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Research Article

SPECTROPHOTOMETRIC METHOD FOR ESTIMATION OF RABEPRAZOLE SODIUM IN TABLETS

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ABSTRACT
A simple, rapid, accurate, economical and reproducible spectrophotometric method for estimation of rabeprazole sodium (RAB) has been developed. The method employs estimation by straight line equation obtained from calibration curve of rabeprazole sodium. Analysis was performed at 284.0nm which is absorbance maximum of the said drug in 20% v/v aqueous methanol as solvent. The method obeys Beer's law between 4.08 – 24.5 µg/. Results of analysis were validated statistically by ICH guidelines 1996.
Keywords: Spectrophotometer, Rabeprazole, Validation and Accuracy.

INTRODUCTION

Rabeprazole sodium I.P. or 2-[[[4-(3-methoxypropoxy)-3-methyl-2-pyridinyl] methyl]sulfinyl]-1H-benzimidazole, is a selective and irreversible proton pump inhibitor and it has proven efficacy in healing, symptoms relief and prevention of relapse of gastric ulcer, duodenal ulcer and gasteroesophageal reflux disease[1]. Various chromatographic[2-6] and spectrometric[7-8] methods have been developed for quantification of rabeprazole sodium. No doubt, available chromatographic methods are accurate and precise with good reproducibility, but the cost of analysis is quite high owing to expensive instrumentation, reagent required, expertise and more time per sample analysis, this makes these chromatographic methods unsuitable for routine analysis. Variations in columns and instruments accuracy due to manufacturer to manufacturer variation complicate transfer of these HPLC methods. Extensive literature survey revealed that only a single UV method is however reported till date for the estimation of rabeprazole sodium in tablet dosage form. That's why it was thought to develop new simple, economical, accurate, reproducible and rapid analytical methods for estimation of rabeprazole sodium in tablets by UV spectroscopy.

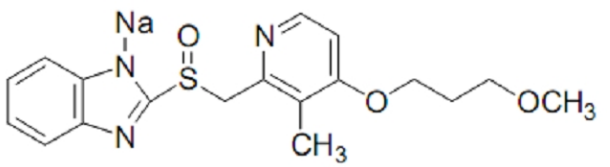

Figure 1: Rabeprazole Sodium I.P.

MATERIAL AND METHOD

Instrumentation

UV/visible double beam spectrophotometer (Jasco Model V530) was employed with spectral bandwidth of 1nm and wavelength accuracy of ±0.3 nm, with a pair of 1 cm matched quartz cells(Optigalss).

Reagents and Chemicals

Analytical pure standard samples of rabeprazole sodium were supplied as gift sample by Vama Pharma. Pvt. Ltd. Nagpur (M.H.) India and used without further purification. The Pharmaceutical dosage form used in this study was a Rabimac tablet (Label claim: 20mg of rabeprazole sodium I.P. as sustained release tablet) manufactured by Macleod pvt. Ltd. Methanol LR grade was purchased from CDH, Rankem and Qualigens, and inbuilt distilled water was used. 20% v/v aqueous methanol was used as solvent.

Preparation of Standard Stock Solution

The stock solution of standard rabeprazole sodium was prepared by dissolving approximately 5mg rabeprazole sodium in 10ml 20% v/v aqueous methanol the suspension was quantitatively transferred into a 25ml calibrated volumetric flask and volume was made up to 25ml with solvent. The strength of the resulting solution will be approx.200 µg/ml.

Preparation of Calibration Curve

In a series of 10ml volumetric flasks, sufficient aliquot of the standard stock solution (200 µg /ml) were transferred and diluted with 20% v/v aqueous methanol so as to give several dilutions of 4.08 – 24.5µg/ml. The absorbance was measured against 20% v/v aqueous methanol at 284.0nm (λ_{max} of rabeprazole sodium)

Table 1: Data for Calibration Curve of Rabeprazole Sodium

Concentration µg/ml	Absorbance at 284.0nm
4.08	0.12728
8.16	0.24071
12.24	0.35016
16.32	0.48871
20.4	0.61162
24.5	0.71783

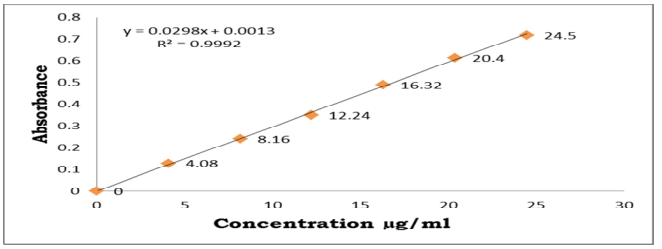

Figure 2: Calibration Curve of Rabeprazole Sodium

Preparation of Sample Stock Solution

Twenty tablets were powdered and weight equivalent to approx. 10 mg of rabeprazole sodium was dissolved in 20 ml of 20% v/v aqueous methanol. The suspension was sonicated vigorously for 5 min to completely dissolve the remaining drug in powder. The solution after filtrations through Whattman filter paper no. 41 was quantitatively transferred to 100ml calibrated volumetric flask and the volume was then made up to 100 ml with 20% v/v aqueous methanol by continuously washing filter paper to quantitatively transfer the total amount of drug. The strength of resulting solution will be of approx.100 µg/ml.

Theory and calculation

Validation

The developed method for the estimation of RAB was validated as per ICH guidelines (ICH 1996). The described method has been validated for linearity, precision, accuracy, specificity, and robustness.

Linearity

Least square regression analysis was carried out for the slope, intercept and correlation coefficient (Table I). The linear fit of the system was illustrated graphically. The linearity range was found to be 4.08 – 24.5 µg/ml Regression equation for RAB was **y= 0.00298 x + 0.0013 (r^2= 0.9992).**

Table 2: Optical Characteristic of the Proposed Method

Parameters	Result obtained
Beer's law limit	4.08 – 24.5µg/ml
Absorption maximum	284.0 nm
Molar absorptivity	11350.273
Percent absorptivity	297.595
Slope	0.00298
Intercept	0.0013
Regression coefficient	0.999

Accuracy

This experiment was performed at three levels in which sample stock solutions were spiked with standard drug solution containing 80, 100 and 120% of sample solution of the rabeprazole sodium. Three replicate samples of each concentration level were prepared and the % recovery at each level (n = 3), and mean % recovery (n=9) were determined. The means of %recovery (%RSD) were found to be low values <2 (Table III). These results revealed that any small change in the drug concentration in the solution could be accurately determined by the proposed analytical methods.

Table 3: Results of Accuracy Experiment Using Proposed Method

Spike Level	Analyte conc. (µg/ml)	Conc. Spike (µg/ml)	Conc. Found (µg/ml)	% Recovery	Mean % Recovery	% R.S.D
80%	10.07	7.84	7.85	100.89	101.061	1.617
80%	10.07	7.84	7.88	101.275		
80%	10.07	7.84	7.86	101.020		
100%	10.07	10.08	9.91	98.313	98.247	1.611
100%	10.07	10.08	9.89	98.115		
100%	10.07	10.08	9.91	98.313		
120%	10.07	12.32	12.04	97.727	97.591	1.613
120%	10.07	12.32	12.01	97.483		
120%	10.07	12.32	12.02	97.564		

Precision

The precision of the proposed method was evaluated by carrying out nine independent assays of test sample (10, 15, 20µg/ml). RSD (%) of nine assay values obtained was calculated. Intermediate precision was carried out by analyzing the samples by a different analyst with deferent reagent on same instrument. No statistically significant difference was observed. The resultant data was presented in table IV. %RSD values were not more than 2.0% in all the cases. RSD values found for all three analytical methods were well with in the acceptable range indicating that these all methods have excellent repeatability and intermediate precision.

Table 4: Data of Precision Study

% R.S.D intraday	% R.S.D interdays	% R.S.D intermediate	Error
1.830005	1.16387	0.8749	0.4133

R.S.D. is relative standard deviation

Specificity

Specificity is the ability to measure accurately and specifically the analyte of interest in the presence of other components that may be expected to be present in the sample matrix. It was found that the proposed method was specific because there is no interference of other active ingredients and excipients, ensuring that the peak response is due only to a single component. Based on the results, obtained from the analysis of standard drug and samples using the described method, it can be concluded that the method is specific for estimation of RAB in presence of degradants.

Robustness

The percentage recovery of RAB was good under most conditions and did not show any significant change when the critical parameters (day, time, reagent, analyst) were modified. Thus the method conditions were robust.

Assay

The validated method was applied to the determination of RAB in commercially available Rabimac® (tab). Appropriate dilution of rabeprazole sodium was prepared and absorbance was recorded and concentration of the drug was determined from the regression equation of standard drug. Figure 3 illustrates overlaid spectra obtained from RAB standard solution and from the assay of Rabimac®. The observed concentration of RAB was found to be 20.09±0.241mg (mean±SD) for Rabimac®. The results of the assay (n = 9) undertaken yielded 100.45 % (%RSD = 0.24) of label claim for RAB in Rabimac® shown in table V. The results of the assay indicate that the method is selective for the estimation of RAB without interference from the excipients used to formulate and produce these tablets.

Table 5: Results of Commercial Formulation Analysis

Drug	Label claim mg/tab	% of label claim estimated[a]	S.D.	% R.S.D.	S.E.
RAB	20	100.45	0.2403	0.2414	0.0801

[a] Average of nine determination, S.D.: Standard deviation, R.S.D. : Relative standard deviation, S.E.: Standard error

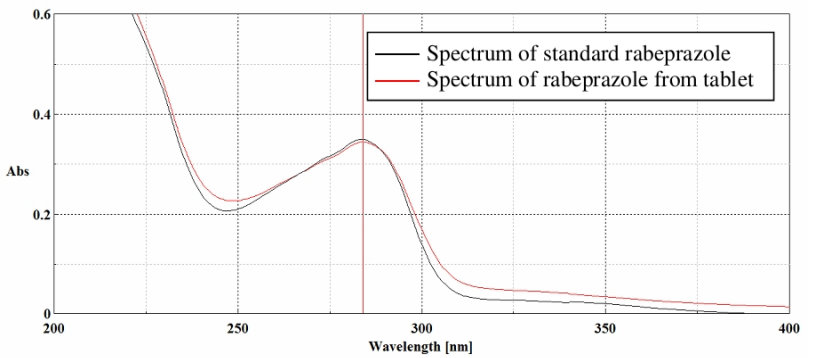

Figure 3: Comparison of Spectra of Rabeprazole Sodium from Tablet and Standard Drug In 20% v/v Aqueous Methanol (conc. approx 12µg/ml)

RESULTS AND DISCUSSION

The proposed method utilizes UV/visible double beam spectrophotometer (Jasco Model V530) with spectral bandwidth of 1nm and wavelength accuracy of ±0.3 nm. The optical characteristics such as absorption maxima, beer's law limit, absorptivity, correlation coefficient (r), slope (m), y-intercept (c) were calculated are shown in table 2. The repeatability, reproducibility were found to be good as evident by the low standard deviation value (less than 2) in all cases reported in table 4. The percentage recovery values obtained were 98.966 reported in table 3. This shows that there is no interference of the excipients in the analysis. The analysis result of tablet formulations are in good agreement with the official standard reported in table 5.

CONCLUSION

The proposed validated three spectrophotometric methods are simple, rapid, accurate, precise and inexpensive and hence can be used for the routine analysis of RAB in tablet. The sample recovery for all three methods was in good agreement with their respective label claims, which suggested non interference of formulation additives in estimation.

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