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Research Article

SIMULTANEOUS SPECTROPHOTOMETRIC METHODS FOR ESTIMATION OF ONDANSETRON HYDROCHLORIDE AND OMEPRAZOLE IN TABLETS

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ABSTRACT

Two simple, rapid, accurate and precise UV-spectrophotometric methods have been developed for simultaneous estimation of ondansetron hydrochloride and omeprazole in bulk and tablet dosage form. Method 1 involves, formation of simultaneous equation using Cramer's rule and Method 2, multicomponent mode of analysis. In ethanol, ondansetron hydrochloride and omeprazole showed λmax at 246.2 nm and 301 nm, respectively. Linearity was observed in the concentration range of 4 - 24 µg/ml for ondansetron hydrochloride and 5 - 30 µg/ml for omeprazole. The methods were successively applied to tablet formulation; no interferences from the tablet excipients were found. The methods have been validated statistically and by recovery studies.

Keywords: Ondansetron hydrochloride, Omeprazole, multicomponent mode.

INTRODUCTION

Ondansetron hydrochloride (OND), 1, 2, 3, 4 – tetrahydro-9-methyl-3-(2-methylimidazol-1-yl methyl) carbazol-4-one hydrochloride is a selective $5HT_3$ receptor antagonist[1,2]. Omeprazole (OMZ), (RS)-5-methoxy-2-[4 – methoxy-3, 5 dimethyl pyridin-2-yl) methyl] sulphinyl]-1H-benzimidazole is substituted benzimidazole sulfoxides that function as proton pump inhibitors [3, 4]. Literature survey revealed spectrophotometric[5] and chromatographic[6,7] methods for analysis of OND. Also, spectrophotometric[8] and chromatographic[9-10] methods are reported for analysis of OMZ. So far, no analytical methods are reported for analysis of both the drugs in combination. The objective of this investigation is to develop, two simple, accurate and economical UV-spectrophotometric methods for simultaneous estimations of OND and OMZ.

EXPERIMENTAL

Instrument

For method 1, UV-vis spectrophotometer (Shimadzu-2450, spectral bandwidth 1nm) and in method 2, UV-vis spectrophotometer (Shimadzu-1700, spectral bandwidth 1nm) with 10 mm matched quartz cells; Electronic balance and Ultrasonicator were used.

Reagent: Ethanol (A.R.)

Procedure

Method 1: Employing Simultaneous Equations using Cramer's Rule [11]

Standard stock solution of OND and OMZ were prepared separately by dissolving 25 mg each drug in 100 ml ethanol (i.e.250 µg/ml). Aliquot of these solutions were further diluted to obtain concentrations 4 µg /ml (OND) and 10 µg/ml (OMZ) and scanned in the UV-range. From the overlain spectra, two wavelengths 246.2 (λ_{max} of OND) and 301 (λ_{max} of OMZ) were selected. The linearity was observed in the concentration range of 4 - 24 µg/ml for OND and 5 - 30 µg/ml for OMZ,

respectively. The absorptivity coefficients of each drug at both wavelengths were determined and the results are presented in Table1.
Using these, a set of two simultaneous equations was framed;

$$A_1 = 251.12 \times C_1 + 455.86 \times C_2 \quad \text{--------} \ I$$
$$A_2 = 463.90 \times C_1 + 361.14 \times C_2 \quad \text{------} \ II$$

Where, C_1 and C_2 are the concentrations of OND and OMZ, respectively in g/100 mL. By rearranging equations **I** and **II** the concentrations C_1 and C_2 can be obtained as;

$$C_1 = A_1 \times 455.86 - A_2 \times 251.12 \ / - 120783.98 \quad \text{-------} \ III$$
$$C_2 = A_2 \times 463.90 - A_1 \times 361.14 \ / - 120783.98 \quad \text{-------} \ IV$$

Method 2: Employing Multicomponent Mode of Analysis [12]
The seven mixed standard solutions with concentration of OND and OMZ in the ratio of 12:0, 0:30, 4:10, 6:15, 8:20, 10:25, 12:30 µg/ml were prepared in ethanol. The mixed standard solutions were scanned over the range of 400 - 200 nm, in the multicomponent mode of instrument (Shimadzu -1700) using two wavelength 246.2 nm (λ_{max} OND) and 301 nm (λ_{max} OMZ). The spectral data from these scans was used to determine the concentration of two drugs in tablet sample solutions.

Analysis of commercial tablet formulation
Twenty tablets were weighed and powdered in a glass mortar. An amount of powder equivalent to 40 mg (OND) and 100 mg (OMZ) was transferred to a 100 ml calibrated volumetric flask, extracted with ethanol by shaking mechanically. The solution was diluted to mark with the same solvent and filtered through Whatmann filter paper. (no. 41). Aliquot portion of this solution was diluted to get concentration 8 µg/ml (OND) and 20 µg/ml (OMZ). Absorbance of the sample solutions were recorded, at 246.2 nm and 301 nm i.e. A_1 and A_2, respectively (Shimadzu 2450). And, using equation III and IV determined the concentrations of two drugs in sample. Also, these solutions were subjected to analysis in the multicomponent mode of instrument (Shimadzu- 1700). The concentration of each drug was determined by analysis of spectral data of the sample solutions with reference to mixed standards. The results are reported in **Table 2.**

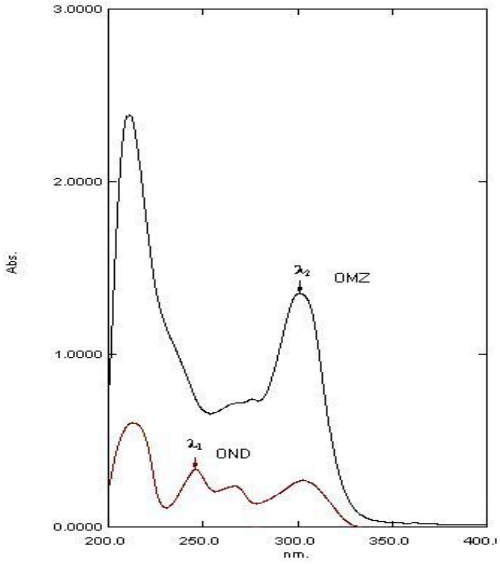

Fig.1: Overlain spectra of OND and OMZ

Recovery Studies
The recovery studies were carried out at three different levels i.e. 80, 100 and 120%. It was performed by adding known amount of standard drug solutions of OND and OMZ to preanalysed tablet solutions. The resulting solutions were then reanalysed by proposed methods. The results of recovery studies are shown in **Table 3.**

RESULTS AND DISCUSSION

The proposed methods are simple, sensitive, accurate, precise, reproducible, economic and rapid for simultaneous analysis of OND and OMZ in tablets. Accuracy of the method was evaluated by carrying out recovery studies. Low values of % RSD are indicative of high precision of the methods. The repeatability and ruggedness study signifies the reproducibility of the method as shown in **Table 4.**
Based on the validation study data, it can be concluded that the proposed methods are accurate and precise for the analysis of both the drugs. No interference was found from excipients used in tablet formulation and hence the methods are suitable for analysis of tablet formulation.

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Table 1: Absorptivity values of OND and OMZ at 246.2 nm and 301.0 nm

	Absorptivity* at 246.2 nm		Absorptivity* at 301.0 nm	
	OMZ	OND	OMZ	OND
Mean	ax_1 = 251.12	ay_1 = 463.90	ax_2 = 455.87	ay_2 = 361.14
SD	1.67	1.98	1.38	1.20

*mean of six estimations

Table 2: Result of Assay

	Label Claim (mg/tab)	% Label Claim	± SD	%RSD	SE
Method 1	OND 4	101.4	0.32	0.36	0.14
	OMZ 10	101.65	0.65	0.53	0.29
Method 2	OND 4	98.71	0.27	0.27	0.12
	OMZ 10	99.25	0.66	0.66	0.29

*mean of Five Estimation

Table 3: Results of Recovery Studies

S. No.	Amount of Drug Added (µg/mL)		Method 1 %Recovery* ± SD		Method 2 %Recovery* ± SD	
	OND	OMZ	OND	OMZ	OND	OMZ
1	6.4	16.0	100.83 ± 0.081	101.30 ± 0.036	100.04± 0.20	99.21 ± 0.57
2	8.0	20.0	101.81 ± 0.113	99.85 ± 0.062	99.98 ± 0.27	98.92 ± 0.72
3	9.6	24.0	101.07 ± 0.05	100.36 ± 0.12	99.68 ± 0.55	99.56 ± 0.75

*mean of three estimations at each level

Table 4: Results of Repeatability and Ruggedness studies

Parameters	Method 1		Method 2	
	OND	OMZ	OND	OMZ
Repeatability %RSD (n=5)	1.10	1.04	0.49	0.35
Precision %RSD				
Intraday (n=5)	1.32-1.70	0.24-0.98	0.43-0.61	0.32-0.63
Interday (n=5)	0.54-1.80	0.26-1.46	0.48-1.15	0.32-0.62
Ruggedness %RSD (n=5)				
Analyst I	0.83	0.79	0.38	0.45
Analyst II	0.83	1.08	0.46	0.62

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