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Research Article

DEVELOPMENT AND VALIDATION OF UV SPECTROPHOTOMETRIC METHOD FOR ESTIMATION OF PANTOPRAZOLE SODIUM IN BULK AND TABLET DOSAGE FORM

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ABSTRACT
Pantoprazole is a gastric proton pump inhibitor. Pantoprazole is used for short-term treatment of erosion and ulceration of the esophagus caused by gastro esophageal reflux disease. In present work, a simple, sensitive, accurate and economical spectrophotometric method has been described for the assay of pantoprazole either in pure form or in pharmaceutical solid dosage form. An absorption maximum of Pantoprazole was found to be at 289 nm. Beer's law is obeyed in the range 3-21 µg/mL with correlation coefficient of 0.997. Result of percentage recovery of Pantoprazole sodium ranges from 99.7 to 100.8% in Pharmaceutical dosage form. Results of the analysis were found to be satisfactory. The proposed methods are simple, rapid and suitable for the routine quality control application.

Keywords: *Pantaprazole Sodium, UV Spectrophotometer, Validation*

INTRODUCTION
Pantoprazole is 6- (difluorom ethoxy) -2- {[(3, 4-dimethoxypyridin-2-yl) methane] sulfinyl}-1H- 1, 3-benzodiazole. It is gastric proton pump inhibitor. Pantoprazole is used for short-term treatment of erosion and ulceration of the esophagus caused by gastro esophageal reflux disease (Kumar *et al.*, 2011). It accumulates in the acidic compartment of parietal cells and is converted to the active form, a sulfanilamide, which binds to hydrogen-potassium-ATP-ase at the secretory surface of gastric parietal cells. Inhibition of hydrogen-potassium-ATP-ase blocks the final step of gastric acid production, leading to inhibition of both basal and stimulated acid secretion (Devi *et al.*, 2010; Patel *et al.*, 2012). The duration of inhibition of acid secretion does not correlate with the much shorter elimination half-life of PTZ. The gastric proton pump inhibitors have structural resemblance to H2 antagonists. They are the prodrugs and after absorption get converted to reactive thiophilic sulphonamide cations. The sulphonamide reacts with the H+/K+AT – Pase, forming a covalent, disulphide linkage, thus, irreversibly inactivating the enzyme (Kalaichelvi *et al.*, 2010; Pimpodkar *et al.*, 2008, Kakde *et al.*, 2009).
The methods reported for quantitative determination of pantoprazole in bulk or pharmaceutical formulations include titrimetry, colorimetery, and high performance liquid chromatography. This paper presents the simple, single step, sensitive, validated and inexpensive spectrophotometric method for the determination of PTZ in pure form and in pharmaceutical dosage form develop a simple and rapid UV spectrophotometric method for the estimation of Pantoprazole in the bulk drugs and in pharmaceutical formulations taking distilled water as a solvent (Basavaiah *et al.*, 2007, Devi *et al.*, 2010, Kalaichelvi *et al.*, 2010, Kshirsagar *et al.*, 2011).

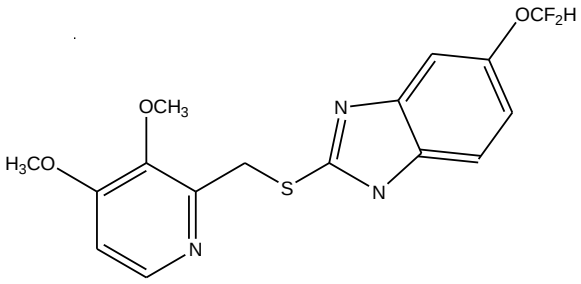

Figure 1: Structure of Pantoprazole Sodium

MATERIALS AND METHODS

All chemicals and reagents used in the proposed methods were of Analytical grade and double distilled water was used to prepare solutions.

Jasco model 630 UV/visible spectrophotometer with 1 cm matched quartz cell was used for spectral measurements.

General Procedure

Preparation of Standard Stock Solution

Accurately weighed 10 mg of Pantoprazole sodium (bulk drug) was dissolved in sufficient quantity of distilled water (100 µg/mL).

Preparation of Sample Solution

Five tablets were weighed. The amount of tablet powder equivalent to 10 mg of Pantoprazole sodium was weighed accurately and transferred to 20 mL distilled water and kept for 10 min and frequent shaking and volume was made upto 100 mL mark with the solvent. The solution was then filtered through Whatmann filter paper #41. This filtrate was diluted suitably with solvent to get solution of 20 µg/mL concentration. The absorbance was measured against blank. The drug content was calculated using standard calibration curve (Table 1)

Detection Method

Preparation of calibration curve: Fresh aliquots from standard stock solution were pipette out and suitably diluted with distilled water to get the final concentration 3-21 µg/mL. The solution were scanned in the spectrum mode for 400-200 nm wavelength range and the first derivative spectra were obtained at n=1 as peak obtained as 289 nm (Figure 2).

The absorbance difference at n=1 ($dA/d\lambda$) was calculated by inbuilt software of the instrument which is directly proportional to concentration of standard solution. A calibration curve was plotted taking the absorbance difference ($dA/d\lambda$) against the concentration of the standard solution. The method was applied for the sample solution of known concentration and was found to be satisfactory for the analysis of tablet formulation.

RESULTS AND DISCUSSION

Results

Accuracy (Recovery Test)

Accuracy of the method was studied by recovery studies. The recovery studies were performed by adding known amounts to tablet. The recovery was performed at three levels 50, 75, 100% of Pantoprazole sodium standard concentration. The solutions were then analyzed and the percentage recoveries were calculated from the calibration curve. The recovery values for Pantoprazole sodium ranges from 99.7 to 100.8 %. (Table 1)

Table 1: Determination of Active Ingredients and Accuracy by Percentage Recovery Method

Ingredient	Tablet Amount (µg/mL)	Level (%)	mg Added	mg Recovered	Recovery (%)	Average Recovery (%)
Pantoprazole	20	50	10.64	10.73	100.2	
Sodium	20	75	15.94	15.95	100.8	100.23
	20	100	20.74	20.72	99.7	

Precision

Assay of method precision (intra-day precision) was evaluated by carrying out three independent assays of test samples of Pantoprazole sodium. The intermediate precision (inter-day precision) of the method was also evaluated using two different analyst, and different days in the same laboratory. The percent relative standard deviation (%RSD) and assay values obtained by two analysts were 1.40, 100.46 and 1.53, 99.55 respectively (Table 2).

Table 2: Determination of Precision

Assay of Pantoprazole Sodium as Percent of Labelled Amount		
Sample No.	**Analyst-I (Intra-Day Precision)**	**Analyst-II (Inter-Day Precision)**
1	100.26	101.16
2	99.35	100.15
3	99.24	99.24
4	101.23	99.08
5	102.26	98.13
Mean	100.46	99.55
%RSD	1.40	1.53

Optical Characteristics

The optical characteristics such as Beers law limit, molar extinction coefficient, percent relative standard deviation (calculation from eight measurements containing ¾ of the amount of the upper Beers law limit) were calculated. Regression characteristics like slope, intercept, correlation coefficient, LOD, LOQ, Standard deviation, variance standard deviation, population standard deviation, variance population standard deviation and the results will be summarized in Table 3.

Table 3: Validation Parameters

Parameter	**UV**
λ_{max} (nm)	289
Beers law limit (µg/ml) (c)	3-21 µg/ml
Limit of Detection (LOD / mcgml-1)	1.89
Limit of Quantification (LOQ/ mcgml-1)	2.98
Correlation coefficient (r)	0.997
Intercept	-3.12×10^{-2}
Slope	4.02×10^{-2}

Linearity

The linearity response of the drug was found in between 3-21 µg/mL concentration range. The calibration curve was obtained by plotting absorbance versus concentration data and found to be linear. The correlation coefficient (r^2) for determination of Pantoprazole sodium was 0.997 (Figure 2).

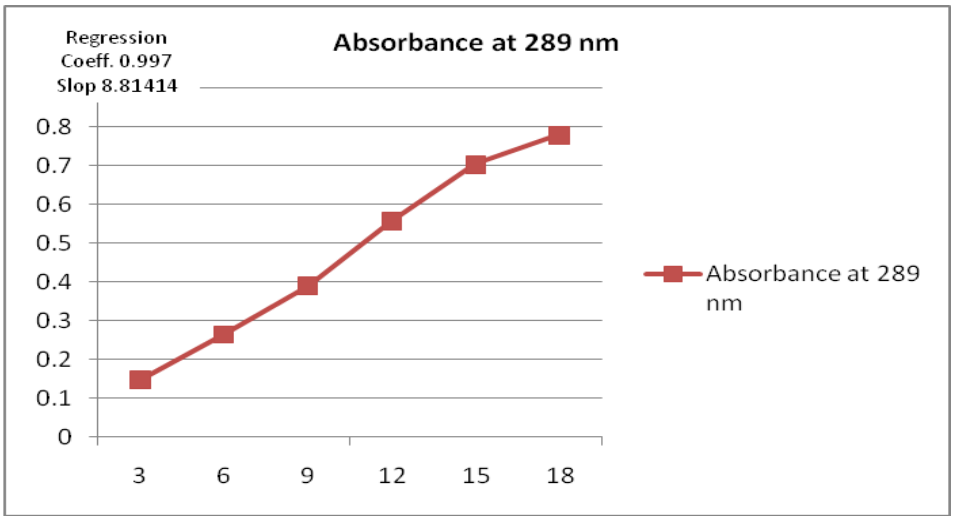

Figure 2: Calibration Curve for Pantoprazole Sodium at 289 nm

Discussion

Commercial formulation of Pantoprazole sodium was successfully analyzed and results were calculated. To evaluate validity and reproducibility of the methods, fixed amounts of drug were added to the reanalyzed formulation. There was no interference of additives or excipients in proposed analytical methods. The method reported was found to be simple, sensitive, accurate and precise according to readings appear and can be used for the routine quality control of this drug in bulk as well as pharmaceutical formulations.

Conclusion

The validated method was found to be simple, economical, sensitive, accurate, precise and reproducible. The UV Spectrophotometric methods can be used for the estimation of drug in bulk as well as in formulations. Therefore, these methods can be useful in the analysis of drug.

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