

SPECTROPHOTOMETRIC DETERMINATION OF REBAPRAZOLE IN PHARMACEUTICALS BY USING DIFFERENCE SPECTROPHOTOMETRIC METHOD

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ABSTRACT

A new spectrophotometric method for the estimation of Rebaprazole in pharmaceutical formulations has been described. In this method the Rebaprazole containing phenolic groups produce a bathochromic shift in UV region under strong alkaline medium. The drug solution in basic medium is scanned over the UV region by taking the acidic drug solution as blank. From the absorbance values, Spectrum was constructed. Two wave lengths are selected one at positive peak and another at negative peak. The sum of the obsolete values at these wavelengths is called amplitude. The amplitude was proportional to the amount of respective drug. Results of analysis of this method were validated statistically evaluated.

Key Words: Rebaprazole, UV, spectrophotometric.

INTRODUCTION

Rebaprazole chemically 2- [4-(3 – Methoxy Propoxy) – 3 –methyl – pyridine – 2 – yl] Methyl sulfinyl] – 1yl – benzoimid. It is freely soluble in chloroform. It is used as an antitussive in treatment of various diseases. The structure of Rebaprazole represented as in figure-1.

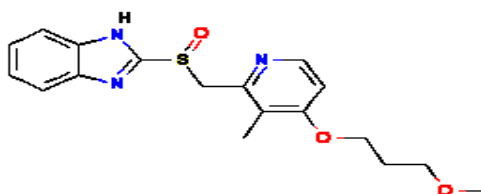


Fig : 1. Rebaprazole

The survey of literature describes various spectrophotometric methods for the analysis of this drug. The objective of the present investigation is to develop a simple, rapid, precise, reproducible and economical method for the estimation of drug formulations by using difference spectrophotometric method.

EXPERIMENTAL

Apparatus

A Spectromic 1001 Spectrometer with 10 mm matched wartz cuvettes was used for absorbance values of the drug solution.

Reagents:

All the chemicals used were of analytical grade and Analytical reagent grade methanol was used as solvent.

1. Standard Solution of Rebaprazole

An accurately weighted 50 mg of Rebaprazole was dissolved in methanol. The volume was adjusted to 50ml with methanol in 50 ml standard flask. Two ml of this solution was diluted to 50 ml with methanol to give a standard working concentration of solution 200 μ g / ml.

Spectrophotometric Method

This method was applied to the estimations of the drug dosage forms were purchased from local commercial sources and subjected to analysis. The contents of ten tablets were ground into a fine powder. A quantity of the powder equivalent to 50mg of Rebaprazole was accurately weighted into a 50 ml standard flask and shaken well with 30 ml of methanol for five minutes. Then the volume was adjusted to 50 ml with methanol in standard flask. Two ml of this solution was diluted to 50 ml with methanol to give a standard working solution. This stock solution concentration of 100 μ g / ml.

Various aliquots of drug solution ranging from 1.0-4.0 ml flask. Was transferred into a serried of 25 ml volumetric flask. To each flask 1 ml of 10% sodium hydroxide was added and made unto the mark with distilled water. These flasks are Scanned over the range of 200-365 nm against the acidic drug solution as blank. From the absorbance values of Rebaprazole spectrum was constructed (Fig-2) Two wave lengths are selected one at positive peak and another values at these wavelengths are called amplitude. The amplitude was

proportional to the amount of drug. The calibration curve was plotted between amplitude values versus amount of drug presented in the figure -3.

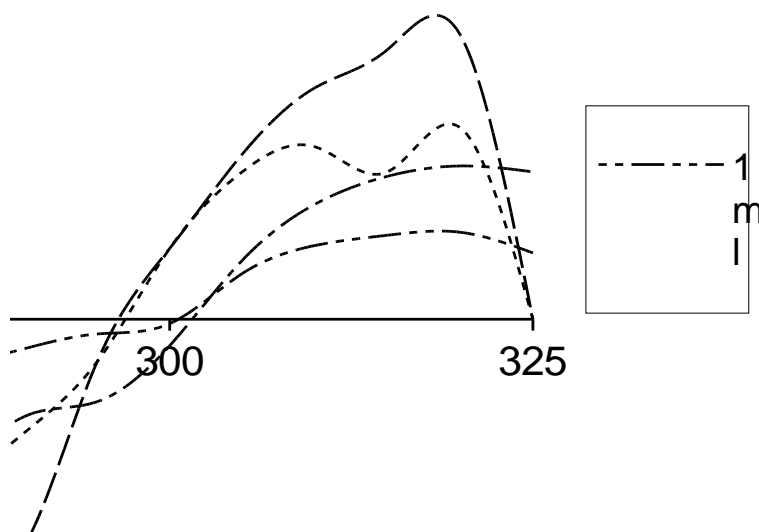


Figure 2 : Spectrum of rebaprazole

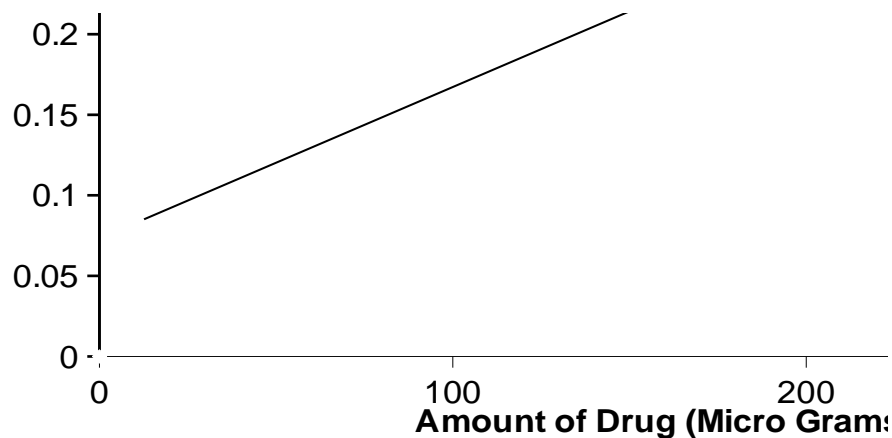


Figure 2: Calibration curve of rebaprazole

Table 1: Spectral data for calibration curve

Amount of drug (µg/ml)	Abs(+ve) 320	Abs(-ve) 275	Amplitude
100	0.059	0.064	0.123
200	0.104	0.14	0.244
400	0.13	0.182	0.312
600	0.193	0.249	0.442

Amount of drug in micrograms / ml.

Method Validation

This method was validated in terms of linearity, accuracy and precision and reproducibility of the sample applications. A linear relation was found between absorbance and concentration in the ranges. Beer's law was obeyed in the concentration ranges.

Statistical analysis

A Statistical analysis was performed on the statistically significant variables using the statistical software. The following parameters were determined. Co-efficient of variation, standard deviation and student t -test.

The Standard deviation and t -test of the methyldopa was calculated from five measurements of replicate samples. The values of standard deviation and t_{cal} were shown in table -1. The values of standard deviation and coefficient variation are low, indicates high accuracy and reproducibility of the method. The calculated ' t ' values are less than ' t ' theoretical values with $4(x-1=5-1)$ degrees of freedom at 5-1. Level of significance, indicate that there is no significant difference between proposed method and standard method.

TABLE -1 :Statistical analysis of the determination of Rebaprazole

Sample	S.D	t_{cal}^a	t_{tab}^*
Tablet – 1	0.3435	2.213	2.78
Tablet – 2	0.3646	1.472	

* standard deviation

'a' calculated ' t ' value by proposed Method.

'b' theoretical values at 95% confidence limit.

RESULTS AND DISCUSSION

This method is applied for the estimation of Rebaprazole on pharmaceutical formulation. The drug solution in basic medium is scanned over the UV region by taking the acidic drug solution as blank. From the absorbance values, the absorbance values, the absorption spectrum of stillboestrol was constructed. Two wavelengths are selected one at 215 nm another at 453 nm the sum of the absolute values at these wavelengths are called amplitude. The amplitude was proportional to the amount of drug. The calibration curve was plotted

with the amplitude values verses amount of drug. The standard deviation values and total of the stilborstrol was calculated from five measurements of replicate samples. The values of standard deviation and teal values are low, indicated high accuracy and reproducibility of the method. The data of assay values of commercial formulations was subjected 't' values are less than 't' theoretical values with $4(2-1=5-1)$ degrees of freedom at 5% level of significance indicate that there was no significant difference between proposed method and standard method. Hence the procedure described by the proposed assay can be successfully adopted for the estimation of Rebaprazole in tablets. The results are given in Table-2.

Table-2

Sample	Labeled Amount mg/tab	Amount found mg/tab	%recovery
Tablet – 1	5	4.86	96.0
Tablet – 2	5	4.76	95.2

CONCLUSIONS

The proposed method was found to be simple, precise, accurate, and less time consuming and it can be successfully adopted for the estimation of Rebaprazole in pharmaceutical formulations.

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