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A SPECTROPHOTOMETRIC METHOD DEVELOPMENT AND VALIDATION OF PANTAPRAZOLE IN BULK AND MARKETED FORMULATION

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ABSTRACT

Pantaprazole was estimated using a straightforward, sensitive, and selective UV approach that was devised and verified. The technique was developed using UV spectrometry; the optimal concentration was 10µg/ml, the absorbance was 0.449, and the λmax was reached at 292nm with solvent water: ethanol (8:2 V/V). The linearity range of the test technique was 0.5 µg/ml to 16 µg/ml, which had an R^2 value of 0.999. It was discovered that the accuracy % assay 98.64-99.96%. The results indicated that the intraday precision and interday precision % RSD values were found in between 0.32 -0.52. The developed method's LOD and LOQ were 0.15µg/ml and 0.44 µg/ml respectively. The robustness results were found to be 99.72%-101.78% for wavelength variation and organic phase change.

KEYWORDS: Pantaprazole, UV-Spectrophotometry, Water, Ethanol.

INTRODUCTION

Pantoprazole sodium sesquihydrate (P) inhibits hydrogen-potassium adenosine triphosphatase (H^+/K^+-ATPase) in gastric parietal cells, making it a common proton pump inhibitor used as an anti-ulcer medication.[1,8] Pantaprazole decreases the production of stomach acid independent of the type of stimulus.[8-10] The chemical description of the pantoprazole tablets, is sodium 5-(difluoromethoxy) -2- [3,4- dimethoxy - 2-pyridyl) methylsulfinyl] 1H sesquihydrate of benzimidazole.[9,13] Previously published techniques for determining Pantaprazole in pharmaceutical formulations

and biological materials included capillary electrophoresis, spectrophotometric measurement, and high performance liquid chromatography (HPLC).[14-31]

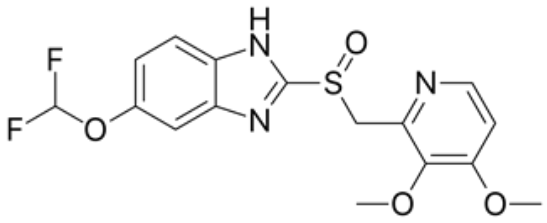

Figure 1: Structure oF Pantaprazole.

MATERIALS AND METHODS

The reagents and chemicals were all of analytical quality. After double distillation, the water was filtered through a membrane filter. Ethanol purchased from SD fine chem, India. Pharmaceutical grade standard drug Pantaprazole kindly gifted by Hetero Drugs, Hyderabad, India.

Preparation of Standard solution

The 20 mg of Pantaprazole standard sample was precisely weighed and deposited into a 10 ml calibrated, clean, and dry volumetric flask. It was then filled with about 10 ml of solvent (Ethanol: Water), shaken thoroughly, and sonicated for improved solubility (Primary stock solution 2000µg/ml). Pipette 0.05 ml of the primary stock solution (above) into a second 10 ml volumetric flask, then top it up to the volume required to create the secondary stock solution (10µg/ml).

Preparation of Marketed formulation

Twenty tablets were precisely weighed, their average weight determined, and they were ground up using a clean motor and pestle. After weighing the 80 mg of pantoprazole tablet powder, place the contents into a 10 ml volumetric flask. After adding roughly 10 ml of the solvent, sonicate it until it dissolves fully, then filter. Make up the last volume. (2000 µg/ml). Pipette out 0.05 ml of the primary stock solution (above) and transfer it to a second 10 ml volumetric flask. Fill it up to the mark to create a secondary stock solution (10µg/ml).

Optimization of the Method

The developed method's optimal concentration was 10µg/ml and absorbance was 0.449 when it was optimized at 292 nm using the solvent Ethanol: Water (20:80).

Validation of the Method[32 & 33]

The International Council for Harmonization's requirements were followed when validating the approach. Specificity, precision, accuracy, linearity, robustness, limit of detection, and limit of quantification are the method validation parameters.

Selectivity & Specificity

The suggested method's specificity (Figure1&2) had shown no interference of the drug with the solvent and excipients of the formulation. The drug selectively estimated by using solvent system ethanol: water at 290 nm.

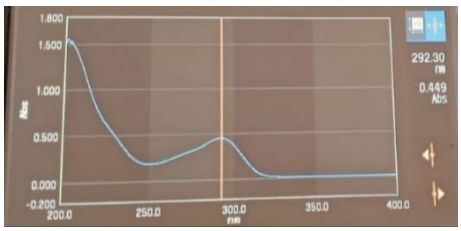

Figure 2: Standard Spectrum.

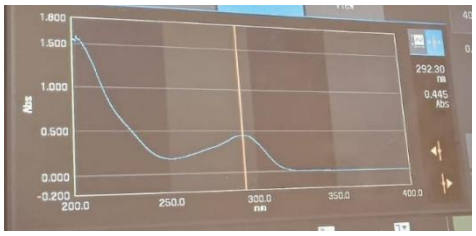

Figure 3: Sample Spectrum.

Linearity

Linearity study the absorbance response on the Y-axis and the concentration on the X-axis were plotted on a graph (Figure-4), and the regression coefficient (R^2) was determined to be 0.999. The Pantoprazole calibration curve was linear across the concentration range 1 µg/mL to 20 µg/mL.

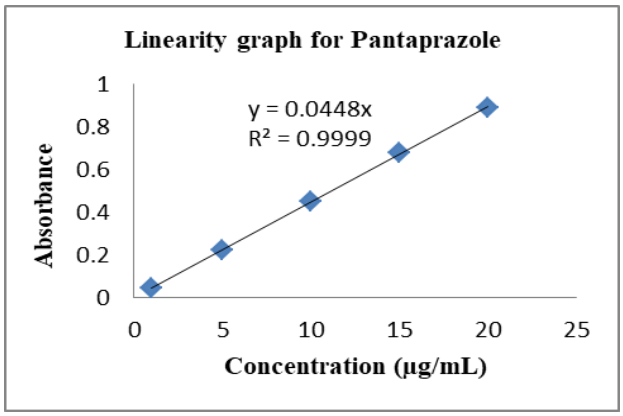

Figure 4: Lineariy graph of Pantaprazole.

Precision

Each level of precision, including intraday and intermediate precision, was evaluated using six Pantaprazole sample solutions that were run in duplicate.

Intraday precision

The intraday precision test was conducted three times a day at 9:00 am, 1:00 pm, and 5:00 pm using a 100% sample solution. Six duplicate measurements were taken at each level. For every interval, the % RSD was determined to be between 0.78 -1.07.

Intraday Precision

The intraday precision was carried out using a 100% solution concentration on days 1, 2, and 3. The computed average of the percentage RSD was found to range between 0.31 to 1.54 after recording the spectrums of six replicated injections at each level.

Accuracy

The accuracy of the process was examined by spiking the standard solution with the analyzed sample solution at three concentration levels: 80%, 100%, and 120%.The recovery investigations were conducted in duplicate under perfect conditions. The 98% to 102% accuracy is the ideal range (Table 2). The RSD percentage shouldn't be higher than 2.0.

Table 1: Results of Accuracy.

Spiked Level	Sample Weight (mg)	Absorbance	µg/ml added	µg/ml found	% Mean recover
80%**	64	0.358	7.95	7.9	99.69
100%*	80	0.452	9.93	10.06	98.64
120%**	96	0.541	11.92	12.05	98.89

**Average of 6 values *Average of 3 values

Detection limit & Quantification limit

The linearity curve's slope and the standard deviation's (precision) response were used to calculate the detection limit and quantification limit. It was found that the LOD and LOQ for Pantaprazole were found to be 0.15µg/mL and 0.44 µg/mL, respectively.

Robustness

The robustness was evaluated at 100% sample concentration with just little modifications to the method's flow rate and mobile phase composition. Six replicate samples' spectrums were collected when the wavelength was altered by ±2 mL/min and the organic phase composition was altered by ± 0.3 mL (Table 2).

Table 2: Results of Robustness.

S. No.	Parameter	Condition	Absorbance	% Assay
1	Wavelength Variation ±2nm	290	0.442	99.95
2		292	0.448	102.00
3		294	0.444	101.55
1	Organic Phase Variation ± 0.3 ml (Water: Ethanol)	8.3 : 1.7	0.43	99.72
2		8:2	0.47	100.63
3		7.7 : 2.3	0.450	101.78

CONCLUSION

The development and validation of various UV-Spectrophotometric techniques for the measurement of Pantaprazole in pharmaceutical dosage forms and bulk was attempted. It was discovered that the suggested spectrophotometric approach was straightforward, accurate, and precise. Ethanol: Water was used to develop the technique. Excipients did not interfere with the active moiety in any way. The technique demonstrated good linearity, durability, accuracy, and precision. The routine analysis of Pantaprazole in bulk and its medicinal dosage forms was conducted using the suggested methodology.

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