Asian Journal of Chemistry Vol. 19, No. 7 (2007), 5634-5638

HPTLC Method for Simultaneous Estimation of Rabeprazole Sodium and Itopride Hydrochloride in Capsule and Bulk Drug

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A simple, rapid, sensitive, high performance thin layer chromatography has been developed and validated for simultaneous estimation of rabeprazole sodium and itopride hydrochloride in capsule. It was performed on TLC plate precoated with silica gel $60F_{254}$ prewashed with methanol as a stationary phase using mobile phase comprising of toluene:chloroform:methanol:ammonia (25 % solution) (25:30:10:1) and the detection was carried out in absorbance at 225 nm. The per cent estimation of labelled claims of rabeprazole sodium and itopride hydrochloride from, market capsule (rabiumplus) formulation was found to be 98.2 and 99.3 %. The method was validated in terms of accuracy, precision, linearity. Linearity was observed between 120-280 µg/mL for rabeprazole sodium and 900-1900 µg/mL for itopride hydrochloride. The recoveries of drugs by standard addition method were found to be in range 98.14 and 99.35 % for both drugs. The proposed method is precise and accurate and can be used for routine analysis of rabeprazole sodium and itopride hydrochloride in capsule formulation.

Key Words: Rabeprazole sodium, Itopride hydrochloride, HPTLC, Validation.

INTRODUCTION

Rabeprazole sodium is proton pump inhibitor and itopride hydrochloride is a gastric prokinetic agent. Rabeprazole sodium suppresses gastric acid secretion by inhibiting the gastric H^+ K^+ ATPase at the secretory surface of the parietal cells. Itopride hydrochloride increases the release of acetylcholine through dopamine D_2 receptor antagonistic action and inhibits the decomposition of release acetylcholine through its acetylcholine esterase inhibitor action, resulting in enhancement of gastro intestinal motility. These combination is mainly used in the treatment of gastrosephageal reflux disease.

Rabeprazole sodium[1] is chemically known as 2-{[4-(3-methoxy propoxy)-3-methyl-2-pyridinyl]-methyl}sulfinyl)-1H-benzimidazole sodium salt. Itopride hydrochloride is N-[4-(2-dimethyl amino)ethoxy]-benzyl]-3,4-dimethoxy benzamide hydrochloride. Literature survey reveals that the HPLC and HPTLC[2-7] methods for individual drugs, columns switching HPLC[8], capillary electrophoresis[9] and visible spectrophotometry[10] for rabeprazole sodium. But no works have been reported for the drug combination. The objective of the present work was to develop a sensitive and reproducible HPTLC method for the estimation of Rabe-Na and Ito-HCl in a fixed dose combination formulation.

EXPERIMENTAL

All chemicals and reagents used were AR/HPLC grade. Silica gel $60GF_{254}$ precoated aluminium plates width of 20 × 20 cm, Merck was used as a stationaryphase. The instrument used was CAMAG LINOMAT IV automatic sample applicator, CAMAG TLC scanner -3 and version 4.01 and CAMAG-UV cabinet. The source of radiation utilized was deuterium lamp emitting a continuous UV spectrum between 190 and 400 nm.

Mixed standard solution: Solution containing Rabe-Na (2 mg/mL) and Ito-HCl (15 mg/mL) was prepared in methanol.

Experimental chromatographic conditions: Optimized standard experimental condition were as follows:

Stationary phase:	Silica gel $60GF_{254}$ TLC precoated aluminium foiled plates with thickness 200 µm.
Mobile phase:	toluene:chloroform:methanol:ammonia (25 % solution) in the ratio of 25:30:10:1.
Volume spotted:	10 µL
Distance between bands:	19 mm scanning between bands.
Mode:	absorbance/reflectance.
Detection wavelength:	225 nm.

The detection wavelength was selected from overlain spectra of the drugs.

Calibration curve response: Ito-HCl solution ranging from 900-1900 µg/mL(1500 µg/mL) and 120-280 µg/mL (200 µg/mL) of rabe-Na, respectively were applied on TLC plates by microlitre syringe with the help of automatic sample applicator. The plates were developed, dried and densitometrically scanned at 225 nm. Curves are plotted using conc. *vs.* peak area.

Assay: 20 Capsules (rabium plus labelled to contain [Rabe-Na (20 mg) and Ito-HCl (150 mg)] were weighed, emptied and mixed. An accurately weighed quantity of capsule powder equivalent to about 150 mg of Ito-HCl and rabe-Na 20 mg was shaken with 80 mL of methanol for

15 min and mixed with aid of ultrasound for 1min added sufficient methanol to produce 100 mL, mixed, filtered through Whatmann filter paper 42, which was used as a sample solution.

The content of the drugs in average weight capsules were calculated as follows:

$$\text{Amount of drug in each capsule} = \frac{\text{Peak area of test} \times \text{conc. of std.} \times \text{av. wt.} \times \text{LOD \%}}{\text{Peak area of std.} \times \text{conc. of test}}$$

$$\text{Labeled claim (\%)} = \frac{\text{Weight of the drug estimated}}{\text{Weight of the drug applied on the basis of labeled claim}} \times 100$$

Validation of the proposed method

The proposed method was validated for the following parameters:

Accuracy: The accuracy of the proposed method was ascertained by carrying out recovery studies by standard addition method. Accurately known amount of standard drug were added to known amount of preanalyzed capsule powder and was analyzed by proposed method to ascertain if there are positive or negative interferences from excipients present in formulation. The present recovery was calculated by using:

$$\text{Recovery (\%)} = \frac{\text{Total drug estimated in mg} - \text{Amount of drug contributed by capsule}}{\text{Amount of pure drug added}}$$

Precision: Replicate estimation of drugs in sample were carried out by proposed method and SD/RSD was calculated as measure of precision.

RESULTS AND DISCUSSION

The mobile phase toluene:chloroform:methanol:ammonia (25 % solution) (25:30:10:1) yields good resolution of drugs under investigation on silica gel $60GF_{254}$ TLC plates. The other parameter as detailed under chromatographic condition were optimized on the basis of exhaustive experimentation (Table-1). Plots of conc. *vs.* peak area have been linear over concentration range 900-1900 µg/mL for Ito-HCl and 120-280 µg/mL for Rabe-Na, respectively (Table-2).

The estimation of standard laboratory mixture with recovery about near 100 % is indicative of mutual non interference of drugs in their estimation (Table-3). The results of replicate estimation of drugs in capsule were quite concurrent indicating the precision (Table-4).

TABLE-1
QUANTITATIVE ESTIMATION

Sample	Label claim (mg)	Label claim (%)	Deviation (%)
Rabeprazole	20	98.20	-1.80
Itopride HCl	150	99.33	-0.67

TABLE-2
LINEARITY

Parameter	Itopride HCl	Raberazole sodium
Linearity range	900-1900 µg/mL	120-280 µg/mL
Regression (r)	0.9998	0.9982
Slope (m)	13.88	46.42
Intercept (c)	-76.51	85.16

TABLE-3
STATISTICAL DATA

Sample	Label claim (%)	SD*	RSD (%)	SE
RABE-Na	98.20	0.0640	0.3304	0.0367
ITO-HCl	99.33	1.6484	1.1060	0.9517

*Mean of five values.

TABLE-4
PRECISION

Parameter	Itopride HCl	Raberazole sodium
Concentration (µg/mL)	120-280	900-1900
Peak area*	9335.6	20377.7
Standard deviation	33.775	149.0016
Relative standard deviation (%)	0.361	0.7311

*Mean of five values.

The recovery of the drugs from the sample matric evaluated (Table-5) on the basis of standard addition method has been almost 100 % indicating the accuracy of the method and non interference of sample matrix.

TABLE-5
RECOVERY STUDIES

Sample	Amount of std. added (mg)	Amount of drug recovered (mg)	Recovery (%)
Rabe-Na	2	1.56	98.14
Ito-HCl	15	13.84	99.35

ACKNOWLEDGEMENT

The authors are thankful to Themis Laboratories for providing gift sample of rabeprazaole sodium and itopride hydrochloride.

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(*Received*: 28 December 2006; *Accepted*: 19 June 2007) AJC-5748