

# Development and Validation of UV Spectrophotometric method for the Simultaneous estimation of Ciprofloxacin Hydrochloride and Ornidazole in Combined Pharmaceutical Dosage Form

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## ABSTRACT

A simple, precise, accurate and economical UV Spectrophotometric method has been developed and validated for the simultaneous estimation of Ciprofloxacin and Ornidazole in combined pharmaceutical dosage form using simultaneous equation method. Ciprofloxacin hydrochloride has absorbance maxima at 270 nm and Ornidazole has absorbance maxima at 319 nm in distilled water. The drugs obeyed Beer's law in the concentration range of 2-12 µg/ml for Ciprofloxacin and 6-16 µg/ml for Ornidazole. The correlation coefficient of Ciprofloxacin HCl and Ornidazole was found to be 0.999 and 0.997 respectively. The method was statistically validated as per the ICH guidelines. The low RSD values indicate good precision and high recovery values indicate accuracy of the proposed method. The developed method was simple, precise, accurate, reproducible and economical which can be efficiently and easily applied to pharmaceutical dosage form.

**Keywords:** Ciprofloxacin, Ornidazole, Method development, Validation, Simultaneous equation method.

## INTRODUCTION

Ciprofloxacin is a broad spectrum anti-biotic active against gram+ve and gram-ve bacteria. It functions by inhibiting DNA gyrase. Chemically Ciprofloxacin is 1-Cyclopropyl-6-fluoro-4-oxo-7-(piperazin-1-yl)-quinoline-3-carboxylic acid Figure. 1a. Ornidazole is used in the treatment of amoebiasis and other protozoal infections. Ornidazole is chemically 1-chloro-3-(2-methyl-5-nitroimidazole-1-yl)-propan-2-ol Figure. 1b. Literature survey reported that very few analytical methods such as UV Spectroscopy, HPLC have been reported for the simultaneous estimation of both the drugs. The aim of the present study is to develop and validate a simple, precise and accurate and reproducible UV Spectrophotometric method for analysis of ciprofloxacin and Ornidazole in a combined dosage form and hence an economical method was developed and validated.

## MATERIALS AND METHODS

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## Instruments used

SHIMADZU double beam UV/Visible Spectrophotometer model UV 1800s was employed with a spectral band width of 1nm and a wavelength accuracy of 0.3 nm (with automatic wavelength correction with a pair of 1cm matched quartz cells). SHIMADZU Electronic balance model AX 200 and Ultra Sonicator (Fast clean) model 2k811056 were also used during the analysis.

## Materials

Analytically pure samples of Ciprofloxacin and Ornidazole were obtained as gift samples from CIPLA LTD. Tablets of brand "Cifran-oz" having combination of Ciprofloxacin (500 mg) and Ornidazole (500 mg) manufactured by Ranbaxy Laboratories Ltd was purchased from local pharmacy.

## Method

The UV spectra of Ciprofloxacin and Ornidazole in different solvents like water, 0.1N NaOH, 0.1N HCl, methanol, ethanol were recorded. These 2 drugs showed good absorbance when dissolved in water. Hence distilled water was selected as the solvent for the method.

Ciprofloxacin and Ornidazole (10 mg each) were separately weighed and transferred to a 100 ml volumetric flask and both the drugs were dissolved in

distilled water to get a solution of 100 µg/ml. Working standard solutions of 10 µg/ml were prepared and scanned in the range 400 nm-200 nm to obtain the absorbance spectra and overlain spectra (figure 2). Two wavelengths 270 nm and 319 nm were selected which are the  $\lambda_{max}$  of Ciprofloxacin and Ornidazole respectively. The absorbance values E (1%,1cm) were determined at the three selected wavelengths. The concentration of two drugs in the mixture can be calculated using the following equation.

$$C_{CPF} = \frac{A_2 a y_1 - A_1 a y_2}{a x_2 a y_1 - a x_1 a y_2}$$

$$C_{ORD} = \frac{A_1 a x_2 - A_2 a x_1}{a x_2 a y_1 - a x_1 a y_2}$$

Where  $C_{CPF}$ ,  $C_{ORD}$  are the concentrations of Ciprofloxacin and Ornidazole in mixture and in sample solutions.  $A_1$ ,  $A_2$  are the absorbances of sample at 270 nm and 319 nm respectively,  $a x_1$ ,  $a x_2$  are the absorptivity values of Ciprofloxacin at 270 nm and 319 nm,  $a y_1$ ,  $a y_2$  are the absorptivity of Ornidazole at 270 nm and 319 nm respectively.

## RESULTS AND DISCUSSION

The analytical method was validated with respect to parameters such as linearity, precision, accuracy, limit of detection (LOD), limit of quantification (LOQ)

### Linearity:

Linearity was established by least squares linear regression analysis of the calibration curve. The calibration curves were linear over the concentration range of 2-12 µg/ml for Ciprofloxacin and 6-16 µg/ml for Ornidazole. Absorbances obtained were plotted against respective concentrations and linear regression analysis was performed on the resultant curves. Correlation coefficient were found to be 0.999 and 0.997 for Ciprofloxacin and Ornidazole (figure 3-4) respectively. The results are given in Table1.

### Precision:

To check the reproducibility of the method, suitable statistical evaluation was carried out. The concentrations of two drugs were measured three times on the same day at intervals of 1hour and on three different days for intra and inter day study respectively. The standard deviation and Relative

Standard Deviation were calculated (RSD) were calculated. The results are given in Table 2.

### Accuracy:

Recovery studies were carried out by applying the method to drug sample to which known amount of standard Ciprofloxacin and Ornidazole corresponding to 50,100 and 150 % of label claim had been added. At each level of the amount six determinations were performed. The results are given in Table3.

### LOD and LOQ

The LOD of ciprofloxacin and ornidazole was found to be 0.17 µg/ml and 0.19 µg/ml respectively and LOQ was found to be 0.5 µg/ml and 0.59 µg/ml respectively. The results are given in Table 4.

### Analysis of marketed formulation:

Twenty cifran-oz tablets each containing 500mg of Ciprofloxacin,500mg of Ornidazole were weighed,average weight was calculated and powdered. A quantity equivalent to 10mg of Ciprofloxacin and 10mg of Ornidazole was weighed and transferred in to 100ml volumetric flask. It is extracted with distilled water. The volumetric flask was sonicated for 2mins to affect the complete dissolution of the drugs and the solution was made up to the volume with distilled water and filtered. Suitable aliquots of formulation were prepared and scanned to obtain concentration of the two drugs in the linearity range. The concentration of each analyte was determined using the simultaneous equation(Figure.5) (Table 5)

## CONCLUSION

The proposed UV Spectrophotometric method was found to be simple, precise, accurate and economical for the simultaneous estimation of Ciprofloxacin and Ornidazole in combined dosage forms. Hence, this method can be easily used for routine quality control analysis of Ciprofloxacin and Ornidazole in pure and its combined dosage form.

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**Table 1:** Linearity and Correlation coefficient

Parameters	Ciprofloxacin	Ornidazole
Regression equation	$Y = 0.067x + 0.035$	$Y = 0.042x - 0.002$
Linearity ( $\mu\text{g/ml}$ )	2-12	6-16
Correlation coefficient	0.999	0.997

**Table 2:** Precision studies

Drug	Concentration $\mu\text{g/ml}$	Intraday Precision $n=3$ %RSD	Interday Precision $n=3$ %RSD
Ciprofloxacin	8 $\mu\text{g/ml}$	0.634	0.582
Ornidazole	12 $\mu\text{g/ml}$	0.511	0.816

**Table 3:** Accuracy

Drug	Amount taken	Amount added	Amount recovered	% Recovery	%*RSD
		250	249.12		
Ciprofloxacin	500	500	497.16	99.573	0.452
		750	748.66		
		250	248.55		
Ornidazole	500	500	498.23	99.646	0.721
		750	749.13		

\*Mean of six observations

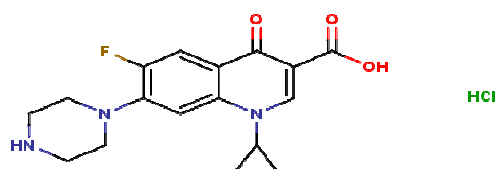
**Table 4:** LOD and LOQ studies

Validation parameters	Ciprofloxacin	Ornidazole
LOD ( $\mu\text{g/ml}$ )	0.546	0.8
LOQ ( $\mu\text{g/ml}$ )	1.65	2.64

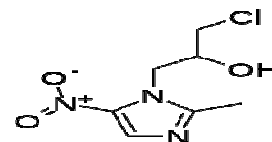
**Table 5:** Analysis of Formulation.

Drug	Labeled amount (mg/tablet)	Amount found (mg/tablet)	%Label claim	%*RSD
Ciprofloxacin	500 mg	498.67	99.73	0.045
Ornidazole	500 mg	497.88	99.57	0.159

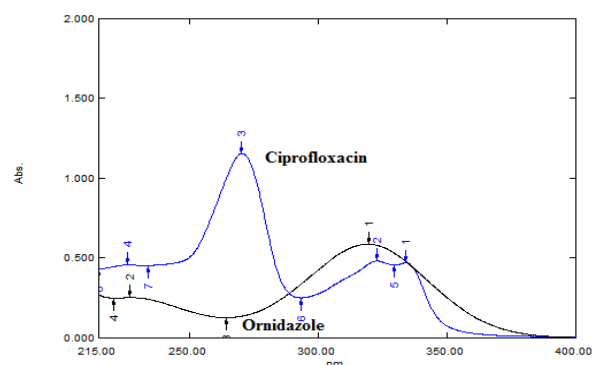
\*mean of six observations



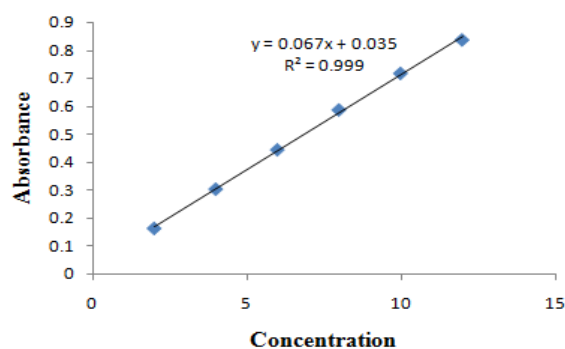
**Figure 1a:** Structure of Ciprofloxacin hydrochloride



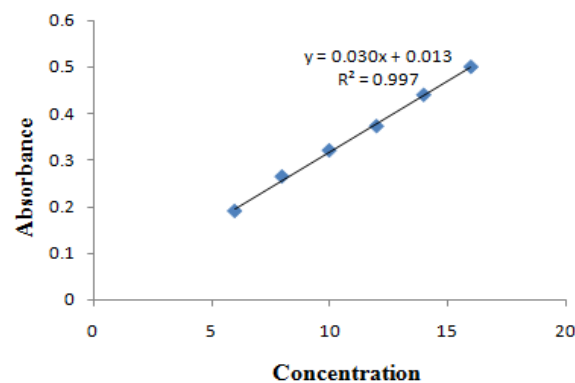
**Figure 1b:** Structure of ornidazole



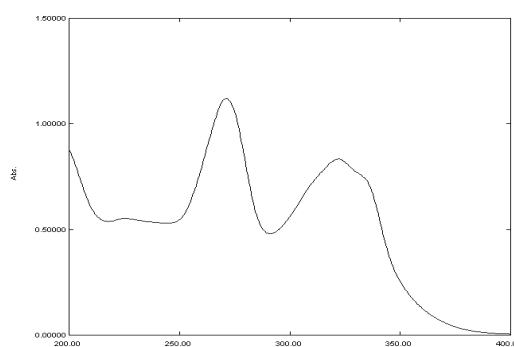
**Figure 2:** Overlay spectra of Ciprofloxacin and Ornidazole



**Figure 3:** Calibration curve of Ciprofloxacin hydrochloride at 270 nm



**Figure 4:** Calibration curve of Ornidazole at 319 nm



**Figure 5:** Spectra of Ciprofloxacin and Ornidazole formulation

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