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Spectrophotometric simultaneous determination of domperidone and pantoprazol in pharmaceutical preparations

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ABSTRACT

Two simple, rapid, precise and accurate spectrophotometric methods have been developed for determination of Domperidone and Pantaprazole by simultaneous equation method and Absorbance ratio method in combined dosage form. The simultaneous equation method is based on measurement of absorbance at 284 nm and 292 nm as two wavelengths selected for quantification of Domperidone and Pantaprazole. The second method is Absorbance ratio method based on the measurement of absorbance at isoabsorptive point at 216nm and 284nm as second wavelength selected as for quantification. Both methods obeyed Beer's law in the concentration range of 5-30 µg/ml for Domperidone and 10-60 µg/ml for Pantaprazole.The proposed methods were validated and can be used for analysis of combined dosage tablet formulation containing Domperidone and Pantaprazole.

Key Words: Domperidone , Pantaprazole, Simultaneous equation method, Q-analysis method.

INTRODUCTION

Domperidone is a D2 – receptor antagonist used as an antiemetic. It is official in EP1. Chemically it is 5-chloro-1-[1-[3-(2, -3-dihydro-2-oxo-1H-benzimidazol-1-yl)-propyl]-4-piperidinyl]-1,3-dihydro-2H-benzimidazol-2-one. Several methods 2-5 have been reported for the assay of domperidone.

Pantoprazole; 5-(difluoro methoxy)-2-[[(3, 4 dimethoxy-2-pyridinyl) methyl] sulfinyl]-1H-benzimidazole, is used as antiulcer drug. Literature survey reveals that there are UV[7-9] and HPLC[10-11] methods reported for the estimation of pantoprazole in pharmaceutical formulations. The review of the literature revealed that no method is yet reported for the simultaneous estimation of both the drugs in combined dosage forms. This paper describes two simple, rapid, accurate, reproducible and economical methods for the simultaneous estimation of domperidone and pantoprazole in tablet formulations using simultaneous equation and absorbance ratio methods.

MATERIALS AND METHODS

Materials

Spectral runs were made on a Jasco-V630 UV-Visible spectrophotometer (Japan) with spectral bandwidth of 0.5 nm and wavelength accuracy of ± 0.3 nm with automatic wavelength corrections with a pair of 10 mm quartz cells.

Selection of common solvent

0.1N HCl was selected as a common solvent for developing spectral characteristics of both drugs. The selection was made after assessing the solubility of both the drugs in different solvents.

Preparation of standard stock solution

Standard stock solutions (100 µg /ml) of Domperidone and Pantaprazole were prepared by dissolving separately 10 mg of each drug in 0.1N HCl and volume was made up to 100 ml with distilled water. The working standard solutions of these drugs were obtained by dilution of the respective stock solution with distilled water.

Analysis of pharmaceutical dosage form

Twenty tablets were weighed accurately. The average weight was determined and then ground to a fine powder. A quantity equivalent to 10 mg of domperidone and 40 mg of pantoprazole were transferred to a 100 mL volumetric flask. The contents were ultrasonicated for 10 min with 0.1N HCl, made to volume and filtered through Whatmann filter paper No.41. The solution was further diluted with Distilled water to give concentrations of 10 mcg/mL and 40 mcg/mL of domperidone and pantoprazole respectively. Absorbances of these solutions were measured at 284 nm and 292 nm as A1 and A2 respectively and concentrations of these two drugs in the sample were calculated using equation (1) and equations (2).

Simultaneous equation method

For the simultaneous equation method, 284 nm and 292 nm were selected as the two sampling wavelengths for Domperidone and Pantaprazole respectively. The Fig.1 represents the overlain UV spectra of Domperidone and Pantaprazole. The Domperidone and Pantaprazole exhibited linearity in the concentration range of 5-30 µg/ml and 10-60 µg/ml at their respective selected wavelengths respectively. Coefficients of correlation were found to be 0.999 and 0.996 for Domperidone and Pantaprazole respectively. The optical characteristics and regression values for the calibration curves are presented in Table 1. For simultaneous estimation of Domperidone and Pantaprazole , mixed standards containing Domperidone and Pantaprazole in a concentration ratio of 1:4 µg/ml each were prepared by appropriate dilution of the standard stock solutions with distilled water. The absorbances of the mixed standard solutions were measured at the selected wavelengths.

The two equations were constructed based upon the fact that at λ_1 and λ_2 the absorbance of the mixture is the sum of individual absorbances of Domperidone and Pantaprazole.

At λ_1, $A_1 = ax_1bc_x + ay_1bc_y$…… (1)
At λ_2, $A_2 = ax_2bc_x + ay_2bc_y$…… (2)

Where, A_1 and A_2 are absorbances of mixed standard at 284 nm and 292 nm respectively.
λ_1 and λ_2 are wavelengths of Domperidone and Pantaprazole respectively,
ax_1 and ax_2 are absorptivity of Domperidone at λ_1 and λ_2 ,
ay_1 and ay_2 are absorptivity of Pantaprazole at λ_1 and λ_2 respectively.
c_x and c_y are concentration of Domperidone and Pantaprazole respectively.

Q-Absorbance ratio method (Method II):

Q-Absorbance method uses the ratio of absorbances at two selected wavelengths, one at isoabsorptive point and other being the maximum wavelength of one of the two compounds. From the overlain spectrum of domperidone and pantoprazole, two wavelengths were selected, one at 216 nm, isoabsorptive point for both the drugs and the other at 284 nm, maximum wavelength of domperidone.

The concentration of two drugs in mixture was calculated by using following equations:
For Domperidone:

$$C_1 = \frac{Qm - Qy}{Qx - Qy} \times \frac{A1}{ax1} \qquad (1)$$

For Pantaprazole:

$$C_2 = \frac{Qm - Qx}{Qy - Qx} \times \frac{A2}{ay1} \qquad (2)$$

Where,
A1 and A2 are the absorbances of mixture at 216 nm and 284 nm,
ax1 , ax2 are absorptivities E (1%, 1 cm) of Domperidone and
ay1, ay2 are absorptivities E (1%, 1 cm) of Pantaprazole
at 216 nm and 284 nm,

and Qm= A2/A1,Qy = ay2/ay1 and Qx = ax2/ax1.

RESULTS AND DISCUSSION

Under the experimental conditions described, calibration curve, assay of tablets and recovery studies were performed. The developed methods were validated as per ICH guidelines for linearity, repeatability, LOD, LOQ as shown in Table 1. The mean % content of Domperidone and Pantaprazole in tablet formulation by the simultaneous equation method was found to be 99.85 % and 99.69% respectively and for absorbance ratio method it was found to be 99.45% and 99.08% respectively as shown in Table 2. The mean % recoveries of Domperidone and Pantaprazole were found to be 99.05% and 100% respectively by simultaneous equation method and 99.42 % and 99.62 % respectively for absorbance ratio method as shown in Table 3.

Table 1: Optical Characteristics and Validation Parameters of Domperidone and Pantaprazole

Parameter	Domperidone		Pantaprazole	
	Method I	**Method II**	**Method I**	**Method II**
λ_{max} (nm)	284	284	292	216
Beer's law range (µg/ml)	5-30	5-30	10-60	10-60
Precision (%RSD)	0.1524	0.1032	0.1286	0.0824
LOD (µg/ml)	0.0934	0.1245	0.1218	0.0848
LOQ (µg/ml)	0.2342	0.2568	0.3296	0.2473
Regression Equation: Y=mx+C I. Slope II. Intercep III. Regression Coefficient (r^2)	 0.0465 0.0281 0.999	 0.0465 0.0281 0.999	 0.0183 0.0123 0.9967	 0.0045 0.035 0.998

Table 2: Analysis of Pharmaceutical Dosage Form

Drug	Method	Label Claim (mg/tab)	Amount Found (%)	S.D.*	% R.S.D
Domperidone	I	10	99.85	0.0141	0.3602
	II		99.45	0.0671	0.2571
Pantaprazole	I	40	99.69	0.2412	0.4103
	II		99.08	0.125	0.1947

**S.D.= Standard Deviation, Mean of six estimations*

Table 3: Statistical Analysis of Recovery Studies

Level of recovery (%)	Method	%Recovery**		% R.S.D	
		Domperidone	**Pantaprazole**	**Domperidone**	**Pantaprazole**
80	**I**	98.52	99.38	1.151	0.546
	II	99.89	99.98	0.911	0.713
100	**I**	99.56	100.08	1.316	0.437
	II	99.03	99.99	0.721	0.985
120	**I**	99.35	100.54	0.305	0.654
	II	99.68	99.67	0.527	0.314

***Mean of three estimations*

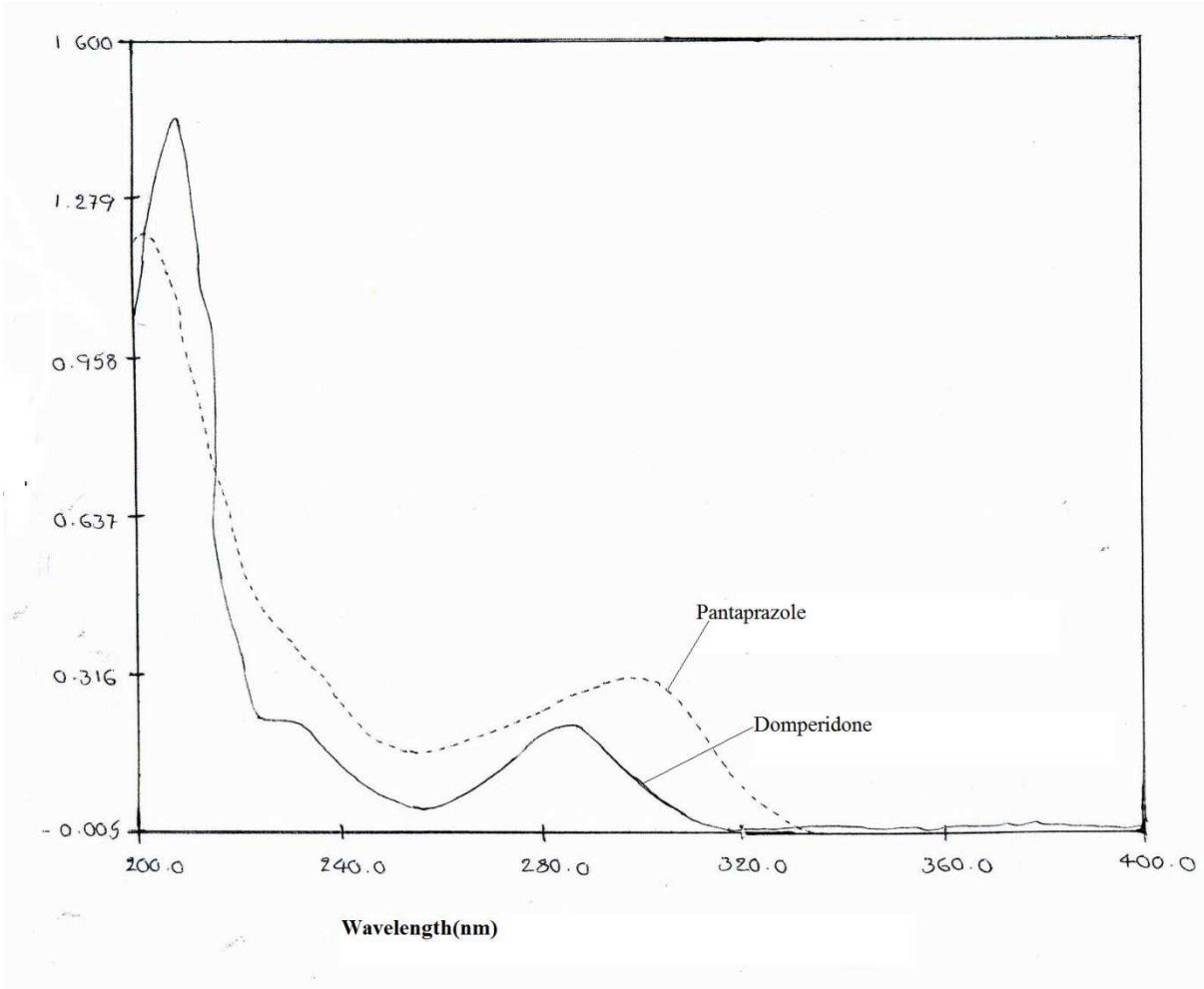

Fig:1 Overlain spectra of Domperidone (10 µg/ml) and Pantaprazole (10 µg/ml)

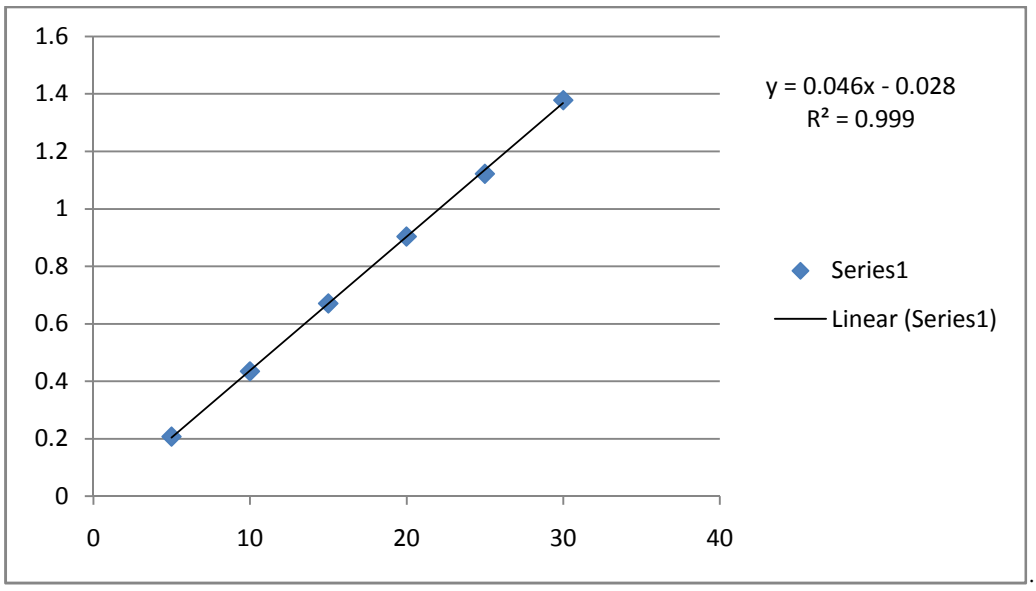

Fig.2: Calibration curve of Domperidone.

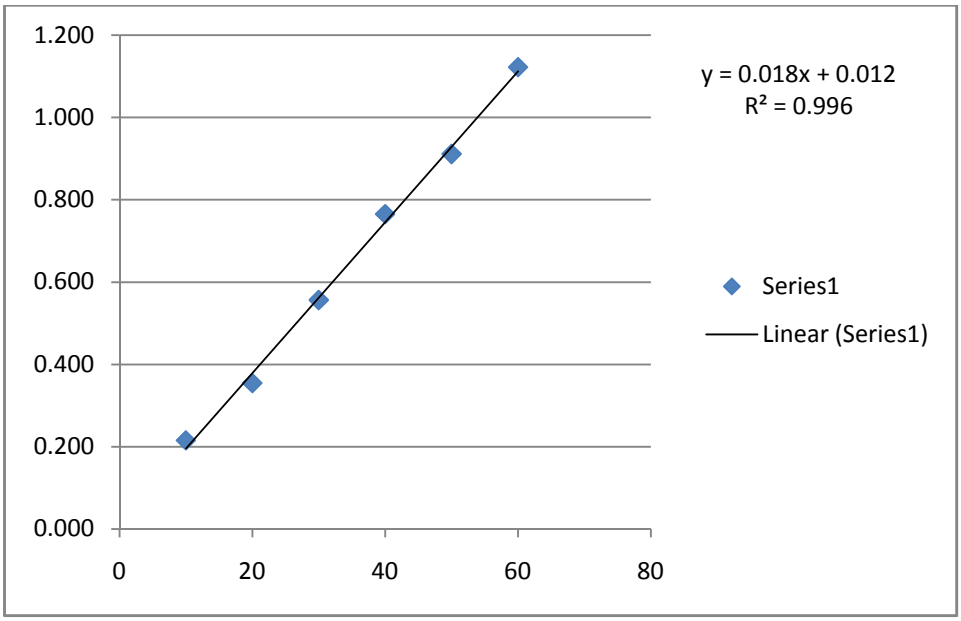

Fig: 3 Calibration Curve of Pantaprazole.

CONCLUSION

Two simple, rapid, precise and accurate spectrophotometric methods have been developed for simultaneous estimation of Domperidone and Pantaprazole by using simultaneous equation and Absorbance ratio method. The standard deviation and RSD were found to be low, indicating high degree of precision of the methods. The % recovery was found to be occurred within a range of 98-102% indicating high degree of accuracy of the proposed method. The developed methods can be employed for the routine estimation of Domperidone and Pantaprazole in both bulk and tablet dosage form.

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