RESEARCH ARTICLE

Simultaneous spectrophotometric estimation of rabeprazole sodium and itopride hydrochloride in capsule formulations

R V Heralgi, C C Simpi, N V Kalyane, S R Karajgi

Department of pharmaceutics, B.L.D.E.A's College of Pharmacy, Bijapur, India

A simple, precise, and economical procedure for the simultaneous estimation of rabeprazole sodium and itopride hydrochloride in tablet formulation has been developed. Rabeprazole sodium belongs to the class of proton pump inhibitor and Itopride hydrochloride belongs to the class of anticholinesterase activity as well as dopamine D2 receptor antagonistic activity, is being used for the symptomatic treatment of various gastrointestinal motility disorders. The present method involves the solving of simultaneous equations (Vierodt's method). Rabeprazole sodium has absorbance maxima at 283 nm in phosphate buffer (pH 7.4) and itopride hydrochloride absorbance maxima at 258 nm in phosphate buffer (pH 7.4). Both these drugs obey Beer's law in the concentration range employed for the present method. The result of analysis has been validated statistically by recovery studies. The slope and intercept for rabeprazole sodium were 0.0407 and 0.02 and for itopride hydrochloride were 0.0214 and 0.168, respectively, as determined by the method of least squares. The results were found satisfactory and reproducible. The method was applied successfully for the estimation of rabeprazole sodium and itopride hydrochloride simultaneously in tablet dosage to form without the interference of common excipients.

Key words: *Itopride hydrochloride, rabeprazole sodium, simultaneous estimation, Vierodt's method*

INTRODUCTION

Rabeprazole sodium is chemically 2-[[[4-(3-methoxypropoxy)-3-methyl-2-pyridinyl]-methyl] sulfinyl]-1H–benzimidazole sodium salt belongs to the class of proton pump inhibitors that reduce the production of acid by blocking the enzyme (hydrogen-potassium adenosine triphosphatase) in parietal cells. Whereas chemically itopride hydrochloride is N-[P-[2-[dimethylamino]ethoxyl]benzyl] veratramide hydrochloride and has anticholinesterase activity as well as dopamine D2 receptor antagonistic activity and is being used for the symptomatic treatment of various gastrointestinal motility disorders.

Objectives of the present study

A very few reports were found for the analysis in capsule formulations in individual form for rabeprazole sodium and itopride hydrochloride,[1-6] a method was reported for their estimation simultaneously by spectrophotometric method.[7] Present work is a simple, accurate, reproducible, and economical method for the simultaneous estimation of these two compounds in capsule formulations as an alternate method.

Address for correspondence:
R V Heralgi, B.L.D.E.A's College of Pharmacy, Bijapur - 586 103, India.
E-mail: bldeascop@yahoo.com

MATERIALS AND METHODS

Materials

Shimadzu's double-beam spectrophotometer (UV Pharmaspec 1700; Shimadzu, Japan) with matched quartz cells corresponding to 1 cm path length. Phosphate buffer (pH 7.4) was prepared as per Indian Pharmacopoeia 1996.

Methods

Preparation of standard stock solution

Standard stock solutions of rabeprazole sodium and itopride hydrochloride were prepared by dissolving 100 mg each in phosphate buffer (pH 7.4) in volumetric flasks and the volume was made up to 100 ml using phosphate buffer (pH 7.4) to get a final concentration of 1 mg/ml, further dilutions were made to get concentrations of 10 mcg/ml each. The two solutions were scanned in the range of 220-320 nm and the λ_{max} of rabeprazole sodium and itopride hydrochloride suitable for simultaneous estimation found to be at 283 nm and 258 nm, respectively [Figure 1].

Dilutions were made to get concentrations 5-30 mcg/ml for rabeprazole sodium and 10-60 mcg/ml for itopride hydrochloride, respectively. Calibration curves were plotted for each drug using absorbance against concentration. The standard plots were constructed

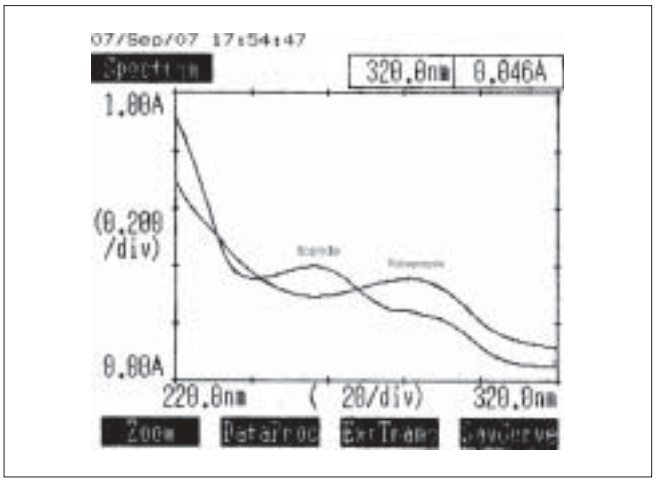

Figure 1: Overlay of UV spectra of solution of rabeprazole sodium and itopride hydrochloride scanned in the range of 220-320 nm

from different concentrations of each compound in the fixed concentration (10 mcg/ml) of the other. The correlation coefficient were found to be 0.9348 (n = 6) and 0.9460 (n = 6) for rabeprazole sodium and itopride hydrochloride, respectively. The slope and intercept for rabeprazole sodium were 0.0407 and 0.02 and for itopride hydrochloride were 0.0214 and 0.168, respectively, as determined by the method of least squares.

Preparation of capsule sample solution

Twenty capsules containing pellets of combination rabeprazole sodium and itopride hydrochloride were weighed and grounded to fine powder. A quantity of powder sample equivalent to 60 mg of rabeprazole sodium and 450 mg of itopride hydrochloride was taken in a volumetric flask and dissolved in phosphate buffer (pH 7.4). The solution was filtered and the volume was made up to 100 ml using phosphate buffer (pH 7.4). The further dilutions were made to get a final concentration of 4 mcg/ml of rabeprazole sodium and 45 mcg/ml of itopride hydrochloride using phosphate buffer (pH 7.4). The absorbance of diluted solution at different wavelengths, i.e., 283 nm (λ_1) and 258 nm (λ_2) were taken and A_1 and A_2 (absorbance) were determined. The two drugs were determined by solving the simultaneous equations.

Calculations

A set of equations[8] were used as given below:

$$A_1 = ax_1 \times Cx + ay_1 \times Cy \quad (1)$$

$$A_2 = ax_2 \times Cx + ay_2 \times Cy \quad (2)$$

where Cx and Cy are concentrations of rabeprazole sodium and itopride hydrochloride, respectively, ax_1 and ax_2 are the molar absorptivities of rabeprazole sodium at (λ_1) and (λ_2); ay_1 and ay_2 are the molar absorptivities of itopride hydrochloride 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 coefficient were found to be 148.76 and 114.42/mol/cm for rabeprazole sodium at (λ_1) and (λ_2) and 157.96 and 102.62/mol/cm for itopride hydrochloride at (λ_1) and (λ_2) which are the means of independent determinations (n = 5).

RESULTS AND DISCUSSIONS

The precision of the method was calculated by conducting recovery studies and the results were found to be satisfactory. The percent recovery SD ranges from 98.6 $\pm$ 0.15 to 99.09 $\pm$ 0.1 for rabeprazole sodium and from 98.0 $\pm$ 0.35 to 100.18 $\pm$ 0.01 for itopride hydrochloride, which is satisfactory with the label claim of the marketed brand used for the study. The recovery studies indicate the noninterference of the tablet excipients used. The present method can be successfully employed for the determination of rabeprazole sodium and itopride hydrochloride simultaneously in capsule formulations.

REFERENCES

1. Mageswari SD, Surendra K, Maheswari R, Krishnan NH, Roosewelt C, Gunasekaran V. HPTLC Method for simultaneous estimation of rabeprazole sodium and itopride hydrochloride in capsule and bulk drug. Asian J Chem 2007;19:5634-8.
2. Gupta P, Umamaheshwari RB, Rusia P, Dangi YS, Jain NK. Simultaneous estimation of amoxycillin trihydrate and rabeprazole sodium. Indian J Pharma Sci 2005;67:380-2.
3. Patel PM, Desai HJ, Patel RC, Patel NM. Spectrophotometric method for the estimation of rabeprazole. Indian J Pharma Sci 2007;69:318-20.
4. Smitha G, Hussainy SA, Swamy PV, Raju SA. Extractive spectrophotometric determination of itopride hydrochloride. Asian J Chem 2007;19: 3445-8.
5. Rao GD, Rao DR, Harika G, Ramya T, Kasulu T, Chaitanya K, *et al*. New spectrophotometric methods for the determination of itopride hydrochloride in Pharmaceutical formulations. M. Acta Ciencia Indica Chem 2006;32:321-4.
6. Hussainy SA, Smitha G, Swamy PV, Raju SA. Spectrophotometric determination of itopride hydrochloride. Int J Chem Sci 2006;4:713-6.
7. Sabnis SS, Dhavale ND, Jadhav VY, Gandhi SV. Spectrophotometric simultaneous determination of rabeprazole sodium and itopride hydrochloride in capsule dosage form. Spectrochim Acta A Mol Biomol Spectrosc 2008;69:849-52.
8. Willard, Merrit, Dean, Settle. Instrumental methods of Analysis. 6th ed. New Delhi: CBS Publication; 1997. p. 281.

Source of Support: Nil, **Conflict of Interest:** None declared.