak area, or %RSD, proving the reliability of the method under varied analytical conditions.

S.NO	PARAMETER		FEXUPRAZAN HYDROCHLORIDE
1	SPECIFICITY		No interface
2	SYSTEM SUITABLITY	Retention Time	2.746
		Peak Area	26666495
		Theoretical Plates	5819
		Tailing Factor	1.12
3	PRECISION (%RSD)	System precision	0.498
		Method precision	0.813
4	LINEARITY AND RANGE	Slope	11696
		Standard deviation	16555.54
		Correlation coefficient	0.993
5	ACCURACY (% RSD)	80%	99.6
		100%	100.3
		120%	99.87
6	ROBUSTNESS		The system suitability parameters were found to match well with the acceptance criteria based on system suitability.
7	LIMIT OF DETECTION		7.062 µl
8	LIMIT OF QUANTIFICATION		18.251 µl

Table: 11 Summary

VI. CONCLUSION:

The developed RP-HPLC method for the estimation of Fexuprazan Hydrochloride is simple, precise, accurate, robust, and economical. The method offers rapid analysis with a short retention time and excellent peak symmetry, making it highly suitable for routine quality control analysis. Validation parameters such as system suitability, linearity, precision, accuracy, and robustness complied with established analytical guidelines, confirming the reliability and reproducibility of the method. Therefore, this validated RP-HPLC method can be effectively applied for the quantitative estimation of Fexuprazan Hydrochloride in bulk drug and pharmaceutical dosage forms.

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