Research Article

Development and Validation of Spectrophotometric Method for Simultaneous Estimation of Rabeprazole and Domperidone in Pure and Tablet Dosage Form

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ABSTRACT

The method for the simultaneous estimation of Rabeprazole and Domperidone in combined tablet dosage form have been developed, based on absorbance ratio method at two selected wavelengths 280.0 nm (Iso-absorptive point) and 291.0nm (λmax of Rabeprazole). The linearity was obtained in the concentration range of 5-25 µg/ml and 5-25 µg/ml for Rabeprazole and Domperidone, respectively. These methods are simple, accurate and results of analysis have been validated statistically and by recovery studies.

Keywords: Rabeprazole, Domperidone, Absorbance ratio method.

INTRODUCTION

Rabeprazole is an antiulcer drug in the class of proton pump inhibitors, used in Short-term treatment in healing and symptomatic relief of duodenal ulcers and erosive or ulcerative gastroesophageal reflux disease (GERD); maintaining healing and reducing relapse rates of heartburn symptoms in patients with GERD; treatment of daytime and nighttime heartburn and other symptoms associated with GERD; long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome and in combination with amoxicillin and clarithromycin to eradicate Helicobacter pylori.

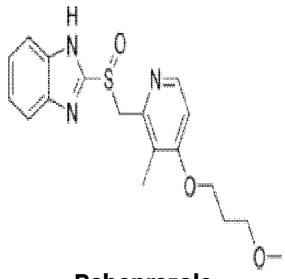
Domperidone is a peripheral dopamine (D2) and (D3) receptor antagonist. It provides relief from nausea by blocking receptors at the chemo-receptor trigger zone (a location in the nervous system that registers nausea) at the floor of the fourth ventricle (a location near the brain).

Few spectroscopic methods have been reported for determination of Rabeprazole as single drug or in combination with other drugs.

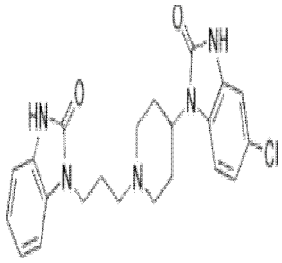
Literature survey reveals, HPLC and HPTLC methods have also been reported for estimation of Rabeprazole in Pharmaceutical dosage forms and also there are various methods such as UV spectrophotometry for Rabeprazole.

Extensive literature survey reveals, none of the method is available that is based on estimation of Rabeprazole and Domperidone simultaneously by absorption ratio UV-spectrophotometric method.

Aim of present work was to develop simple, precise, accurate and economical spectrophotometric methods for simultaneous determination of binary drug formulation. The proposed method was optimized and validated in accordance with International Conference on Harmonization (ICH) guidelines.[1,2,3]



Rabeprazole



Domperidon

MATERIALS AND METHODS

Instrumentation[2,3,4]

A double-beam Jasco UV- 2075; UV Visible spectrophotometer, spectral bandwidth of 2nm, wavelength accuracy ± 0.5 nm and a pair of 1-cm matched quartz cells was used to measure absorbance of the resulting solution.

Samples

Standard samples of Rabeprazole and Domperidone were taken. Combined dose Rabeprazole and Domperidone tablets (RAB-D-20 mg Rabeprazole & 10 mg Domperidone manufactured by Stedman pharmaceuticals Pvt. Ltd.) taken.

Solvent

Methanol selected as solvent for developing spectral characteristics of drug. The selection was made after assessing the solubility of both the drugs in different solvents.

Preparation of Standard Stock Solutions[5,6,7]

Rabeprazole (RAB) and Domperidone (DOM) (10mg each) were accurately weighed and dissolved separately in100ml of methanol to give stock (100 µg/ml).

From the standard stock solution, 1ml each of RAB and DOM was taken in 10ml volumetric flask. Volume was made up to mark with methanol. Aliquot portion was appropriately diluted with distilled water to get final concentration of 5-25 µg/ml (IBU) and 5-25 µg/ml (TRAM) prepared respectively to give final concentrations and scanned between 200-400 nm.

Application of the Proposed Method for the Determination of RAB and DOM in Tablet Dosage Form

Absorbance Ratio Method[6,7,8,9]

In the absorbance ratio method, from the overlain spectra of both drugs (Fig-1), wavelengths 280.0 nm (Iso-absorptive point) and 291.0 nm (λmax of Rabeprazole) were selected for analysis. The calibration curves for Rabeprazole and Domperidone were plotted in the concentration range of 5-25 µg/ml and 5-25 µg/ml at both the wavelengths respectively. The absorptivities values were determined for both the drugs at both the wavelengths. From the following set of equations the concentration of each component in sample was calculated,

$$C_x = \frac{Q_m - Q_y}{Q_x - Q_y} \times \frac{A_1}{ax_1} \quad (1) \text{ and}$$

$$C_y = \frac{Q_m - Q_x}{Q_y - Q_x} \times \frac{A_1}{ay_1} \quad (2)$$

Where

C_x=concentration of Rabeprazole,

C_y=concentration of Domperidone,

A_1=absorbance of sample at wavelength 291.0nm

A_2=absorbance of sample at wavelength 280.0nm

ax_1=absorbtivity of Rabeprazole at 264nm,

ay_1=absorbtivity of Domperidone at 284nm,

Q_m=ratio of absorbance of sample solution at 291nm and 280nm resp.,

Q_x=ratio of absorbtivities of Rabeprazole at 291nm and 280nm and

Q_y=ratio of absorbtivities of Domperidone at 291nm and 284nm.

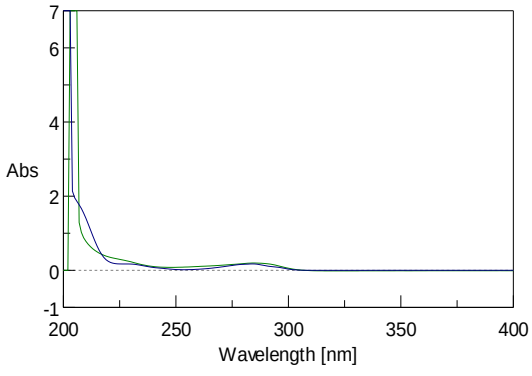


Figure 1: Overlain or Absorbance spectra for Rabeprazole & Domperidone.

Validation Parameter[8,10]

Linearity

The linearity was obtained in the concentration range of 5-25 µg/ml and 5-25 µg/ml for Rabeprazole & Domperidone respectively in both methods which obeys Beer-Lambert's law. The results of the same are shown in Fig 2 and Fig 3.

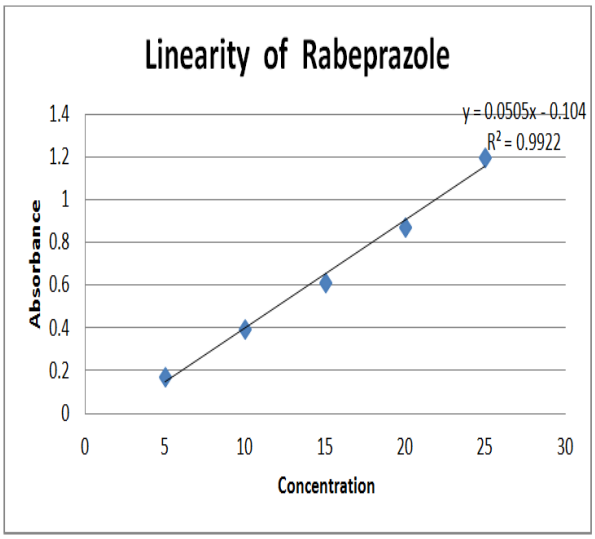


Figure 2: Linearity of Rabeprazole.

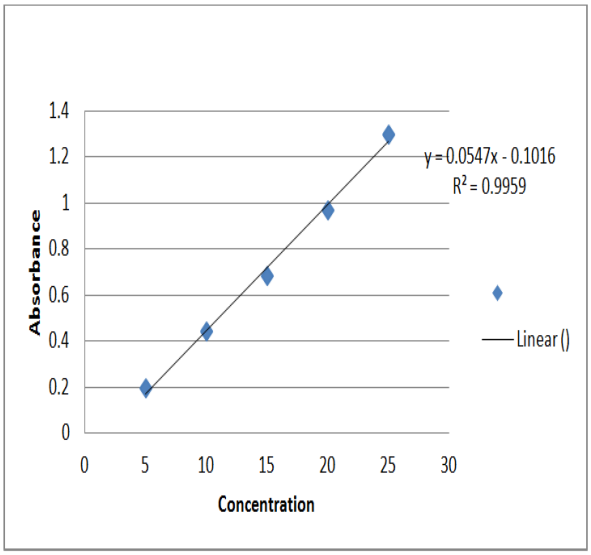


Figure 3: Linearity of Domperidone.

Accuracy

To ascertain the accuracy of the proposed methods, recovery studies were carried out by standard addition method at Table 1.

Limit of Detection (LOD) and Limit of Quantitation (LOQ)

The LOD and LOQ by proposed methods were determined using calibration standards. LOD and LOQ were calculated as 3.3s/S and 10s/S, respectively, where S is the slope of the calibration curve and s is the standard deviation of response. The results of the same are shown in Table 1.

Results of Analysis of Tablet Formulation

Table 1: Absorbance Ratio Method

Drug	Label Claim (µg/ml)	Amount Taken (mg/tab)	Amount Found (mg)	% Recovery	S.D	S.E	C.V	LOD (µg/ml)	LOQ (µg/ml)
RAB	20	10	9.91	99.1	0.251	0.1454	0.25	0.8311	0.251
			9.88	98.8					
			9.93	99.3					
DOM	10	5	4.95	99	0.2	0.1156	0.23	0.6606	0.2
			4.94	98.8					
			4.96	99.2					

S.D: Standard Deviation**, S.E:** Standard Error**, C.V:** Coefficient Variation

RESULTS AND DISCUSSION

From the proposed research, it was found that Rabeprazole and Domperidone obeys linearity within the concentration range 5-25 ppm & 5-25 ppm respectively.

Percentage lable claim for Rabeprazole and Domperidone in tablet, by absorption ratio methods was found in the range of 98.8% to 99.3% and 98.8% to 99.2% respectively. For coefficient of variation (CV) were calculated, which was found to be less than 2% indicating the both method has good reproducibility.

Accuracy of proposed methods was ascertained by recovery studies & results are expressed as % recovery. Percent recovery for Rabeprazole & Domperidone by absorption ratio method was found in range of 98.8 to 99.3 and 98.8 to 99.2 respectively, values of standard deviation, standard error and coefficient of variation for range of 0.2 to 0.2516, 0.1156 to 0.1454, 0.23 to 0.254 respectively indicating the accuracy of proposed method.

CONCLUSION

Based on the results obtained, it is found that the proposed methods are accurate, precise, reproducible and economical and can be employed for routine quality control of Rabeprazole and Domperidone in combined dose tablet formulation.

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