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Research Article

RP-HPLC METHOD DEVELOPMENT AND VALIDATION FOR ESTIMATION OF MOXIFLOXACIN HCL IN TABLET DOSAGE FORM

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Abstract: A rapid, sensitive and specific RP-HPLC method involving UV detection was developed and validated for determination and quantification of Moxifloxacin HCl in tablet dosage form. Chromatography was carried out on a pre-packed Enable C-18, 5µ (250 x 4.6) mm column using filtered and degassed mixture of Buffer:Acetonitril (55:45) as mobile phase at a flow rate of 1.0 ml/min and effluent was monitored at 293 nm. The pH of the mobile phase was adjusted with triethyl amine to 3.3±0.4. The method was validated in terms of linearity, precision, accuracy, and specificity, limit of quantification and limit of detection. The assay was linear over the concentration range of 20 mcg-80 mcg/ml. Accuracy of the method was determined through recovery studies by adding known quantities of standard drug to the pre analysed test solution and was found to be 99.3 %-100.2 % within precision RSD of 0.62 for Moxifloxacin HCl. The system suitability parameters such as theoritical plates, retention time factor and tailintg factor were found to be 7968, 5.855 and 1.207 respectively. The method does require only 6 mins as run time for analysis which prove the adoptability of the method for the routine quality control of the drug.

Key**words:** Moxifloxacin HCl, RP-HPLC, Estimation, Validation

INTRODUCTION

Moxifloxacin HCl is chemically 1-cyclopropyl-7-((s,s)-2,8-diazabicyclo(4.3.0)non-8-yl)-6-fluoro-8-methoxy-1,4-dihydro-4-oxo-3 quinoline carboxylic acid. Moxifloxacin is an antibiotic used to treat respiratory infections, including acute sinusitis, acute exacerbations of chronic bronchitis, and community-acquired pneumonia, as well as dermatological infections, as a second-line agent in tuberculosis. The literature survey[1-9] reveals that there is some HPLC methods have been reported. In this paper we describe a simple, inexpensive, sensitive and validated HPLC method for the determination of Moxifloxacin HCl in bulk and pharmaceutical formulation.

MATERIALS AND METHODS

Working standard of Moxifloxacin HCl was obtained from well reputed research laboratories. HPLC grade Methanol, Mankind grade Orthophosphoric acid and Triethylamine and Milli-Q water were procured from the market. The separation was carried out on isocratic HPLC system with pre-packed enable C-18, 5 µ (250 x 4.6) mm column using filtered and degassed mixture of Buffer:Acetonitrile (55:45) as mobile phase.

Buffer preparation: Transferred 2.5ml of orthophosphoric acid into 1000 ml of water and the P^H was adjusted to 3 with triethylamine, filtered through 0.45µm nylon membrane filter and degassed.

Mobile phase: Buffer and Acetonitrile were mixed in the ratio of 55:45 and sonicated to degas

Standard Preparation: Accurately Weighed and transferred Moxifloxacin HCl equivalent to 20 mg of Moxifloxacin Working Standard into a 50 ml clean dry volumetric flask, and 30 ml of mobile phase was added, sonicated for 10 minutes, and diluted to volume with mobile phase. Further diluted 5 ml to 50 ml with mobile phase.

Procedure
Flow rate 1.0 ml/min; detection wavelength 293 nm; injection volume 10 µl; column used Enable C18 (5 µm, 250x4.6 mm); column temperature: 25° C; mobile phase: Buffer:Acetonitrile (55:45).Working standard of various concentrations was prepared by taking aliquots of standard solution and diluted to get required concentration for calibration plot and which was injected.

Sample preparation: Weighed and powered 20 tablets. Transferred the powder equivalent to 400 mg of Moxifloxacin into 100 ml of clean, dry, volumetric flask and, to this added 70 ml of mobile phase and sonicated for about 15 minutes, further made up the volume with mobile phase and then filtered through 0.45 micron filter. Further diluted 1 ml of the filtrate to 100 ml with mobile phase and 10 µl of the standard preparation and assay preparation were separately injected and chromatographed.

RESULTS AND DISCUSSION

Linearity:

Linearity was demonstrated by analysing 8 different concentrations of active compound. Peak areas were recorded for all the peaks and calibration plot was constructed by plotting peak area vs concentrations of Moxifloxacin HCl which were found to be linear in the range of 20 mcg/ml-80 mcg/ml given in Table-1 and Coefficient of correlation was found 0.9990 from Fig-1

Table-1: Linearity of Moxifloxacin HCl

Concentration of moxifloxacin HCL	Average area
20	2473095
30	3617056
40	4844409
50	6011781
60	7251281
70	8361408
80	9673236

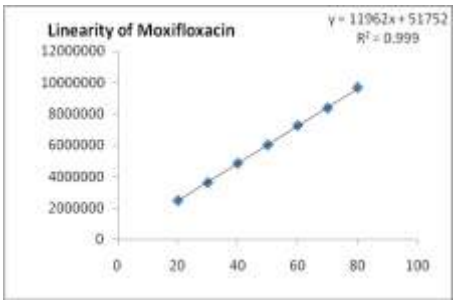

Fig-1: Linearity curve of Moxifloxacin HCl

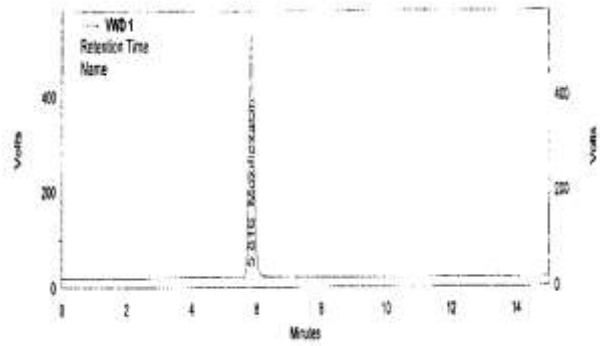

Fig-2: Chromatogram of Moxifloxacin HCL

Accuracy

Accuracy was done by recovery study using standard addition method, known amount of standard Moxifloxacin HCl in to pre-analysed samples and subjected to proposed HPLC method. The results of recovery studies are shown in Table-2.

Table-2: Accuracy Moxifloxacin HCL

	standard 50mcg (mean)	standard 100mcg (mean)	standard 120mcg (mean)
Peak Area	2444673.67	4801245.85	7249933.667
Amount found	**50.83**	**100.56**	**150.73**
%recovery	**101.66**	**100.56**	**100.49**

Precision:

To demonstrate agreement among results, a series of measurements are done with Moxifloxacin HCl six replicate injections of the specific standard at various time intervals on the same day were injected into the chromatograph and the value of % RSD was found to be 0.62. In inter-day precision same standard was injected on different days and the found % RSD was found to be 0.95 %. The results were showed in the Table -3

Table-3: Moxifloxacin HCl

	Injection	**Rt** Moxifloxacin hydrochloride	**Peak Areas** Moxifloxacin hydrochloride
Concentration 100%	1	5.406	5511356
	2	5.403	5505241
	3	5.406	5495487
	4	5.402	5506875
	5	5.412	5568214
	6	5.404	5462136
Statistical **Analysis**	**Mean**	5.4055	5508218.167
	SD	0.003563706	34367.60778
	% RSD	**0.07**	**0.62**

CONCLUSION

The regression value was found to be 0.9990 for Moxifloxacin HCl, which shows the response is linear from 20 µg/ml to 80 µg/ml. Selectivity experiment showed that there is no interference or overlapping of the peaks either due to excipients or diluents with the main peak of Moxifloxacin HCl. The percentage RSD for precision is < 2 which confirms that method is sufficiently precise and the total run time required for the method is only 6 mins for eluting Moxifloxacin HCl. The proposed method is simple, fast, accurate, and precise and can be used for routine analysis in quality control of Moxifloxacin HCl.

REFERENCES

1. Motwani SK, Khar RK, Ahmad FJ, Chopra S, Kohli K, et al. Application of a validated stability-indicating densitometric thin-layer chromatographic method to stress degradation studies on moxifloxacin. *Anal Chim Acta* , **2007**; 582: 75-82.
2. SA Shah, IS Rathod, BN Suhagia, MV Baladaniya. An HPTLC method was developed and validated for the estimation of Moxifloxacin in its tablet formulation. *Indian J Pharm Sci* , **2005**; 67: 112-115.
3. Motwani SK, Chopra S, Ahmad FJ, Khar RK. A Simple UVSpectrophotometric method was developed for the estimation of Moxifloxacin both as bulk drug and pharmaceutical formulation. *Spectrochim Acta A Mol Biomol Spectrosc* , **2007**; 68: 250-256.
4. Guerra FL, Paim CS, Steppe M, Schapoval EE. Microbiological assay method was developed and validated for the estimation of Moxifloxacin in Tablets. *J AOAC Int* ; **2005**; 88: 1086-1092.
5. Wen D, Lin Z, Milosavlsev S, Shum L An LC-MS/MS method was developed for the estimation of Moxifloxacin in human plasmaAvantix Laboratories, Inc, 2Novartis Pharmaceuticals Corporation.
6. Boubakar B Ba, Etienne R, Ducint D, Quentinc, Sauxmc. An HPLC method was developed and validated for the estimation of Moxifloxacin in growth media. *J Chromatogr B Biomed Sci Appl* , **2001**; 754: 107-112.
7. Taylor, Francis.Developed Differential pulse polarographic method for the determination of Moxifloxacin in pharmaceutics, serum and urine. *Analytical letters ;* **2007***;* 40: 529-546.
8. Mendum J, Denny RC,Thomas MN Vogel's Text book of Quantitative Analysis, sixth Edn, Pearson education ltd. **2004.**
9. Swartz ME, Krull IS Analytical Method Development and Validation, Marcel Decker, Inc., New York, **1997**; 25-91