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RESEARCH ARTICLE

DIFFERENCE SPECTROSCOPIC ESTIMATION OF LOMEFLOXACIN IN MARKETED FORMULATION

Mamta Maheshwari[1], Ketki Verma[1], Kavita Soni[1], Prabhat Jain*[2]

1. Department of Chemistry, Sarojini Naidu Government Girls P.G. (Autonomous) College, Bhopal (M.P.)
2. Scan Research Laboratories, Bhopal (M.P.)

prabhatjain16@gmail.com

Abstract
An attempt has been made to develop a simple, sensitive and rapid spectrophotometric method of analysis for lomefloxacin in pharmaceutical dosage form using different media such as 0.1N NaOH, 0.1N HCl buffer as solvent system. These solvent systems were used to dissolve lomefloxacin and 0.100 mg/mL stock solutions were prepared for each solvent system. Lomefloxacin solution was scanned with UV spectrophotometer and the absorption maximum (λmax) was found to be 287 nm. These solvent systems could be used for routine analysis of lomefloxacin in both research laboratories and pharmaceutical industries. The methods were validated statistically as per the ICH guidelines which yielded good results concerning range, precision, accuracy, specificity and repeatability. The proposed method has been applied successfully for the determination of lomefloxacin in pharmaceutical dosage forms. No significant interference was observed from excipients, coloring and flavouring agents commonly used in the formulation. It was, thus, concluded that the proposed method is new, simple, cost effective, accurately, precise, safe and free from pollution and can be successfully employed in the routine analysis of lomefloxacin in bulk drug and tablet dosage forms.

Keywords: Lomefloxacin, spectrophotometry, analysis, reproducible.

INTRODUCTION

Lomefloxacin is one of the third generation fluoroquinolones with some specific activity in upper respiratory tract infections and community acquired pneumonia. It is also used in meningitis, osteomyclitis, urinary tract infections, sexually transmitted diseases, bacteraemia, nosocomially acquired infections, gastrointestinal infections and in combination with other agents in the treatment of tuberculosis.[1] Lomefloxacin is an antibacterial drug with wide antibacterial spectrum.[2] Chemically lomefloxacin hydrochloride is 1-ethyl-6,8 difluoro-1-4 dehydro-7-(3-methyl-1-piperazinyl)-4-oxo-3 quinoline carboxylic acid mono hydrochloride (Figure1). The diflourination at positions 6 and 8 of the quinolone ring and a piperazinyl ring at 7 carrying a methyl group improve the activity spectrum and also pharmacokinetics.[3]Complementing this broad antibacterial activity are excellent pharmacokinetics of lomefloxacin including almost complete absorption, good tissue distribution, prolonged half-life and significant post antibiotic effect permitting once daily administration.

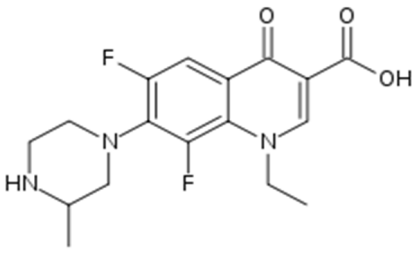

Figure 1: Chemical structure of lomefloxacin.

The purpose of the present study was to develop spectrophotometric method for the analysis of lomefloxacin in pharmaceutical dosage form which would be simple, rapid, cost-effective, reproducible and can also be used for quantitative estimation in research laboratory for research purpose and in pharmaceutical industries for routine analysis of lomefloxacin.

MATERIALS AND METHODS

Instrument

The proposed work was carried out on a Lab India 3000+ UV Visible spectrophotometer, which possesses a double beam double detector configuration with matched 1 cm quarts cells.

Chemicals and solvent

Standard lomefloxacin hydrochloride (potency 99.99%] was a kind gift from Intas Pharma Ltd. Mumbai. It was collected in an air tight vial, stored in a cool & dry place and was used without further purification. Urea obtained from Merck Chemical Division, Mumbai. Commercial tablets of lomefloxacin-400 mg (Intas Pharma) were procured from the local drug market.

Preparation of drug solutions

Stock solution - 10.0 mg of standard lomefloxacin was accurately weighed and taken in a 100 mL volumetric flask containing 50 mL of double distilled water. It was dissolved and diluted to 100mL with water. This was solution of 0.100 mg/mL and it was used as stock solution for subsequent experiments.

Determination of wavelength of maximum absorption (λmax)

The stock solution (0.100 mg/mL) was diluted 10 times to give a solution of 0.0100 mg/mL or 10.0 µg/mL solution and 3 mL of this solution was taken in a cuvette and scanned from 200 to 400 nm with Shimadzu Double Beam Lab India Spectrophotometer. The double distilled water, 0.1N NaOH, 0.1N HCl were used as the blank. Lomefloxacin was found to absorb maximum radiation at 287 nm.

Calibration curve

The series of standard solutions prepared by diluting the stock solution with double distilled water, 0.1N NaOH, 0.1N HCl, separately and the concentrations were 2 µg/mL, 4 µg/mL, 6 µg/mL, 8 µg/mL and 10 µg/mL. Absorbances of the above solutions were measured with Shimadzu Double Beam UV-VIS 160A Spectrophotometer and calibration curve was constructed by plotting absorbance versus concentration (Figures 2a-c).

Analysis of tablet formulation

Marketed formulation lomefloxacin -400 mg (Intas Pharma) were selected for tablet analysis. Twenty tablets of formulation were weighed and ground to a fine powder. An accurately weighed powder sample equivalent to 10 mg of lomefloxacin was transferred to 100 ml of volumetric flask containing 10 ml of 0.1N NaOH and 0.1N HCl. The flask was sonicate for about 10 min to solubilize the drug and the volume was make up to mark with distilled water. The solution was filtered through Wattman filter paper No 41. The filtrate was diluted appropriately with distilled water and was analysed on UV spectrophotometer against distilled 0.1N NaOH and 0.1N HCl as blank separately. Drug content of tablet formulation were calculated using calibration curve & results of statistical data shown in Table-1.

Method validation

The method was validated in accordance with ICH guidelines.[4]

Linearity & Range

The linearity of calibration curves (absorbance Vs concentration) in pure solution was checked over the concentration ranges of about 05-25 µg/ml of lomefloxacin.

Accuracy

To check the degree of accuracy of the method, recovery studies were performed in triplicate by standard addition method at 80%, 100% and 120%. In preanalyzed tablet solution, a definite amount of drug was added and then its recovery was studied. These studies were performed in by adding fixed amount of pure drug solution to the final dilution while varying the concentration of

tablet sample solution in the final dilution. The percentage recovery and percentage relative standard deviation of the recovery were calculated and shown in Table-2

Precision

To evaluate precision at different parameter like repeatability, intermediate precision and reproducibility, five dilutions in three replicates were analysed in same day, in two different days and by two analysts for day to day and analyst to analyst variation. The %RSD values for Intraday and Interday precision were < 2%, indicating that the method was sufficiently precise. The results were shown in the Table-3.

Results and discussion

The present method offers several advantages in terms of simplicity, rapidity and accuracy over many of the known procedures and can be applied for the quality control analysis of lomefloxacin in pharmaceutical reparations. Double distilled water, 0.1N NaOH, 0.1N HCl buffer were established as solvents by long trial and error method for the analysis of lomefloxacin. The proposed method is simple, rapid and handy because the solvent systems were easy to prepare. It does not require any complex calculation. The standard calibration obtained by plotting known concentrations of lomefloxacin against absorbance values was found to be linear (Figure 2a-c).

Table 1. Standard curve using 0.1N NaOH & 0.1N HCl

Conc.	Standard curve using 0.1N NaOH buffer as solvent	Standard curve using 0.1N HCl as solvent	Difference In Absorbances
0	0	0	0
2	0.245	0.125	0.12
4	0.465	0.235	0.23
6	0.668	0.355	0.313
8	0.885	0.477	0.408
10	1.123	0.589	0.534

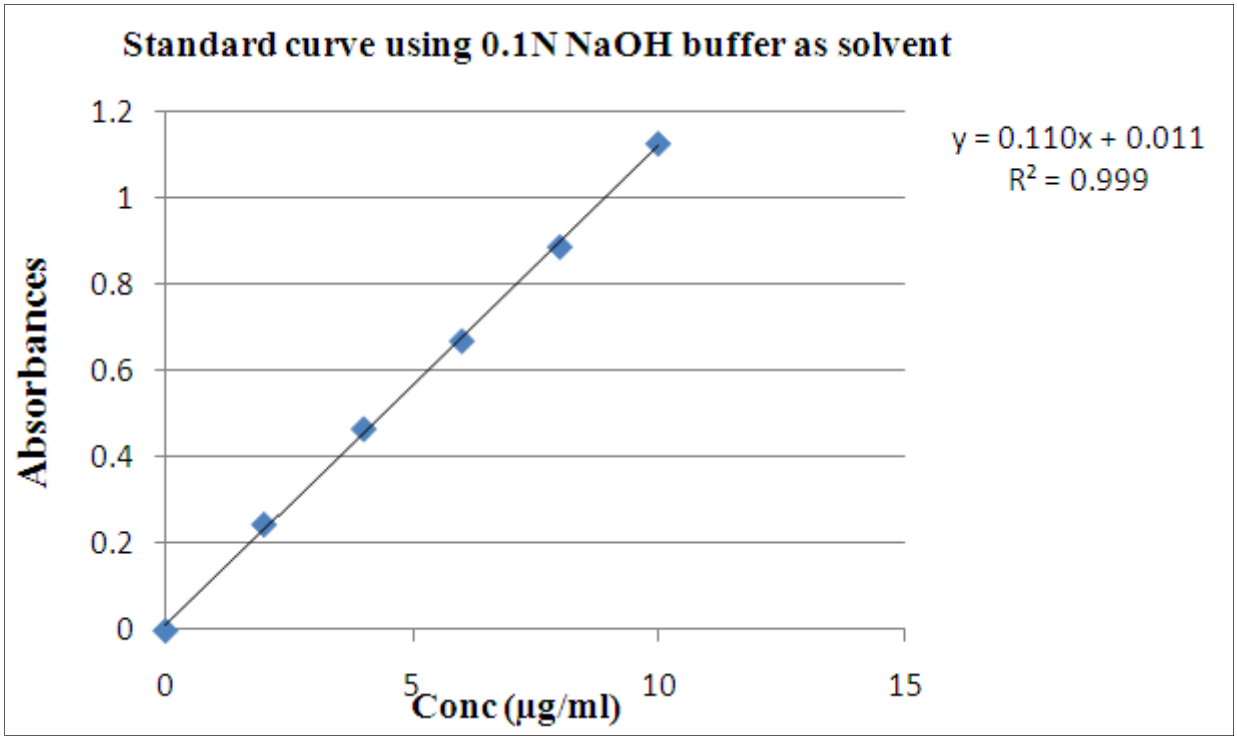

Figure 2a. Standard curve of lomefloxacin using 0.1N NaOH buffer as solvent

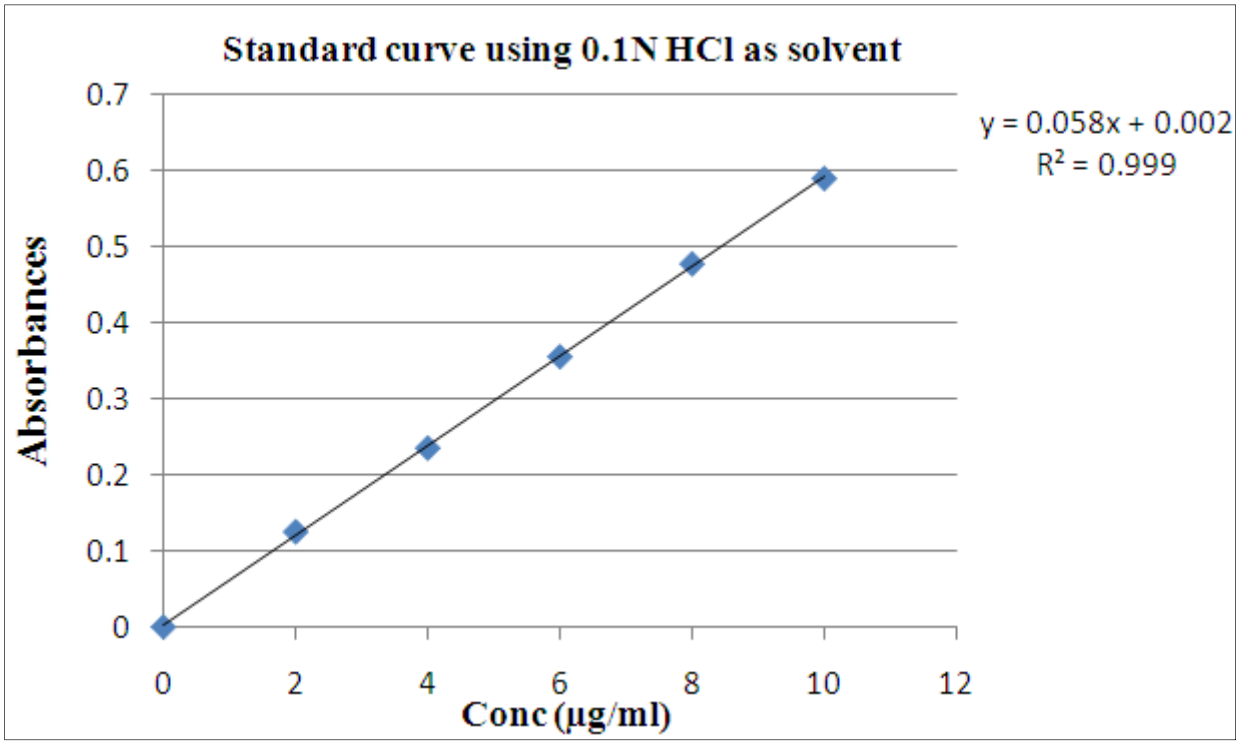

Figure 2b. Standard curve of lomefloxacin using 0.1N HCl as solvent

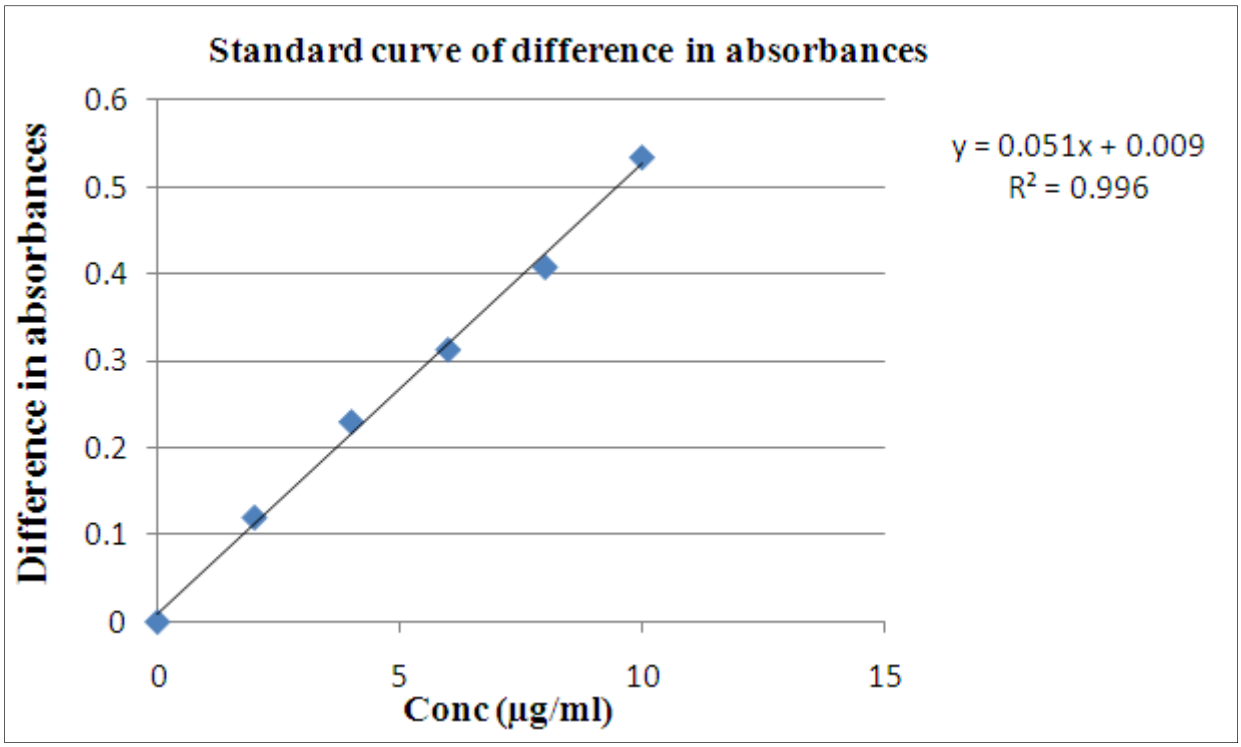

Figure 2c. Standard curve of lomefloxacin using 0.1N HCl as solvent

Table 2: Results and statistical parameters for tablet analysis

Drug	Claimed drug (in mg)	Amount found (in mg)	% mean*	S. D.*	% COV*	STD. ERROR*
Lomefloxacin	400	379.91	99.23	0.21	0.22	0.28
Lomefloxacin	400	398.13	97.66	0.96	0.98	0.76
Lomefloxacin	400	349.40	98.25	0.78	0.77	0.62

*Average of five determination

Table 3: Results of recovery studies on marketed formulations

Drug	QC Conc (µg/ml)	Recovery Level % (Amount Drug Added)	Amount of Drug Found (Mean±SD)*	% RSD
Lomefloxacin	10	80	99. 05±0. 37	0.74
		100	98. 76±0. 39	0.93
		120	99. 22±0.92	1.04
Lomefloxacin	20	80	98. 95±0. 23	0.36
		100	98. 30±0. 56	0.68
		120	98. 28±0. 58	0.88

*Average of five determination

Table 4: Results of precision

Parameter		**Mean±SD***	**%RSD**
Precision (Mean±SD)*	Repeatability	98.72±1.28	1.30
	Intermediate Precision		
	Day to Day	97.98±1.02	1.04
	Analyst to Analyst	98.49±0.12	0.12
	Reproducibility	99.91±0.72	0.72

*Average of five determination

The methods were validated in terms of accuracy, precision, repeatability and the results are recorded in Table 1-3. The accuracy of the method was determined by performing recovery studies by standard addition method in which preanalyzed samples were taken and standard drug was added at three different levels. Values of recovery greater than 98.0% indicate that proposed method is accurate for the analysis of the drug. The precision of the proposed method was estimated in terms of interday precision and intraday precision wherein the method was repeated on three different days and repeated for three different time periods in the same day respectively. SD less than 2% at each level clearly indicate that the proposed method is precise enough for the analysis of the drug.

The selectivity of the method was checked by monitoring a standard solution of lomefloxacin in presence of excipients at the same concentration level as used in tablets using the method described in the procedure for calibration curve in pharmaceutical tablets. The excipients did not show any effect on the estimation of lomefloxacin. Hence, the determination of lomefloxacin in the tablets were considered to be free from interference due to the excipients. This reveals that the potential utility of this method for the routine analysis of lomefloxacin in pharmaceutical preparations.

Conclusion

The purpose of the present study thus was to develop handy and easily operable spectrophotometric method for the analysis of lomefloxacin in pharmaceutical dosage forms which would be simple, rapid, cost-effective and reproducible. It was, thus, concluded that the proposed method is new, simple, cost effective, accurately, precise, safe and free from pollution and can be successfully employed in the routine analysis of lomefloxacin in bulk drug and tablet dosage forms.

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