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Research Paper

Analytical Method Development and Validation of UV Spectrophotometric for Levofloxacin in Bulk and Pharmaceutical Dosage Form

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ABSTRACT

Levofloxacin is pure S(-) isomer of the racemic drug substance ofloxacin, which was introduced in 1997. It is a 3rd generation fluoroquinolone with a wide spectrum of action against antibacterial, anaerobic microorganisms and atypical pathogens. Various analytical methods have been reported in scientific literature for the analysis of levofloxacin in pharmaceutical formulations. The price of different formulations of levofloxacin varies considerably. Generic tablets are cheaper than the branded ones. In order to assure the bioequivalence and therapeutic equivalence, pharmaceutical equivalence study needs to be investigated and hence the present study was undertaken to compare the pharmaceutical equivalence of the generic and some branded formulations of levofloxacin and to compare the findings spectrophotometer. The analytical method developed for the quantification of levofloxacin in bulk samples showed absorbance maximum (λ_{max}) of 320 nm in distilled water between 200 nm and 400 nm. Linearity study between 2 μ g/ml to 10 μ g/ml was found to be linear with regression equation of $y = 0.092x + 0.0676$; ($r^2 = 0.9997$). The accuracy, precision studies showed that the recovery of drug from bulk sample and dosage form are highly accurate and precise with minimum error. The above analytical parameters indicated that the developed UV Spectrophotometric method for Levofloxacin was simple, accurate, precise and reproducible.

INTRODUCTION

Levofloxacin 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-

carboxylic acid hemihydrate (Fig.1). Levofloxacin is a chiral fluorinated carboxyquinolone, a racemate of ofloxacin. Its molecular weight is

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370.38. It is S(-) isomer of the fluoroquinolone antibacterial ofloxacin and has broad spectrum antimicrobial activity and penetrates well into cerebrospinal fluid (CSF), bone tissue, bronchial mucosa, and subcutaneous adipose tissue. Levofloxacin is given as the hemihydrate, but doses are expressed in terms of the base;

levofloxacin hemihydrate 256 mg is equivalent to about 250 mg of the base. Levofloxacin is given by mouth or intravenously to treat the susceptible infections [1]. The price of different formulations of levofloxacin varies considerably. Generic tablets are cheaper than branded ones.

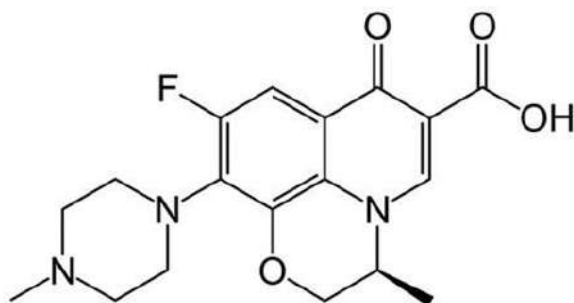


Figure 1: Structure of Levofloxacin

The FDA defines pharmaceutical equivalent products as follows “drug products are considered to be pharmaceutical equivalents if they contain the same active ingredient(s) and are identical in strength or concentration, dosage forms, and route of administration.” Pharmaceutical equivalent drug products must contain the same amount of active ingredient in the same dosage form. They may differ from each other in a variety of physical characteristics e.g. shape and size of the dosage form, scoring and / or embossing configuration of the product, packaging of (e.g. fillers, binders, lubricants, disintegrating agents) including colors, preservatives, flavors, etc. Literature survey revealed spectrophotometric method for analysis of levofloxacin [2-5]. Spectrophotometer method, because of simplicity, cost-effectiveness, sensitivity, selectivity, fair accuracy and precision, has remained competitive in an era of chromatographic technique for pharmaceutical analysis. In order to assure the bioequivalence and therapeutic equivalence, pharmaceutical equivalence study needs to be investigated and hence the present study undertaken to conduct the pharmaceutical equivalence study of the generic and some commercial formulations of

levofloxacin. Another objective of the study was to use simple and cheap chemicals and technique like spectrophotometer for determination of levofloxacin and compare it to the sophisticated technique like HPLC (high performance liquid chromatography).

MATERIALS AND METHODS

Materials

Tablets of levofloxacin (different brands viz. Generic, Ranbaxy, Dr. Reddy’s, Gland Pharma, Hetro Labs and Mankind) were procured from local drug stores. All tablets of each brand were of the same batch. The levofloxacin reference substance (assigned purity 98 %) was kindly provided by Macleods Pharmaceuticals Pvt. Ltd, Baddi, HP, INDIA. The materials were kept protected from light and moisture throughout the procedure.

Preparation of stock solution

Stock solution of levofloxacin (100 µg/ml) is prepared by dissolving exactly weighed 100mg of drug in 100ml distilled water and from this 1ml is pipetted out and diluted to 10 ml to get 100µg/ml. The obtained solution was scanned for wavelength in UV-Visible spectrophotometer in the range of 200 to 400 nm. In UV-Spectrophotometric method

wavelength 320nm was selected for determination of Levofloxacin (Fig. 2).

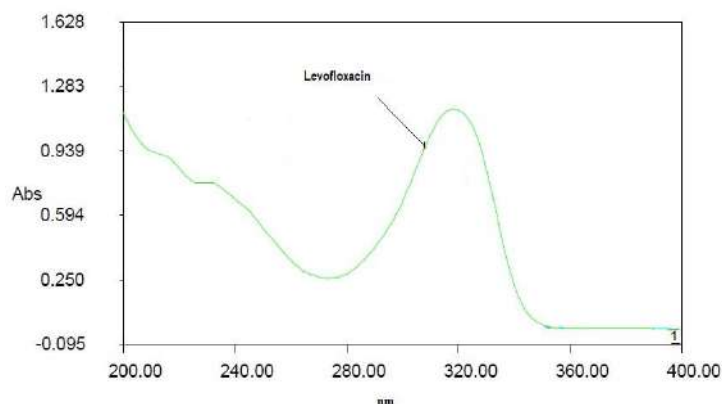


Figure 2: UV Spectra for levofloxacin

Calibration curve of levofloxacin

The standard stock solutions were transferred into series of 10ml volumetric flask and volume in each flask adjusted with distilled water to get concentration range of 2 – 10 µg/ml. The resulting solutions absorbance was measured at wavelength of 320 nm against blank distilled water. The calibration curve was constructed by plotting absorbance versus concentration. The developed analytical method was further studied for linearity, accuracy, precession and LOD and LOQ.

Linearity

The linearity of the proposed UV-VIS spectrometer method was determined in terms of correlation coefficient between concentration of the drug and its respective absorbance at different concentrations range. The data were subjected to regression analysis using least square method.

Accuracy

The accuracy study was carried out by adding a known amount of drug from the pre-analyzed tablet powder and percentage recoveries were calculated. The reproducibility of estimation was determined by performing the tablet drug content of different samples. The result shown that best recoveries 99% were obtained at each added concentration, indicating that the method was accurate [6].

Precession

Precession of the analytical method is ascertained by carrying out the analysis six times of the same sample. Calculate the % assay, mean assay and % deviation. The developed method was found to be precise as the % deviation values were below 2, respectively [6].

Ruggedness:

Ruggedness is a measure of reproducibility of test results under various conditions.

Robustness:

The robustness of an analytical procedure is a measure of its capacity to remain unaffected. It provides an indication of reliability during normal usage.

LOD

The limit of detection is the lowest amount of analyte in a sample that can be detected, but not necessarily quantitated under the stated experimental conditions and it is calculated by [7].

$$LOD = \frac{(\text{Standard Deviation})}{\text{Slope}} \times 3.3$$

LOQ

The limit of quantification is the lowest amount of analyte in a sample that can be quantified with the acceptable accuracy and precision under the stated experimental conditions and it is calculated by [7].

$$LOQ = \frac{(\text{Standard Deviation})}{\text{Slope}} \times 10$$

RESULTS



Table 1. Calibration of levofloxacin

S. No	Concentration (µg/ml)	Absorbance	Regression Data	
1	2	0.245	m = Slope (0.092)	R ² = 0.9997
2	4	0.442		
3	6	0.624		
4	8	0.802		
5	10	0.985		

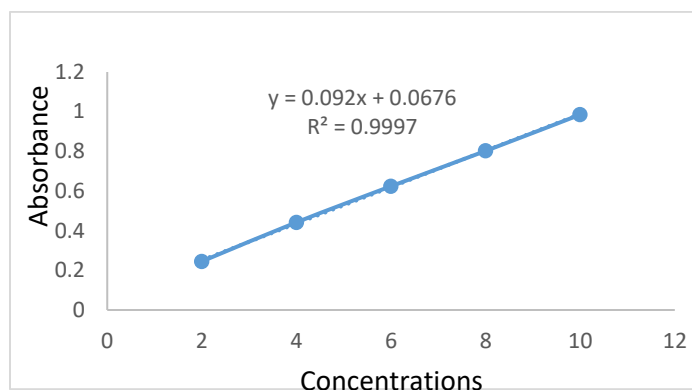


Figure 3. Calibration curve of levofloxacin

Limit of Detection (LOD): The limit of detection was found to be 0.0365µg/ml.

Precision:

Table 2: Precision of levofloxacin

Limit of Quantitation (LOQ): The limit of quantitation was found to be 0.1108µg/ml.

S.NO	Concentration	Absorbance	Mean	SD	%RSD
1	4	0.442	0.4434	0.0014966	0.3375424
2	4	0.446			
3	4	0.443			
4	4	0.444			
5	4	0.442			

Accuracy:

Table 3: Accuracy of levofloxacin

Concentration	Mean % Recovery	SD	%RSD
80%	100.2	0.001633	0.203109
100%	100.5	0.000471	0.051147
120%	99.5	0.000471	0.047203

Ruggedness:

Table 4: Ruggedness of levofloxacin

Concentration	Absorbance		SD	% RSD
	Analyst-1	Analyst-2		
2	0.245	0.246	0.00147902	0.6030662
4	0.442	0.441	0.001496663	0.3375424
6	0.624	0.626	0.001019804	0.1633254
8	0.802	0.803	0.001019804	0.127221
10	0.985	0.984	0.001019804	0.1035755



Robustness:**Table 4: Robustness of levofloxacin**

Concentration	Wavelength			SD	% RSD
	288 nm	290 nm	292 nm		
2	0.244	0.245	0.246	0.00147902	0.6030662
4	0.441	0.442	0.443	0.001496663	0.3375424
6	0.623	0.624	0.625	0.001019804	0.1633254
8	0.801	0.802	0.803	0.001019804	0.127221
10	0.984	0.985	0.983	0.001019804	0.1035755

DISCUSSION

The U.V. absorption maxima of levofloxacin in solvent were found to be 320nm. Results of the study suggest the value validating with previously reported literature values. The slope (m) of calibration curve of levofloxacin was found to be 0.092 and the linear regression equation was $Y = 0.092X + 0.0676$. Linearity studies indicated that estimation of levofloxacin between 2 µg/ml to 10 µg/ml was found to be linear with a correlation coefficient $r^2 = 0.9997$. The Accuracy and precision studies of levofloxacin showed that the accuracy of drug recovery rate was 99% and the precision was found to be below 2. The Limit of detection and quantification calculated by above equation method was found to be 0.0365 and 0.1108. Hence the developed analytical method for levofloxacin by using UV spectrophotometer was found to be accurate and precise to analyze the drug sample.

CONCLUSION

The developed UV spectrophotometric analytical was found to be economic and a simple method in estimation of levofloxacin in bulk sample. Accurate and precise result of estimation of levofloxacin in bulk sample ascertained that the method is suitable in quantification of levofloxacin in solutions and tablet dosages.

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