Spectrophotometric Method for Estimation of Rabeprazole

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A simple new spectrophotometric method has been developed for determination of rabeprazole in pharmaceutical bulk dosage form. The method was based on the formation of ion-pair complexes of the drug with four dyes, viz. bromo thymol blue, bromocresol green, bromophenol blue and bromocresol purple in acidic buffer solutions followed by their extraction in chloroform. The absorbance of the organic layer was measured at its respective wavelength of maximum absorbance against the corresponding reagent blank. The method has been statistically evaluated and was found to be precise and accurate. Phosphate buffer of pH 2 and bromocresol green dye gave maximum absorbance of rabeprazole at 454 nm.

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Rabeprazole is chemically 2-[[[4-(3-methoxypropoxy)-3-methyl-2-pyridinyl]-methyl]sulfinyl]-1H-benzimidazole sodium. It is not yet official in any of the pharmacopoeias[1-2]. Literature survey revealed HPLC, spectrophotometric and spectrofluorometric methods for determination of rabeprazole in bulk and dosage forms[3]. The proposed spectrophotometric method was based on the formation of ion-pair complexes with bromothymol blue, bromocresol green, bromophenol blue and bromocresol purple.

Shimadzu UV spectrophotometer-1601 with 1 cm-matched curettes was used for all spectral measurements. All the chemicals used were of analytical reagent grade. Bromothymol blue (BTB), bromocresol green (BCG), bromophenol blue (BPB) and bromocresol purple (BCP) solutions were prepared and treated with chloroform to remove chloroform soluble impurities, if any. Phosphate buffer solution of pH 2, 2.4 and 3 were prepared. Rabeprazole was accurately weighed equivalent to 100 mg and dissolved in 100 ml of methanol (100 µg/ml). The solution was further diluted to prepare working standard solution of 0.1 mg/ml.

In a series of 125 ml separating funnels, aliquots of the standard drug solution of rabeprazole were transferred. To each funnel, potassium hydrogen phthalate buffer and dye solutions were added. The total volume of aqueous phase was adjusted to 2 ml. Chloroform (5 ml) was added to each separating funnel. The contents were shaken for thorough mixing of two phases and were allowed to stand for clear separation of the layers. The absorbance of the separated chloroform layer was measured against their reagent blank at respective wavelength of maximum absorbance. The sample solution was treated in a similar manner and the amount of rabeprazole was determined by referring to the calibration curve.

Twenty tablets of marketed brand Rabicip from Cipla Limited, Mumbai were weighed and powdered in a glass mortar. Powder equivalent to 100 mg of rabeprazole was extracted with two 30 ml portions of methanol and filtered into a 100 ml volumetric flask through 0.45 µ Whatman filter paper, washed with 10 ml portions of methanol and volume was made up to 100 ml with methanol.

Experiments were carried out to optimize the reaction conditions for complete color formation. It was found that 1 ml of BCP, BCG, BTP and BPB reagent and 2 ml of respective buffer solutions were optimum for the achievement of maximum color intensity. Bromocresol green dye along with phosphate buffer of pH 2 gave more absorbance at λ_{max} of 454 nm this process was optimized.

TABLE 1: OPTICAL CHARACTERISTICS, REGRESSION EQUATION AND CORRELATION CO-EFFICIENT OF THE METHOD

Data	Results
Maximum wavelength (λ max)	454 nm
Beer's law limit	10-100 µg/ml
Molar absorptivity (1 $mole^{-1}$ cm^{-1})	2.77×10^4
Sandell's sensitivity	0.024 µg/cm^2/0.001 absorbance unit
Regression equation	Y=0.0234X + 0.0602
Slope	0.0234
Intercept	0.0602
Correlation co-efficient (r)	0.995

TABLE 2: RESULTS OF ANALYSIS OF TABLETS

Formulations	Labeled claim (mg)	Amount found (mg)	% Recovery*
T-1	5.0	4.83±0.3	98.3% ±0.44
T-2	5.0	5.0±0.24	

*Average of three determinations

The optical characteristics such as Beer's law limit (µg/ml), correlation co-efficient (r), slope (m), Y intercept©, molar absorptivity (l/mole cm^{-1}) and Sandell's sensitivity (µg/cm^2/0.001) were calculated for all the methods and the results are summarized in Table 1 for the method using Bromocresol green dye along with phosphate buffer of pH 2.

The analysis results of marketed formulations were in good agreement with their labeled claim. The recovery ranged between 98 to 100% for BCG. The proposed method was simple, sensitive, accurate and precise and can be successfully applied in estimation of rabeprazole in tablet dosage forms.

Most of the formulations contain excipients and binders, which are added along with the active drug constituents. These substances may cause some interference during estimation of the active drug constituents. The results of recovery studies are shown in Table 2. Non - interference from the excipients was confirmed by performing the recovery experiment for which standard addition method was employed.

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