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UV-Spectrophotometry and first order derivative spectrophotometry methods for determination of rabeprazole sodium in bulk and tablets

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ABSTRACT

Two simple, rapid, sensitive and accurate UV- spectrophotometry (method I) and First order derivative (method II) have been developed for estimation of rabeprazole sodium in bulk and tablets. In (10% *v/v*) acetonitrile, the λmax of rabeprazole sodium was found to be 284 nm. The same spectrum was derivatised into first order derivative at $\Delta\lambda = 2$ and amplitude of the trough was recorded at 298 nm. In both the proposed methods, linearity was observed in the concentration range 4-28 µg/ml. The assay results were found to be in good agreement with label claim. The methods were validated statistically and by recovery studies.

Key words: Rabeprazole sodium, UV-spectrophotometry, first order derivative.

INTRODUCTION

Raberprazole sodium (RAB), - [[[4 –(3-methoxypropoxy) -3-methyl-2-pyridinyl] – methyl] sulfinyl] – 1H benzimidazole sodium suppresses gastric acid secretion by inhibiting H^+/K^+- ATPase enzyme[1,2]. Literature survey revealed few spectrophotometric[3,4], chromatographic[5,6] methods for estimation of RAB in bulk, pharmaceutical formulations and biological fluids. RAB is not official in IP, BP and USP. Present investigation describes UV- Spectrophotometry and First order derivative methods for estimation of RAB in bulk and tablets.

MATERIAL AND METHODS

All the chemicals used were of analytical grades.

Preparation of standard stock solution

Standard stock solution was prepared by dissolving 10 mg of RAB in 100 ml acetonitrile (10% *v/v)* i.e. 100 µg/ml.

Method I: UV-Spectrophotometry

Different aliquots using micropipette were taken from the stock solution, diluted to 10 ml mark to obtain series of concentrations. The solutions were scanned in the UV- range 200 - 400 nm on UV-visible spectrophotometer- 2450 (Shimadzu). RAB showed absorbance maxima at 284 nm. The linearity was observed in the concentration range 4 - 28 µg/ml ($Y = 0.03524 \times + 0.00774$; $r^2 = 0.9999$)

Method II: First order derivative spectrophotometry

The prepared solutions in method first were derivatised into first order derivative, at $\Delta\lambda = 2$ and amplitude of the troughs was recorded at 298 nm. The linearity was observed in the concentration range of 4 - 28 µg/ml ($Y = 0.0027 X + 0.00079$; $r^2 = 0.9999$). The overlain first order derivative spectra is shown in figure.

Preparation of sample solution

For analysis of commercial formulation;

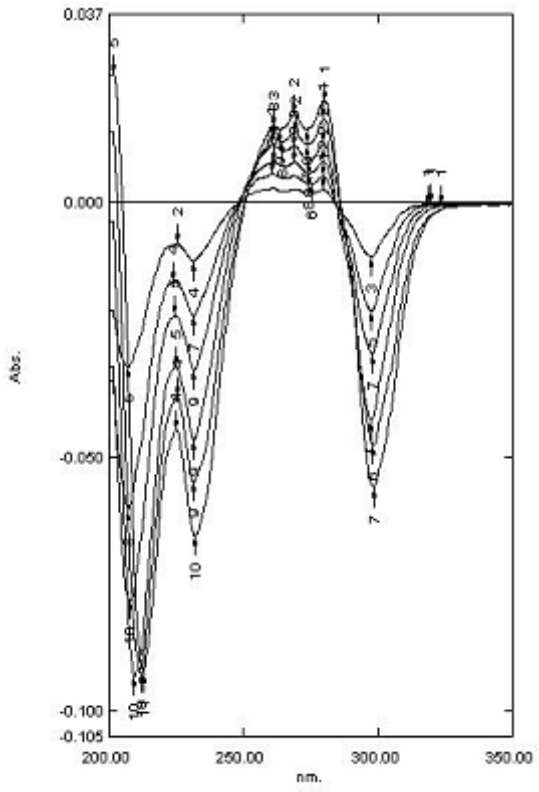

Fig. 1: Overlain first order derivative spectra of RAB in 10%*v/v* acetonitrile

twenty tablets were accurately weighed, average weight determined and crushed into fine powder. A quantity of tablet powder equivalent to 10 mg of rabeprazole was transferred into 100 ml volumetric flask containing 30 ml acetonitrile (10% *v/v*), shaken manually for 10 min, volume was adjusted to mark with same solvent and filtered through Whatmann filter paper no. 41. After appropriate dilutions, the absorbances of solution in 'method I' and amplitudes in 'method II' were recorded at selected wavelengths against blank. The amount of drug estimated by linear regression equations; results are shown in table 1.

Recovery study

To study the accuracy of proposed methods; recovery studies were carried out by adding the known amount of standard drug solution to the pre-analyzed sample solution at three different levels i.e. 80%, 100%, 120%. The solutions were re-analyzed; the results are shown in table 2

RESULTS AND DISCUSSION

In acetonitrile (10% *v/v*), RAB showed absorbance maxima at 284 nm. In first order derivative the drug showed well resolved trough at 298 nm. In both the methods, RAB follows linearity in the concentration range 4 – 28 µg/ml. Amount of

Table 1: Results from analysis of marketed formulation

	Method- I		Method- II	
	Brand I	**Brand II**	**Brand I**	**Brand II**
Label claim (mg/tab)	10	20	10	20
%Amount found* (mg)	98.23	98.10	98.84	98.47
%RSD	0.232	0.151	0.313	0.314

*mean of five estimations

Table 2: Results from recovery studies

	Method- I		Method -II	
	Brand I	**Brand II**	**Brand I**	**Brand II**
% Recovery*	98.77	98.73	98.54	98.04
%RSD	0.393	0.527	0.447	0.291

*mean of nine estimations

drug determined by proposed methods was in good agreement with the label claim. The methods were validated[7] for accuracy, precision and ruggedness; the % RSD values were found to be less than 2. The results did not show any statistical difference between operators (%RSD less than 2) suggesting that methods developed were rugged. Both the developed methods are simple, accurate and economical and can be used for routine analysis of RAB in bulk and tablets.

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