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DEVELOPMENT AND VALIDATION OF STABILITY INDICATING RP-HPLC METHOD FOR ESTIMATION OF TEGOPRAZAN IN API

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ABSTRACT

A simple, accurate, and sensitive RP-HPLC method was developed and validated for the estimation of Tegoprazan in API. The chromatographic separation was carried out using an Agilent eclipse ODS (150 × 4.6 mm, 5 µm) column under isocratic conditions. The mobile phase consisted of acetate buffer and acetonitrile in an optimized ratio. The flow rate was maintained at 1.0 mL/min, with detection performed at 245 nm. The injection volume was set at 20 µL, and the total run time was 30 minutes. Forced degradation studies were performed to evaluate the stability-indicating capability of the method were subjected to various stress conditions, including acidic, alkaline, oxidative, thermal, photolytic, and hydrolytic degradation. The developed method was validated according to ICH Q2 (R2) guidelines by assessing parameters such as specificity,

linearity, accuracy, precision, limit of detection (LOD), limit of quantification (LOQ), and robustness. Linearity was established in the concentration range 150-450 µg/ml for Tegoprazan. Hence, the developed RP-HPLC Method was found to be Specific, Accurate, Precise, and Robust. The result confirmed that the method is reliable, reproducible, and suitable for routine analysis.

Keywords: Stability Indicating method, Forced Degradation, Method Development, Tegoprazan

INTRODUCTION

Analytical method development is an important part of pharmaceutical analysis for accurate estimation of drug substances. Stability-indicating methods are essential to determine the purity of a drug in the presence of its degradation products. Tegoprazan is a novel potassium-competitive acid blocker (P-CAB) used in the treatment of gastroesophageal reflux disease (GERD) and shows rapid and effective acid suppression. Chemical structure of Tegoprazan is shown in **Figure 1**. Reverse Phase High Performance Liquid Chromatography (RP-HPLC) is a widely used technique for drug analysis due to its accuracy, precision, and reliability. In the present study, an attempt has been made to develop and validate a simple, precise, and stability-indicating RP-HPLC method for the estimation of Tegoprazan in API. The method is validated as per ICH guidelines to ensure its suitability for routine analysis **[1-4]**.

METHOD AND MATERIALS:

Shimadzu HPLC and LC 2010 CHT model LC Solution software was used. Shimadzu UV-1800 double-beam UV-VIS spectrophotometer Instrument was used. Cosmosil C_{18} (250 mm × 4.6 mm internal diameter × 5-micron particle size). API was obtained as gift sample from TORRENT Pharmaceutical LTD. Acetonitrile, methanol, water, phosphate buffer of HPLC grade from Merck Life Science Pvt. Ltd./Advent Chembio Pvt. Ltd./Thermo Fisher Scientific Pvt. Ltd./Spectrochem Pvt. Ltd.

Identification of API: Identification of API was done using IR scanning of sample **(Figure 2)** along with solubility study and melting point.

Forced degradation study: To determine whether the analytical procedure and assay are capable of indicating stability, Tegoprazan was exposed to various stress conditions as part of forced degradation studies.

Acid degradation an aliquot of 1 mL of the filtered Tegoprazan stock solution was transferred into a 10 mL volumetric flask. To this, 0.1 mL of 1 N hydrochloric acid (HCl) was added, and the mixture was allowed to stand for 30 minutes to facilitate degradation. After the specified time, the solution was

neutralized by adding 1 mL of 0.1 N sodium hydroxide (NaOH). Finally, the volume was adjusted to the mark with the appropriate diluent, and the chromatogram was recorded.

Base degradation: For base degradation, 1 mL of the filtered Tegoprazan stock solution was taken in a 10 mL volumetric flask. An equal volume (1 mL) of 0.1 M sodium hydroxide was added, and the mixture was kept aside for 15 minutes to allow degradation to occur. After completion of the reaction, the solution was neutralized using 1 mL of 1 N hydrochloric acid. The final volume was then made up with a suitable diluent, and the sample was analyzed using chromatographic technique.

Oxidative degradation: For oxidative degradation, an aliquot of the stock solution was transferred into a 10 mL volumetric flask. To this, 1 mL of 3% hydrogen peroxide (H_2O_2) was added and the mixture was mixed properly. The solution was kept at room temperature for 8 hours to allow oxidation to occur. After the specified time, the volume was made up to the mark using the appropriate diluent, and the resulting solution was subjected to chromatographic analysis.

Photolytic degradation An aliquot of 1 mL of the filtered Tegoprazan stock solution was transferred into a 10 mL volumetric flask. The solution was then exposed to direct sunlight for 60 minutes to induce photolytic degradation. After exposure, the volume was adjusted to the mark using the appropriate diluent, and the resulting solution was analyzed by recording the chromatogram.

Thermal degradation

A measured volume of the filtered Tegoprazan stock solution (1 mL) was transferred into a 10 mL volumetric flask. The solution was then subjected to heat by placing it in a hot air oven for a specified period to induce thermal degradation. After exposure, the solution was allowed to cool to room temperature, the volume was adjusted to the mark with a suitable diluent, and the sample was analyzed by recording the chromatogram.

RESULT AND DISCUSSION

Forced degradation study

Tegoprazan get degraded in various extent in acidic, basic, thermal, oxidative and photolytic stress condition. Result Shows in **Table 1**.

RP-HPLC Method Validation

Linearity: For linearity study concentration range 150-450 ppm solution were prepared and injected for chromatographic analysis **(Table 2)**. Calibration curve and overlay show in **Figure 3 and 4** respectively.

Specificity: The ability of an analytical technique to provide a signal solely attributable to the compound of interest,

disregarding potential interferences from impurities or placebo components.

Precision-Repeatability: Repeatability was evaluated by analyzing a single concentration and recording the response six times within the same day **(Table 3)**.

Intraday precision: Intraday precision was evaluated by injecting the standard solution three times on the same day under Improved chromatographic conditions, and the %RSD along with peak areas were calculated **(Table 4)**.

Interday precision: Interday precision was performed by injecting standard preparation three times on the day by adjusting the optimized chromatographic conditions and calculate %

RSD and peak area **(Table 5)**.

Accuracy: The accuracy of the method was established using the standard addition method. Tegoprazan solutions were prepared at 50%, 100%, and 150% of the target concentration, and the % recovery was calculated **(Table 6)**.

LOD and LOQ:

LOD=3.3σ/s

The LOD and LOQ were calculated by assessing the signal's standard deviation and the calibration curve's slope.

LOQ=10 σ/s

Were, σ = Standard deviation of responses

S=Slope of calibration curve **(Table 7)**

Robustness: Minor intentional change in method parameters was introduced, and the results remained within acceptable limits **(Table 8)**.

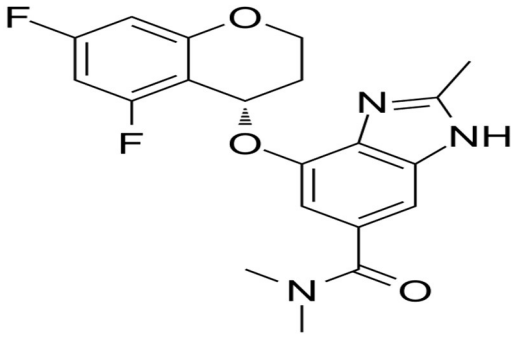


Fig 1: Structure of Tegoprazan [5]

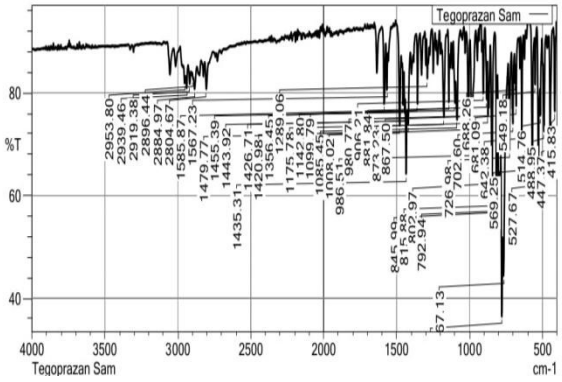


Fig 2: FT-IR Spectra of Tegoprazan sample

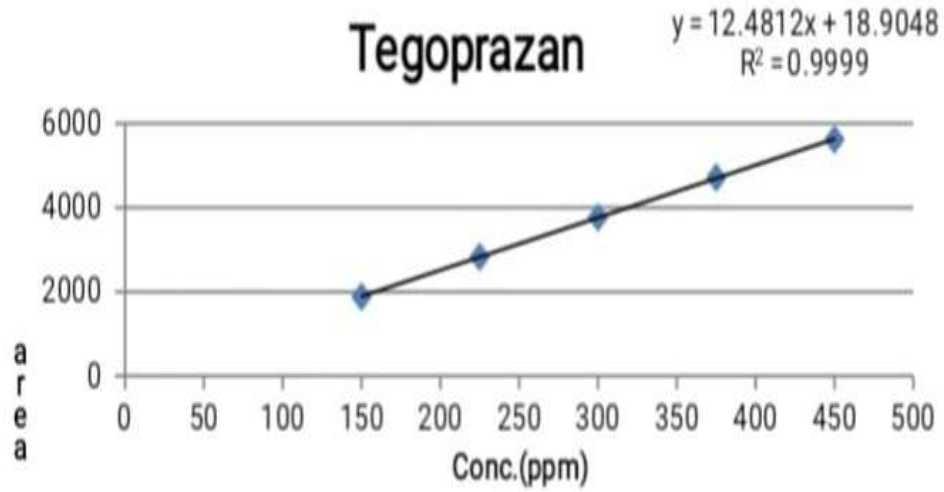


Fig 3: Calibration curve of Tegoprazan

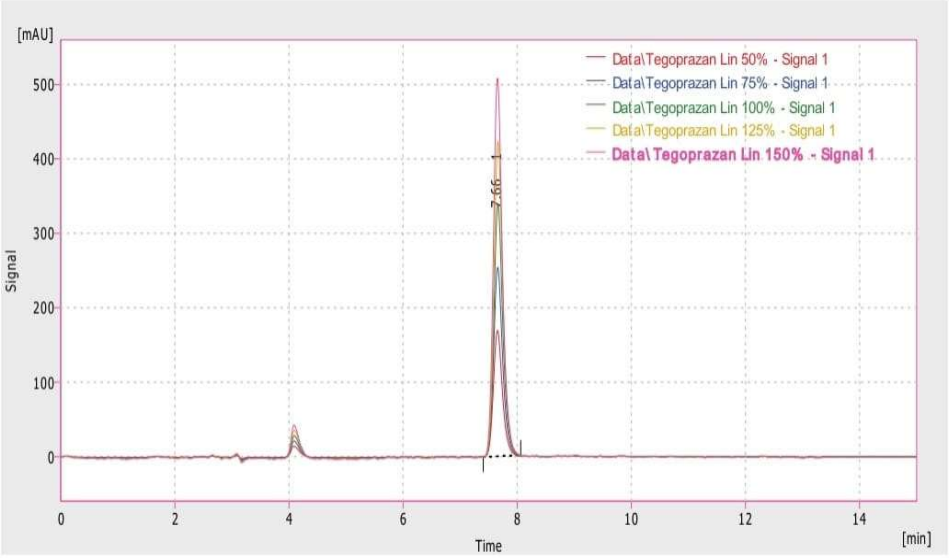


Fig 4: Overlay Linearity chromatogram of Tegoprazan

Table 1: Result of forced degradation studies

Condition	Area (Standard area: 3758.403)	% Degradation
Acid degradation 45 min at room Temperature	**3416.651**	**9.093**
Base degradation 90 min at room Temperature	**3517.532**	**6.408**
Oxidation degradation 60 min at room Temperature	**3303.787**	**12.095**
Photolytic degradation 80 Min at room Temperature	**3585.767**	**4.593**
Thermal degradation 20 Min at room Temperature	**3234.986**	**13.92**

Table 2: Linearity data for Tegoprazan

Concentration	Area Mean ±SD N=3)	%RSD
150	1882.121 ±1.8210	0.09675
300	3770.314±0.9495	0.02518
450	5620.122±1.2313	0.02191

Table 3: Repeatability data for Tegoprazan

Tegoprazan	
Concentration(mcg/ml)	Area
300	3770.523
300	3762.091
300	3776.239
300	3742.519
300	3750.116
300	3769.525
Avg	3761.8355
SD	13.05833842
%RSD	0.347126779

Table 4: Intraday Precision of Tegoprazan

Sr no.	Concentration (ug/mL)	Area
1	150	1882.84
2	225	2828.687
3	300	3769.449
4	375	4715.345
5	450	5619.947
Correlation		0.999966
R^2		0.9999
Y-Intercept		18.9048
Slope		12.48116

Table 5: Interday Precision of Tegoprazan

Concentration	Area Mean ±SD N=3)	%RSD
150	1881.134 ±0.9964	0.05297
300	3769.78 ±1.1761	0.03119
450	5617.367±1.3580	0.02417

Table: 6 Accuracy data for Tegoprazan (n=3)

Sr no.	Concentration Levels %	Amount added (mg)	Amount recovered (mg)	%Recovery	% Mean recovery ± SD	% RSD
1	80%	0.24	0.24019	100.08	100.33±0.77	0.77
			0.23930	99.71		
			0.24285	101.19		
2	100%	0.30	0.30081	100.27	100.50±0.30	0.30
			0.30251	100.84		
			0.3011 4	100.38		
3	120%	0.36	0.36204	100.57	100.27±0.31	0.31
			0.35984	99.25		
			0.36103	100.29		

Table 7: Limit of detection and limit of qualification data for Tegoprazan

Drug name	LOD	LOQ
Tegoprazan	3.7527	11.3720

Table 8: Robustness of Tegoprazan

Drug	Area at Flow rate (+2)	Area at Flow rate (-2)	Area at Mobile phase rate (+2)	Area at Mobile phase rate (-2)	Area at pH (+0.2)	Area at pH (-0.2)
Tegoprazan (n=3)	3858.321	3719.253	3945.235	3697.248	3823.789	3808.949
	3864.215	3705.648	3966.397	3688.497	3834.586	3812.576
	3845.648	3715.255	3998.452	3679.568	3859.987	3801.895
Mean	3856.061	3713.485	3970.028	3688.444	3839.454	3807.807
SD	9.488	6.993	26.794	8.850	18.584	5.431
%RSD	0.246	0.188	0.675	0.240	0.484	0.143

CONCLUSION

In this work, a stability-indicating reverse-phase HPLC method was established and validated for the determination of Tegoprazan in its active pharmaceutical ingredient form. The developed procedure is user-friendly, economical, and employs a readily accessible mobile phase composition. It offers adequate sensitivity with low detection and quantification limits, and the reduced run time enhances its applicability for routine analysis. The adoption of an isocratic mode further simplifies the chromatographic process while maintaining consistent performance.

Method validation, performed as per ICH recommendations, confirmed acceptable levels of accuracy, precision, specificity, and robustness. The reproducibility of the method was demonstrated through intra-day and inter-day precision studies. Overall, the method proves to be dependable and suitable for routine quality control as well as stability evaluation of Tegoprazan

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