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RESEARCH ARTICLE

New Spectrophotometric Method for the Estimation of Lomefloxacin in Tablets using Sodium benzoate as Hydrotropic Agent

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ABSTRACT:

A novel, safe and sensitive method of spectrophotometric estimation in ultraviolet region has been developed using 8.0 M *Sodium benzoate* solution as hydrotropic agent for the quantitative determination of lomefloxacin, a poorly water-soluble drug in tablet dosage form. Lomefloxacin shows maximum absorbance at 389 nm. Beer's law was obeyed in the concentration range of 10 to 50µg/ml, sodium benzoate does not absorb above 220nm. Commonly used tablet excipients and *Sodium benzoate* did not interfere in spectrophotometric estimation. Results of the analysis were validated statistically and by recovery studies. Using 8 M *Sodium benzoate* solution for analysis of tablet formulations of lomefloxacin, the percent label claims and percent recoveries estimated were close to 100 with low values of standard deviation, percent relative standard deviation.

Keywords: Lomefloxacin, hydrotropy, Sodium benzoate, spectrophotometry.

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INTRODUCTION:

Lomefloxacin is an antibacterial drug with wide antibacterial spectrum.[1] Chemically Lomefloxacin is 1-ethyl-6, 8-difluoro-7-(3-methylpiperazin-1-yl)-4-oxo-1, 4-dihydroquinoline-3-carboxylic acid. 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.[2]

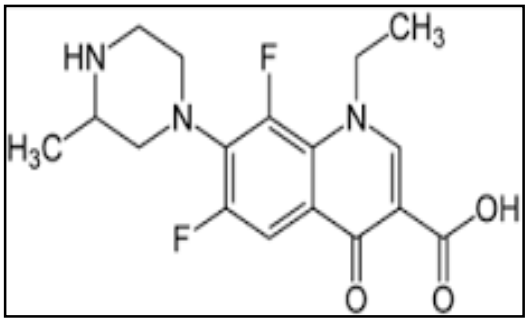

Figure 1: Structure of lomefloxacin

Hydrotropes with an amphiphilic molecular structure possess the ability to increase the solubility of sparingly soluble organic molecules in water.[3,4] It is a molecular phenomenon whereby adding a second solute (hydrotrope) helps to increase the aqueous solubility of poorly soluble solutes.[5,6]Hydrotropic agents are mentioned to be ionic organic salts. Additives or salts that increase the solubility in a given solvent are said to “salt in” the solute and those salts that decrease the solubility are said to “salt out” the solute. Several salts with large anions or cations that are themselves very soluble in water result in “salting in” of nonelectrolytes called “hydrotropic salts” a phenomenon known as “hydrotropism”.[7,8]

Materials and Methods:

Sodium benzoate was obtained from Himedia Laboratories Pvt. Ltd. and Lomefloxacin was obtained as a gift sample from Lupin limited, Bhopal and lomefloxacin tablets were purchased from the local market. All chemicals and solvents used were of analytical grade.

Preliminary solubility studies of Lomefloxacin

Solubility of lomefloxacin was determined in distilled water and 8.0 M Sodium benzoate solution at 28 ± 1^0C there was more than 15-fold enhancement in solubility of Lomefloxacin in 8.0 M *Sodium benzoate* solution, as compared to solubility in distilled water.

LINEARITY RANGE AND CALIBRATION GRAPH

Preparation of Standard Stock Solution (Stock-A)

Standard stock solutions were prepared by dissolving separately 100 mg of each drug in 80`mL mixed hydrotropic solution containing *Sodium benzoate* and the flask was sonicated for about 10minto solubilize the drug and the volume was made up to the mark with hydrotropic agent to get a concentration of 1000µg/ml (Stock-A) for both drugs.

Preparation of Sub Stock Solution (Stock-B)

Aliquots of 2.5 ml withdrawn with help of pipette from standard stock solution A of lomefloxacin and transferred into 25 ml volumetric flask separately and diluted up to 25 ml with RO Water that gave concentration of 100µg/ml (Stock-B).

Preparation of Working Standard Solution

1) Aliquots of 1.0 ml, 2.0 ml, 3.0 ml, 4.0 ml and 5.0 ml withdrawn with help of pipette from standard stock solution (Stock-B) in 10 ml volumetric flask and volume was made up to 10 ml with RO Water. This gave the solutions of 10µg/ml, 20µg/ml, 30 µg/ml, 40µg/ml and 50µg/ml of lomefloxacin.

Analysis of lomefloxacin tablets by the proposed method

Analysis of tablet formulation of Lomefloxacin by the proposed method was done by a method in which two different marketed tablet formulations of Lomefloxacin were used. Twenty tablets of

Lomefloxacin from Lomefloxacin 400mg tablets were weighed and ground to a fine powder. An accurately weighed powder sample equivalent to 100 mg of lomefloxacin was transferred to a 100.0 ml of volumetric flask containing 40 ml of 8.0 M Sodium benzoate solution. The flask was shaken for about 5 min to solubilize the drug and the volume was made up to mark with distilled water. The solution was filtered through Whatmann filter paper No 41. The filtrate was diluted appropriately with distilled water and was analyzed on UV spectrophotometer against reagent blank. Drug content of tablet formulation was then calculated Table 1.

Recovery studies

Recovery studies performed in three level (80%, 100% & 120%) using standard addition method. taking 8mg, 10 mg, and 12 mg of pure drug as spiked drug, together with preanalysed tablet powder (equivalent to 10 mg drug), were performed using the same proposed method of analysis. The percentage recoveries estimated are presented in Table 2

RESULTS AND DISCUSSION

The mean percentage drug estimated was 99.81 for formulation. These values are close to 100, indicating the accuracy of proposed analytical method. Standard deviation for marketed formulation was found to be 1.141 respectively. The value of mean percentage recoveries for formulation was found in the range from 99.04 to 99.82, which are again close to 100. This fact together with satisfactorily low values of statistical parameters further validated the method.

Determination of λmax of lomefloxacin

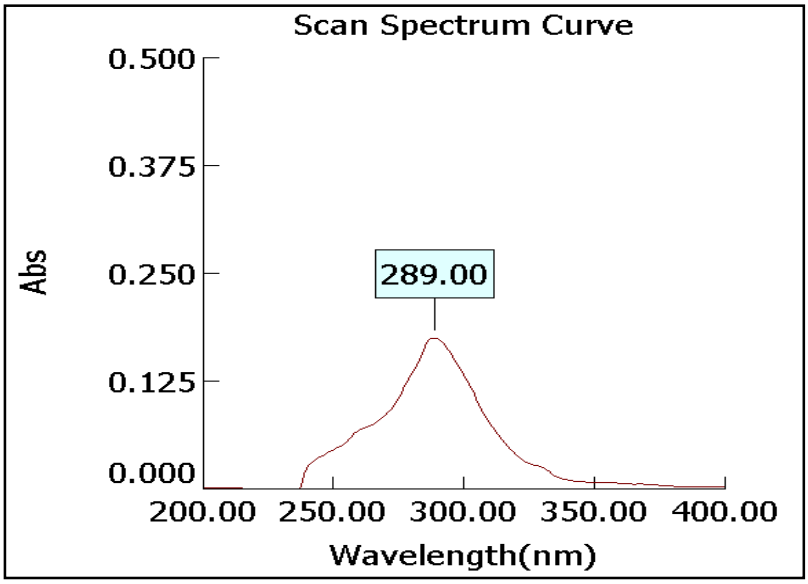

Figure 2: Determination of λmax of lomefloxacin

Table 1: Analysis data of Lomefloxacin tablet formulations with statistical evaluation

Tablet Formulation	Label claim mg/Tablets	Percentage drug estimated* (mean ± S.D)	Standard error	% RSD
I	400	99.81	1.145	0.485

*n=3

Table 2: Result of recovery studies of tablet formulations with statistical evaluation

Recovery Level %	% Recovery*	S.D.	% RSD
80	99.04	0.258	0.265
100	99.05	0.400	0.412
120	99.82	0.105	0.161

*n=3

CONCLUSION

Sodium benzoate does not absorb above 220nm (wavelength). Therefore, a large number of poorly water soluble drugs having λmax above 220 nm may be tried for the estimation by this method, provided their solubility are enhanced sufficiently by *Sodium benzoate* solution. It was thus, concluded that the proposed method is new, simple, accurate, safe, free form pollution, precise and can be successfully employed in the routine analysis. The eco-friendly, simplicity, rapidity reproducibility and economy of the proposed methods completely fulfil the objective of this research work.

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