

SIMULTANEOUS ESTIMATION OF DICLOFENAC SODIUM and RABEPRAZOLE IN COMBINED DOSAGE FORM

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ABSTRACT

An accurate and economical method for the simultaneous estimation of Diclofenac sodium and Rabeprazole in tablet formulation has been developed. The method involves the solving of simultaneous equations. Diclofenac sodium has absorbance maxima at 279.8 nm and Rabeprazole has absorbance maxima at 293.8 nm in solvent mixture (methanol:0.1N NaOH, 50:50v/v). Both these drugs obey Beer's law in concentration ranges employed for the present method. The result of analysis has been validated statistically by recovery studies.

Keywords: Diclofenac sodium, Rabeprazole, Simultaneous estimation.

INTRODUCTION

Diclofenac sodium, chemically is Sodium 2-[(2,6 dichloroanilino)phenyl]acetate. It is used for the treatment of rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis, and also for a variety of nonrheumatic inflammatory conditions¹⁻³. Rabeprazole sodium, 2-[[[4-(3-methoxypropoxy)-3-methyl-2-pyridinyl]-methyl]sulfinyl]-1H-benzimidazole sodium, Rabeprazole is a Proton Pump Inhibitor that suppresses gastric acid secretion by inhibiting the gastric H⁺/K⁺ ATPase at the secretory surface of the gastric parietal cell^{22, 23}. Few reports were found for the analysis in formulation in individual form particularly for Diclofenac sodium and Rabeprazole sodium⁴⁻¹⁷, but no methods were reported for their estimation simultaneously by spectrophotometric methods. So this work presents a simple, accurate, reproducible and economical method for the simultaneous estimation of these two compounds in tablet formulations. Shimadzu double beam spectrophotometer (model: UV PharmaSpec 1800) with matched quartz cells corresponding to 10 mm path length was used in present studies.

Preparation of standard stock solution

Standard stock solutions of Diclofenac sodium and Rabeprazole sodium were prepared by dissolving 100 mg each in solvent mixture (methanol:0.1N NaOH, 50:50v/v) in volumetric flasks and the volume was made up to 100 mL using solvent mixture to get a final concentration of 1 mg/mL. Two solutions were scanned at the range of 220 to 400 nm and the λ_{max} of Diclofenac sodium and Rabeprazole suitable for simultaneous estimation found to be at 279.8 and 293.8 nm, respectively. Dilutions were made to get concentrations 5-70 $\mu\text{g/mL}$ for Diclofenac sodium and 2-80 $\mu\text{g/mL}$ for Rabeprazole sodium, respectively. Calibration curves were plotted for each drug using absorbance vs. concentration. The correlation coefficients were 0.9991 ($n = 9$) and 0.99945 ($n = 8$) for Diclofenac sodium and Rabeprazole, respectively. The slope and intercept for Diclofenac sodium were 0.0294 and 0.0041 and for Rabeprazole sodium were 0.0186 and 0.0213, respectively as determined by the method of least squares.

Preparation of tablet sample solution

20 Tablets containing combination of Diclofenac sodium and Rabeprazole were weighed and average weight was calculated and ground to fine powder. A quantity of powder sample equivalent to 100 mg of Diclofenac sodium and 20 mg of Rabeprazole was taken in a volumetric flask and dissolved in solvent mixture. The solution was filtered through a Whatmann filter paper No. 10 and the volume was made up to 100 mL using solvent mixture. The absorbance of diluted solution at different wavelengths *i.e.* 279.8 nm (λ_1) and 293.8 nm (λ_2) were taken and A1 and A2 were determined. The two drugs were determined by solving the simultaneous equations.

Calculations

A set of equations were used as given below:

$$A_1 = ax_1 \times C_x + ay_1 \times C_y \quad (1)$$

$$A_2 = ax_2 \times C_x + ay_2 \times C_y \quad (2)$$

where C_x and C_y are concentrations of Diclofenac sodium and Rabeprazole respectively,

ax_1 and ax_2 are the molar absorptivities of Diclofenac sodium at λ_1 and λ_2 ; ay_1 and ay_2 are the molar absorptivities of Rabeprazole at λ_1 and λ_2 . A_1 and A_2 are the absorbance of diluted formulation at λ_1 and λ_2 .

The molar absorption co-efficients were found to be 7.01×10^3 and $9.47 \times 10^3 \text{ mol}^{-1} \text{ cm}^{-1}$ for Diclofenac sodium at λ_1 and λ_2 and 1.21×10^4 and $7.78 \times 10^3 \text{ mol}^{-1} \text{ cm}^{-1}$ for Rabeprazole sodium at λ_1 and λ_2 , which are the means of independent determinations ($n = 5$). The precision of the method was calculated by conducting recovery studies. Recovery studies were carried out and the results were found satisfactory. The per cent recovery \pm SD ranges from 99.782 ± 0.216 for Diclofenac sodium and 99.383 ± 0.752 for Rabeprazole which are satisfactory with the label claim. The recovery studies indicate the non-interference of the tablet excipients used. The present method can be successfully employed for the determination of Diclofenac sodium and Rabeprazole simultaneously in tablet formulations.

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