RESEARCH ARTICLE

Development and Validation of a Stability-Indicating RP-HPLC Method for the Quantitative Determination of Tegoprazan in Bulk Drug and Pharmaceutical Dosage Forms

Sai Prudhvi N[1], Raghavendra Kumar Gunda[2*], Lakshmi Swarupa Ch[3], Soumya M [4], Bhavya Sri J [4], Anjali K[4], Kousar Begum Sk[4]

[1]Associate Professor, Department of Pharmaceutical Analysis, Victoria College of Pharmacy, Nallapadu, Guntur (Dt), Andhra Pradesh, India-522005.

[2]Associate Professor, Department of Pharmaceutics, Narasaraopeta Institute of Pharmaceutical Sciences (Autonomous), Narasaraopet, Palnadu (Dt), Andhra Pradesh, India-522601.

[3]Associate Professor, Department of Pharmaceutics, Victoria College of Pharmacy, Nallapadu, Guntur (Dt), Andhra Pradesh, India-522005.

[4]Research Scholar, Department of Pharmaceutical Analysis, Victoria College of Pharmacy, Nallapadu, Guntur (Dt), Andhra Pradesh, India-522005.

Corresponding Author Email ID: raghav.gunda@gmail.com

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Abstract

Objective: the current study objective was to develop and validate a simple, rapid, and stability-indicating RP-HPLC method for the quantitative determination of tegoprazan in bulk drug and pharmaceutical formulations.

Materials & Methods: The chromatographic separation was achieved on Waters XBridge C18 column (250 × 4.6 mm, 5 µm) using acetonitrile and 0.02 M potassium dihydrogen phosphate buffer (60:40, v/v) adjusted to pH 5.2 at 1.0 mL/min as mobile phase. Detection was carried out at 303 nm with a total run time of 6 min. In the optimized conditions, tegoprazan display sharp and symmetrical peak at a retention time of approximately 2.5 min.

Results: The developed method produces excellent linearity over 10–60 µg/mL with a regression coefficient (R^2) of 0.9994. The limits of detection (LOD) and quantification (LOQ) were noticed to be 0.03 µg/mL and 0.10 µg/mL, respectively indicates high sensitivity of the method. Precision studies produce %RSD values of <2%, proves good repeatability and intermediate precision. Accuracy assessed by recovery studies at 50%, 100%, and 150% levels yields recoveries between 98.30% and 101.11%. Robustness evaluation demonstrates minimal variation (<2%) upon small deliberate changes in chromatographic parameters. The forced degradation studies reveal that tegoprazan was most susceptible to acidic conditions and display good stability under oxidative, thermal, and photolytic stress. The method was successfully applied to the analysis of a commercial formulation with an assay value of 99.52%.

Conclusion: The developed method was simple, accurate, precise, and stability-indicating and suitable for routine quality control as well as stability analysis of tegoprazan in bulk drug and pharmaceutical dosage forms.

Keywords: Tegoprazan, HPLC analysis, stability indicating method, method validation

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Introduction

Tegoprazan (TPZ) is a novel potassium-competitive acid blocker developed for in the management of acid-related gastrointestinal disorders such as gastroesophageal reflux disease, erosive esophagitis, and gastric ulcers.[1] Unlike conventional proton pump inhibitors, TPZ inhibits gastric H^+/K^+-ATPase through reversible potassium-competitive binding. This binding results in rapid onset of action and contentious suppression of gastric acid secretion.[2] It exhibit improved pharmacokinetic profile, longer duration of acid suppression, and reduction in variability than other drugs of similar class and hence it gained considerable attention as an effective therapeutic alternative for acid-related disorders.[3] Consequently, the it display clinical use and pharmaceutical development of tegoprazan necessitate the establishment of reliable, accurate, and stability-indicating analytical methods for its quantitative determination in bulk drug substances and pharmaceutical formulations.[4] The molecular structure of TPZ was presented in Figure 1.

Analytical techniques play a crucial role to ensure quality, safety, and efficacy of pharmaceutical products.[5] Several analytical methods have been reported for the determination and characterization of tegoprazan in different matrices. The reported analytical methods and research gap was presented in Table 1.[6-11]

Despite the availability of these analytical techniques, there remains a need for a simple, robust, and stability-indicating chromatographic method with a capability to detect, and accurately quantify the tegoprazan in both bulk drug substances and pharmaceutical dosage forms. These reported methods do not comprehensively evaluate forced degradation behavior or demonstrate clear stability-indicating capability under different stress conditions. Moreover, there was limited literature that combines simplicity, robustness, and reliable quantification suitable for routine quality control and stability studies of tegoprazan formulations. Therefore, the development of a rapid and reliable stability-indicating HPLC method remains an important requirement for regulatory compliance and pharmaceutical analysis.

In view of these considerations, this study aims to develop and validate a simple, accurate, and robust stability-indicating HPLC method for the quantitative determination of tegoprazan in bulk drug and pharmaceutical dosage forms. This study intended to provide efficient chromatographic separation of tegoprazan from potential degradation products and other interfering components. The specific objectives of this study include the optimization of chromatographic conditions to achieve efficient separation, validation of the developed method according to ICH guidelines with respect to parameters such as specificity, linearity, accuracy, precision, robustness, and sensitivity, and evaluation of the stability-indicating capability of the method through comprehensive forced degradation studies under various stress conditions. The proposed method was expected to offer a reliable analytical tool for routine quality control and stability assessment of tegoprazan in pharmaceutical preparations

Materials and Methods

The chromatographic analysis was carried out using a PEAK HPLC system (LC–7000, India) equipped with an LC-P7000 pump and a UV detector. The sample injection was performed manually using a Rheodyne injector (Model 7725) fitted with a fixed 20 µL sample loop, and Hamilton syringes (USA) were used for sample loading. The data acquisition and processing were performed using Autochro-3000 software (Young Lin, Korea). An analytical balance (Denver SI-234, Bohemia) was used to accurately weigh samples and reagents. UV-Visible measurement was performed through Teccomp UV-2301 spectrophotometer (India). The pH was adjusted through Systronics pH meter (Sr No. S1326, India). An ultrasonic bath sonicator (GT Sonic, India) was employed for dissolution of samples. The filtration of solutions was conducted through borosilicate vacuum filtration kit with 0.2 µm membrane filters (Merck Millipore, USA).

Materials

The reference standard of tegoprazan with a certified purity of 99% and marketed tablet formulation with 50 mg of tegoprazan (PCAB-50 mg) was kindly provided by Dr. Reddy's Laboratories Ltd., Hyderabad, India. HPLC grade organic solvents such as methanol, acetonitrile, and water, were procured from Merck Chemicals Pvt. Ltd., Mumbai, India, and

Table 1: Summary of previously reported techniques along with their applications, key findings, and research gaps with corresponding references

S.No	*Method*	*Application / Matrix*	*Key Findings*	*Research Gap*
1	LC–MS/MS	Plasma (bioanalysis)	Method showed good sensitivity, precision (<15% RSD) and accuracy (92.6–105%) for quantifying tegoprazan and its metabolite M1 in plasma	Primarily designed for pharmacokinetic studies; not applicable for routine quality control or stability evaluation in formulations.6
2	UPLC–MS/MS	Plasma pharmacokinetics	Highly sensitive and selective quantification method used for pharmacokinetic studies of tegoprazan formulations	Requires sophisticated instrumentation and complex sample preparation; not suitable for routine pharmaceutical analysis.7
3	LC-HRMS / LC-MS^n / GC-QTOF-MS	Degradation product characterization	Eight degradation products were identified and degradation pathways of tegoprazan were proposed	Study focused mainly on structural identification; lacks simple validated chromatographic method for routine quantitative stability analysis.8
4	RP-HPLC (Impurity profiling)	Bulk drug substance	Successfully quantified four related impurities with good sensitivity and accuracy; suitable for impurity control	Limited focus on complete stability-indicating evaluation and routine dosage form analysis.9
5	Chiral HPLC	Enantiomeric impurity determination	Efficient separation of tegoprazan enantiomeric impurities in drug substance	Method limited to stereochemical impurity monitoring; not applicable for routine quantification of drug in dosage forms.10
6	RP-HPLC-UV	Pharmaceutical formulation analysis	Demonstrated acceptable precision, accuracy, and applicability for pharmaceutical samples	Limited information on forced degradation and stability-indicating capability.11

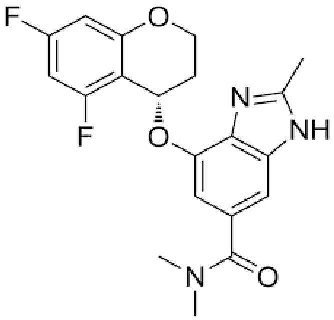

Figure 1: molecular structure of Tegoprazan (TPZ)

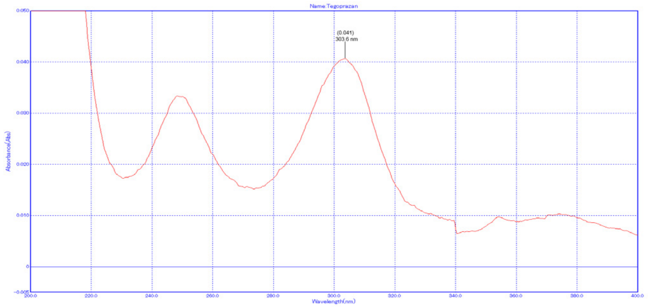

Figure 2: UV-visible spectrum (λmax) of tegoprazan in methanol

were used throughout the analysis. The buffer components employed in the study were of analytical reagent (AR) grade and were also procured from same source. All chemicals and reagents used in this study were of suitable analytical quality and were used without any further purification.

Preparation of Standard Drug Solution

The primary stock solution of tegoprazan at 1000 µg/mL was prepared by accurately weighed 10 mg of the pure drug and transfers it into a 10 mL volumetric flask. The small quantity of methanol was added to the flask to dissolve the drug, and the solution was gently shaken to complete dissolution of drug. The volume was then adjusted to the mark with the same solvent and was then passed through a 0.45 µm membrane filter to remove any insoluble particles or impurities. The filtered stock solution was stored properly and used for further dilutions during the study.

The working standard solutions were prepared by appropriate dilution of the stock solution with the diluent to obtain different concentrations suitable for calibration. An aliquot of 1–6 mL of the stock solution were transferred into separate 10 mL volumetric flasks and diluted to volume with the diluent to produce solutions with final concentrations in the range of 10 to 60 µg/mL.

Preparation of Formulation Solution

An amount of the tablet powder equivalent to 10 mg of tegoprazan was accurately weighed and transferred into a 10 mL volumetric flask with about 5 mL of methanol. The mixture was sonicated for 5 min to ensure complete extraction of the drug into the solvent. Then, the solution was filtered through a 0.45 µm membrane filter to remove insoluble excipients. The filtrate was then diluted to the final volume with the same solvent. Further appropriate dilutions were made from this solution when required for the analysis of the formulation samples.

Analytical Method Development

In method development process, different chromatographic conditions such as various compositions of mobile phase, flow rates, and detection wavelengths was investigated to achieve good separation and suitable peak shape of the analyte. The selection of solvent system and mobile phase ratio was optimized to obtain adequate resolution, acceptable retention time, and stable baseline during analysis. The detection wavelength was chosen based on the maximum absorbance of tegoprazan obtained from UV spectral scanning. The chromatographic parameters such as column type, injection volume, and run time was also optimized for the production of consistent and reproducible method.

Method Validation

The developed HPLC method was validated in accordance with ICH guidelines to ensure its suitability for quantitative analysis. Validation parameters were evaluated using appropriate

Table 2: Optimized chromatographic conditions for analysis of tegoprazan

S. No	*Parameter*	*Results*
1	Mobile phase	Acetonitrile: 0.02 M potassium dihydrogen phosphate in 60:40 (v/v)
2	Wavelength	303 nm
3	Stationary Phase	Waters XBridge C18 (250 × 4.6 mm), 5 µm
4	pH of MP	5.2
5	Flow Rate	1.0 mL/min
6	Pump Mode	Isocratic
7	Pump Pressure	10.9±6 MPa
8	Run time	6 min

Table 3: The linearity data along with calibration plot

S. No	*Concentration in µg/mL*	*Peak Area*	*Calibration plot*
1	10	498798.4	
2	20	966457.2	
3	30	1483774.1	
4	40	1898036.6	
5	50	2427892.7	
6	60	2884874.2	

experimental procedures through freshly prepared standard and sample solutions under chromatographic conditions to assess the performance of the method. These studies prove the reliable, reproducible, and suitability of proposed method for quantification of tegoprazan in bulk drug and pharmaceutical dosage forms.[12]

Forced Degradation Studies

The forced degradation study was performed to evaluate the stability of tegoprazan under different stress conditions. In acid degradation, 50 mg of the drug was treated with 50 mL of 0.1 N HCl and kept for 24 hours. Then, the solution was neutralized and diluted to obtain a final concentration of 40 µg/mL before analysis. In alkaline degradation, 50 mg of the drug was mixed with 50 mL of 0.1 N NaOH and kept for 24 hours. Then the solution was neutralization with dilute HCl prior to analysis. In oxidative degradation, 50 mg of drug was mixed with 50 mL of 3% hydrogen peroxide solution. The stress solution was kept for 24 hours and then diluted to 40 µg/mL prior to analyziz. In photolytic degradation, 50 mg of the drug sample was exposed to UV light at 247 nm for 24 hours whereas thermal degradation was induced by exposing 50 mg of the drug sample at 60 °C for 24 hours in a hot air oven.

Results and Discussion

This investigation was undertaken to establish a simple, reliable, and precise HPLC method for the quantitative determination of tegoprazan in pharmaceutical dosage forms. The initial stage of method development involves the selection of an appropriate detection wavelength that ensures the optimal sensitivity and accurate measurement of the analyte on UV detector in HPLC. In this purpose, the absorption characteristics of tegoprazan were evaluated using a UV–visible spectrophotometer. The dilute solution of tegoprazan was scanned over an appropriate ultraviolet wavelength range to obtain the absorption spectrum. The recorded spectra confirm that tegoprazan exhibits a prominent absorption maximum around 303 nm (Figure 2). Therefore this was selected as the detection wavelength for all subsequent chromatographic analyses.

In the initial stage of method development, several chromatographic trials were performed to establish suitable separation conditions for the analysis of tegoprazan. The first trial was performed with amethanol and acetonitrile (50:50, v/v) on ProntoSIL C18 (250 mm) column at 1.0 mL/min. In these conditions, chromatogram display unsatisfactory performance characterized by poor resolution, multiple retention responses, and significant baseline disturbances (Figure 3A). Then stationary phase was replaced with Waters XBridge C18 (250 × 4.6 mm, 5 µm) column with same mobile phase composition and flow rate to improve chromatographic behavior. This modification produces relatively stable baseline and the appearance of a major chromatographic signal corresponds to tegoprazan. However, the peak was noticed to be split, indicates the incomplete peak integrity and possible heterogeneous interactions within the chromatographic system (Figure 3B). Further, composition of mobile phase was modified to acetonitrile and water (75:25, v/v) with the maintenance of same other conditions. This condition results rapid elution of tegoprazan with broad and asymmetric peak suggests excessive elution strength and inadequate interaction of the analyte with the stationary phase (Figure 3C). Further refinement was attempted by introducing a buffered aqueous component, using acetonitrile and 0.02 M potassium dihydrogen phosphate (90:10, v/v). This trial produces comparatively best chromatographic profile with a single, symmetrical peak and minimal baseline disturbance with better sensitivity and peak integrity relative to the earlier trials (Figure 3D). However, these conditions were considered preliminary and needs further optimization to achieve the desired chromatographic performance for the reliable determination of tegoprazan.

The preliminary investigations described above were further refined to produce reliable analytical method for the determination of tegoprazan. The systematic evaluation of mobile phase composition, buffer conditions, and chromatographic performance produces optimized chromatographic conditions that display highly satisfactory separation profile. In the finalized conditions, tegoprazan exhibits single, sharp, and symmetrical peak with a stable baseline and consistent retention behavior across repeated injections. The optimized conditions were tabulated in table 2 and these conditions produce excellent sensitivity, minimal

Table 4: Results of precision (intra-day and inter-day) and ruggedness studies

S. No	*Intraday precision*	*Interday precision*	*Ruggedness*
1	1844974.1	1848932.7	1884648.8
2	1884076.5	1839394.6	1894765.2
3	1864592.3	1847362.2	1873644.6
4	1873618.7	1872046.3	1865485.3
5	1862974.2	1837464.4	1834875.1
6	1894638.4	1889483.9	1898704.7
% RSD	0.93	1.11	1.25

Table 5: Recovery study results for tegoprazan

% Recovery	*Concentration in µg/mL*			*Amount Found*	*% Recovery*	*% RSD*
	Target	*Spiked*	*Total*			
50%	20	10	30	29.9164	99.72	0.90
	20	10	30	29.6163	98.72	
	20	10	30	30.1553	100.52	
100%	20	20	40	19.7536	98.77	0.25
	20	20	40	19.6593	98.30	
	20	20	40	19.6794	98.40	
150%	20	30	50	50.1411	100.28	0.41
	20	30	50	50.4035	100.81	
	20	30	50	50.5557	101.11	

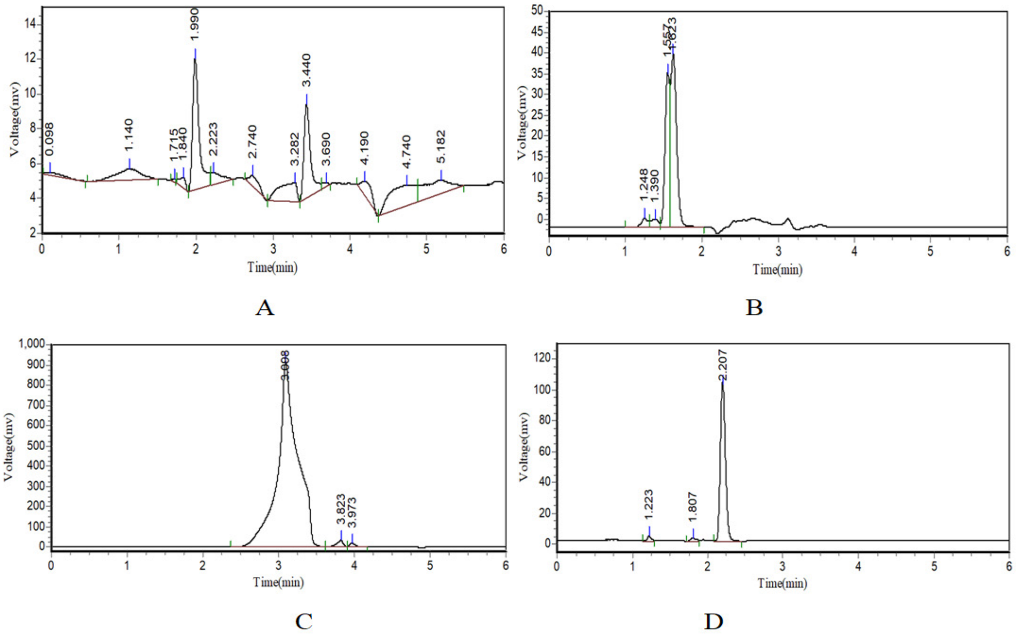

Figure 3: Chromatograms obtained during preliminary HPLC method development trials for tegoprazan showing the effect of different mobile phase compositions and stationary phases on chromatographic performance

baseline fluctuation, and reproducible peak area responses. In comparison with the earlier trials, this optimized method effectively resolve the issues such as multiple retention responses, peak splitting, peak fronting, and baseline instability.

The chromatograms noticed during analysis of blank, standard, and sample solutions prove the method specificity. This analysis demonstrates that no interfere peaks were observed at the retention time of tegoprazan in the blank solution indicates the absence of interference from solvents or other components. A distinct and well-defined peak corresponds to tegoprazan was observed at a retention time of approximately 2.5 min in both the standard and sample chromatograms. The retention time of the analyte remains consistent in the standard solution, mixed standard solution, and formulation sample proves the reliable identification of the compound. In addition, no peaks arises from excipients present in the tablet formulation were detected near the analyte peak demonstrate that the developed method possesses good specificity and selectivity for tegoprazan determination. The system suitability parameters were also evaluated, and the results show the acceptable chromatographic performance with a theoretical plate count of 7518 and a tailing factor of 0.96. The representative system suitability chromatogram was presented in Figure 4.

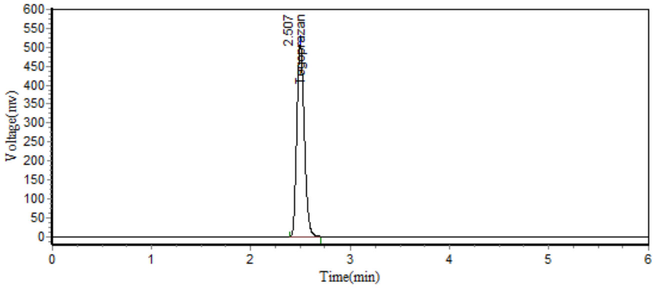

Figure 4: System suitability chromatogram of tegoprazan obtained under optimized chromatographic conditions

Table 6: Results of Robustness study

S. No	*Condition*	*Change*	*Area*	*% Change*
1	Standard	No change	1898036.6	0.00
2	MP 1	Acetonitrile: 0.02 M potassium dihydrogen phosphate in 65:35 (v/v)	1867587.4	-1.60
3	MP 2	Acetonitrile: 0.02 M potassium dihydrogen phosphate in 55:45 (v/v)	1885603.2	-0.66
4	WL 1	308 nm	1874476.3	-1.24
5	WL 2	298 nm	1877685.8	-1.07
6	pH 1	5.1	1875790.5	-1.17
7	pH 2	5.3	1887464.7	-0.56

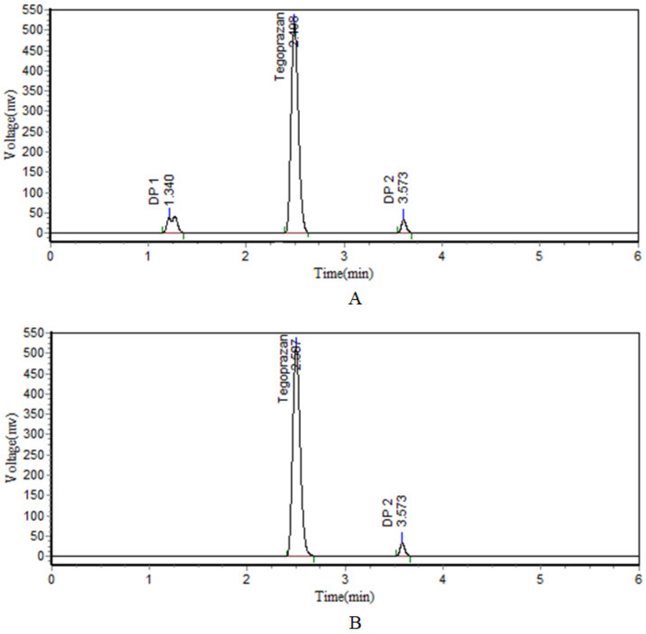

Figure 5: Degradation study peaks Acid (A) and Base (B)

The evaluation of limit of detection (LOD) and limit of quantification (LOQ) proves the method sensitivity. The LOD and LOQ values were noticed to be 0.03 µg/mL and 0.10 µg/mL, respectively indicates that the method was sufficiently sensitive to detect and quantify very low levels of the analyte. These low detection limits demonstrate the suitability of the method for trace level analysis and quality control applications.

The method linearity was evaluated by analysing series of standard solutions of tegoprazan at different concentration levels within the working range. The average peak areas were calculated for each concentration level, and a calibration curve was constructed by plotting analyte concentration against mean peak area. The method displays excellent linear behavior over 10-60 µg/mL for tegoprazan. The regression equation obtained for calibration curve was noticed to be $y = 47797x + 20411$, with a correlation coefficient (R^2) of 0.9994. These regression results demonstrate a strong linear relationship between concentration and detector response. The detailed linearity data along with calibration plot was presented in Table 3.

The precision of proposed method was evaluated by performing intra-day and inter-day studies using replicate injections of tegoprazan at a concentration of 40 µg/mL. In intra-day precision, the sample solution was analyzed multiple times within the same day under identical experimental conditions, whereas inter-day precision was assessed by repeated analysis in different days. The percentage %RSD values were observed to be 0.93% in intra-day precision and 1.11% in inter-day precision. These values were noticed to be well within the acceptable limit of less than 2%.

The ruggedness was also investigated to evaluate the reliability of the method under normal laboratory variations, such as changes in analyst. The variation between the results was noticed to be 1.25% and was within the acceptable limit of 2%. The low %RSD value proves that the developed method was rugged and capable to produce consistent results under slight variations in analytical conditions. The detailed results of the precision and ruggedness studies are summarized in Table 4.

The method accuracy was evaluated through recovery experiments and was performed in accordance with ICH guidelines. In this study, known amounts of tegoprazan standard were added to a previously analyzed sample solution at three different concentration levels of 50%, 100%, and 150% of the nominal concentration. In level, the solutions were prepared and analyzed to determine the percentage recovery of the added analyte using the optimized chromatographic conditions. The obtained recovery values in the range of 98.30% to 101.11% indicate good agreement between the measured and expected concentrations. The %RSD values for the three spiking levels were 0.90%, 0.25%, and 0.41%, respectively in studied levels (Table 5). These values fall well within the acceptable limits specified by ICH guidelines provides accurate quantification of tegoprazan in the presence of formulation components.

The robustness proposed method was evaluated by introducing small and deliberate variations in key chromatographic parameters to assess the reliability of the method under slightly altered conditions. The effect of these changes was monitored by compare the peak area responses of tegoprazan with those obtained under the optimized conditions. As shown in Table 6, minor changes in the mobile phase ratio (acetonitrile: 0.02 M potassium dihydrogen phosphate buffer adjusted to 65:35 and 55:45, v/v) indices the peak area variations of 1.60% and 0.66%, respectively. Similarly, small variations in the detection wavelength (308 nm and 298 nm) produce % changes of 1.24% and 1.07% in peak area. The adjustment in mobile phase pH slightly to 5.1 and 5.3 also display minimal impact, with % changes of 1.17% and 0.56%, respectively. In all cases, the observed variations in peak area remain within ±2% indicates that these small changes in analytical parameters did not significantly affect the chromatographic response. These findings confirm that the proposed method was robust and capable to produce reliable results even under minor variations in experimental conditions.

The forced degradation experiment was conducted to investigate the stability behavior of tegoprazan under different stress conditions. This test confirms the stability-indicating capability of proposed method. This test results shows that tegoprazan was most sensitive to acidic hydrolysis. In this, two degradation products were clearly separated from the main drug peak with 7.75% degradation and 92.25% assay. In alkaline stress, one degradation product was detected with 5.91% degradation and an assay value of 94.09% indicates moderate susceptibility in basic conditions. No additional degradation peaks were observed with % assay of 96.33% and 3.67% degradation in oxidative stress suggest that the drug exhibits good resistance to oxidation (Figure 5). Thermal stress studies also display no formation of new degradation peaks, with 4.15% degradation, demonstrates acceptable thermal stability. Among all the conditions tested, exposure to UV light produces the least degradation, with only 1.85% degradation and a high assay value of 98.15% proves an excellent photostability of the drug. Overall, the results indicate that tegoprazan was particularly vulnerable to acidic conditions with moderate affect by alkaline and thermal stress, and relatively stable under oxidative and photolytic environments. Importantly, all degradation products were well separated from the parent peak without any interference proves that the developed method was capable to selectively detect tegoprazan in the presence of its degradation products. The representative acid and base chromatograms obtained in this study was shown in Figures 5.

The applicability method was further verified by analyzing tegoprazan in its pharmaceutical formulation prepared from the commercially available formulation product. The sample solution was prepared according to the procedure described in the materials and methods section and analyzed under the optimized chromatographic conditions. The obtained chromatogram display a well-defined and symmetrical peak corresponds to tegoprazan without any interference from formulation excipients proves the selectivity of the method for formulation analysis.

The quantitative evaluation of the formulation sample indicated an assay value of 99.52% for tegoprazan and the observed results were very close to the label claim of the dosage form. The assay result falls well within the acceptable pharmaceutical limits of 98–102%, demonstrates the accuracy and reliability of the developed analytical procedure. In addition, the chromatographic response was consistent and reproducible indicates good precision during formulation analysis. These findings confirm that the proposed method was capable of accurately determine tegoprazan in pharmaceutical preparations with high sensitivity and reproducibility. Therefore, the developed method can effectively employs for routine quality control analysis of tegoprazan in both bulk drug substances and finished dosage forms in pharmaceutical laboratories.

Literature Comparison and study advantages

In comparison with previously reported analytical procedures for tegoprazan, the present study offers several practical and methodological advantages. The many of the earlier methods rely on advanced techniques such as LC–MS/MS or other hyphenated mass spectrometric approaches and were mainly intended for pharmacokinetic or metabolite analysis. These reported methods require expensive instrumentation, complex sample preparation, and highly skilled operation. In contrast, this method utilizes a simple UV detection system and readily available chromatographic conditions and makes it more economical and convenient for routine pharmaceutical quality control laboratories. The optimized method provides rapid analysis with a short run time, excellent peak symmetry, and high sensitivity with strong linearity, accuracy, and precision. In addition, the method was validated to be stability-indicating through comprehensive forced degradation studies with were well resolved degradation products from the parent drug peak without interference. The combination of simplicity, robustness, short analysis time, and stability-indicating capability was not reported in earlier methods for tegoprazan determination. Therefore, the developed method represents an efficient and reliable alternative for the routine quantification and stability assessment of tegoprazan in bulk drug and pharmaceutical formulations.

Conclusion

In conclusion, simple, reliable, and stability-indicating RP-HPLC method was successfully developed and validated for the quantitative determination of tegoprazan in bulk drug and pharmaceutical formulations. The optimized chromatographic conditions produce sharp, well-resolved peak with excellent baseline stability and reproducible retention behavior. The method demonstrates good analytical performance with high sensitivity, excellent linearity over the studied concentration range, and satisfactory accuracy and precision in accordance with ICH validation guidelines. Robustness studies prove that small variations in analytical parameters did not significantly affect the method performance, indicates its reliability for routine application. The forced degradation experiments further establish its stability-indicating capability by effectively resolves parent drug from its degradation products under different stress conditions. The successful application of the method for the analysis of a commercial formulation with an assay value close to the label claim confirms its suitability for pharmaceutical quality control. Overall, the developed HPLC method provides a rapid, accurate, and cost-effective analytical approach for the routine determination and stability assessment of tegoprazan in bulk drug substances and finished dosage forms.

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