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RESEARCH ARTICLE

Validated Derivative Spectrophotometric Estimation of Pantoprazole in Bulk and Tablet Dosage form.

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Abstract

A simple and sensitive First order derivative spectrophotometric method has been developed for the estimation of Pantoprazole both in pure form and in pharmaceutical solid dosage form. Absorption maxima of Pantoprazole in 0.1N sodium hydroxide was found to be at 286.2 nm. Beer's law is obeyed in the range 4-20 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 Pharmaceutical solid dosage form.

INTRODUCTION

Pantoprazole is a proton pump inhibitor drug used for short-term treatment of erosion and ulceration of the esophagus caused by gastro esophageal reflux disease.Chemically Pantoprazole sodium is Sodium 5-(difluoro methoxy)-2-[[(3,4-dimethoxy-2-pyridinyl) methyl] sulfinyl]-1H-benzimidazole sesquihydrate. It has an empirical formula of $C_{16}H_{15}F_2N_3O_4S$ and molecular weight of 383.37.

Pantoprazole is a proton pump inhibitor (PPI)[1-5] that suppresses the final step in gastric acid production by forming a covalent bond to two sites of the (H+,K+)- ATPase enzyme system at the secretory surface of the gastric parietal cell[6].

The literature survey shows that UV spectroscopic[7-14], RP-HPLC[15-25] and HPTLC[26-28] method reported for PTZ. The attempt is been made to develop accurate, precise and sensitive UV spectrophotometric method in pure and pharmaceutical dosage form.

Materials and Methods:

Instrument: used was an UV-Visible double beam spectrophotometer, SCHIMADZU (model UV-1800) with UV Probe software.

Preparation of Standard and Sample Pantoprazole solution

The standard solution of Pantoprazole was prepared by dissolving 100 mg in 100 ml standard volumetric flask diluting with 0.1N sodium hydroxide solution and made upto the mark then 10 ml of this solution is pipetted out into 100 ml standard volumetric flask and diluting with 0.1N sodium hydroxide solution to produce 100µg/ml.

Twenty tablets were weighed and powdered. The Tablet powder equivalent to100 mg of Pantoprazole was transferred into 100 ml volumetric flask then it was diluted with the 0.1 N sodium hydroxide solution and made upto the mark and the solution was filtered through whatman filter paper NO. 41. From the above solution 10 ml was pipetted out into 100 ml volumetric flask and the volume was made upto the mark with 0.1 N sodium hydroxide

solution. The final concentration of Pantoprazole was brought to 100µg/ml with 0.1 N sodium hydroxide solution and used for the analysis. Aliquots of Pantoprazole ranging from 0.4 – 2.0ml of standard solution were transferred into a series of 10 ml volumetric flasks.

The first order derivative Spectra, showed zero crossing at 294nm, with a maximum absorbance at 286.2 nm when n=1. The same λ max was used for further measurement of drug. A calibration curve for absorbance V/S concentration was plotted (Fig. 3).
The absorbance difference at n=1 dA/dλ is calculated by the inbuilt software of instrument which is directly proportional to the concentration of the standard solution. The standard drug solution was diluted so as to get the final concentration in the range of 4 µg/ml -20 µg/ml and scanned in the first order derivative spectra. The calibration curve of dA/dλ against concentration of the drug showed linearity. Similarly absorbance of sample solution was measured and amount of pantoprazole was determined from standard calibration curve.

Results, discussion and conclusion:

The absorption spectral analysis shows the λ max at 286.2nm. The calibration curve was obtained for the series of concentration in the range of 4 to 20 µg/ml. They were found to be linear and hence, suitable for the estimation of the drug. The slope, intercept, correlation coefficient and optical characteristics are summarized in Table 1. Regression analysis of Beer's law plot revealed a good correlation. The effects of various excipients generally present in the tablet dosage form of Pantoprazole were investigated. The results indicated that they did not interfere in the assay in amounts far in excess of their normal occurrence in it. The proposed methods were validated as per the ICH guidelines. The precision was measured in terms of repeatability, which was determined by sufficient number of aliquots of a homogenous sample. The % RSD was found and lying within the range of ± 2.0. This showed that the precision of the methods are satisfactory. The recovery technique was performed to study the accuracy and reproducibility of the proposed methods. For this, known quantities of the Pantoprazole solution were mixed with definite amounts of pre-analyzed formulations and the mixtures were analyzed. The total amount of Pantoprazole was determined by using the proposed methods and the amount of added drug was calculated by the difference. The % RSD was less than ± 2.0. This showed that the recoveries of Pantoprazole by the proposed methods are satisfactory and the results are shown in Table 2. Ruggedness and Robustness were determined and the % RSD values were calculated from precision study was less than ± 2.0. Limit of detection (LOD) and Limit of quantitation (LOQ) were determined by the proposed methods. Thus it can be concluded that the methods developed in the present investigation are simple, sensitive, accurate, rapid and precise. Hence, the above said methods can be successfully applied for the estimation of Pantoprazole in tablet dosage form.

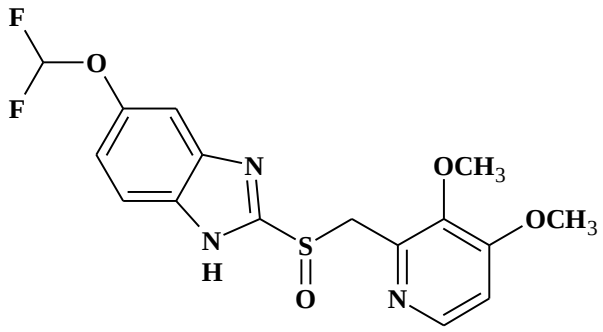

Fig.1: Pantoprazole

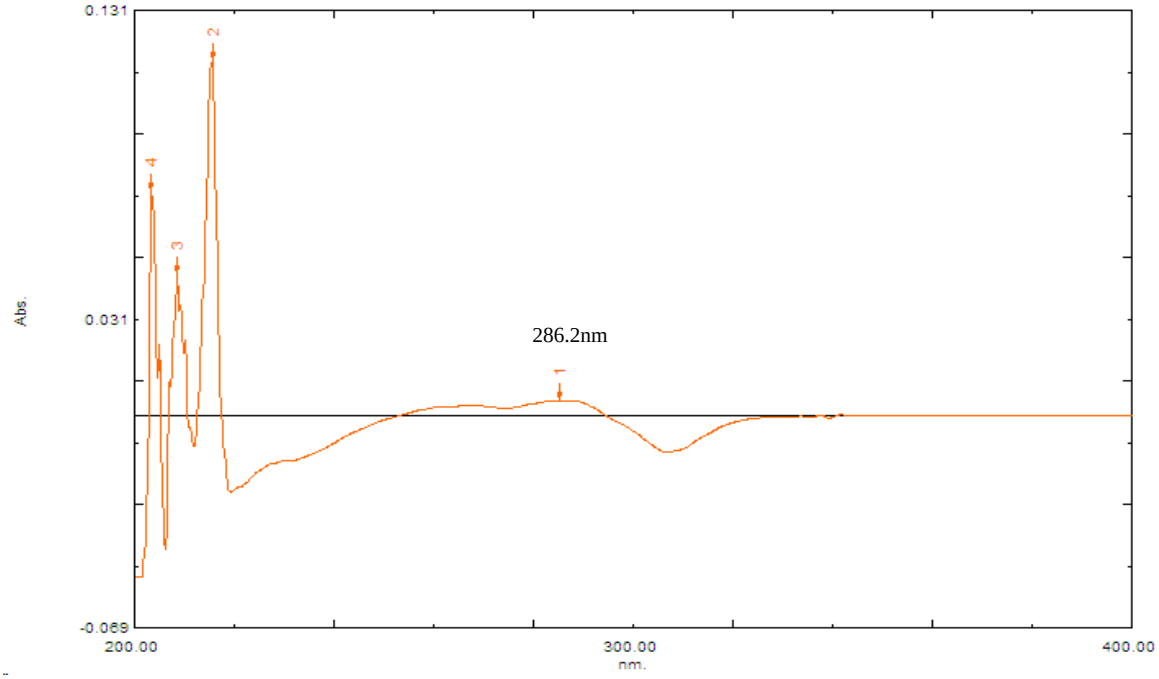

Fig.2: Spectrum shows the λ max at 286.2 nm

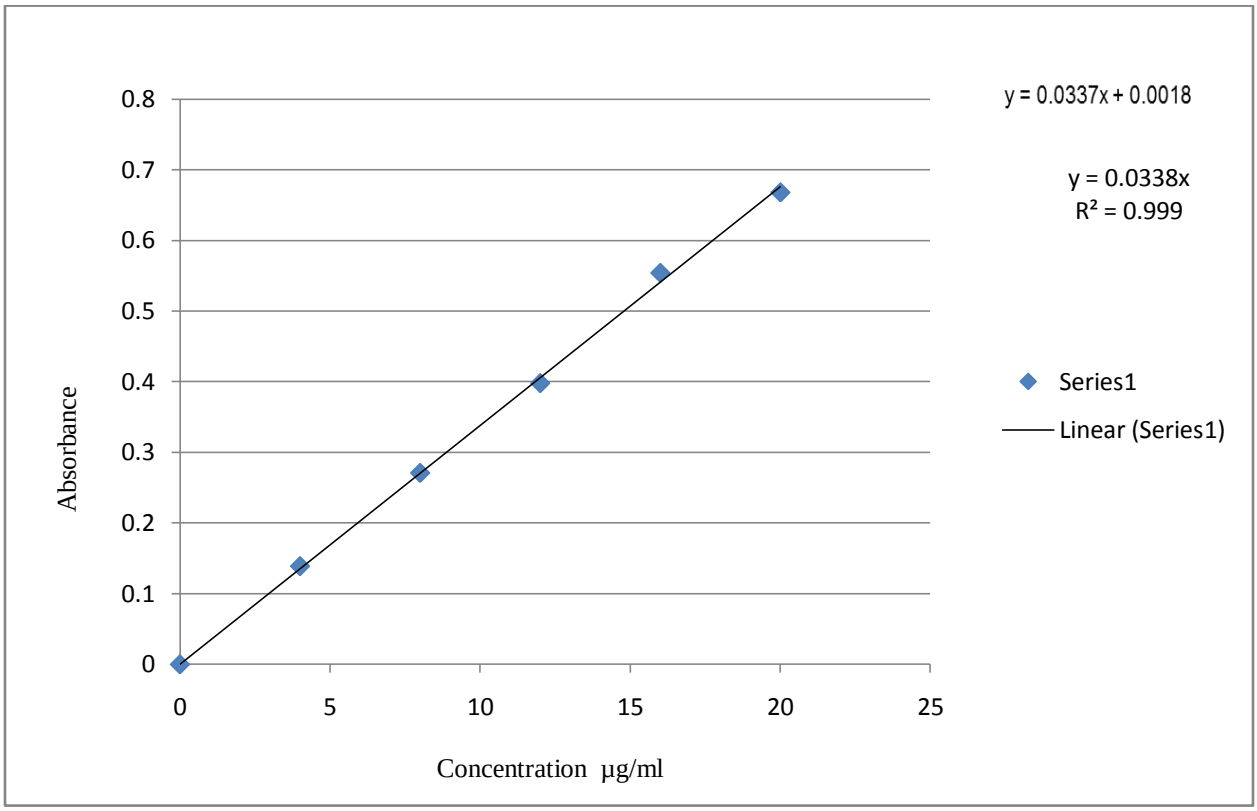

Fig.3: Calibration curve at 286.2 nm

Table 1: Regression analysis of the calibration curve for the proposed method

Parameters	Values
Absorbance maximum (nm)	286.2
Linearity range (µg/ml)	4 – 20
Sandell's sensitivity(µg/cm^2-0.001 absorbance units)	0.020
Correlation coefficient (r^2)	0.999
Regression equation	Y = 0.0337x + 0.0018
Slope	0.0337
Intercept	0.0018
Limit of detection (µg/ml)	0.62
Limit of quantitation (µg/ml)	1.89

Table 2: summary of validation parameters

Parameters	Values
Label claim (Tablet mg)	20
Amount found ± SEM[a]	20.02 ± 05
Precision (RSD, %)	0.48
% Recovery ± SEM[a]	99.42 ± 0.13

[a]Mean of six determinations, SEM indicates standard error mean, RSD indicates relative standard deviation.

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