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Simultaneous Estimation of Ofloxacin and Ornidazole in Synthetic Mixture by Q-Analysis UV-Spectrophotometric Method

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Abstract:

Ofloxacin and ornidazole in combination are available as tablet dosage forms in the ratio of 2:5. A simple, reproducible and efficient method for the simultaneous determination of ofloxacin and ornidazole in synthetic mixture was developed. The proposed method is based on the Q-analysis UV Spectrophotometric method. The absorbance maxima of ofloxacin and ornidazole were found to be 286.2 nm and 319.2 nm, respectively in 5% methanol in distilled water. In Q-analysis, the isoabsorptive point for both the drugs was found at 294 nm. The linearity range lies between 1-15 µg/ml for ofloxacin and 1-30 µg/ml for ornidazole at their respective wavelengths. Both the drugs obey Beer's law. The recovery studies confirmed the accuracy of the proposed methods.

Key words: Q-analysis, simultaneous estimation, Ornidazole, Ofloxacine

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Introduction:

Ornidazole is a 5-nitroimidazole derivative. Chemically, ornidazole is α - (chloro-methyl) - 2 - methyl – 5 – nitroimidazole – 1 ethanol. It is a broad-spectrum antiprotozoal, antimicrobial and antifungal[1] used for treatment in severe hepatic and intestinal amoebiasis, giardiasis, trichomoniasis of urogenital tract and bacterial vaginosis. It is not official in I.P., U.S.P. and B.P. till date. A survey of literature reveals that ornidazole is estimated by voltametry[2] and H.P.L.C (in biological fluids[3], plasma, red blood cell and human serum). Chemically, ofloxacin is (±)-9-fluoro-2, 3-dihydro-3-methyl-10- (4-methyl-1- piperazinyl)-7-oxo-7H-pyrido [1, 2, 3-de]-1, 4-benzoxazine-6-carboxylic acid. It is a floroquinolone and used mainly as antibacterial[1] for the treatment of urinary tract infection and sexually transmitted diseases.

Ofloxacin, official in U.S.P.[4] and B.P.[5] but not in I.P. The method of analysis given in U.S.P and B.P is by titrimetry[6]. A survey of literature reveals that ofloxacin is estimated by spectrophotometery[7], RP-H.P.L.C[8] and spectroflourimetery[9]. Only two types of dosage form containing ornidazole in combination with ofloxacin is available in the market these formulations are recommended for the treatment of diarrhoea and dysentery caused by bacteria resistant to ciprofloxacin. Also, ornidazole relatively has much longer half-life as compared to metronidazole and tinidazole.

Both these drugs are available in combined tablet dosage form (200 mg ofloxacin and 500 mg ornidazole) as an antiamoebic.

MATERIAL AND METHODS

Instrument:

(1) Double beam UV-VIS Spectrophotometer **UV-1800, Shimadzu corporation**

(2) GR 200 Analytical weighing balance (A&D Company).

(3) Sonicator (Enertech Electronics).

Drug Sample:

Ofloxacin and ornidazole were obtained as gift sample from Asian Remedies Pvt. Ltd., Gwalior (M.P) and Ravi Pharmaceutical Pvt. Ltd. G.I.D.C., Kansari (Gujarat).

Chemicals and Reagents:

Methanol A.R grade was procured from Loba Chem. Ltd., Mumbai. Double distilled water was used for making aqueous methanol (5 %v/v).

Procedure:

Ofloxacin (10 mg) and ornidazole (10 mg) separately were dissolved in methanol (5 ml) and further diluted with distilled water to get a stock solution of 100 mcg/ml. From these stock solutions, working standard solutions were prepared. These were scanned in the entire UV range to determine the λ max. The λ max of Ofloxacin and Ornidazole were found to be 286.2 nm and 319.2 nm respectively. For Q-analysis method, firstly all the aliquots of synthetic mixture were made in drug dose strength ratio i.e 2:5 (ofloxacin**:** ornidazole) and the absorbance values were taken at 294 nm (isoabsorptive point) and 286.2 nm from the overlain spectra of both the drugs (Figure 1).

For estimating the concentration of ofloxacin and ornidazole by Q-analysis method, the absorbance and the absorptivity values at the particular wavelengths were calculated and substituted in the following equation: $C_X = (Q_0 - Q_2) \times A_1 / (Q_1 - Q_2) \times a_1$, $C_Y = (Q_0 - Q_1) \times A_1 / (Q_2 - Q_1) \times a_2$, where C_X and C_Y are concentration of ofloxacin and ornidazole, respectively. A_1 is the absorbance of sample at 294 nm, a_1 and a_2 are the absorptivity values of ofloxacin and ornidazole at 294 nm, respectively, Q_0 was obtained by using the

equation, (absorbance of sample at 286.2 nm) / (absorbance of sample at 294 nm), Q_1 was obtained from (absorbance of ofloxacin at 286.2 nm) / (absorbance of ofloxacin at 294 nm), and Q_2 was obtained from (absorbance of ornidazole at 286.2 nm) / (absorbance of ornidazole at 294 nm).

The regression analysis of the calibration curves suggests the level of precision of the method and the optical characteristics such as Beer's law limits, detection limit, molar absorptivities and Sandell's sensitivities are presented in Table I

Recovery Studies and Validation of the Method according to I.C.H Q2A Guidelines:

To study the validation parameters; accuracy, reproducibility, reliability, interference and recovery experiments were carried out by standard addition. The recovery of added standard (60%, 80%, 100%, and 120%) was found at four same concentration levels for each drug. From the total amount of drug found, the percentage recovery was calculated. From the total amount of drug found, the percentage recovery was calculated. Table 2 shows assay and recovery studies results of ofloxacin and ornidazole in the synthetic mixture.

RESULTS AND DISCUSSIONS

The molar absorptivity and Sandell's sensitivity values show the sensitivity of ofloxacin and ornidazole at respective and at isoabsorptive point wavelengths, while precision is confirmed by % RSD (% relative standard deviation. The reproducibility, repeatability and accuracy of these methods were found to be good, evidenced by low standard deviation.

Thus, the proposed method for simultaneous estimation of ofloxacin and ornidazole in synthetic mixture was found to be simple, accurate, sensitive and economical. Therefore, the method can be useful in routine equality quality control analysis.

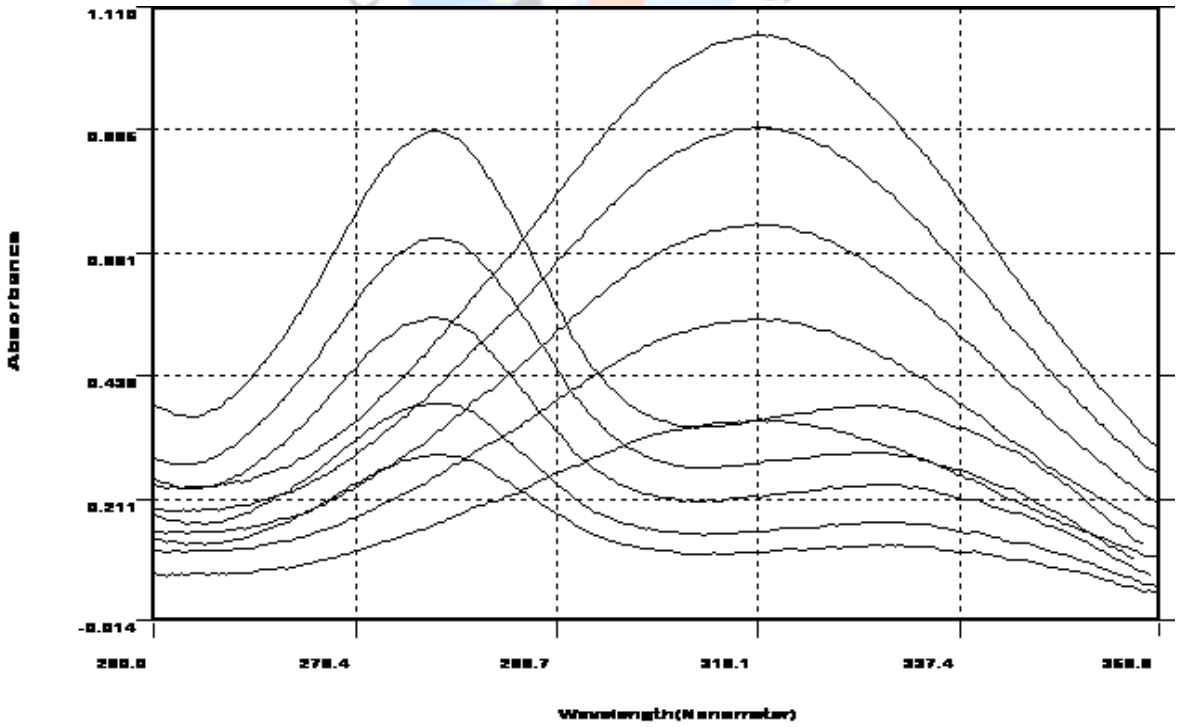

Figure 1. Isoabsorptive point for ofloxacin and ornidazole was found at 294 nm

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Table: 1 Optical and regression characteristics of ofloxacin and ornidazole

Parameters	Ofloxacin		Ornidazole	
	286.2 nm	**294 nm**	**286.2 nm**	**294 nm**
Beers's law limit (µg/ml)	1-15	1-30	1-30	1-30
Molar absorptivity (l mole^{-1}cm^{-1})	2.29 x 10^4	1.95 x 10^4	3.25 x 10^3	4.74 x 10^3
Sandell's sensitivity (mg/cm^2/.001abs.unit)	0.0150	0.0463	0.0067	0.0185
Regression equation (y= a + bc)				
Slope (b)	0.0674	0.0542	0.0152	0.0217
Intercept (a)	- 0.0302	- 0.0012	- 0.0034	- 0.0012
Correlation coefficient	0.9982	0.9997	0.9977	0.9997

Table 2: Results of recovery studies of ofloxacin and ornidazole in the synthetic mixture

Mixture	Drug Name	Conc. Before Spiking	Conc. After Spiking	% Recovery	Mean ± S.D.	% C.V.
1	**OFL**	6.230	9.972	101.444	**OFL**	**OFL**
	ONZ	15.118	24.142	100.099		
2	**OFL**	6.261	11.275	101.934	101.843 ± 0.2723	0.2674
	ONZ	15.948	26.856	99.653		
3	**OFL**	6.250	12.502	102.058	**ONZ**	**ONZ**
	ONZ	15.205	30.410	100.677		
4	**OFL**	6.208	13.668	101.939	100.225 ± 0.4476	0.4466
	ONZ	15.172	33.327	100.467		

*Average ± standard deviation of four determination

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