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NEW SPECTROPHOTOMETRIC METHOD FOR THE ESTIMATION OF PANTOPRAZOLE IN BULK AND PHARMACEUTICAL FORMULATION

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ABSTRACT

A simple, sensitive, rapid and accurate colorimetric method has been developed for the estimation of pantoprazole in bulk and pharmaceutical dosage forms. This method is based on oxidative coupling reaction of pantoprazole with 3-methyl-2-benzathiazoline hydrazone (MBTH) in presence of ferric ammonium sulphate producing orange red colored chromogen, which exhibits absorption maximum at 504 nm. It obeyed Beer's law in concentration range of 10-90 μg/mL. The results obtained with the proposed method are in good agreement with labeled amounts, when marketed pharmaceutical preparations are analyzed. Results obtained are statistically validated and found to be reproducible.

Key words: Spectrophotometry, Pantoprazole, Phannacentrial formulation.

INTRODUCTION

Pantoprazole sodium sesquihydrate a white to off white crystalline powder, chemically is 5-(difluoromethoxy)-2{[(3,4–dimethoxy-2-pyridinyl) methyl] sulfinyl]–1H benzimidazole sesquihydrate. The compound is having clinical efficacy as a proton pump inhibitor by inhibiting H^+, K^+ ATPase enzyme, which is responsible for acid secretion in the parietal cells of the stomach. It is freely soluble in phosphate buffer at pH 7.4 and practically insoluble in n-hexane[1-3]. This is not official in any pharmacopoeia. Few analytical methods like spectrophotometric determination of pantoprazole by, precipitation[4], DDQ[5], HPLC[6] and initial rate method[7] are reported. However, to develop simple, rapid and sensitive method for the estimation of pantoprazole sodium is still need of today.

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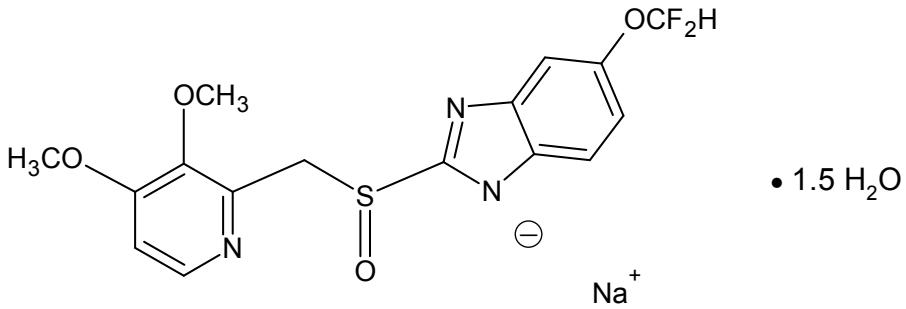
The authors attempted to design a precise, inexpensive colorimetric method for estimation, which could be applied to analyze pantoprazole sodium sesquihydrate in pure and pharmaceutical dosage form and will be helpful to the pharmaceutical industry.



EXPERIMENTAL

A Shimadzu model No.1700, double beam UV-visible spectrophotometer with a pair of 1 cm matched quartz cells was used to measure the absorbance of the resulting solutions.

Sample of pantoprazole sodium sesquihydrate

A gift sample of pantoprazole sodium sesquihydrate was obtained from Sun Pharmaceutical Ltd., Pune.

Reagents and its preparations

All chemicals used are of A.R. grade and were purchased from S.D. fine chemicals and LOBA-Chemi, Mumbai.

(i) Doubled distilled water

(ii) 0.5% Ferric ammonium sulphate was prepared by dissolving 0.5 g ferric ammonium sulphate in 100 mL distilled water

(iii) 0.3% MBTH – (3 methyl – 2- benzathiazoline hydrazone). 0.3% MBTH was prepared by dissolving 0.3 g of MBTH in 100 mL of distilled water.

(iv) Working standard of drug solution. Standard solution of pantoprazole was prepared by dissolving 100 mg of pantoprazole in 100 mL of water i.e. 1000 µg/mL.

Selection of wavelength of maximum absorption (λ_{max})

0.5 mL of standard solution was transferred to 10 mL volumetric flask in which 2

mL ferric ammonium sulphate and 2 mL MBTH were added. The volume was adjusted to 10 mL with distilled water. After thorough shaking, the flask was set aside for 10 min. for reaction to complete. The absorbance was measured in the range of 400 to 700 nm against reagent blank.(λ_{max} = 504 nm)

Stability study of the chromogen

Chromogen was prepared as above and the absorbance was measured at 504 nm at the interval of 15 min for 2 hrs.

Calibration curve

Aliquots of drug solution ranging from 0.1 mL to 0.9 mL were transferred to series of 10 mL volumetric flask. To each flask, 2 mL ferric ammonium sulphate and 2 mL MBTH reagent were added. The volume of each volumetric flask was made up to 10 mL with distilled water. After thorough shaking, the flasks were kept aside for 15 min for reaction to complete. The absorbance of solution in each flask was measured at 504 nm against reagent blank.

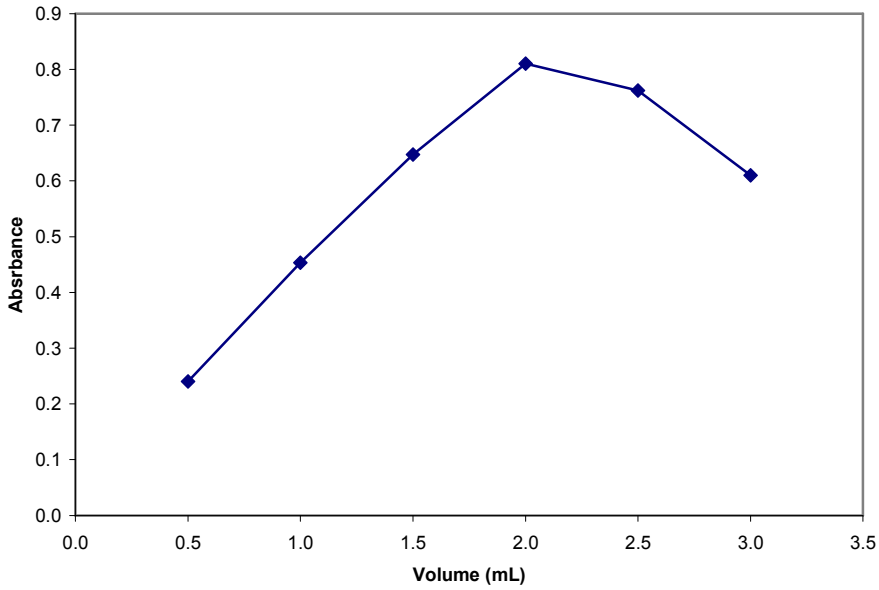


Fig. 1: Effect of MBTH concentration on colour intensity

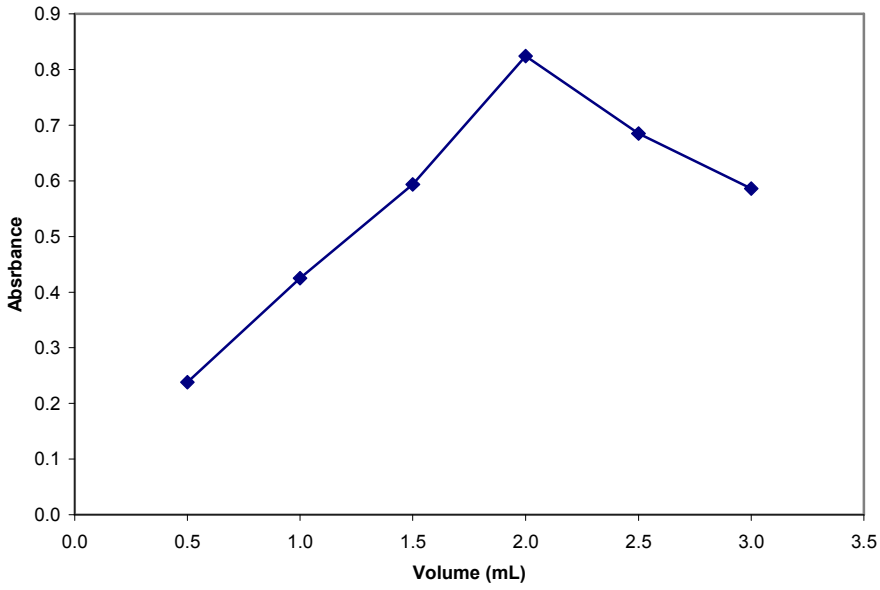


Fig. 2: Effect of FAS concentration on colour intensity

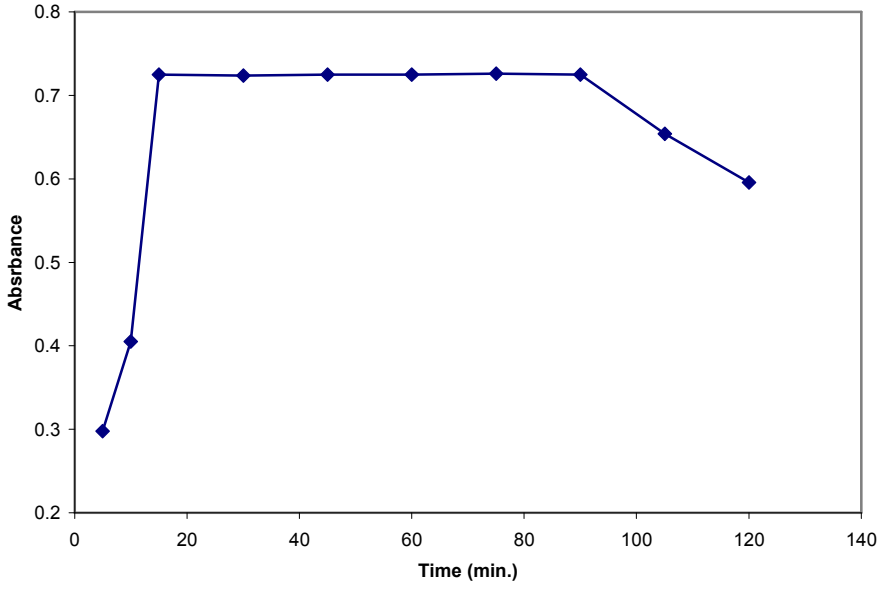


Fig. 3: Stability of chromogen

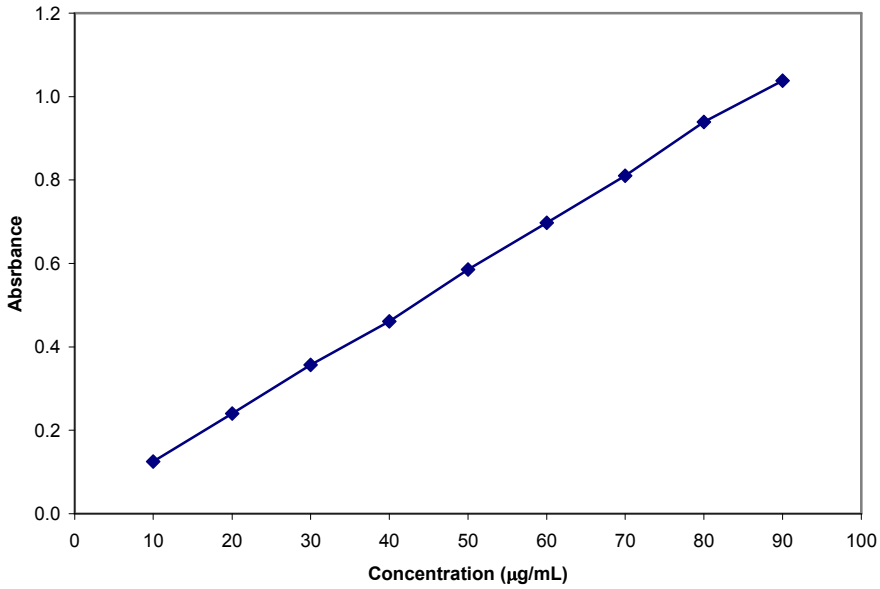


Fig. 4: Calibration curve of pantoprazole

Sample preparation

Twenty tablets, each of which contained 40 mg of pantoprazole sodium sesquihydrate were taken and weighed. Their mean weight was determined and then finely powdered. Tablet powder equivalent to100 mg of pantoprazole sodium sesquihydrate was taken in 100 mL volumetric flask and volume was made upto 100 mL with distilled water. Then this solution was filtered through Whatman filter paper No. 42 and was used as test solution for the analysis. The sample solution was analyzed in the same way as mentioned in the calibration curve.

Assay

Aliquots of test solution ranging from 0.1 to 0.9 mL were transferred into a series of 10 mL volumetric flasks. In each of the flask, 2 mL ferric ammonium sulphate and 2 mL MBTH reagents were added. The volume of each volumetric flask was made up to 10 mL with distilled water. After shaking, the flasks were kept aside for 15 min for reaction to complete. The absorbance of solution in each flask was measured at 504 nm against reagent blank.

The amount of pantoprazole sodium sesquihydrate in the test solution was computed from calibration curve.

RESULTS AND DISCUSSION

The optical characteristics such as absorption maxima, Beer's law limits, molar absorptivity, Sandell's sensitivity and percent relative standard deviation were calculated and the results are summarized in Table 1. The optimum conditions for color development have been established by varying the parameters one at a time and keeping the other parameters fixed and observing the effect of product on the absorbance of the colored species. Then it was incorporated in the procedure.

Table 1. Optical characteristics and precision data

Parameter	Value obtained
Absorption maxima	504
Beer's law limit μg/mL	10-90
Correlation coefficient	0.9998
Molar absorptivity (lit/mole/cm)	4.966×10^3
Sandell's sensitivity(mcg/sq.cm/0.001)	0.08707
Regression Equation	
Slope (m)	0.0114
Intercept	0.0093
% co v	0.1253
Confidence limit with 0.05 level	0.0014

The values obtained for the determination of pantoprazole sodium sesquihydrate in different tablet samples T_1 and T_2 by proposed method are presented in Table 2.

To evaluate the validity and reproducibility of the methods, known amount of pure drug was added to the previously analyzed pharmaceutical preparation and the mixtures were analyzed by the proposed methods. The percent recoveries are also given in Table 2.

Table 2. Result of analysis

Formulation	Label claim (mg)	% Estimated	% Recovery
T_1	40	99.9513	100.9142
T_2	40	100.0275	98.9986

These studies revealed that the common excipients and other additives such as starch, talc, lactose and magnesium stearate, that are usually present in tablet dosage forms, did not interfere at their regularly added levels.

CONCLUSION

New, simple, sensitive and precise colorimetric method using MBTH has been developed for the quantitative determination of pantoprazole sodium sesquihydrate and it can be successfully applied for its estimation in tablet samples.

REFERENCES

1. S. Budavari, The Merck Index, Merck & Co. Inc., White House Station, NJ, 12th Edn, (1996) p. 1205.
2. Martindale, The Complete Drug Reference, K. Parafitt (Ed.),, The Pharmaceutical Press, London, 32 nd Edition, (1999) p. 1144.
3. http: // www. rxlist. com/cgi/generic3/protonix. htm.
4. R. J. Huber, Chromatogr., **529**, 389 (1960).
5. Azza A. M. Moustafa, J. Pharm. Biomed. Anal., **22(1)**, 45 (2000).
6. N. Rahmam. and M. Kashif., J. Chromatogr. B, **822 (1-2)**, 326 (2005).
7. N. V. S. Ramkrishana, K. N. Vishwottam, S. Wishnu and M. Koteshwara., Pharmazie., **60(3)**, 197 (2005).

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