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Analytical Method Devlopment and Validation of Gasterointestinal Drug

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ABSTRACT

A simple, selective, rapid, and precise high-performance liquid chromatography (HPLC) method for the estimation of vanoprazan has been developed. The compounds were well separated on a column (id4.6×150mm)length with a mobile phase consisting of buffer containing 10 ml methanol: 0.1% acetic acid with (ph2.8) (58:42v/v) at a flow rate of 0.8mL/min and ultraviolet detection at 254nm. The retention time of vanoprazan were found 3.445min. Validation of the proposed method was carried out according to International Conference on Harmonisation (ICH) guidelines. Linearity range was obtained for vanoprazan over the concentration range of 5-25mg/mL and the r2 values was0.999. The calculated limit of detection (LOD) value was 0.0509709 mg/mL and limit of quantitation (LOQ) value was0.1544574 mg/mL. Thus, the current study showed that the developed liquid chromatography method is effective for estimation of vanoprazan.

INTRODUCTION

Vanoprazan 1-[5-(2-fluorophenyl)-1-(pyridine-3-ylsulfonyl-1H-pyrrol-3-yl]-N-metylmethanamine (fig-1) is a new- generation acid-suppressing drug used to reduced stomach acid.it belongs to the class called Potassium-Competitive Acid Blockers (P-CABs).it is used for the treatment of gastroesophageal reflux disease (GERD), Peptic ulcer disease (gastric and duodenal ulcers), H. pylori eradication therapy.

It works by the mechanism by blocking the H+/K=-ATPase enzyme (proton pump) in stomach cells.it competes with potassium ions-strong and long-lasting acid suppression and works fater and more consistently than PPIs like omeprazole. The increasing clinical use of Vonoprazan, a novel potassium-competitive acid blocker (P-CAB), has created a need for reliable and precise analytical methods for its quantitative determination in pharmaceutical dosage forms and biological

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matrices. Vonoprazan has gained significant attention due to its rapid onset of action, potent acid suppression, and improved therapeutic efficacy compared to conventional proton pump inhibitors such as Omeprazole. It is widely used in the treatment of acid-related disorders, including gastroesophageal reflux disease, peptic ulcers, and Helicobacter pylori infections.

IUPAC NAME: 1-[5-(2-fluorophenyl)-1-(pyridin-3-ylsulfonyl)-1H-pyrrol-3-yl]-N-methylmethanamine

CHEMCAL FORMULA: $C_{17}H_{16}FN_3O_2S$

MOLECULAR WEIGHT: ~345.39 g/mol

CATEGORY: Potassium- Competitive Acid Blocker (P-CAB)

DISCRIPTION: white to off-white crystalline powder

MELTING PONT: 228°C – 232°C (for vonoprazan base)

SOLUBILITY: slightly soluble in water, more soluble in organic solvent

HALF LIFE(t½): ~ 7 to 9 hours

Pka VALUE: ~ 9.1 – 9.3

DOSE: 10-20 Mg

STORAGE: store at (20- 25°C)

MECHANISM OF ACTION: Vonoprazan acts by directly inhibiting the gastric proton pump (H^+/K^+-ATPase) in the parietal cells of the stomach.

- It competitively blocks potassium (K^+) binding sites on the proton pump
- This prevents the exchange of H^+ ions into the gastric lumen
- As a result, gastric acid secretion is strongly suppressed

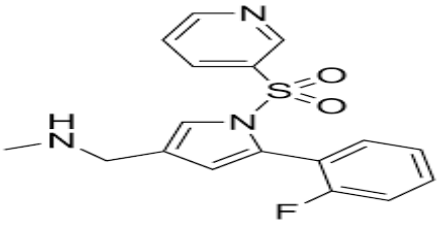

Fig 1.1: Vanoprazan

With the growing demand for quality control and regulatory compliance, the development of robust analytical methods is essential to ensure the safety, efficacy, and consistency of pharmaceutical products containing Vonoprazan. Analytical techniques such as high-performance liquid chromatography (HPLC), UV–visible spectrophotometry, and liquid chromatography–mass spectrometry (LC-MS) are commonly employed for the estimation of drug substances. Among these, HPLC is the most widely preferred due to its high sensitivity, specificity, accuracy, and reproducibility.Method development involves the systematic selection and optimization of chromatographic conditions, including mobile phase composition, column type, flow rate, detection wavelength, and sample preparation techniques, to achieve optimal separation and quantification of the drug. Once developed, the analytical method must be validated according to guidelines established by the International Council for Harmonization, particularly ICH Q2(R1), to demonstrate its suitability for intended use.Validation parameters such as accuracy, precision, linearity, specificity, limit of detection (LOD), limit of quantification (LOQ), robustness, and system suitability are critical in confirming the reliability of the developed method. A well-validated analytical method ensures consistent drug quality and supports regulatory submissions.

Therefore, the present study focuses on the development and validation of a simple, accurate, precise, and cost-effective analytical method for the estimation of Vonoprazan in pharmaceutical formulations, in accordance with ICH guidelines.

2. MATERIALS AND METHODS:

2.1 Chemicals:

Methanol (HPLC grade), 0.1% Acetic Acid (AR grade) and water are used as solvent in method development by HPLC. Active pharmaceutical ingredient (APIs) Vanoprazan as reference standard was obtained from Swaroop drugs and pharmaceuticals, Aurangabad, Maharashtra.

2.2 Equipment's:

HPLC: Agilent Tech Gradient system with Auto injector was used for method development and validation

UV-Spectrophotometer: Analytical technology

pH meter: VSI pH meter (VSI 1-B)

Analytical Balance: WENSAR tm High resolution balance

Sonicator: Ultrasonic electronic instrument

2.3 Method development and optimization of chromatographic conditions for separation:

The chromatographic condition was optimized by using different columns (Agilent C18 250mmX 4.6, 5um), mobile phase composition (methanol: 0.1% acetic acid in the ratio 58:42), pH, wavelength (254nm), flow rate (0.8ml/min), column temperature (ambient to 45C), and injection volume (20ml) and particle size packaging (5um).

2.4. Sample preparation

2.4.1 Physical form of the API:

Vanoprazan is white to off- white crystalline powder and it is freely soluble in methanol, water and sightly soluble in ethanol MP is around 140-144 degree Celsius.

2.4.2. Preparation of stock solutions:

Accurately weighed 20 mg of Vanoprazan was transferred to a 50 ml volumetric flask, dissolved in 10ml methanol to obtain a concentration of 500 µg/ml, and sonicated for 2 minutes to ensure complete dissolution.

2.4.3. Preparation of standard solution:

Aliquots were withdrawn from the stock solution and diluted with mobile phase to obtain concentrations of 0.1, 0.2, 0.3,0.4, and 0.5 µg/ml. These solutions were used for calibration curve preparation.

2.4.4. Marketed Tablet Test Preparation:

Twenty tablets were weighed, powdered, and average weight was calculated. Powder equivalent to 8.75 mg of Vanoprazan was transferred into a 50 ml volumetric flask, dissolved in 10 ml methanol, and sonicated for 15 minutes to ensure complete extraction of drug. Further dilution was carried out to obtain a final concentration of 20 µg/ml.

2.4.5. Assay Preparation:

An aliquot of 0.4 ml from stock solution was diluted up to 10 ml with mobile phase for assay determination. The prepared solutions were filtered before injection to avoid particulate interference.

METHOD DEVLOPMENT

High Performance Liquid Chromatography (HPLC):

It is the most commonly used technique for the quantitation of drugs in a formulation. It is used in various fields, industries along with pharmaceutical industries. It is analytical tool used for drug discovery, development, research and production. It is used to separate, identify and detect the amount present in a mixture.

Principle

The separation is based on the distribution of the sample between a mobile phase and a stationary phase. It depends on the chemical structure of analyte that gets adhered to the stationary phase. The component which has less affinity towards stationary phase moves faster than the one which has high affinity towards stationary phase.

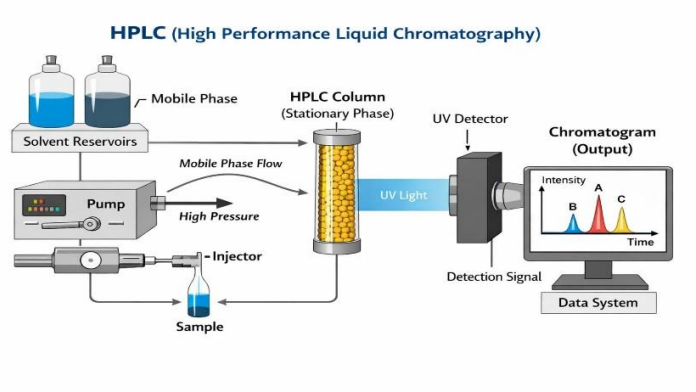

Fig.2: Instrumentation of HPLC

System suitability parameter:

1. **Theoretical plates (N):** It is also called as column efficiency. It is given by the following relationship.

$$N=16(t)2/W$$

Where, t is retention time and w is width at the base of the peak

2. **Height Equivalent to Theoretical plate (H):** The efficiency of the column can be expressed as the height equivalent theoretical plate.

$$H=L/N$$

Where, L= length, N= no of theoretical plates, H= height equivalent to theoretical plate

3. **Retention Time (RT):** it is time between which the sample is injected and the chromatographic peak is recorded in to chromatogram

4. **Resolution (Rs):** the resolution of two neighboring peaks is defined by the ratio of the distance between the two peak maxima.

5. **Capacity factor (K):** this value gives n indication of how long each component is retained on the column

6. **Tailing factor (T):** it is measure of peak symmetry and is unity for perfectly symmetrical peaks and its value increases as tailing become more pronounced.

Validation:

WHO guidelines define validation as "Validation is the documented act of proving that any procedure, process, equipment, material, activity or system actually leads to the expected result." Validation is an important requirement in the practice of an analytical process, Method validation can be interpreted as the process of defining an analytical requirement, and confirming that the method under consideration has performance capabilities consistent with that the application requires.

1.Prospective validation
2.Retrospective validation
3.Concurrent validation
4.Revalidation

Method development:

Need of analytical method validation

To provide accurate validation data for different sites and parameters, as well as to show intra- and inter-laboratory dependability. it is crucial to access the analytical result when sample analysis for a specific study is conducted at multiple location and in a commercial batch for consumption method(s) in compline with ICIH recommendations." Methods are developed for new products when no official methods are available. An alternative approach improve precisions and robustness for current (non-pharmacopeial) products is to cut cost around times. When a different approach is suggested to replace the current process, comparative laboratory data with advantages and disadvantages arc made accessible.The primary active ingredient, any reaction impurities all synthetics intermediates that are available, and any degradants are to be separated and quantified using the HPLC- method

Steps involved in Method development are:

1. Understanding the Physicochemical properties of drug molecule.
2. Selection of Chromatographic Conditions.
3. Developing the Approach of Analysis.
4. Sample Preparation
5. Method Optimization
6. Method Validation

METHOD VALIDATION:

The word Validation" comes from the Latin word "Strong ness." The power or robustness of method,

process, or piece of equipment to function is known as Validation. It is the act demonstrating an approach's acceptance by confirmation and documenting it legally using evidence from science. The process of proving through laboratory testing that analytical metho performance characteristics satisfy the demands of the planned analytical application is known validation. Any new or modified procedure must be validated to make sure it can produce repeat and trustworthy results when utilized by various operators using the same equipment in various laboratories.Complete method validation according to ICH guidelines.

VALIDATION OF DEVELOPED METHOD:

After developing the RP-HPLC method, validation was carried out to confirm the suitability of the method for its intended purpose. The validation of the developed method for Vanoprazan was performed as per ICH guidelines. The following parameters were evaluated:

A. Accuracy

Accuracy is defined as the closeness of agreement between the true value and the value found. It is also referred to as trueness. In this study, accuracy

was determined by injecting known concentrations of the drug at different levels and calculating the mean peak area. The standard deviation and %RSD were calculated. Acceptance Criteria: The percentage relative standard deviation (%RSD) should be not more than 2%.

B. Precision

recision of the method was evaluated by intraday and interlay studies. In intraday precision, the sample solution was injected multiple times within the same day, while interday precision was performed on different days. The peak areas were recorded and %RSD was calculated.Acceptance Criteria: RSD of the mean concentration of replicate readings should be NMT 2%.

C. Recovery Studies:

Recovery studies were carried out by spiking known amounts of standard drug into the pre-analyzed sample. The concentration obtained was compared with the added amount to calculate % recovery. Acceptance Criteria: For assay method, mean recovery should be in the range of 98–102%.

D. Linearity

Linearity was established by preparing standard solutions of Vanoprazan in the concentration range of 5–25 µg/ml. A calibration curve was plotted between concentration (x-axis) and peak area (y-axis). Acceptance Criteria: The correlation coefficient (r^2) should be not less than 0.999.

E. Limit of Quantification (LOQ)

LOQ is the lowest concentration of analyte that can be quantitatively determined with acceptable precision and accuracy. LOQ = 10 × SD / Slope

Acceptance Criteria: Signal-to-noise ratio should be approximately 10:1.

F. Limit of Detection (LOD)

OD is the lowest concentration of analyte that can be detected but not necessarily quantified.

$$LOD = 3.3 \times SD / Slope$$

Acceptance Criteria: Signal-to-noise ratio should be approximately 3:1.

G. Specificity

Specificity of the method was evaluated by comparing chromatograms of standard and sample. No interference was observed at the retention time of Vanoprazan, confirming specificity of the method.

Acceptance Criteria: No interference at retention time and peak purity should be acceptable.

H. Robustness

Robustness was studied by making small deliberate changes in chromatographic conditions such as: Flow rate (±2%) Wavelength (±2 nm) The effect on peak area and retention time was observed.

Acceptance Criteria: Deviation in results should be less than 2%.

I. System Suitability Studies:

System suitability studies were performed to confirm the adequacy and reliability of the chromatographic system prior to analysis. Various parameters, including column efficiency (theoretical plates), resolution, capacity factor, tailing factor, and repeatability (%RSD), were evaluated by repeated injections of standard solutions. The results obtained were compared

with established acceptance criteria to ensure consistent system performance. These studies were conducted in compliance with USP guidelines.

Capacity factor (k')

It is measurement of sample molecule how good is retained by a column during separation. The ideal k value ranges from 2-10.

Capacity Factor (k') = V1-Vo/Vo

Where,

VI is the retention volume at the apex of the peak (solute) and

Vo is the void volume of the system.

Resolution (Rs)

It is the difference between the retention times of two solutes divided by their average peak width. The ideal value of (Rs) is 1.5

Resolution (Rs) = Rt1-Rt2/0.5(W1-W2)

Where, Rt1 and Rt2 are the retention times of component 1 and 2, respectively.

Column Efficiency (N) of a column is measured by the number of theoretical plates per meter. For ideal good separation, column efficiency N value ranging from 5,000 to 100,000 plates/meters.

Column efficiency (N) = Rt 2/W2

Where, Rt is the retention time and W is the peak width.

Peak asymmetry factor- For better column performance it was calculated by the formula. When asymmetry factor of value 0.9 to 1.1 then it is achievable for a well packed column.

Peak asymmetry factor (As)-b/a

Where a and b are the distances on either side of the peak midpoint.

Table 1: acceptance criteria for validation parameter

Validation parameter	Acceptance criteria
Accuracy	Recovery 98-102%
Precision	RSD<2%
Repeatability	RSD<2%
Specificity	NO interference
LOD	S/N>2 or 3
LOQ	S/N>10
Linearity	r2<0.999
Robustness	RSD<2%

3. RESULT AND DISCUSSION:

Proper selection of the HPLC method depends on the nature of the sample (ionic or ionizable or neutral molecule), its molecular weight, and solubility. The drugs selected for the current study are polar in nature; hence, RP-HPLC was selected for its separation because of its simplicity and suitability. A reverse-phase high-performance liquid chromatographic (RP-HPLC) method was developed and validated for the estimation of Vanoprazan. Various chromatographic parameters were systematically optimized to obtain a sharp, well-resolved peak with good symmetry and reproducibility. The standard solution was prepared and analyzed under optimized

conditions, and the chromatograms were recorded. The developed method was found to be simple, precise, and suitable for the quantitative analysis of Vanoprazan.

3.1. Optimization of the chromatographic condition

The selection of detection wavelength plays a significant role in determining the sensitivity of the analytical method. The UV spectrum of Vanoprazan was scanned over a suitable wavelength range to identify the wavelength of maximum absorbance. Based on the spectral analysis, 254 nm was selected as the detection wavelength, as the drug exhibited adequate absorbance at this wavelength. This ensured reliable detection and consistent analytical performance.

3.1.1Column selection

Experiments with different columns were conducted to achieve best separation of analyte peak with other blank and placebo peaks. It was found that the peak shape, retention time, tailing factor, and column efficiency were good with Agilent C18 column (250mmX 4.6mm, 5um)

3.1.2Mobile phase composition

On the basis of the solubility study, methanol and 0.1% acetic acid to be used as mobile phase.

A mixture of methanol and 0.1% acetic acid solvents in different proportions were tested, as variation in the mobile phase composition led to substantial changes in the chromatographic performance. Decreasing the organic modifier content resulted in decrease in retention time of the analyte but had no effect on analyte response. Hence, methanol and acetic acid was selected as an organic modifier. Many trials on the composition of buffer and organic solvents were made to decide the ultimate composition of the mobile phase as methanol and 0.1% acetic acid (58:42).Based on the peak shape, peak symmetry, and retention time, the flow rate of 0.8mL/min, injection volume was 20ul and ambient column temperature were also optimized.

3.1.3Detection wavelength

The sensitivity of a HPLC method with UV detection depends on the proper selection of detection wavelength, which can be determined by recording overlaid UV spectra. In the current study, solutions containing 20mg/mL of Vanoprazan was prepared in mobile phase and scanned under 200 to 400 nm of UV region to record the overlaid UV spectra.

3.1.4pH of the buffer

pH plays an important role in achieving the chromatographic separation as it controls the elution properties by controlling ionization characteristics. The pKa 2.8 value for Vanoprazan 0.1% acetic acid was selected based on the solubility studies. Various trials on pH were made to determine the optimized pH at which the API reseparated well. At pH2.8, peak shape, peak tailing and theoretical plate count were found to be satisfactory; hence, 2.8 was decided as the pH of the buffer. A tolerable limit of pH 2.8 ± 0.1 was optimized using a pH meter. In order to determine the adequate resolution and reproducibility of the proposed method, suitability parameters including retention time, plate number were investigated and were found to be justified, which indicates the method suitability. The optimized chromatographic conditions are mobile phase concentration buffer (methanol: 0.1% acetic acid) in the ratio 58: 42% v/v, pH 2.8, 254 nm as detection wavelength, 0.8 mL/min flow rate, ambient column temperature, 20 mL injection volume.

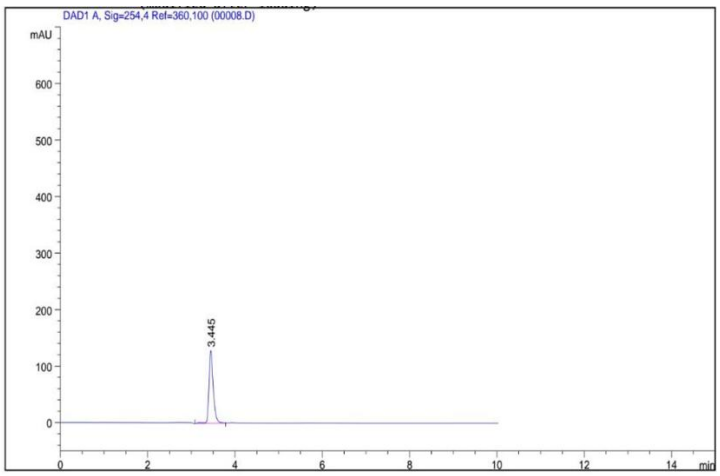

Figure 3: The chromatographic representation of Vanoprazan, the peakat retention time is 3.445 min.

3.2. Validation of method

3.2.1. Specificity

The specificity of the existing method of analysis by HPLC is shown in figure 3; the complete clear separation of Vanoprazan was observed without any interference in retention time.

3.2.2. Accuracy

The accuracy of the method was determined by recovery experiment. Studies were carried out with three injections and three different concentrations. The percent recovery, mean and relative standard deviation (%RSD) were calculated and present in Table 2. API with the concentration 8,10,12mg/ml of Vanoprazan were prepared. The test solution was injected for each spike level and the assay was performed as per the method. Analysis of the result has shown the percentage recovery values were close to 100% and also the RSD values were less than ±5%. The accuracy and Reliability of the developed method was established.

Table 2: Accuracy at 80%, 100% and 120%

Vanoprazan			Amount added	Amount Recovered	Recovery (97-103)
Name	Preparations	Area	Ug/ml	Ug/ml	%
Accuracy at 80%	Prep -1	712.53	8	8.22	102.71
Accuracy At 80%	Prep -2	710.53	8	8.16	102.05
Accuracy At 100%	Prep -1	786.24	10	10.172	101.73
Accuracy At 100%	Prep -2	782.69	10	10.078	100.78
Accuracy At 120%	Prep -1	860.62	12	12.146	101.22
Accuracy At 120%	Prep- 2	855.62	12	12.013	100.11

Table 3: Accuracy result

Accuracy Level	Mean % Recovery	SD	% RSD (NMT2)
Accuracy at 80%	102.38	0.47	0.46
Accuracy at 100%	101.25	0.67	0.66
Accuracy at 120%	100.67	0.78	0.78

3.2.3. Precision

The precision of the method was demonstrated by interday and intraday variation studies at various concentrations:5,10.15ug/ml and the data are summarized in Table 4. The lower RSD% values (<1.00) indicate good precision of the developed method.

Preparation		**Measured concentration(mg/mL), RSD (%) (n¼6)**	
		Intraday (% assay)	**Interday (% assay)**
Set-1	Prep-1	99.73	99.41
	Prep-2	100.99	101.30
Set-2	Prep-1	102.76	102.70
	Prep-2	99.73	101.30
Mean		100.80	101.17
SD		1.43	1.34
%RSD(NMT2.0)		1.42	1.33

3.2.4. Linearity

Linearity for Vanoprazan

The linearity graph of average peak area at each level against the concentration in ug/ml is plotted and found to be straight line graph. This method proved to be linear between µg/ml of Vanoprazan, with a typical Linearity curve of correlation equation.

$y = 37.69x + 25.94$

Correlation coefficient > 0.999

The chromatograms of linearity standards with concentrations 5, 10, 15, 20 and 25 µg ml were recorded and their peak areas of drug were 219.93, 397.74, 588.23,778.96, 971.56repectively. The linearity curve for Vanoprazan was plotted as peak Area vs. concentration of the Vanoprazan Linearity standards.

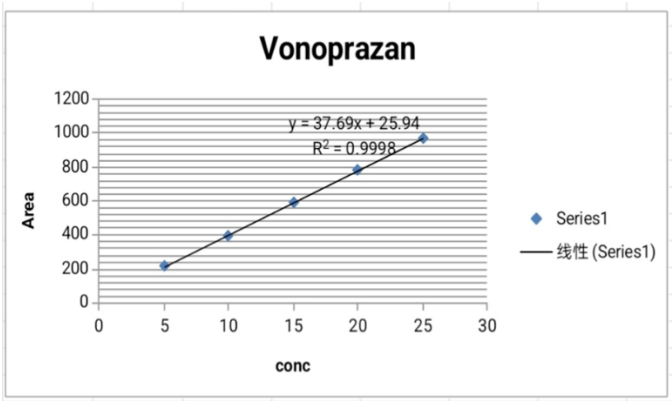

Figure 4: linearity curve of Vanoprazan

The correlation coefficient of Vanoprazan was found to be 0.9998, which was within acceptable limits. The calibration curve plotted was found to be linear and showed that the method has adequate sensitivity to the concentration (5-25 µg/ml) of the drug. Finally, the data obtained in this study was within limits. The coefficient of correlation of Vanoprazan was found to be 0.9998.

3.2.5. LOD and LOQ

The LOD and LOQ of the compounds were determined by injecting progressively lower concentration of the standard solution into the HPLC column the optimized chromatographic condition. The LOD values was found to be 0.0509 mg/ml. The LOQ value was found to be 0.154mg/ml respectively.

3.2.6. Robustness

Robustness was performed by making deliberate changes in chromatographic conditions to evaluate the effect of variations in mobile phase composition and wavelength. Robustness was studied for Vanoprazan and the results was obtained. In this study, the mobile phase composition was varied slightly, and wavelength was changed by ±2 nm. These variations were evaluated to observe their effect on the chromatographic response. No significant changes were observed in the results due to these variations. However, slight changes were noticed in some system suitability parameters. Mean was found to be 3493.47 and SD value was found to be 35.0 and % RSD was 1.00. The standard deviation values for all robustness conditions were found to be within acceptable limits, indicating that the developed method is robust.

3.2.7 Ruggedness:

Ruggedness of the analytical method was evaluated by making small variations in different conditions such as analyst and instrument to study their effect on the method performance. Ruggedness was studied for Vanoprazan with the concentration 10.ug/ml for analyst 1 and 10ug/ml for analyst 2 and the peak areas were found to be 399.884 and 397.523 respectively by calculating these value mean w.as found to be 398.70 and SD was 1.669 and % RSD was found to be 0.419 In this study, the analysis was carried out by different analysts and/or using different instruments. The effect of these variations was evaluated on the chromatographic response. No significant changes were observed in the results due to these variations.

3.2.8 System suitability:

These parameters were shown to be within specified limits. Column efficiency (theoretical plates), resolution factor, and peak asymmetry factor, tailing factor, and %RSD are the system

suitability parameters. These parameters of the optimized method were found satisfactory. The system suitability was evaluated using trial injections of Vanoprazan, and the results indicated good repeatability and efficient chromatographic performance. These parameters were found to be within specified limits.

3.2.8 Marketed sample analysis:

This study was conducted on market sample dosage form which contain average tablet weight of 35 mg of vanoprazan two test solution with concentration of 20 mg there area was found to be 779.238 and 777.562 with retention time 3.425 and 4.423 and the mean was found to be 777.40 and SD was found to be 1.185 and %RSD was found to be 0.152 respectively

4. SUMMURY AND CONCLUSION

The Analytical method development was developed for the determination of Vanoprazan by RP-HPLC method and it was validated as per ICH guideline.Literature survey revealed that no particular method is yet reported for the estimation of the drug. The present study was undertaken with an objective of developing suitable, sensitive, simple, precise analytical RP-HPLC method for drug.Before going to development of method the drug sample were analyzed for solubility study, melting point determination, UV study for conformation of drug sample.In RP-HPLC method, the analyte was resolved using methanol: acetic acid in ratio 58:42 at a flow rate of 0.8 ml/min, on Thermo Separation Product Quaternary Gradient HPLC pump Spectra System P4000 system containing of UV- 1000 UV- visible detector with CHEMSTATION Software and (column 4.6 X 150mm length Particle size: 5 um) The detection was carried out at 254nm. The method gave the good resolution and suitable retention timeThe results of analysis in all the method were validated in terms of Accuracy, Precision, Ruggedness Linearity and Range. The methods were found to be sensitive, reliable, reproducible. rapid and economic also. The method shows good reproducibility, the RP-HPLC method is Accurate. Precise Specifie, Reproducible and Sensitive. The analysis of Vanoprazan successfully performed by the RP. HPLC methods. The method has been found to be better because of its less retention time. isocratic mode and use of economical readily available mobile phase, readily available column, UV detection and better resolution of peaks The method provides selective quantification of Vanoprazan. No interference of additives is encountered in this method.The method was completely validated showing satisfactory data for all the method validation parameters tested as per standard acceptance criteria. Hence this method can be used for determination of Vanoprazan.

CONCLUSION

A Rapid, user friendly, Precise method for determination of the Vanoprazan was developed and validated. All the validation parameters like Accuracy, Precision (Intraday and Interday), Linearity, Robustness, LOD and LOQ was under acceptance criteria. The method was Linear with a correlation coefficient of acceptable agreement, which is suitable for the estimation of Vanoprazan. This is method also shows the good reproducibility result.

REFERENCES

1. Anju G, Pandey P. Process Validation of Pharmaceutical Dosages Form: A Review. Biomedical Journal of Scientific and Technical Research. 2017;1(5):1467–75.
2. Ahir KB, Singh KD, Yadav SP, Patel HS, Poyahari CB. Overview of Validation and Basic Concepts of Process Validation.

Scholars Academic Journal of Pharmacy (SAJP). 2014;3(2):178–90.
3. Harpreet K, Gurpreet S, Nimrata S. Pharmaceutical Process validation: A Review. Journal of Drug Delivery and Therapeutics. 2013;3(4):189–94.
4. Ojha A, Bharkatiya M, Kitawat S. Pharmaceutical Process Validation of Solid Dosage Forms: a Review. World Journal of Pharmacy and Pharmaceutical Sciences. 2014;3(6):476–84.
5. Aleem H, Zhao Y, Lord S, McCarthy T, Sharratt P. Pharmaceutical process validation: An overview. Proceedings of the Institution of Mechanical Engineers, Part E: Journal of Process Mechanical Engineering. 2003;217(2):141–51. ICH Q2(R2)
6. FDA: Analytical Procedures and Methods Validation for Drugs and Biologics
7. Review of Models & Methods for GI Drug Performance Evaluation
8. Review of Physiological Variables Affecting GI Drug Absorption
9. Karakan T, Ozkul C, Küpeli Akkol E, Bilici S, Sobarzo-Sánchez E, Capasso R. Gut-Brain-Microbiota Axis: Antibiotics and Functional Gastrointestinal Disorders. Nutrients. 2021 Jan 27;13
10. Everhart JE, Ruhl CE. Burden of digestive diseases in the United States part I: overall and upper gastrointestinal diseases. Gastroenterology 2009; 136: 376–386.
11. Quigley EMM. Prokinetics in the management of functional gastrointestinal disorders. Curr Gastroenterol Rep 2017; 19: 53.
12. Kale H, Fass R. Prokinetic agents and antiemetics. In: MM Wolfe, RC Lowe, eds. Pocket Guide to Gastrointestinal Drugs. Chichester, UK: John Wiley & Sons, Ltd, 2014: 1–14.
13. Rajage GN, et al. Green assessment-based stability-indicating RP-HPLC method for determination of vonoprazan fumarate. Rev Electron Vet. 2024;25(2):1–10. doi:10.69980/redvet.v25i2.1831.
14. Alzaghal NM, et al. Method development and validation for estimation of vonoprazan by RP-HPLC in bulk and tablet dosage form. Egypt J Chem. 2024;67(3):1–12. doi:10.21608/ejchem.2023.193129.7593.
15. Yoneyama T, et al. Quantification of vonoprazan and its metabolites in human plasma by LC-MS/MS. J Chromatogram B. 2016;1015–1016:42–49.
16. Zhang Y, et al. Stability-indicating HPLC method for determination of related substances in vonoprazan fumarate. J Pharm Biomed Anal. 2018; 150:322–329. doi: 10.1016/j.jpba.2017.11.011.
17. Abdelaleem EA, et al. Optimization of RP-LC method for determination of vonoprazan impurities using Six Sigma approach. Microchem J. 2024; 198:111535. doi: 10.1016/j.microc.2024.111535.
18. Sharma K, et al. Eco-friendly spectrophotometric methods for determination of vonoprazan in pharmaceutical formulations. Spectrochim Acta A Mol Biomol Spectrosc. 2025; 300:123456.
19. International Council for Harmonization (ICH). ICH guideline Q2(R2): Validation of analytical procedures. Geneva: ICH; 2023.
20. Kagami T, et al. Pharmacokinetics, pharmacodynamics and safety of vonoprazan: A novel potassium-competitive acid blocker. Clin Pharmacokinetic. 2016;55(4):409–418.

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