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Research Article

# Simultaneous estimation of Rabeprazole and Domperidone in dosage forms by RP-HPLC

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**ABSTRACT**

A rapid and accurate high performance reverse phase liquid chromatography has been developed for the simultaneous estimation of Rabeprazole and Domperidone in pharmaceutical dosage forms. Chromatography was carried out on a C-18 column (4.6 mm × 150 mm, 5 µm) using a mixture of phosphate buffer (pH 7.4) and acetonitrile in the ratio of 60:40 (v/v) as the mobile phase at a flow rate of 1.5 mL/min and eluents are monitored at 287 nm. The calibration curves were linear over the range of 0.1 – 1.0 mg/mL of Rabeprazole. The average retention time of Rabeprazole and Domperidone was found to be 3.33 and 5.74 min respectively. The % recovery value for Rabeprazole is 100.2% and for Domperidone is 102% confirms the non-interferences of the excipients in the formulation. Due to its simplicity, rapidness and high precision, the proposed HPLC method may be used for the simultaneous estimation of these two drugs in pharmaceutical dosage forms.

**Keywords:** RP-HPLC; Rabeprazole; Domperidone

## INTRODUCTION

Rabeprazole sodium is chemically known as 2-[[[4-(3-methoxypropoxy)-3-methyl-2-pyridinyl]-methyl] sulfinyl]-1*H*-benzimidazole sodium salt. It is a proton pump inhibitor and used for the treatment of peptic ulcer or GERD, Dyspepsia. It is not official in any pharmacopoeia. Domperidone is chemically known as 5-chloro-1-[1-[3-(2, 3-dihydro-2-oxo-1*H*-benzimidazol-1-yl) propyl] piperidin-4-yl]-2, 3-dihydro-1*H*-benzimidazol-2-one. It is a gastro-kinetic and anti-emetic. It is a peripheral dopamine-2 receptor antagonist. It is official in B.P. The present work describes the development of a validated RP-HPLC method, which can quantify these components simultaneously from a combined dosage form. A few chromatographic methods have been described for the individual determination of Rabeprazole and Domperidone in both dosage forms and biological fluids (M. Kobylinska *et al.,* 2000, Journal of Clinical investigation, 2005, Argekar *et al.,* 1999, Rindi *et al.,* 2005, M. Mondal *et al.,* 2004). The aim of the present work was to develop and validate a precise method for the simultaneous determination of these two drugs in dosage forms. The present RP-HPLC method was validated following the ICH guidelines (ICH, Q3B 1996, ICH, Q2A 1994).

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## EXPERIMENTAL

### Instrumentation

Hitachi Elite Lachome HPLC model, Containing Pump: L2130, Detector: UV, L2400, Software: D2000 Elite was used for the study. Elico SL 210 Double beam UV/Vis Spectrophotometer, Using a digital pH meter checked the pH of the solution.

### Chemicals and reagents

Materials used were either AR/LR grade or the best possible Pharma grade Available as supplied by the manufacturer or supplier without further purification or investigation were obtained (Rabeprazole sodium and Domperidone) from Comprime Labs Pvt. Ltd., Hyderabad. Marketed formulation Trapcid D Rabeprazole sodium 20 mg and Domperidone 30 mg Medreich healthcare. Bangalore. Water –HPLC grade, Acetonitrile --- HPLC grade, Potassium Dihydrogen Phosphate, DiPotassium Hydrogen Phosphate chemicals and solvents were supplied by S.D. Fine Chemicals Ltd., India; Qualigens Fine Chemicals Ltd., Mumbai, India and Ranbaxy Chemicals Ltd., New Delhi, India.

### Preparation of stock solutions

Stock solutions containing 1 mg/mL of Rabeprazole and 1 mg/mL of Domperidone were prepared by dissolving each 100 mg in a separate 100 mL volumetric flasks containing 100 mL mobile phase. The working concentrations for the determination of both drugs were 1 mg/mL.

**Chromatographic conditions**

The mobile phase used in this study was a mixture of phosphate buffer pH 7.2 and acetonitrile in the ratio 60:40 % v/v. The mobile phase was filtered before use through a 0.45µ membrane filter under vacuum and degassed for 10 min. using ultrasonic water bath. The mobile phase was pumped from solvent reservoir to the column at a flow rate of 1 mL/min. The column temperature was maintained at ± 280C. The events were monitored at 287nm.

**Recommend procedure for standard graph**

After a systematic and detailed study of various parameters involved, the following procedure and conditions are recommended for the determination of Rabeprazole and Domperidone in pure samples and in dosage forms. Prior to injection of the drug solutions, the column was equilibrated at least for 30 min with the mobile phase flowing through the system. The prepared dilutions containing the concentration of Rabeprazole in the range of 0.1 – 1.0 mg/mL maintaining the Domperidone concentration at a fixed level (15 µg/mL) and 0.1 – 1.0 mg/mL maintaining the Rabeprazole concentration at a constant level (10 µg/mL). Each of these samples (20 µL) was injected five times into the column and the peak area ratio of drug to that of internal standard was calculated. Standard graph was plotted by taking concentration of drug on x-axis and peak area ratio of drug to that of internal standard on y-axis.

**Assay determination of Rabeprazole and Domperidone from formulations**

Capsules of Rabeprazole and Domperidone: Twenty weighed capsules of Trapcid D contents were ground to a fine powder. From each formulation an amount of powder equivalent to 10 mg was accurately weighed and dissolved with mobile phase in a 25 mL volumetric flask.

**Simultaneous quantification of Rabeprazole and Domperidone**

Suitable dilutions of both of the capsules were made with mobile phase so as to obtain a concentration of the two drugs in the range of linearity determined. 20 µL volume of sample was injected into the column.

**METHOD VALIDATION**

**Linearity**

The calibration was linear for Rabeprazole at concentration range of 0.5 – 5.0 µg mL-1, with regression 0.998, intercept – 0.0082 and slope 0.0642 and the calibration was linear for Domperidone at concentration range of 0.75 – 7.5 µg mL-1, with regression 0.999, intercept +0.005 and slope 0.0649 respectively. % R.S.D of Rabeprazole and Domperidone are 0.2449 and 1.0082 respectively. The low values of % R.S.D. indicate the method is precise and accurate. The mean recoveries were found in the range of 100 – 102 %.

**Precision:** The reproducibility of the proposed methods were determined by performing capsule assay at different time intervals on same day (Intra-day assay precision) and on three different days (Inter-day assay precision).

**Accuracy**

The accuracy of HPLC method was assessed by adding known amount of drug to a drug solution of pre-analyzed sample subjecting the samples to the proposed HPLC method. All solutions were prepared and analyzed in triplicate.

**Limit of detection (L.O.D.) and limit of quantification (L.O.Q.)**

Limit of detection was found to be 0.012 and 0.015 mg/mL for Rabeprazole and Domperidone and limit of quantification was found to be 0.036 and 0.045 mg/mL.

**RESULTS AND DISCUSSION**

To estimate the percentage recovery of Rabeprazole and Domperidone in capsules, typical chromatograms of Rabeprazole and Domperidone were also recorded individually under identical chromatographic conditions. The order of the elution was Rabeprazole followed by Domperidone at 3.33 and 5.74 min, respectively. The calibration curve plotted for Rabeprazole and Domperidone were later used to determine concentrations of the drug in capsules. Subjecting with pre-analyzed sample to the proposed HPLC method assessed the accuracy of HPLC method. All the solutions were prepared and analyzed in triplicate. There was a high recovery 100.2 of Rabeprazole and 102 of Domperidone (Table.1) indicating the proposed method is highly accurate. The HPLC method, developed in the present study is used for simultaneous quantification of Rabeprazole and Domperidone in capsule dosage forms. High percentage recoveries of Rabeprazole ranging from 99.8 to 100.2 and 101.92 to 102 of Domperidone (Table.1) were observed with the capsule dosage forms. No interfering peaks were found in the chromatogram indicating the excipients used in capsule formulations did not interfere with the estimation of drug by the proposed HPLC method.

The proposed method is simple, precise, accurate and rapid for the simultaneous quantification of Rabeprazole and Domperidone in capsule dosage forms. Hence, it can be easily and conveniently adopted for routine quality control analysis.

**CONCLUSION**

A sensitive and selective stability indicating RP-HPLC method has been developed and validated for the analysis of Rabeprazole and Domperidone as per ICH guidelines. The results of the recovery studies per-

**Table 1: Results of Analysis of formulation and Recovery Studies**

| Drug | Amount mg/tab | | % Recovery* |
|---|---|---|---|
| | Labelled | Found * | |
| RABEPRAZOLE | 20 | 20.1 | 100.2 |
| DOMPERIDONE | 30 | 30.6 | 102 |

*Average of six determinations; Each tablet containing 20 mg of Rabeprazole and 30 mg of Domperidone

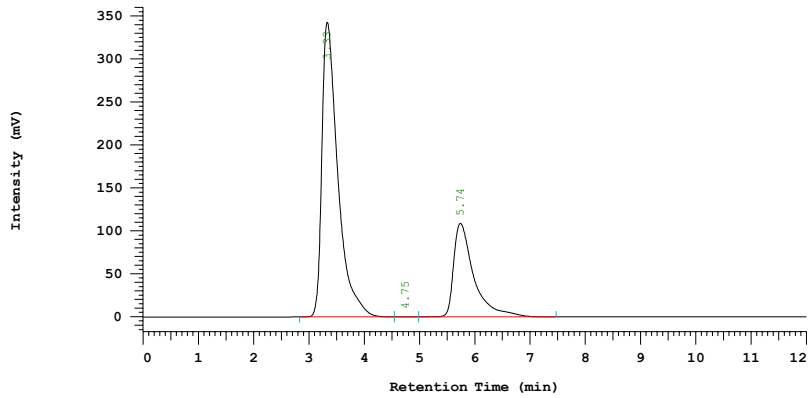


**Figure 1: Typical chromatogram of optimized method**

formed show the high degree of accuracy of the pro--- posed methods Hence, it can be concluded that the developed RP --- HPLC method is accurate, precise and selective and can be employed successfully for the es--- timation of Rabeprazole and Domperidone in marketed formulation.

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