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AQBD ASSISTED DEVELOPMENT AND VALIDATION OF STABILITY INDICATING RP-HPLC METHOD FOR THE DETERMINATION OF FEXUPRAZAN HYDROCHLORIDE IN ITS TABLET DOSAGE FORM

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ABSTRACT

Fexuprazan Hydrochloride, a novel potassium-competitive acid blocker, requires a reliable analytical method for quality control. In the present study, a simple, accurate, precise, and stability-indicating RP-HPLC method was successfully developed and validated s per ICH guidelines. The method demonstrated excellent linearity (R^2 = 0.999), satisfactory precision, high accuracy (100.02–100.06% recovery), and good sensitivity. The assay of the marketed formulation was found to be 99.54%. Furthermore, the Quality by Design (QbD) approach enabled systematic optimization of chromatographic conditions, resulting in a robust and reliable method suitable for routine analysis of Fexuprazan Hydrochloride.

KEYWORDS: Method Development, Validation, AQBD, Robust.

INTRODUCTION

Fexuprazan Hydrochloride is a medication primarily used to treat conditions related to excess stomach acid. It is a proton pump inhibitor (PPI), which works by reducing the amount of acid produced in the stomach. This class of drugs is commonly prescribed for conditions like gastroesophageal reflux disease (GERD), peptic ulcers, and gastric ulcers, as well as to help in the healing of acid-related damage to the esophagus and stomach lining. Fexuprazan works by inhibiting the proton pump (H+/K+ ATPase) in the stomach lining, which is responsible for the final step in acid secretion. This decreases stomach acid production, thereby providing relief from symptoms related to acid reflux, heartburn, and ulcers. Fexuprazan Hydrochloride is indicated in Gastroesophageal reflux disease (GERD) to helps manage acid reflux by reducing stomach acid, Peptic and gastric ulcers to aids in the healing of ulcers by creating a less acidic environment and Helicobacter pylori eradication which often part of combination therapy to eradicate this bacteria, which is linked to ulcers. Fexuprazan Hydrochloride is administered orally in the form of its hydrochloride salt, and its absorption is optimized when taken before meals. After administration, it undergoes rapid absorption with peak plasma concentrations typically achieved within a few hours. Fexuprazan Hydrochloride's reversible mechanism of action may confer several advantages over older PPIs. These include a faster onset of action and a more consistent pH profile, which could enhance therapeutic outcomes in patients with severe GERD or ulcers. Additionally, early studies suggest that Fexuprazan Hydrochloride may present a lower risk of adverse effects commonly associated with PPIs, such as bone fractures, hypomagnesemia, and vitamin B12 deficiency. Furthermore, it may be more effective at maintaining a higher and more stable intragastric pH, potentially leading to better healing outcomes in gastric and duodenal ulcers.

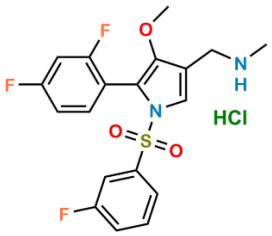

Figure 1: Structure of Fexuprazan HCl.

MATERIALS AND METHODS

Chemicals and reagents: Throughout the analysis, all HPLC and AR-grade solvents were employed, The High-Performance Liquid Chromatography (HPLC) system used was an **Agilent 1100** (Model: **HPLC-1100**) equipped with a **reversed-phase (RP-HPLC)** configuration. The instrument was fitted with a **UV-Visible detector** and operated using **EZChrom Elite** software. Chromatographic separation was performed on an **Agilent C18 column** (100 mm × 4.6 mm, 5 µm particle size). The system was equipped with a **high-pressure gradient reciprocating pump** for solvent delivery.

Selection of wavelength

To determine the wavelength for measurement, standard spectra of Fexuprazan HCl were scanned between 200-400 nm against the absorbance and the absorbance maximum was obtained at 227nm for fexuprazan HCl.

Selection of Chromatographic Conditions

The selection of an appropriate HPLC method depends primarily on the physicochemical characteristics of the analyte, including its ionic nature (ionic, ionisable or neutral), molecular weight, pKa and solubility. Based on this consideration and a review of previously reported analytical methods, RP-HPLC was chosen as the initial technique due to its simplicity, reliability and broad applicability in pharmaceutical analysis. To achieve optimal chromatographic performance, several experimental parameters were systematically evaluated. These included the composition of the mobile phase, flow rate, and the ratio of organic solvent to aqueous phase. The chromatographic conditions were progressively optimized to obtain well – resolved peaks with acceptable symmetry and appropriate retention characteristics. The final optimized method provided adequate resolution, suitable peak shape and an appropriate capacity factor, enabling accurate and reliable estimation of both drug components.

Selection of column

For fexuprazan HCl analysis Aglient C18 column (100mm X 4.6mm; particle size – 5 micron) was chosen for method development.

Selection of Mobile phase

Based on the literature survey and solubility data, ACN, water, Formic acid and methanol were considered for method development trials.

Preparation of solutions

Preparation of the mobile phase

The chromatographic method was developed using a mobile phase comprising methanol, water and acetonitrile. Additionally, 0.1% formic acid was incorporated to improve peak shape and achieve optimal retention time.

Preparation of 0.1% formic acid

0.1 % v/v formic acid was prepared by diluting 1 mL of formic acid to 1000 mL with HPLC-grade water.

Preparation of standard stock solution (Fexuprazan HCl)

A standard stock solution of fexuprazan HCl was initially prepared by accurately weighing 20 mg of the drug and dissolving it in methanol in a 50 mL volumetric flask using methanol, followed by thorough mixing to obtain a clear solution for UV analysis. For HPLC, a standard stock solution of fexuprazan HCl (1000 µg/mL) was prepared by accurately weighing 100 mg of the drug and dissolving it in a 100 mL volumetric flask, followed by sonication and making up to volume to mark.

Preparation of standard solution (Fexuprazan HCl)

From this stock solution of UV, an aliquot of 0.5mL was transferred into a 20 mL volumetric flask and diluted to volume with methanol to obtain a working solution with a final concentration of 10µg/mL.

Preparation of sample solution (Fexuprazan HCl tablet)

To prepare the sample solution, first determine the average weight to enable subsequent calculations. Tablets containing fexuprazan HCl were used. Based on the labelled claim of 40 mg of fexuprazan per tablet, an appropriate number of tablets equivalent to 100 mg of the API were selected. The tablets were accurately weighed and finely powdered using a mortar and pestle to obtain a homogeneous mixture. A portion of the powdered tablet blend equivalent to 100 mg of fexuprazan was transferred into a 100 mL volumetric flask. The sample was then mixed with diluent and subjected to sonication to facilitate complete dissolution of the drug.

Forced degradation study

To evaluate whether the developed analytical method and assay were stability-indicating, forced degradation(0.1N HCl at RT. 0.1 N NaOH at 3hr, mL 3% Hydrogen Peroxide at 3hrs, studies were performed on Fexuprazan HCl. The drug product was subjected to various stress conditions to assess the stability behaviour of components. 1000 µg/mL of fexuprazan solution prepared using a methanol solution. And further analysis was done.

Method Validation

As per ICH guidelines (Q2R2), the method validation parameters studied were specificity, linearity, accuracy,

precision, limit of Detection, limit of Quantification and robustness.

Specificity

The specificity of the developed HPLC method was evaluated by injecting different solutions under optimised chromatographic conditions. The diluent was injected in triplicate to confirm the absence of interference from the solvent system. In addition, standard and sample solutions at 100% assay concentration were prepared and analysed in triplicate to verify that the analyte peak was free from interference, thereby confirming the specificity of the method**.**

Linearity and range

Linearity was evaluated based on the correlation coefficient obtained from linear regression analysis. Standard calibration curves were prepared using five calibration solutions within the concentration ranges of 500-1500 µg/ml for Fexuprzan HCl. Each solution was analysed using Ezcrome Elite software, and the samples were scanned over a wavelength range 200-400nm to record the corresponding spectra.

Precision

Repeatability

Repeatability was assessed by analyzing the test solution containing Fexuprazan HCl under identical experimental conditions. The percentage relative deviation (%RSD) was found to be satisfactory.

Inter-day Precision

Inter-day precision was evaluated by analysing Fexuprzan solution at concentrations of 500,1000,1500 µg/mL each intraplate on different days. The precision of the method was assessed by calculating the %RSD for Fexuprzan HCl.

Intra-day Precision

Intra-day precision was evaluated by analysing fexuprazan solution at concentrations of 500, 1000,1500 µg/mL each intraplate on different days. The precision of the method was assessed by calculating the %RSD for Fexuprzan HCl.

Accuracy

The accuracy of the method was evaluated by performing recovery studies using the standard addition technique. Known quantities of standard solutions of Fexuprzan HCl (800,1000, 1200µg/ml) were added to the previously analysed sample solution containing 1000µg/ml. Each measurement was carried out in a triplate, and the average response was recorded. The percentage recovery was determined by measuring the absorbance and applying the obtained values to the regression equation of the respective calibration curves.

Limit of Detection and Limit of Quantification

LOD and LOQ are determined from the standard deviation of response and slope of the calibration curve using ICH guidelines.

RESULT AND DISCUSSION

Selection of wavelength

To determine wavelength for measurement, standard spectra of Fexuprazan HCl was scanned 200-400 nm against. Absorbance maxima were obtained at 227nm for Fexuprazan HCl.

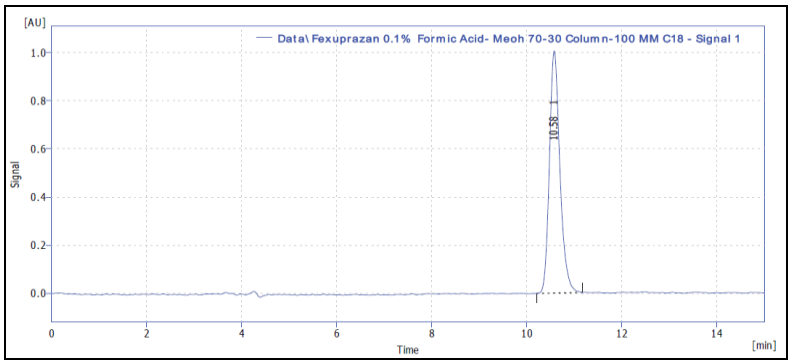

Figure 2: 0.1% Formic acid: Methanol (70:30) % v/v concentration.

Selection of critical factors and responses for further optimisation: Based on the above trials, the factors and responses that have a significant impact can be identified as critical parameters for method development. These parameters are further used to establish appropriate levels for the experimental design. The selected factors for the Design of Experiments (DoE) study were mobile phase volume (Factor 1) and flow rate (Factor 2). The responses evaluated were retention time (Response 1), peak area (Response 2), and tailing factor (Response 3) to determine the effect of chromatographic variables on the performance of the developed method.

Optimization of chromatographic conditions using DOE approach

Conventional HPLC method development mainly relies on a trial-and-error approach, which is time-consuming and provides limited information on the effects and interactions of chromatographic variables. To overcome these limitations, response surface methodology (RSM) was employed for systematic optimization. In the present study, a Central Composite Design (CCD) was selected due to its suitability for HPLC optimization and its ability to evaluate both individual and interactive effects of the selected factors.Based on preliminary

experimental trials, flow rate (A) and mobile phase ratio (B) were selected as the independent variables, while the retention times of both analytes and their resolution were chosen as the response variables. A rotatable two-factor CCD comprising 10 experimental runs, including four center points, was performed in a randomized order to minimize experimental bias.

Table 1: Final Equation for actual factors of Fexuprazan HCl.

Retention Time	=
+56.02602	
-3.03361	MP
+14.60798	Flow rate
-0.407500	MP * Flow rate
+0.051214	MP²
-3.00357	Flow rate²

Contour Plot: The contour plot illustrates in Figure 5.9 that the influence of mobile phase composition (A: 28-32ml) and flow rate (B:0.8-1.2 ml/min). The response surface indicates that retention time decreases with an increase in both mobile phase composition and flow rate. R_t observed at 11.8 min to 9.1 min as indicated by colour gradient. The optimize region around MP ≈ 30mL and Flow rate ≈ 1.0 ml/min.

3D Response Surface Plot

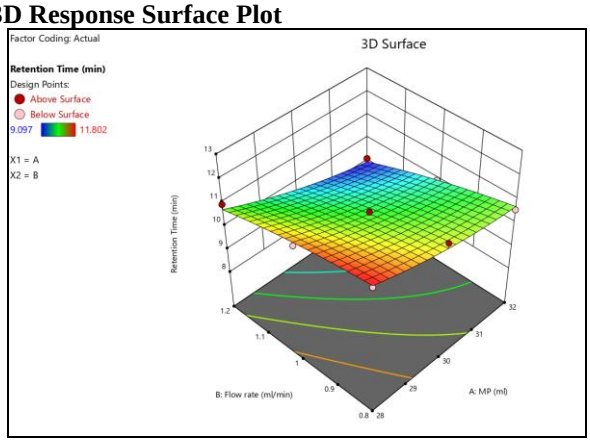

Figure 3: 3D Response Surface Plot for retention time of Fexuprazan HCl.

Response 2: Area

Final Equation in Terms of Actual Factors.

Table 2: Final equation of actual factor of fexuprazan HCl.

Area	=
+30902.20983	
-347.14708	MP
-4940.27083	Flow rate

Contour Plot: The contour plot illustrates in Figure 5.12 shows that at lower flow rate and lower mobile phase level the area response reaches the highest region. As the mobile phase increases towards 32 ml and flowrate increases towards 1.2 ml/min, the area gradually decreases to 14000-15000.

3D Response surface plot: as shown in Figure 5.14 the predicted are response varies approximately from 13,418 to 17,202. At lower flow rate and lower mobile phase the area response is observed in the higher region 16,500-1700 as the flow rate increases toward 1.2ml/min and the mobile phase level increases towards 32 ml, the area response gradually decreases to approximately 14,000-15,000.

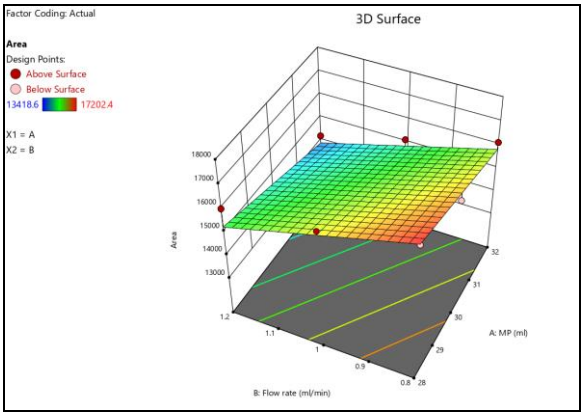

Figure 4: 3D representation for Area of Fexuprazan.

Response 3: Tailing Factor

Table 3: Final Equation of actual factors.

Tailing Factor	=
+1.52488	
-0.010798	MP
-0.034881	Flow rate
+8.68608E-16	MP * Flow rate
+0.000179	MP²
+0.017857	Flow rate²

Contour Plot: The contour plot represented in Figure 5.15 explains the tailing factor is 1.345, which is indicated by the green region. This suggest optimal chromatographic peak symmetry.

3D Response Plot: The 3D response in Figure 5.17 explains the effect of mobile phase composition and flow rate on the tailing factor. It can be observed that both mobile phase composition and flow rate significantly influence the tailing factor. The curved surface indicates the interactive effect between the two variables, at moderate levels of flow rate ~1.0 mL/min) and mobile phase composition (~30 mL), the tailing factor reaches its minimum value 1.344 - 1.345 indicating optimal chromatographic performance.

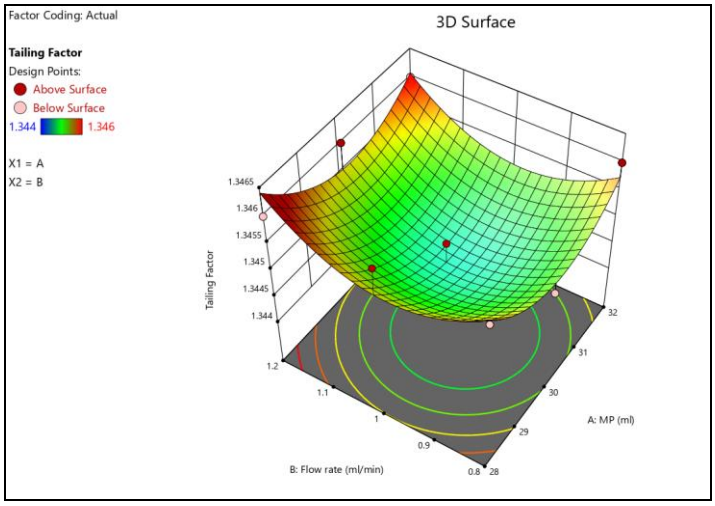

Figure 5: 3D representation for tailing factor of fexuprazan HCl.

➢ NUMERICAL OPTIMIZATION

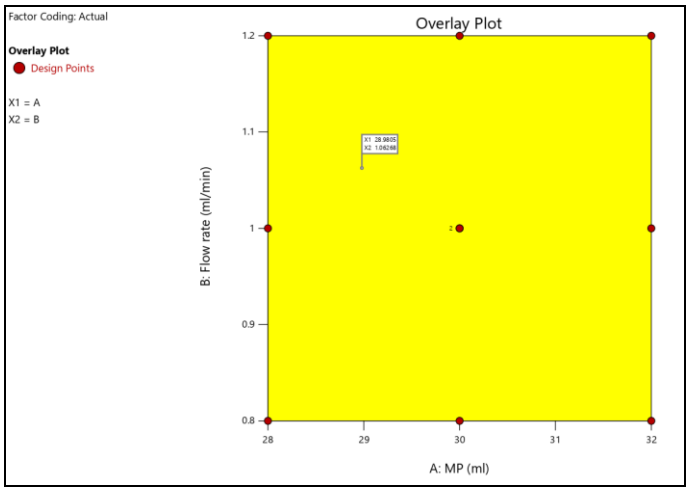

Figure 6: Overalay Plot for Fexuprazan HCl.

➢ Following optimization, experimental trials were conducted under the selected optimum conditions to validate the model. The predictive capability of model assessed by comparing the experimental results with the predicted response. The percentage prediction error was calculated using Prediction Error (%) = (Experimental − Predicted) / Predicted × 100 and found satisfactory.

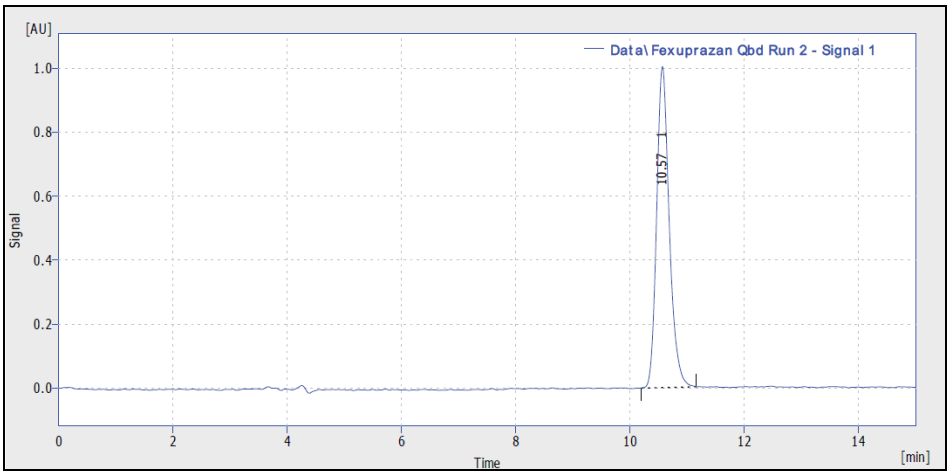

Figure 7: Chromatogram of optimised mobile phase trial for Fexuprazan (20 µL) using methanol and 0.1 % formic acid (30:70) %v/v concentration.

Table 4: System suitability parameter of optimized chromatogram.

Parameter	Fexuprazan HCl		
	Mean	± SD (n=3)	RSD
Retention Time (R_t)(min)	10.567	0.0052	0.049
Tailing Factor	1.345	0.0006	0.04
Number of Theoretical Plates	11171.33	4.04	0.036

Force Degradation Study

Table 5: Degradation Results of Fexuprazan HCl by RP –HPLC.

Degradation	Area	Percentage Degradation
Acid Degradation	14252.82	7.298
Base Degradation	14197.66	7.657
Oxidation Degradation	13420.57	12.711
Thermal Degradation	13895.74	9.621
Photo Degradation	14586.44	5.128

Method Validation

Specificity

The specificity of the method was confirmed by analysing standard and sample chromatograms. A sharp and well-defined peak of Fexuprazan HCl was observed at a retention time of approximately 10.5–10.6 minutes in all samples. No additional peaks or interference were observed at the retention time of the analyte. This indicates that the method is specific for the determination of Fexuprazan HCl.

Linearity

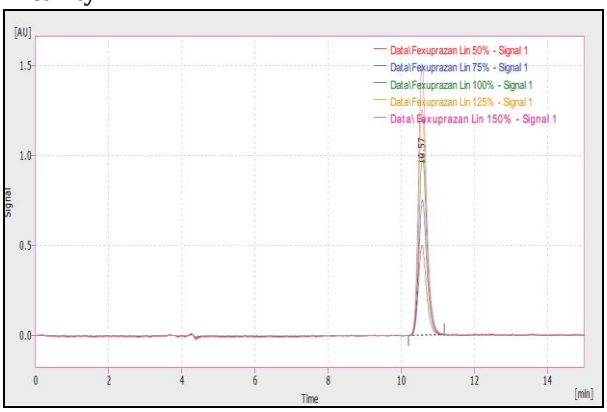

Figure 8: Overlay of linearity spectra of Fexuprazan HCl.

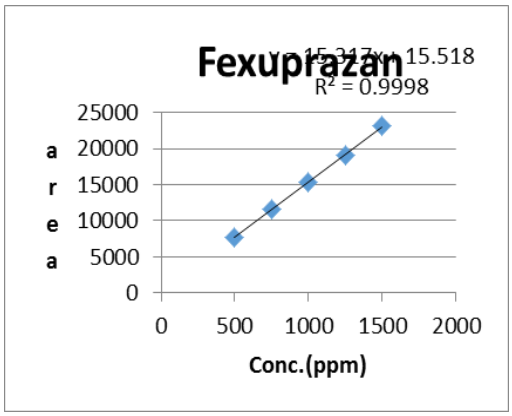

Figure 9: Calibration curve of Fexuprazan HCl.

Precision

Repeatability

The data of reproducibility for fexuprazan HCl are present in the table 5.29. The %RSD for reproducibility was found is 0.79%.

Table 6: Repeatability data for Fexuprazan HCl.

Drug	Concentration (µg/ml)	Mean peak area ± SD (n=6)	%RSD
Fexuprazan HCl	1000µg/ml	15394.783 ± 122.5	0.79

Inter-day Precision

The interday precision of the developed HPLC method for Fexuprazan Hydrochloride was evaluated at concentrations of 500, 1000, and 1500 µg/mL. The mean peak areas obtained were 7670.468 ± 0.618, 15347.350 ± 1.074, and 23081.800 ± 1.260, respectively. The corresponding %RSD values were 0.008%, 0.007%, and 0.005%, demonstrating excellent precision and reproducibility of the developed method.

Intra-day Precision

The intraday precision of the developed HPLC method for Fexuprazan Hydrochloride was evaluated at concentrations of 500, 1000, and 1500 µg/mL. The mean peak areas obtained were 7666.644 ± 1.91, 15345.286 ± 1.42, and 23080.817 ± 0.99, respectively. The corresponding %RSD values were 0.024%, 0.009%, and 0.004%, indicating excellent intraday precision and repeatability of the developed method.

Accuracy

The accuracy of the developed HPLC method for Fexuprazan Hydrochloride was evaluated by recovery studies at 80%, 100%, and 120% levels using a sample concentration of 1000 µg/mL. The mean amounts recovered were 800.230 ± 0.10, 1000.590 ± 0.34, and 1200.200 ± 0.11 µg/mL, with corresponding percentage recoveries of 100.03%, 100.06%, and 100.02%, respectively. The recovery results demonstrate the excellent accuracy of the developed method.

LOD and LOQ

The Limit of Detection (LOD) value was found to be 2.78 µg/ml and Limit of Quantification (LOQ) value found to be 8.73 µg/ml.

Analysis of marketed Product

The Purposed method was successfully applied to the analysis of the commercially available tablet formulation. The % drugs were found satisfactory, which is comparable with the compounding label claim.

Table 7: analysis of marketed formulation.

Dosage Form	Label Claim (mg)	% Assay mean ± SD*
Fexeclue 40mg	Fexuprazan 40mg	99.54 ± 0.26

SUMMARY OF METHOD VALIDATION

Table 7: Summary of validation parameters for RP-HPLC method.

Sr.No.	Parameter	Fexuprazan HCl
1	Linearity Range (µg/mL)	500-1500
2	Co-relation Coefficient	0.999
3	Precision Repeatability (n=6) Intra-day Precision (n=3) Inter-day (n=3)	 0.79 0.0042-0.024% 0.0054-0.0080%
4	Accuracy (%Recovery)	100.02 - 100.06
5	Limit of detection (LOD) (µg/ml)	2.78
6	Limit of Detection (LOQ) (µg/ml)	8.43
7	Assay (%) marketed formulation	99.54%

CONCLUSION

- The present study describes the successful development and validation of a robust, precise and stability-indicating RP-HPLC method for the quantitative estimation of fexuprazan hydrochloride. Notably, no Quality by Design (QbD) based analytical method has been previously reported for this drug; therefore, a systemic QbD approach was employed to enhance method understanding, reliability and robustness.
- During the initial method development phase, a trial-and-error approach was adopted to establish suitable chromatographic condition. Various mobile phase system, including ACN-water and methanol-water combinations in different proportions, were evaluated using a C18 column; however, these resulted in suboptimal chromatographic performance, including poor peak symmetry and inadequate resolution. To address this limitation, an acidic modifier was introduced, leading to the selection of an optimized mobile phase consisting of 0.1% formic acid and methanol (70:30), which provides sharp, symmetrical peaks with acceptable retention behavior and tailing.
- Subsequently, QbD based optimization was carried out using central composite Design to evaluate the effect of critical method parameters (CMPs), namely mobile phase composition and flow rate, on critical quality attributes such as retention time, peak area and tailing factor. A total of **10** experimental runs were performed as per the design matrix. The observed response demonstrated that retention time ranged from **9.097 to 11.802** minutes, peak area between **13418.6 and 17202.4** and tailing factor within **1.344-1.346**, indicating consistent chromatographic performance. Statistical evaluation and response surface analysis facilitated the establishment of design space and identification of optimized chromatographic conditions.
- The developed method was validated in compliance with ICH Q2(R1) guidelines for analytical method validation. The method exhibited excellent linearity over concentration range of **500-1500 µg/mL**, with a correlation coefficient ((R^2) of **0.999**, demonstrating a strong linear relationship between concentration and response. Precision studies showed satisfactory repeatability with %RSD of 0.79% while intra - day and inter-day precision values were within acceptable limits, confirming method reproducibility. Accuracy was confirmed by recovery values ranging from 100.02% to 100.06% indicating the absence of interference from excipients,
- The LOD and LOQ observed at 2.78 and 7.83 respectively. The assay of the marketed formulation was found to be 99.54%, which complies, confirming the suitability of the method for routine quality control analysis
- Furthermore, the stability indicating capability of the method was established through forced degradation studies conducted under acidic, basic oxidative, thermal, and photolytic condition in accordance with

ICH Q1A (R2) guidelines. The % of degradation is **7.657%,12.711%, 9.621% and 5.128%.** The method effectively separated degradation products from the analyte peak, confirming its specificity and stability-indicating nature.

- In conclusion, the developed Rp-HPLC method is simple, accurate, precise, robust and stability-indicating. The integration of conventional method development with QbD principles, along with compliance with ICH regulatory guidelines, ensured systemic optimization and reliable analytical performance. Therefore, the proposed method is highly suitable for routine quality control analysis, stability studies and pharmaceutical evaluation of Fexuprazan Hydrochloride in bulk and dosage form.

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