Development and validation of novel UV spectrophotometric determination of levofloxacin hemi hydrate in bulk and pharmaceutical dosage forms

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ABSTRACT

The objective of this research was to develop and validate a simple, rapid, accurate and economical UV Spectrophotometric method for determination of levofloxacin hemi hydrate in bulk and marketed formulation. In Water, the λmax of the drug was found to be 286.4 nm. In the proposed method, levofloxacin hemi hydrate follows linearity in the concentration range 4 –10 µg/ml with a correlation coefficient (R^2) greater than 0.997 .The method was validated by following the analytical performance parameters suggested by the International Conference on Harmonization (ICH). All validation parameters were within the acceptable range. Under experimental conditions described, calibration curve, assay of tablets and recovery studies were performed. Parameters of validation prove the precision of the method and its applicability for the determination of Levofloxacin Hemi hydrate in pharmaceutical tablet formulations. The method is fast and is suitable for high throughput analysis of the drug.

Key words: Levofloxacin, Spectrophotometry, Validation, Correlation coefficient.
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INTRODUCTION

Levofloxacin Hemi hydrate is designated chemically (S)-9-Fluoro-3-methyl-10-(4-methylpiperazin-1-yl)-7-oxo-2,3-dihydro-7Hpyrido[1,2,3-de]-1,4-benzoxazine-6-carboxylicacidhemihydrate Literature survey reveals that the drug can be estimated by spectrophotometric methods, extractive spectrophotometric methods HPLC methods[1-6]. In the present investigation, Water is used in spectrophotometric estimation of drug which is safe and inexpensive when compared with existing method with 0.1NHcl. Levofloxacin is a broad-spectrum antibiotic that is active against both Gram-positive and Gram negative bacteria[7-11]. It functions by inhibiting DNA gyrase, a type II topoisomerase, which is an enzyme necessary to separate replicated DNA, there by inhibiting cell division[12].

MATERIALS AND METHODS

Instruments used
1. Balance
2. Single pan electronic balance- Sartorius GE412
3. UV visible spectrophotometer
4. UV visible double beam spectrophotometer
5. Systronics 2203(smart)
6. Matched quartz cells corresponding to 1 cm path length Reagents
1. Water

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2. Reference standard Levofloxacin
Tablets brands used
Levomac-500mg
Levoday-500mg

PROCEDURE:
*Preparation of standard stock solutions:*
The standard stock solution of drug was prepared by dissolving 50mg of the drug in 50 ml standard flask using water as a solvent to give a concentration of 1000 µg/ml. This stock solution on further dilutions is used for establishing following parameters.

Concentration of solvent and Wavelength selection:
Solutions of concentration of 9 µg/ml, 10 µg/ml, 20 µg/ml was prepared. They were subjected to scanning from 200-400nm. The dilutions were made using Water and scanned. From the different absorbance values obtained Maximum absorbance at286.4nm was selected for the present work.

Beer's law range:
The stock solution was suitably diluted with water to get concentration range from 1 to 1000 µg/ml. The solutions are scanned in UV regions between 200 to 300nm the absorption were measured at λ_{max} found. Using absorbance values against concentrations plotted the calibration curve and the linearity range can be found.
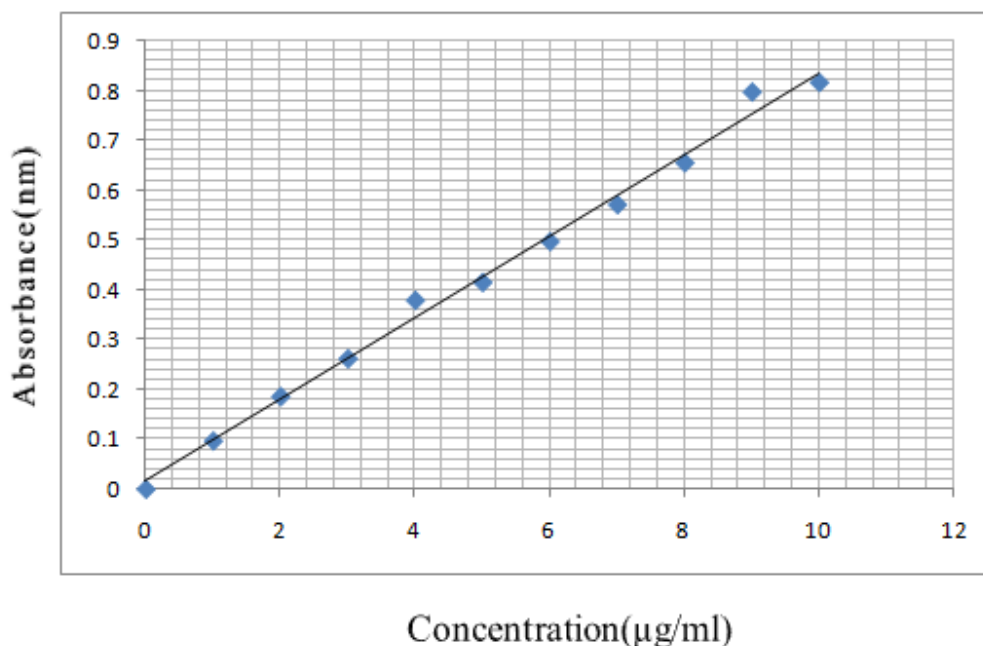
Analysis of formulation:
The proposed method is applied to the analysis of various marketed formulation

RESULTS AND DISCUSSION

1.The UV spectra of Levofloxacin were presented. the absorption maxima was observed at 286.4nm.Obeyance to beers law was confirmed by the linearity of the calibration curve of Levofloxacin .Levofloxacin showed linearity in the concentration range of 4-10µg/ml.
2.The quantitative estimation was carried out in tablet formulations by taking concentrations of 4.0-10 µg/ml. The brands of formulations shows the percentage purity values range from   98.4 to 101.2 the percentage deviation values were found to be between 01.6to 1.2.

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3. The quantitative results obtained were subjected to statistical analysis to find out standard deviation and standard error values. The relative standard deviation values are below, indicating the precision of the methodology and low standard error values show the accuracy of the method.

4.The repeatability of the method was confirmed by the assay procedures with 3 different concentrations of 3 replicates each. The results obtained in repeatability test expresses the precision of the given method.

5.The validation of the proposed method was further confirmed by recovery studies. The recovery values vary from 99.54 to 101.27% w/w. This serves as a good index of accuracy and reproducibility of the study.

CONCLUSION

The proposed method of analysis is novel, simple, cost-effective, environment friendly, safe ,accurate and Reproducible.

This method can be routinely employed in the analysis of Levofloxacin Hemi hydrate in tablet formulations precluding using Water as a solvent

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