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Method Development and Validation of Moxifloxacin in Bulk Dosage Form by UV Spectroscopy

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ABSTRACT

A simple, reliable, sensitive spectrophotometric method has been developed for the estimation of moxifloxacin in the bulk dosage form. The solution of the standard was prepared in water and methanol in the ratio of 90:10. The wavelength of moxifloxacin was found to be 232 nm. The method developed may be recommended for routine and quality control analysis of the investigated drug. The drug showed linearity in the range of100-600µg/ml with a correlation coefficient of 0.9995. The method validated for different validation parameters such as linearity, accuracy, precision, detection limit, quantitation limits, robustness, ruggedness, and the results were found to be within the acceptable limits as per the guidelines of the International Conference on Harmonisation (ICH).

INTRODUCTION:

Moxifloxacin is an antibiotic used to treat several bacterial infections like respiratory tract infections, cellulitis, anthrax, intra-abdominal infections, endocarditis, meningitis, and tuberculosis. It is available under the brand name Avelox. The chemical name of moxifloxacin is 1-Cyclopropyl-7-[(1S,6S)-2,8-diazabicyclo[4.3.0]nonan-8-yl]-6-fluoro-8-methoxy-4-oxoquinoline-3-carboxylic acid. It has a molecular formula of $C_{21}H_{24}FN_3O_4$. Moxifloxacin yellow to the yellow crystalline substance. Moxifloxacin is freely soluble in water.

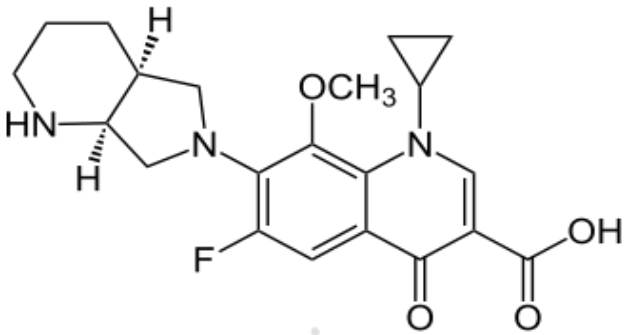

Figure No. 01: Structure of Moxifloxacin

MATERIALS AND METHODS

Drug, solvents, chemicals:

Moxifloxacin was obtained as a gift sample from Aurobindo Pharmacy Ltd. Distilled water and methanol are used as a solvent for this method and were procured from the local market.

Instruments:

Instruments employed for the study were

- ELICO-Double beam SL-210/ UV-Visible spectrophotometer with pair of 10mm matched quartz cells.

Preparation of reagents:

Preparation of stock solution:

Weighed about 100mg of Moxifloxacin and transferred into 100 ml volumetric flask and dissolve with diluents up to the mark. The concentration of Moxifloxacin about 1000µg/ml.

Preparation of Sample solution:

To determine the content of Moxifloxacin in conventional tablets, 20 tablets were weighed; their average weight was determined, and finally made the fine powder form. Tablet powder equivalent to 400 mg of Moxifloxacin was weighed and transferred into volumetric flask then dissolve with water to mark. It was kept for ultra-sonication for30mins. This was filtered through a PVDF syringe filter and then the filtrate was collected and made the final stock solution of 1000µg/ml. The same resulting solution was used for further analysis.

METHODOLOGY

Method development:

Based on the solubility and physical parameters of the drug the standard stock solution of the drug was prepared and wavelength maxima were determined. The λ max was found to be 232nm.

Based on the absorbance maxima of the drug, different dilutions were prepared and the formulation estimation was carried out.

Selection of the solvent:

The solubility of moxifloxacin was determined in a variety of solvents as per Indian pharmacopeia standards. Solubility test for moxifloxacin was carried out in different polar solvents. From the solubility studies, water and methanol in the ratio of 90:10 were selected as suitable solvents for the proposed method.

Selection of λ max:

All dilutions were scanned between the 200-400nm range using diluent as blank. From the UV spectra, 232nm was selected for the analysis of moxifloxacin.

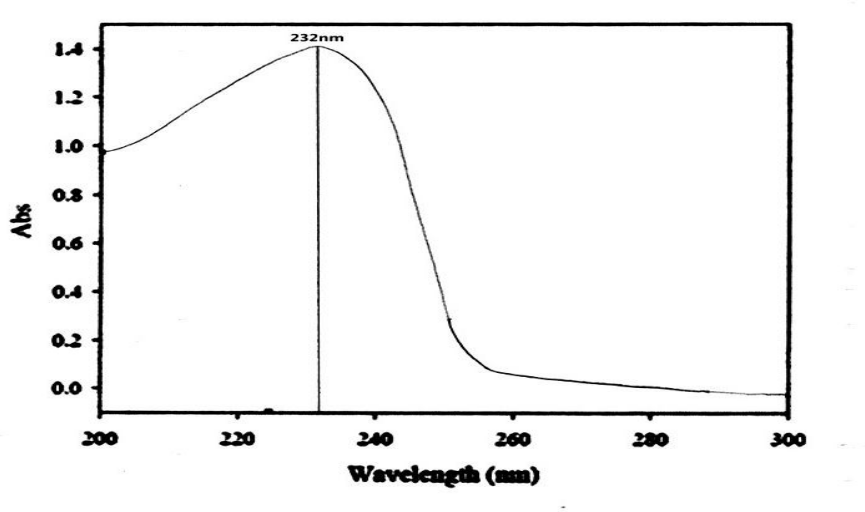

Figure No. 02: UV absorption spectrum of MOXIFLOXACIN showing absorbance at 232nm

METHOD VALIDATION

Linearity:

Weighed 100mg of Moxifloxacin API and transferred into 100 ml volumetric flask and added 60 ml of solvent to dissolve the content, mixed well, mask up to the mark with the diluent.

Linearity level - 1 (25%):

Transferred 1ml of above linearity stock into 10ml volumetric flask and diluted up to the mark. The concentration of Moxifloxacin about 100µg/ml.

Linearity level – 2 (50%):

Transferred 2ml of above linearity stock into 10ml volumetric flask and diluted upto the mark. The concentration of Moxifloxacin about 200µg/ml.

Linearity level - 3 (75%):

Transferred 3ml of above linearity stock into 10ml volumetric flask and diluted upto the mark. The concentration of Moxifloxacin about 300µg/ml.

Linearity level – 4 (100%):

Transferred 4ml of above linearity stock into 10ml volumetric flask and diluted up to the mark. The concentration of Moxifloxacin about 400µg/ml.

Linearity level - 5 (125%) :

Transferred 5ml of above linearity stock into 10ml volumetric flask and diluted up to the mark. The concentration of Moxifloxacin about 500µg/ml.

Linearity level – 6 (150%) :

Transferred 6ml of above linearity stock into 10ml volumetric flask and diluted up to the mark. The concentration of Moxifloxacin about 600µg/ml.

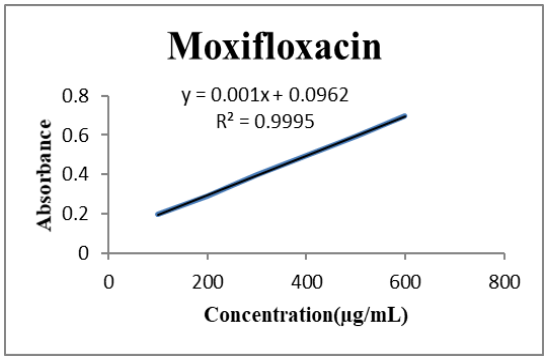

Figure No. 03: Calibration curve of moxifloxacin

Precision:

System precision: Standard solution of Moxifloxacin was prepared as per requirement and measured the absorbance.

Table no 01: Precision result

Precision	%RSD
Repeatability	0.6472
Intraday precision	0.6471
Interday precision	0.0081

Ruggedness:

To determine this parameter, the analysis was performed at the same operating conditions and the same environmental conditions but using different analyses.

Table no 02: Ruggedness result

Parameter	%RSD
Ruggedness	0.28140

Limit of detection (LOD) and limit of quantification (LOQ):

The detection limit and quantification limit of the method were calculated as 0.699µg/ml and 2.117µg/ml respectively.

Table no.03 Optical characteristics of moxifloxacin by UV method

S.NO	PARAMETERS	RESULTS
1	Wavelength λ (nm)	232
2	Linearity range (µg/ml)	200-600 µg/ml
3	Standard regression equation	0.001x+0.0962
4	The correlation coefficient (r)	0.9995
5	Slope	0.001
6	Intercept	0.0962
8	Percentage recovery	100.25%
9	LOD (µg/ml)	0.06
10	LOQ (µg/ml)	0.19

RESULTS AND DISCUSSION:

In the present work, we have estimated moxifloxacin in bulk dosage form by UV spectroscopic method. The method was validated as per ICH guidelines. The linearity was found to be 200-600 µg/ml for the UV spectroscopic method showing the correlation coefficient of 0.9995. The UV spectroscopic method was validated for linearity, precision; LOD, LOQ, and ruggedness, and the results were tabulated 1, 2, and 3. All the results were found to be within the limits as per ICH guidelines and hence the proposed method was successfully employed for the determination of moxifloxacin in its API for regular and routine analysis.

CONCLUSION:

A simple, accurate, precise method was developed for the estimation of moxifloxacin in the bulk dosage form. The method was validated as per ICH guidelines.

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