SIMULTANEOUS ESTIMATION OF DICLOFENAC SODIUM and RABEPRAZOLE IN COMBINED DOSAGE FORM

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INTRODUCTION
Diclofenac sodium, chemically is Sodium2-[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-pyrindinyl]-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 cell22, 23. Few reports were found for the analysis in formulation in individual form particularly for Diclofenac sodium and Rabeprazole sodium3-17, 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 λmax 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 μg/mL for Diclofenac sodium and 2-80 μg/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 Whatman 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 (λ1) and 293.8 nm (λ2) were taken and A1 and A2 were determined. The two drugs were determined by solving the simultaneous equations.

Calculations

A set of equations8 were used as given below:

\[ A1 = ax1 \times Cx + ay1 \times Cy (1) \]
\[ A2 = ax2 \times Cx + ay2 \times Cy (2) \]

where Cx and Cy are concentrations of Diclofenac sodium and Rabeprazole respectively, ax1 and ax2 are the molar absorptivities of Diclofenac sodium at λ1 and λ2; ay1 and ay2 are the molar absorptivities of Rabeprazole at λ1 and λ2. A1 and A2 are the absorbance of diluted formulation at λ1 and λ2.

The molar absorption co-efficients were found to be 7.01x10^5 and 9.47x10^5 mol^{-1} cm^{-1} for Diclofenac sodium at λ1 and λ2 and 1.21x10^4 and 7.78x10^3 mol^{-1} cm^{-1} for Rabeprazole sodium at λ1 and λ2, 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 ± 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.

REFERENCES


