Simultaneous Estimation of Domperidone and Pantoprazole in Solid Dosage Form by UV Spectrophotometry

P. RAVI KUMAR *, P. BHANU PRAKASH, M. MURALI KRISHNA,
M. SANTHA YADAV and C. ASHA DEEPTHI

Department of Pharmaceutical Sciences
Andhra University
Visakhapatnam-530 003, A.P., India

Received 23 February 2006; Accepted 14 April 2006.

Abstract: Domperidone is an antiemetic and pantoprazole is an antiulcer drug. Simple, precise, rapid and selective simultaneous equation and Q- analysis UV spectrophotometric methods have been developed for the simultaneous determination of domperidone and pantoprazole from combined tablet dosage forms. The methods involve solving of simultaneous equations and Q-value analysis based on measurement absorptivity at 216, 287 and 290 nm respectively. Linearity lies between 1-15 mcg/mL for domperidone and 0-50 mcg/mL for pantoprazole.

Keywords: Domperidone, Pantoprazole, Absorbance ratio 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 and

HPLC methods reported⁶⁻⁷ 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.

Experimental

Instrument

Elico UV-Visible Spectrophotometer SL159 model was used for spectral measurements with spectral band width 1 nm, wavelength accuracy is 0.5 nm and 1 cm matched quartz cells.

Method 1: Employing Simultaneous Equations Using Cramer's Rule

Pure drug samples of domperidone and pantoprazole were dissolved separately in methanol so as to give several dilutions of standard in the concentration range of 1-15 mcg/mL and 0-50 mcg/mL for domperidone and pantoprazole respectively. All dilutions were scanned in the wavelength range of 200-350 nm.

Two wavelengths selected for the formation of simultaneous equations were 287 nm and 290 nm respectively. Similarly, mixed standard solutions were also used and the drugs showed linearity range of 1-15 mcg/mL and 0-50 mcg/mL. The absorptivity for the two drugs is presented in Table 1. Figure 1 represents the overlain spectra of both the drugs.

Table 1 Absorptivity values for domperidone and pantoprazole

Concentration (mcg/mL)		Absorptivity at 216 nm		Absorptivity at 287 nm		Absorptivity at 290 nm	
Dompe-ridone	Panto-prazole	Domp-eridone	Panto-prazole	Dompe-ridone	Panto-prazole	Domp-eridone	Panto-prazole
1	10	880	508	243	348	229	381
2	20	879	508.5	242.2	348.5	228	381
5	30	880	508	242	348.3	228	382.3
10	40	880	508.7	243	349	229	381.5
15	50	879.5	510	243.3	348	229.3	381.6
mean	mean	879.7	508.6	243.7	348.4	228.7	381.5

The method employs solving of simultaneous equations using Cramer's rule and matrices. The simultaneous equations formed were

$$A_1 = 242.7 \times C_1 + 348.4 \times C_2 \quad (1)$$

$$A_2 = 228.7 \times C_1 + 381.5 \times C_2 \quad (2)$$

Where A_1 and A_2 are absorbances of sample solution at 287 nm and 290 nm respectively. C_1 and C_2 are concentrations of domperidone and pantoprazole respectively in sample solution. By substituting the value of C_1 from equation (1) into equation (2), the value of C_1 can be obtained. Similarly C_2 can also be obtained.

Procedure for Analysis of Tablet Formulation

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 methanol, made to volume and filtered through Whatmann

filter paper No.41. The solution was further diluted with methanol to give concentrations of 10 mcg/mL and 40 mcg/mL of domperidone and pantoprazole respectively. Absorbances of these solutions were measured at 287 nm and 290 nm as A_1 and A_2 respectively and concentrations of these two drugs in the sample were calculated using equation (1) and equations (2). Results of the analysis of the tablet formulations are reported in Table 2.

Figure 1.

Table 2 Determination of domperidone and pantoprazole in combined tablet dosage form

Samples	Label claim(mg)		Amount of drug found in mg	
	domperidone	pantoprazole	domperidone	pantoprazole
Tablet A	10	40	9.98	39.97
Tablet B	10	40	10.04	40.01

Method 2: Absorbance Ratio or Q - Analysis Method

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 287 nm, λ_{max} of domperidone. The absorbance of the standard and sample solutions were prepared and measured in the same manner as in the previous method. The absorptivity values for both drugs at the selected wavelengths are presented in Table 1. The method employs Q values; the concentrations of drugs in sample solution were determined by using the following formula.

For domperidone

$$C_1 = \frac{Q_0 - Q_2}{Q_1 - Q_2} \times \frac{A}{a_1}$$

For pantoprazole

$$C_2 = \frac{Q_0 - Q_1}{Q_2 - Q_1} \times \frac{A}{a_2}$$

$$Q_0 = \frac{\text{Absorbance of sample at 287 nm}}{\text{Absorbance of sample at 216 nm}}$$

$$Q_1 = \frac{\text{Absorptivity of domperidone at 287 nm}}{\text{Absorptivity of domperidone at 216 nm}}$$

$$Q_2 = \frac{\text{Absorptivity of pantoprazole at 287 nm}}{\text{Absorptivity of pantoprazole at 216 nm}}$$

A = Absorbance of sample at isoabsorptive point

a_1 and $a_2 \rightarrow$ absorptivities of domperidone and pantoprazole respectively at isoabsorptive point.

Results and Discussion

The proposed methods for simultaneous estimation of domperidone and pantoprazole in combined dosage forms were found to be simple, accurate, economical and rapid. In both the methods, the values of coefficient of variation were satisfactorily low and recovery was close to 100 % for both the drugs.

Conclusion

The proposed method is simple, precise, accurate and rapid for the determination of domperidone and pantoprazole in combined tablet dosage forms. This method can be adopted as an alternative to the existing spectrophotometric methods. Analysis of authentic samples containing domperidone and pantoprazole showed no interference from the common additives and excipients. Hence, recommended procedure is well suited for the assay and evaluation of drugs in pharmaceutical preparations. It can be easily and conveniently adopted for routine quality control analysis.

References

1. The European Pharmacopoeia, III edition, 1997, 779.
2. Zhang D, Yao H and Zhang X, *Yaowu Fenxi Zazhi*, 2003, **23(5)**, 378.
3. Kagan M, Chlenov M and Kraml C M, *J. Chromatogr*, 2004, **1033(2)**, 321.
4. Kale U N, Naidu K R and Shingare M S, *Indian Pharmacist*, 2002, **1(6)**, 58.
5. Amin A S and Ragab G H, *Analytical Sci*, 2003, **19(5)**, 747.
6. Sueslue I, Altinoer S and Yildiz E, *J. Pharm.Sci*, 2003, **28(2)**, 85.
7. Raju M S M, Sankar D G and Sastry C S P, *Asian. J. Chem*, 2004, **16(2)**, 669.