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Development and validation of new analytical method for the simultaneous estimation of omeprazole and domperidone in pharmaceutical dosage form by UV spectrophotometry

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ABSTRACT

A simple, rapid and precise method was developed for the quantitative simultaneous determination of Omeprazole and Domperidone in combined pharmaceutical-dosage forms. The method was based on UV-Spectrophotometric determination of two drugs, using simultaneous equation method. It involves absorbance measurement at 291 nm (λmax of Omeprazole) and 289 nm (λmax of Domperidone) in Methanol: Acetonitrile (30:70 v/v). For UV Spectrophotometric method, linearity was obtained in concentration range of 1-15 µg/ml for Domperidone and 1-50 µg/ml for Omeprazole respectively, with regression 0.999 and 0.999 for Domperidone and Omeprazole respectively. Recovery was in the range of 99 -103%; the value of standard deviation and %R.S.D were found to be < 2 %; shows the high precision of the method., in accordance with ICH guidelines. The method has been successively applied to pharmaceutical formulation and was validated according to ICH guidelines.

Keywords: UV-spectrophotometer; Omeprazole; Domperidone.

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INTRODUCTION

Development of the simple and reproducible analytical methods for estimation of multicomponent drugs is very important part of quality control and for social awareness which was established in present work.

Omeprazole[1] (PP), 5-Methoxy-2-[(4-methoxy-3,5-dimethylpyridin-2-yl)methanesulfinyl]-1H-benzimidazole , is a selective and long-acting proton-pump inhibitor used for treatment of acid-related gastrointestinal disorders[2].

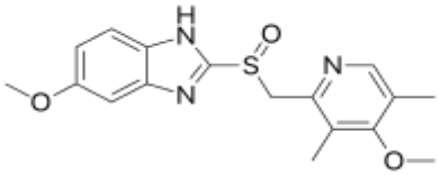

Figure 1: Omeprazole

Domperidone[1] 5-Chloro-1-[1-[3-(2-oxo-2, 3-dihydro-1*H*-benzimidazol-1-yl)propyl]piperidin-4-yl]-1, 3-Dihydro-2H-benzimidazol-2-onehydrogen (*Z*)-butenedioate is a synthetic benzimidazole compound that acts as a dopamine receptor antagonist.

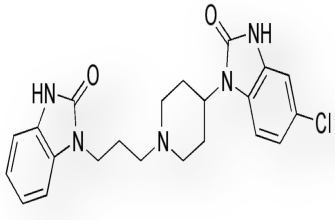

Figure 2: Domperidone

Domperidone is an antiemetic agent[3]. Domperidone is a butyrophenone derivative and is a potent D2 receptor antagonist that does not enter the CNS (Blood Brain Barrier) to a significant extent. However, it inhibits D2 Receptors in the CTZ (Chemo Trigger Zone) and causes prolactin release from the anterior pituitary[2]. The combination of Omeprazole and Domperidone was very useful in the treatment of major antiulcer disorder, generalized gastroesophageal reflux disorder. The validation of method was carried out as per ICH guidelines.

MATERIALS AND METHODS

Chemical and Reagents: Domperidone and Omeprazole were kindly gifted by Nutech Biosciences Pvt Ltd, Hyderabad certified to contain 99.9% and 99.6% purity respectively. The drugs were used without further purification. All the solvents used in analysis were of HPLC grade. Ome-D capsules (label claim 10 mg Domperidone and 20 mg Omeprazole) of Aristo pharma was used in analysis.

UV-spectrophotometry: UV- spectrophotometer (Analytical Technologies-1800) with spectral bandwidth of 2 nm and 10 mm matched quartz cells was used.

Preparation of standard stock solutions: Pure drug samples of Domperidone and Omeprazole were dissolved separately in methanol so as to give several dilutions of standard in the concentration range of 1-15 mcg/ml for Domperidone and 1-50 mcg/ml for Omeprazole respectively. All dilutions were scanned in the wavelength range of 190-400 nm.

Simultaneous equation method based on the principle that, the total absorbance of the components in a mixture is the sum of individual absorbance, two wavelength selected to frame the simultaneous equation method were at 289 and 291 nm. For calibration curves, stock solutions of Domperidone and Omeprazole in the concentration range of 1-15 mcg/ml and 1-50 mcg/ml. The absorbance of Domperidone and Omeprazole were measured at 289 nm and 291 nm, calibration curves were plotted. The absorptivity's of both the drugs at both the wavelengths were determined

Table 1: Absorptivity of Omeprazole and Domperidone capsules

Name	Absorptivity at 289 nm	Absorptivity at 291 nm
Ome	ax_1=0.03680233	ax_2=0.0371652
Dom	ay_1=0.02731832	ay_2=0.0257032
capsule	A_1=1.092	A_2=1.084

Cx(Ome) = A1*ay2-A2*ay1/ (ax2*ay1)-(ax1*ay2)
Cy(dom) =A2*ax1-A1*ax2/ (ax2*ay1)-(ax1*ay2)

Recovery studies: To check the accuracy of sample by the developed methods and to study the interference of formulation additives, analytical recovery experiments were carried out by standard addition method at 80, 100 and 120 % level. From the total amount of drug found, the percentage recovery was calculated. The results are reported as below.

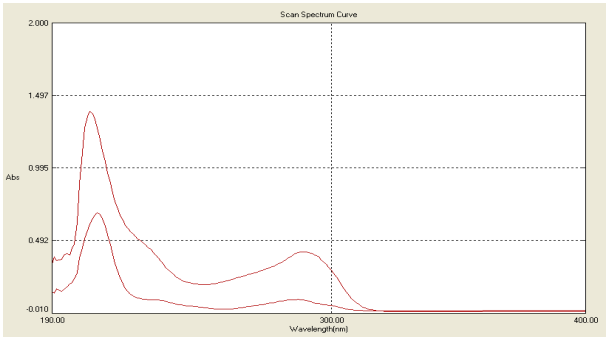

Figure 3: Overlain Spectra of Omeprazole & Domperidone

Table 2: Analysis data of Capsule formulations

Parameter	UV-spectrophotometry	
	OME	DOM
Label claim	20	10
Drug found	20.28	9.95
% Accuracy	98-102	98-102
% Recovery ± RSD	101.4±0.254	99.5±0.213

UV Validation

Linearity & Range: The linearity of calibration curves (Absorbance Vs. concentration) in pure drug solution was checked over the concentration ranges of about 1-50 µg/ml and 1-15 µg/ml for Omeprazole and Domperidone.

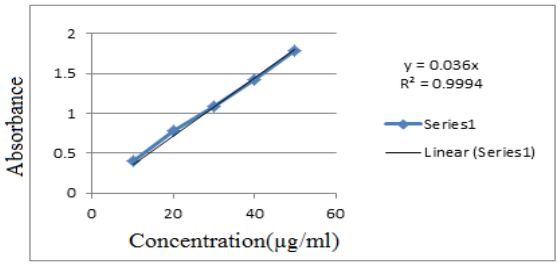

Figure 4: Calibration curve of Omeprazole

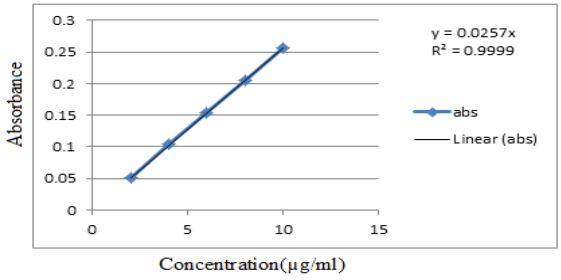

Figure 5: Calibration curve of Domperidone

Accuracy: Accuracy of the method was determined by recovery experiments. To the formulation, the reference standards of the drug were added at the level of 80%, 100%, 120%. The recovery studies were carried out three times and the percentage recovery was found to be within the range of 98-102

Precision: The data for Intraday and Inter-day precision studies at three different concentrations in the linearity range. The %RSD values for Intraday and Interday precision were < 2%, indicating that the method was sufficiently precise.

LOD & LOQ: The LOD & LOQ were separately determined based on the standard deviation of Y-intercept of the calibration curve. The standard deviation of the Y-intercept and the slope of the calibration curves were used to calculate the LOD and LOQ by using the equations, 3.3*std.dev/slope for LOD, 10*std.dev/slope for LOQ.

Table 3: LOD and LOQ of Omeprazole, Domperidone

	Omeprazole	Domperidone
LOD	0.264 µg/ml	0.331 µg/ml
LOQ	0.816 µg/ml	1.123 µg/ml

CONCLUSION

The method described for simultaneous estimation of Omeprazole and Domperidone are found to be simple, sensitive, accurate, precise, economical and rapid. Hence method could be successfully employed for routine analysis of Omeprazole and Domperidone in their combined Pharmaceutical dosage forms.

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