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Development of UV Spectrophotometric method for estimation of Pantoprazole in pharmaceutical dosage forms

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ABSTRACT

A simple and sensitive spectrophotometric method has been described for the assay of pantoprazole either in pure form or in pharmaceutical solid dosage form. Absorption maxima of Pantoprazole in water were found to be at 292 nm. Beer's law is obeyed in the range 5-70 µg/mL. Result of percentage recovery and placebo interference shows that the method was not affected by the presence of common excipients. The percentages assay of Pantoprazole in tablet was more than 99%. The method was validated by determining its sensitivity, accuracy and precision which proves suitability of the developed method for the routine estimation of pantoprazole in bulk and solid dosage form.

Key Words: Pantoprazole sodium, UV spectrophotometer.

INTRODUCTION

Pantoprazole is 5- (Difluoromethoxy) – [[(3,4- dimethoxy-2-Pyridiynyl) Methyl] sulphinyl] -1*H* – benzimidazole. It is gastric proton pump inhibitor [1]. The gastric proton pump inhibitors have structural resemblance to H_2 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 [2]. The methods reported for quantitative determination of pantoprazole in bulk or pharmaceutical formulations include titrimetry, colorimetery [3-9], and high performance liquid chromatography [10-13]. This paper presents the simple, accurate and reproducible UV spectrophotometric methods for determination of Pantoprazole in tablet dosage form. In the literature survey it is

found that methods have been reported for estimation of Pantoprazole and domperidone in combined tablet dosage form by UV spectrophotometry [14]. But to the best of our knowledge, there is no work in the literature reported about the UV spectrophotometric method for the analysis of Pantoprazole in pharmaceutical formulations using water as solvent. Hence, the authors have made an attempt to develop a simple and rapid UV spectrophotometric method for the estimation of Pantoprazole in the bulk drugs and in pharmaceutical formulations taking water as solvent.

EXPERIMENTAL SECTION

Instrument and apparatus

Perkin Elmer UV-Visible Spectrophotometer Lambda 25 model was used for spectral measurements with spectral band width 1 nm, wavelength accuracy is 0.5 nm and 1 cm matched quartz cells. Glassware used in each procedure were soaked overnight in a mixture of chromic acid and sulphuric acid rinsed thoroughly with double distilled water and dried in hot air oven.

Reagents and Materials

All chemicals were of analytical reagent grade and double distilled water was used to prepare solutions.

Standard drug solution

Pharmaceutical grade Pantoprazole was kindly provided by Torrent Pharmaceutical Ltd., India. A stock standard solution equivalent to 1mg/mL Pantoprazole was prepared by dissolving 50 mg of pure drug in water and diluting to 50 mL in calibrated flask with water.

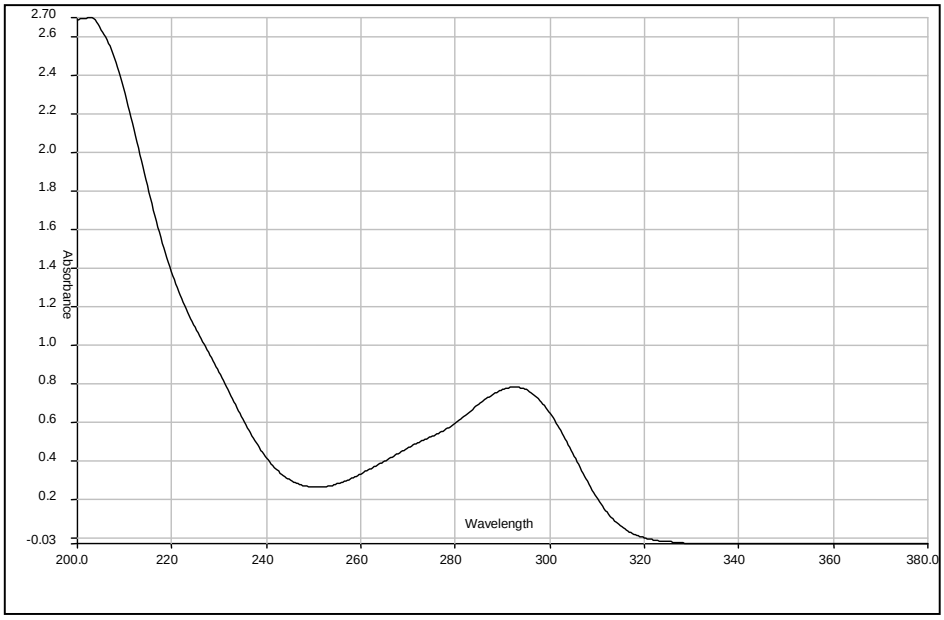

Fig.1: UV spectra of Pantoprazole

Method

Different aliquots (0.0, 0.5, 1.0,…… , 7.0 mL) of 1 mg/mL Pantoprazole solution were accurately measured and transferred into a series of 100 mL volumetric flasks and volume made

up to the mark with water. Then all dilutions were scanned between 200-400 nm against blank which shows the maximum absorbance at 292 nm (Fig. 1).

The same λ max was used for further measurement of drug. A calibration curve for absorbance vs. concentration was plotted (Fig. 2).

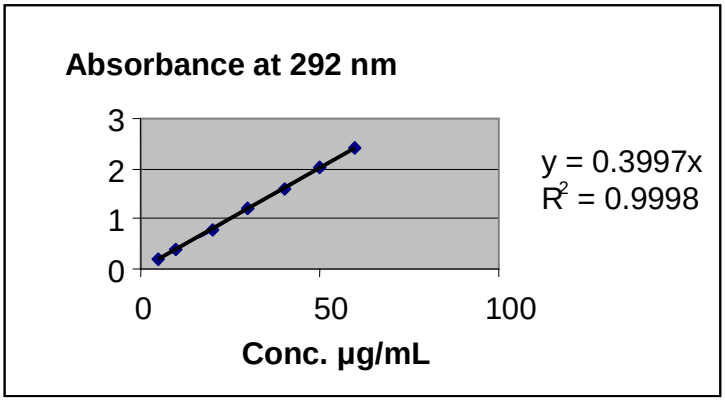

Fig. 2: Standard plot for Pantoprazole

Assay of pharmaceutical Formulations

Twenty tablets were weighed accurately and ground into a fine powder. Powder equivalent to 100mg of Pantoprazole was weighed accurately and transferred into a 100 mL volumetric flask with 60 mL water. The content was shaken for 15-20 min, diluted to volume with water, and filtered using a Whatman No. 42 filter paper. First 10 mL portion of filtrate was discarded and subsequent portions were subjected to analysis.

RESULTS AND DISCUSSION

The absorption spectrum of Pantoprazole was measured in the range 200–400 nm against the blank solution water similarly prepared (Figure 3). The standard solution show maximum absorbance at λ max for each three systems as recorded in Table 1. And the method was validated by studying the following parameters

Table1: Parameters for determination of Pantoprazole against water

Parameters	Values
λ max, nm	292
Beer's law limit, µg /mL	5– 70
Molar absorptivity, L $mol^{-1}cm^{-1}$	$1.52x10^4$
Regression equation	
Slope (m)	0.399
Intercept (c)	0.01547
Correlation coefficient	0.9998

The accuracy of the above method was ascertained by comparing the results obtained with the proposed and reference methods in the case of formulation are presented in Table 2.

Table 2: Assay and Recovery of Pantorazole in Pharmaceutical Formulations

Formulation	Label Claim (mg)	Amount Found (mg)	% Recovery Proposed method #	% Recovery Reference method*
I	40	39.63	99.07	98.56
II	40	39.71	99.27	99.13

I and II are tablets from different batches (PEP-40, Cosmas Pharmacls)
** Reference method [8]*
 # Recovery amount was the average of six determinants.

As an additional check on the accuracy of these methods, recovery experiments were performed by adding known amounts of pure drug to pre-analyzed formulation and percent recovery experiments were also done. Recovery experiments indicated the absence of interferences from the commonly encountered pharmaceutical additives and excipients.

CONCLUSION

It could be concluded that the developed method for estimation of Pantoprazole in pharmaceutical dosage forms and in bulk is simple, sensitive, relatively precise and economical. The proposed methods are used for the routine analysis of the drugs in the quality control.

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