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ORIGINAL RESEARCH ARTICLE

Q-Analysis Methods for the Simultaneous Spectrophotometric Estimation of Levofloxacin Hemihydrate and Ornidazole in Tablet Dosage Form

*Rekha Rajeev Kumar[1] and P. Rajeev Kumar[2]

[1]Department of Pharmaceutical Analysis, Srinivas College of Pharmacy Valachil, Mangalore-574143 (Karnataka), India.
[2]Department of Pharmaceutics, Srinivas College of Pharmacy Valachil, Mangalore-574143 (Karnataka), India.

***Corresponding Author**
Rekha Rajeev Kumar
Lecturer
Department of Pharmaceutical Analysis
Srinivas College of Pharmacy
Mangalore- 574143.
Contact no.: +91 09480 266 008
E-mail: rekhavas@gmail.com

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ABSTRACT

Two simple, accurate and economic Q-analysis and two wavelength methods have been developed and validated for the simultaneous estimation of Levofloxacin Hemihydrate (LFH) and Ornidazole (ORN) in tablet dosage form. In 0.1M HCl AR grade the λ_{max} were found to be 293 and 277nm, respectively. Beer's lamberts law was obeyed in the concentration range of 2-12 µg/ml for LFH and 2-32 µg/ml for ORN. The results of analysis have been validated by statistical and recovery studies.

Key words: Levofloxacin, Ornidazole, UV-spectrophotometry, Q-Analysis.

INTRODUCTION

Levofloxacin hemihydrates (LFH) and ornidazole (ORN) are available in tablet dosage form in the ratio 2.5:5. Chemically Levofloxacin hemihydrate, a chiral fluorinated carboxy quinolone, is the pure (-)-(s)-enantiomer of the racemic drug substance Oflaxacin. The chemical name is (-)-(s-)-9-fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7H-pyrido[1,2,3-de]-1,4-benzoxazine -6-caroxylic acid hemihydrates (Budavari S,2001). It is yet not official in any pharmacopoeia. It is antibacterial agent. Ornidazole is an antibacterial and antiprotozoal agent (Budavari S, 1996), not in official pharmacopoeia. Chemically, it is 1(3-chloro-2-hydroxypropyl)-2-methyl-5-nitro imidazole; alpha-(chloromethyl)-2-methyl-5-nitro-1H-imidazole-1-ethanol. Both the drugs in combination are used for the synergistic activity. Literature survey revealed various methods for the determination of LFH and ORN in combination with other drugs (Lakshmi Sivasubramaniam et al., 2004, Nagori BP et al., 2006, Kale UN et al., 2003, Kasture VS et al., 2004, Patel UN et al., 2005, Somashekar M et al., 2005, Groppi A et al., 1986) but no method was found to be developed for its simultaneous estimation of LFH and ORN. This paper presents two simple, rapid, reproducible and economical methods for the simultaneous analysis of levofloxacin hemihydrates (LFH) and ornidazole (ORN) in tablet dosage forms.

MATERIALS AND METHODS

Materials: Standard gift samples of Levofloxacin hemihydrate and ornidazole were procured from Glenmark Research, Mumbai. Combined Levofloxacin hemihydrate and Ornidazole tablets were procured from local market. ***Solvent:*** 0.1M HCl AR grade was used as a solvent in the study and obtained from Qualigens Ltd, Mumbai. ***Stock solution:*** Standard stock solutions of 100µg/mL of LFH and 100µg/mL of ORN were prepared and used for analysis.

Preparation of calibration curves

Solution of 10µg/ml of LFH and ORN were prepared separately. Both the solutions were scanned in the spectrum mode from 400nm to 200nm. The maximum absorbance of LFH and ORN was observed at 293nm and 277nm, respectively. LFH and ORN show linearity in absorbances in the concentration range 2-12 µg/ml and 2-32 µg/ml at their respective maximas. The coefficient of correlation was found to be 0.9995 for LFH and 0.9998 for ORN.

Method I- Q analysis method

In the quantitative assay of two components by Q analysis method (Beckett AH, *et al* 2002) absorbances were measured at two wavelengths, one being the isobsorptive point and other being the wavelength of maximum absorption of one of the two components solution of 20µg/ml of LFH and ORN were prepared separately. Both the solutions were scanned in the spectrum mode from 400nm to 200nm. From overlain spectra of LFH and ORN, absorbances were measured at the selected wavelengths i.e. 267nm (isoabsorptive point) and 277 nm (λmax of ORN) (Fig.1). The mixed standards having concentration 2-12µg/ml of LFH and 2-32µg/ml of ORN respectively were prepared and scanned in the spectrum mode from 400nm-200 nm. The absorbances of mixed standards were measured of each component can be calculated by mathematical treatment of the following mentioned equation:

For Levofloxacin Hemihydrate,

$$C_1 = \frac{Qm - Qy}{Qx - Qy} \times \frac{A_1}{a_1}$$

For Ornidazole,

$$C_2 = \frac{Qm - Qx}{Qy - Qx} \times \frac{A_1}{a_2}$$

Where, C_1=Concentration of LFH

C_2=Concentration of ORN

A_1=Absorbance of sample at isoabsorptive wavelength at 267nm

a_1 and a_2=Absorptivity of LFH at 277nm/ Absorptivity of LFH at 267nm

Q*x*= Absorptivity of LFH at 277nm/ Absorptivity of ORN at 267nm

Q*y*= Absorptivity of sample solution at 277nm/ Absorptivity of sample solution at 267nm

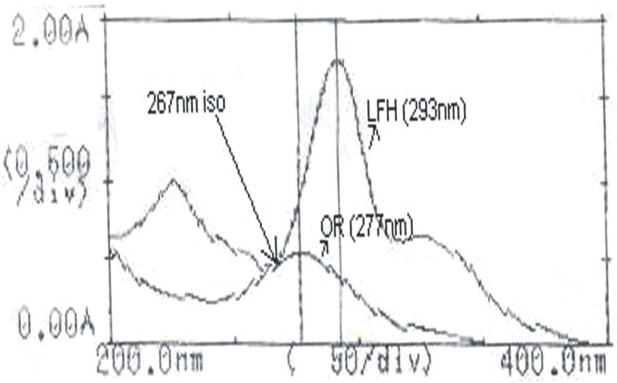

Figure1: Overlain spectrum of LFH and OR in 0.1M HCl

Analysis of tablet formulation

Twenty tablets were weighed and crushed to fine powder. The powder sample equivalent to 125mg of LFH and 250mg of ORN was weighed and transferred to 100 ml volumetric flask. The drug content was dissolved in small quantity of 0.1M HCl AR grade and was kept in ultrasonicator for 20 min. Finally the volume was made up to the mark with 0.1M HCl AR grade. The solution was filtered through whatmann filter paper no.41.Appropriate dilution were made up to obtain the final concentration of both drugs in the linearity range. The absorbances of sample solutions were measured at 267nm and 277nm. The values were equated in the above mentioned equation and the concentration of each drug was calculated. Recovery studies were carried out by adding a known quantity of standard to the preanalysed sample.

Method II: Two Wavelength Method

For estimation of one component by this method two wavelengths were selected (Beckett AH, *et al* 2002), where absorbance of other component remains same. Therefore the difference in the absorbances in the mixed spectra at corresponding wavelength will be directly proportional to the concentration of that component. For LFH, 267nm (λ_1) and 287nm (λ_2) and for ORN, 272nm ((λ_1) and 322nm (λ_2) were selected. All the mixed standards were scanned at these selected wavelengths separately using spectrum mode of the instrument. The difference in the absorbance

at selected wavelengths; λ_1 and λ_2 were plotted against the respective concentration to obtain the concentration curves. The mixed standard solutions were scanned at selected wavelengths for LFH and ORN. From the absorbance difference values, the concentration of each component was obtained.

Analysis of Tablet Formulation

Tablet solution was prepared in 0.1M HCl AR grade as described earlier and was further diluted with 0.1 MHCl AR grade to obtain mixed sample solutions in Beer lambert's range for each drug in the ratio of 2.5:5 from 2-12 µg/ml of LFH and 2-32 µg/ml of ORN respectively. The mixed sample solutions were analysed to obtain spectra's and absorbance values were measured at selected wavelengths for LFH and ORN. Recovery studies were carried out by adding a known quantity of standard to the preanalysed sample. The tablet analysis obtained by proposed method was validated by statistical evaluation Table 1.

RESULTS AND DISCUSSION

All the developed methods were found suitable for routine simultaneous estimation of LFH and ORN in tablet dosage form. The results of tablet analysis were validated (ICH guidelines, 1995) by statistical evaluation Table 1. The recoveries were in the range of 99.74% - 100.2% by different methods for both the analysis.

Table 1: Analysis of Tablet Formulation.

Method	Label Claim (mg/tablet)		% Label Claim Found*		Standard Deviation (SD)		Standard Error of the Mean (SEM)	
	LFH	ORN	LFH	ORN	LFH	ORN	LFH	ORN
I	250	500	99.72	100.32	0.940	0.960	0.36	0.24
II	250	500	100.41	100.37	0.252	0.309	0.09	0.18

*Average of six estimations LFH and ORN denotes levofloxacin hemihydrates and ornidazole respectively.

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