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NOTE

Spectrometric Estimation of Rabeprazole Sodium from Tablet Formulation

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Two simple and sensitive visible spectrophotometric methods have been developed for the quantitative estimation of rabeprazole sodium from its tablet formulation. The first developed method is based on formation of chloroform extractable coloured complex of drug with bromo phenol red and the second developed method is the formation of yellowish brown complex of drug with crystal violet. The chloroform extracted complex of the drug with bromo phenol red showed absorbance maxima at 418 nm and linearity was observed in the concentration range of 10–50 μg/mL. The complex of the drug with crystal violet showed absorbance maxima at 412 nm and linearity was observed in the concentration range of 100–600 μg/mL. Results of analysis for both the developed methods were validated statistically and by recovery studies.

Key Words: Rabeprazole sodium, Spectrophotometric method, Tablet formulation.

Rabeprazole sodium, chemically 2-[[[4-(3-methoxy propoxy)-3-methyl-2-pyridinyl]methyl]sulfinyl]-1H-benzimidazole sodium is the latest proton pump inhibitor[1] and is used in the management of acid related disorders. Few analytical methods for estimation of rabeprazole sodium including HPCL[2, 3], LC-MS[4], LC-NMR[5], capillary electrophoresis[6] and column switching LC[7] are reported.

A Systronics UV/Visible double beam spectrophotometer (model 2101) with 1 cm matched quartz cells was used for spectral measurement. All the chemicals used were of analytical grade. Bromo phenol red solution (0.3%) was prepared in phosphate buffer (pH 4) and extracted several times with chloroform so as to remove chloroform-soluble impurities; crystal violet solution (0.2%) was repared in double distilled water. Drug solution and buffer was prepared in double distilled water. The tablet samples of rabeprazole sodium were procured from the local market.

For method I, in a series of 10 mL volumetric flasks aliquots of standard drug solution of rabeprazole sodium (100 μg/mL) in distilled water were transferred and diluted with the same so as to give several dilutions in the concentration range

of 10–50 μg/mL of drug. To 5 mL of each dilution taken in a separating funnel, 5 mL of bromo phenol red solution was added, shaken and allowed to stand for 10 min for the formation of coloured complex. The coloured complex was extracted with 5, 3 and 2 mL portions of chloroform and absorbance of the combined chloroform layer was measured at 418 nm against a reagent blank. A calibration curve was prepared by plotting concentration *vs.* absorbance.

For method **II**, in a series of 10 mL volumetric flasks aliquots of standard drug solution of rabeprazole sodium (1000 μg/mL) in distilled water were transferred and diluted with the same so as to give several dilutions in the concentration range of 100–600 μg/mL of drug. To 5 mL of each dilution taken in a test tube, 5 mL of crystal violet solution was added, shaken and allowed to stand for 5 min for the formation of coloured complex and absorbance of the complex was measured at 412 nm against a reagent blank. A calibration curve was prepared by plotting concentration *vs.* absorbance.

For analysis of formulation, twenty tablets of rabeprazole sodium were accurately weighed and average weight per tablet was determined. The tablets were powdered and powder equivalent to 20 mg of rabeprazole sodium was accurately weighed and extracted four times with 20 mL portions of distilled water; the combined extract was filtered through Whatmann filter paper No. 41 into 100 mL volumetric flask. The residue was washed with distilled water and the washings were added to the filtrate; final volume of filtrate was made up to the mark with distilled water.

For method **I**, 1 mL of filtrate was diluted to 10 mL with distilled water. this was treated as per the respective procedure for the calibrated curve and absorbance was measured at 418 nm; the amount of drug present in the sample was computed from the respective calibrated curve.

For method **II**, 5 mL of filtrate was diluted to 10 mL with distilled water. This was treated as per the respective procedure for the calibration curve and absorbance was measured at 412 nm; the amount of drug present in the sample was computed from the respective calibrated curve.

Both the developed methods were repeated five times for two different strengths of tablet formulation. Results of analysis are reported in Table-1.

TABLE-1
ANALYSIS OF TABLET FORMULATION

Method	Formulation	Label claim (mg/tab)	Label claim estimated* (%)	Recovery† (%)	Standard deviation
I	Tablet 1	10	98.53	99.82	0.486
	Tablet 2	20	100.2	99.86	0.115
II	Tablet 1	10	98.79	99.96	0.628
	Tablet 2	20	100.52	99.75	0.755

* Average of five determinations.

† Average of determination at three different concentration levels.

Recovery studies were carried out for both the developed methods by addition of known quality of pure drug solution to preanalyzed tablet sample solution at three different concentration levels. The result of recovery studies is reported in Table-1.

The proposed spectrophotometric methods for determination of rabeprazole sodium from tablet formulations are based on formation of chloroform extractable coloured complex of drug with bromo phenol red and formation of coloured complex with crystal violet. The pH required for method I was optimized at pH 4 and method II showed best results with crystal violet solution in distilled water. The results of analysis for both the developed methods were close to 100% and standard deviation was satisfactorily low indicating accuracy and reproducibility of the methods. Recovery studies were satisfactory which shows that there is no interference of excipients. The developed methods were found to be simple, rapid, accurate and can be used for routine analysis of drug tablet formulations.

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