IOSR Journal Of Pharmacy *www.iosrphr.org*
(e)-ISSN: 2250-3013, (p)-ISSN: 2319-4219
Volume 9, Issue 4 Series. I (April 2019), PP. 30-41

Development and Validation of a Stability-Indicating Method for Assay of Moxifloxacin in Oral Pharmaceutical Dosage Forms by HPLC

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ABSTRACT: The current study describes a novel stability indicating Reversed Phase High-Performance LC method for the determination of Moxifloxacin (MOXI) in pharmaceutical formulation and separate impurities which may be present in the formulation from the core drug peak. The chromatographic separation was carried out on Agilent technologies model SPD 20A prominence UV detector, utilizing Agilent zorbax eclipse XBD - C_{18} Column (based on 99.99 % ultra high purity silica) 150 mm × 4.6 mm, 3.5 µm particle size, utilizing methanol : phosphate buffer pH 2.5, (60:40 % v/v) as mobile phase at flow rate of 1.2 ml/minute with an injection volume of 20 µl was selected for this study. The separation was carried out at a room temperature and the eluents were observed by photo diode array detector set at 295.5 nm. The retention time of MOXI obtained was at 5.495 minutes. The calibration curve for MOXI was linear ($r^2 = 0.9999$) over the concentration range of 4 - 18 µg/ml with LOD and LOQ of 0.001 µg/ml and 0.003 µg/ml respectively. A recovery of MOXI in tablet formulation was observed in the range 100.883 - 101.66 % w/w. Intraday and Interday precision is less than 2 in all cases. Percentage assay of MOXI tablets (Avelox) was found to be 99.74 ± 1 % w/w. The stability of the method was demonstrated by forced degradation studies under conditions of acidic, alkaline, oxidation, photolytic, thermal and UV stress conditions as per ICH Q1A (R2) guidelines. Thus the proposed method for MOXI was found to be simple, precise, accurate and robust and practicable for the estimation of MOXI in bulk as well as pharmaceutical oral dosage form without an interference with time.

Key words: Moxifloxacin, RP-HPLC, Validation, Forced degradation.

Date of Submission: 27-03-2019 Date of acceptance: 12-04-2019

I. INTRODUCTION

Moxifloxacin (1-cyclopropyl-6-fluoro-1,4-dihydro-8-methoxy-7-[(4aS,7aS)-octahydro-6H-pyrrolo [3,4-b] pyridin -6-yl]-4-oxo-3-quinoline carboxylic acid). The 4th generation antibiotic drug of the fluoroquinolone antibiotic act by targeting the bacterial enzymes in cell DNA gyrase and topoisomerase IV. In moxifloxacin the fluorine on position six of naphthyridine ring. The fluorine atom helps to make broad range of activity against Gram -ve as well as Gram +ve pathogens. The very important results are achieved via the methoxy at C_8 which significantly delays the selection of resistance and the bicyclic amine at C_7 minimizes drug efflux. Moxifloxacin solubility in water 1146 mg/L at 25^{O}C. LogP is Log K 0/w=0.95. It has both acidic pKa (5.69) and basic pKa of 9.42.

Literature Survey shows that the MOXI has been estimated by Ultra violet spectrophotometric method [1-2], High performance liquid chromatographic method [3-4], RP-HPLC [5-7], High performance thin layer liquid chromatographic method [8] and LC-MS/MS [9] in biological fluids like human and rat plasma. However no stability indicating High Performance LC method has been reported for the estimation of MOXI in bulk and pharmaceutical dosage forms thus far. Hence the prominent important objective of the present research is to develop and validate a precise, sensitive, robust and simple liquid chromatography method for MOXI in its bulk and pharmaceutical dosage form and stress degradation studies of MOXI as per International Conference on Harmonization (ICH) Q2 (R2) guidelines. Figure 1 shows the chemical structure of Moxifloxacin.

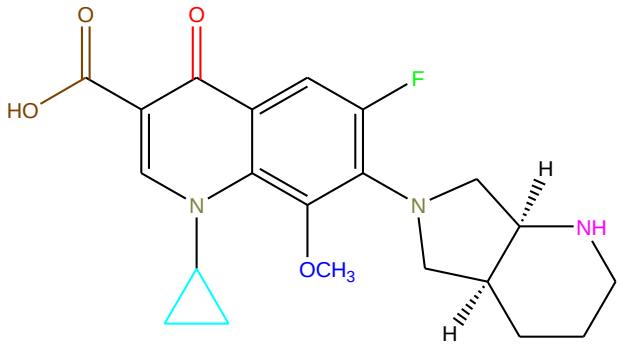

Figure 1: Chemical structure of Moxifloxacin.

II. MATERIALS AND METHODS

2.1 Chemicals and Reagents

MOXI drug was supplied as gift sample by Hetero Drugs Ltd., Hyderabad, Telangana, India. The marketed formulation Avelox tablets containing 400 mg of MOXI were obtained from local market. Acetonitrile, HPLC grade water, Methanol was obtained from E. Merck specialties private Ltd., Mumbai, India. Na_2HPO_4 is obtained from Merck. Triethylamine is procured from Sigma-Aldrich.

2.2 Instrument

The HPLC system utilized was Agilent technologies HPLC with a gradient pump connected to UV detector set at 295.5 nm. Empower pro 2 software was utilized for data acquisition. A digital balance (Essae vibra AJ (0.001 g)) and a sonicator (Model no-91250 mode) were utilized in this study.

2.3 Method development

2.3.1 Selection of chromatographic technique: MOXI is soluble in methanol. So, RP-HPLC method was tried first for the analysis of MOXI and it showed proper elution during the preliminary trials. SIAM need separation of impurities and degradants during degradation and drug peak need to be separated for obtaining precise and accurate assay values.

2.3.2 Selection of detection wavelength: The UV-DAD detector is used for MOXI. The UV spectrum of the MOXI was recorded by scanning ranging from 200 - 400 nm using methanol/water (50:50) as medium. From this absorption spectrum λ_{max} at 295.5 nm was selected for the well-mannered study. Fig 2 shows the overlain spectra of MOXI. In actual fact photo diode array detector is used which help in identifying closely related substances by looking purity plots.

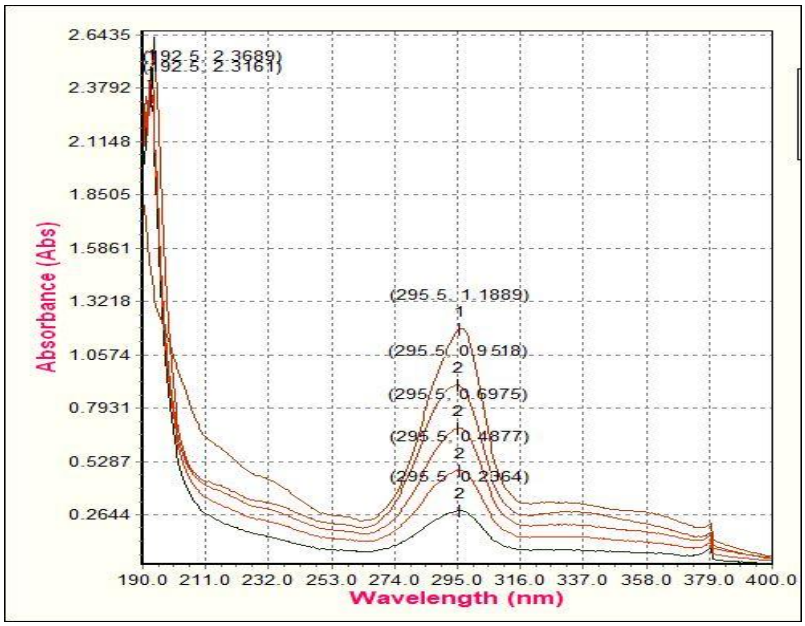

Figure 2: Overlain spectra of Moxifloxacin (λ_{max} 295.5 nm).

2.3.3 Chromatographic conditions

Chromatographic separation was attained on Agilent zorbax eclipse XBD - C_{18} Column (based on 99.99 % ultra high purity silica) 150 mm × 4.6 mm, 3.5 µm particle size utilizing methanol and phosphate buffer (pH 2.5) as mobile phase. The mobile phase was filtered and degassed through 0.22 mm filter paper. The Flow rate was kept at 1.2 ml/minutes. Column temperature is set to ambient (30 °C), for a high-quality peak shape with required peak area was obtained with injection volume of 20 µl with a flow rate of 1.2 ml/min and the detector wavelength of 295.5 nm were set for the chromatographic study. The retention time obtained of MOXI was at 5.495 min. Diluent used was mobile phase, filtered through 0.45 micron filter and degassed before use. Table 1 represents the Optimum chromatographic conditions and system suitability results.

Table 1: Optimum chromatographic conditions and system suitability results.

Parameter	**Chromatographic conditions**
Instrument	Agilent Technologies
Column	Agilent zorbax eclipse XBD - C_{18} Column (based on 99.99 % ultra high purity silica) 150 mm × 4.6 mm, 3.5 µm particle size.
Detector	photo diode array detector(PDA)
Flow rate	1.2 ml/min
Detection wavelength	295.5 nm
Run time	10 minutes
Temperature	Ambient temperature (30 °C)
Volume of injection loop	20 µl
Retention time (Rt)	5.495 minutes
System suitability results	
Theoretical plates (acceptance criteria NLT 2000)	8865
USP tailing factor (Acceptance criteria NMT 1.5)	1.12
% RSD for MOXI peak area from 6 replicate injections of standard solution (Acceptance criteria NMT 2.0)	0.1185

2.4 Method development trials

Infact the main aim of the method development trials was getting shorter run time less than ten minutes. Plate count and tailing should be optimum. Method development trails are shown in table 2.

Table 2: Method development trails of moxifloxacin.

Name	**Column**	**Mobile phase**	**Flow rate and detection wavelength**	**Observation**
Moxifloxacin	Agilent zorbax eclipse XBD - C_{18} Column 150 mm × 4.6 mm, 5 µm)	Glacial acetic acid pH 4.0: methanol (50:50)	1 ml and 295.5 nm	More peak tailing and lesser plate count is observed.
Moxifloxacin	Welchrom C_{18} (100 mm × 4.6 mm, 5 µm particle size	Glacial acetic acid pH4.0: acetonitrile (60:40)	1 ml and 295.5 nm	Unacceptable tailing(2.8) is observed. Plate count and retention time reduced.
Moxifloxacin	Welchrom C_{18} (150 mm × 4.6 mm, 5 µm particle size	Phosphate buffer pH 4.0: acetonitrile (60:40)	1ml /min and 295.5 nm	Retention time is more reduced and may cause problems with impurities, tailing is also somewhat reduced.
Moxifloxacin	Welchrom C_{18} (150 mm × 4.6 mm, 5 µm particle	Acetate buffer 4.0: acetonitrile (50:50)	0.9 ml/min and 295.5 nm	There is unacceptable tailing is observed and

	size			retention time and plate count is reduced.
Moxifloxacin	Agilent zorbax eclipse XBD - C_{18} Column 150 mm × 4.6 mm, 5 µm)	Phosphate buffer pH 3.0: methanol (65:35 v/v).	1 ml/min and 295.5.	good quality response observed for moxifloxacin standard.

2.5 Preparation of phosphate buffer pH 2.5

Dissolve 2.76 g sodium dihydrogen phosphate (NaH_2PO_4) in 1000 ml of HPLC grade water and add 1 ml of triethyl amine and adjust the pH to 2.5 ± 0.05 with diluted ortho phosphoric acid solution. Filter through 0.45 µm membrane filter.

2.5.1 Preparation of mobile phase

The above stated prepared phosphate buffer (pH 2.5) 630 ml is mixed with 370 ml volume of methanol and degassed by sonication. The prepared solution is used as mobile phase.

2.5.2 Preparation of standard stock solution and standard solution

For preparation of standard stock solution, 30 mg of MOXI was precisely weighed and transferred to 100 ml of volumetric flask which contains 50 ml mobile phase and sonicate to dissolve and dilute to volume with mobile phase and mix well. For preparing standard solution pipette out 4 ml of the above said stock solution is taken into a 100 ml of volumetric flask and dilute to volume with mobile phase and mix well. Filter the above prepared solution with 0.45 µm millipore filter paper.

2.5.3 Tablets sample preparation

Twenty Avelox® (MOXI) tablets were weighed, average weight was calculated, and was made to fine powder with mortar and pestle. MOXI tablet powder equivalent to 250 mg is taken into a 250 ml volumetric flask to which 200 ml of Mobile phase was added. The flask is then ultra-sonicated for 20 minutes and volume is made up with the mobile phase and mix well. From the above solution 3 ml is pipetted out and transferred into 250 ml volumetric flask and filled up with mobile phase and mix well. The tablet MOXI solution is then filtered through 0.45 micron filter. Inject mobile phase as blank, standard preparation should be injected 5 injections and test preparation (in duplicate) record the chromatogram and measure the peak response.

2.6 Analytical method validation

The developed method was validated for different parameters like linearity, precision, accuracy, specificity, ruggedness, robustness, LOD and LOQ as per Q1A (R2) guidelines[10-11].

2.6.1 System suitability

The system suitability test was carried out on freshly prepared MOXI standard solution was used for the evaluation (as per test method) of the system suitability parameters such as theoretical plate count, tailing factor, % RSD and results were observed. The system suitability data and the optimum chromatographic conditions are reported. System suitability parameters are represented in table 3.

Table 3: System suitability parameters.

Injection Number	Peak area in AU
1	1183572
2	1180569
3	1180367
4	1180574
5	1180689
6	1180673
Mean	1188112.8
SD	1399.7
% RSD (acceptance criteria: The % RSD for peak area of MOXI form 6 replicate injections of standard solution should not be more than 2.0)	0.1186

2.6.2 Linearity

Linearity of detector response was established by plotting a graph between concentrations versus area. A series of dilutions of MOXI standard were prepared in the concentration range of 4 µg/ml to 18 µg/ml from MOXI standard stock solution which is 12 µg/ml and analyzed as per test method. A graph was plotted with concentration in µg/ml on X- axis versus peak area on Y-axis and the correlation coefficient was determined. Calibration of moxifloxacin is shown in Fig 3.

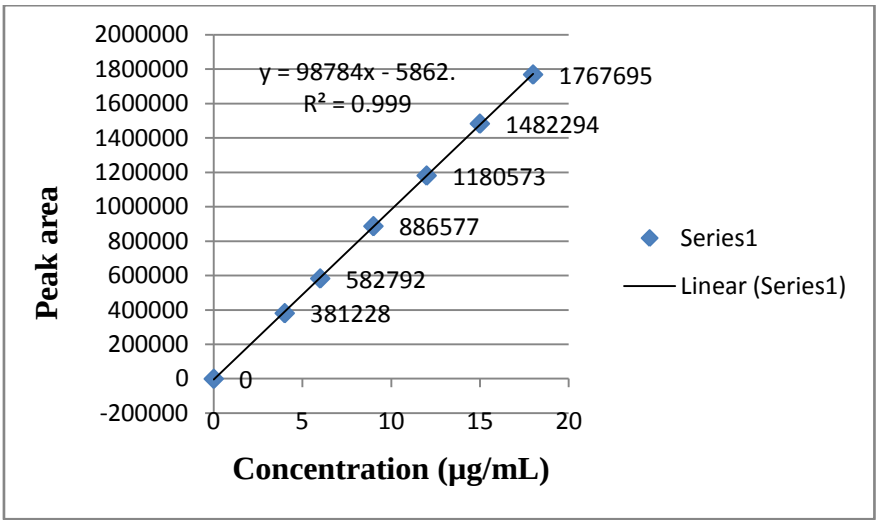

Figure 3: Calibration graph of Moxifloxacin.

2.6.3 Precision

Precision of the test method was determined by repeatability, intra-day and inter-day precision. Repeatability was confirmed by injecting same concentration in six replicates and corresponding areas were calculated. Intra-day and Inter-day variation MOXI was analyzed by selecting three concentrations which were 9, 12 and 15 µg/ml from linearity range. Intra-day analysis assay was performing same day whereas inter-day analysis assay was carried on three different days in replicates of three as per test method. The respective peak areas for different concentrations were reported. The % relative standard deviation for % assay results is found to be within the limit. Indeed no significant variation in % assay. Intra-day and Inter-day precision studies are shown in table 4 and 5 respectively.

Table 4: Intra-day precision studies of Moxifloxacin.

Amount of Standard taken (µg/mL)	Area (mAU)	Retention Time (Rt) (minutes)	Tailing factor	Theoretical plates	% Relative Standard Deviation (n =3)
Day-1 (Morning)					
9	886577	5.493	1.2	9348	0.23
12	1180573	5.492	1.4	9359	0.12
15	1482294	5.493	1.3	9327	0.14
Day-1 (Afternoon)					
9	886573	5.493	1.0	9342	0.22
12	1180571	5.493	1.4	9355	0.11
15	1482291	5.493	1.1	9329	0.12
Day-1 (Evening)					
9	886571	5.493	1.2	9347	0.11
12	1180570	5.492	1.3	9357	0.13
15	1482293	5.493	1.0	9324	0.22

Table 5: Inter-day precision studies of Moxifloxacin.

Amount of Standard taken (µg/ml)	Area (mAU)	Retention Time (Rt) (minutes)	Asymmetry factor	Theoretical plates	% Relative Standard Deviation (n =3)
Day-1					
9	886576	5.494	1.1	9346	0.12
12	1180571	5.493	1.2	9357	0.14
15	1482292	5.493	1.3	9329	0.13

Day-2					
9	886570	5.493	1.0	9348	0.13
12	1180573	5.492	1.2	9359	0.14
15	1482294	5.493	1.2	9322	0.24
Day-3					
9	886572	5.492	1.4	9342	0.23
12	1180570	5.493	1.1	9351	0.11
15	1482291	5.493	1.0	9327	0.12

2.6.4 Accuracy

Accuracy study was determined by recovery studies. This accuracy study was conducted for MOXI intact tablet from about 50 %, 100 % and 150 % of the initial assay concentration. Sample solutions were prepared in triplicate for each level and analyzed as stated by test method. The individual % recovery, mean % recovery and % relative standard deviation for recovery at each level were calculated and analyzed. Indeed the individual recovery should be between 95.0 and 105.0. The average recovery of each level should be between 97.0 and 102 %. As a matter of fact the results are found to be within limit. Recovery studies for moxifloxacin is shown in table 6.

Table 6: Recovery studies for moxifloxacin.

% Level spiked	Sample No.	% Recovery	Mean % Recovery	% RSD
50	1	103.5	101.0667	3.25
	2	100.5		
	3	103.4		
100	1	100.8	101.5333	0.93
	2	101.2		
	3	102.6		
150	1	101.4	100.8333	1.15
	2	99.5		
	3	101.6		

Acceptance Criteria

1) The Individual % recovery should be between 95.0 and 105.0.

2) The average % recovery of each level should be between 97.0 and 102.0 and % RSD for Recovery at each level should not be more than ±5.

2.6.5 Specificity

The purpose of this study is to evaluate by determining the effect of excipients, additives present in the formulations interfered with the analysis or not. MOXI standard was injected with known quantities of impurities. All the impurities were resolved and are not interfering with the retention time of MOXI. Specificity chromatogram of moxifloxacin with impurities is shown in Fig 4.

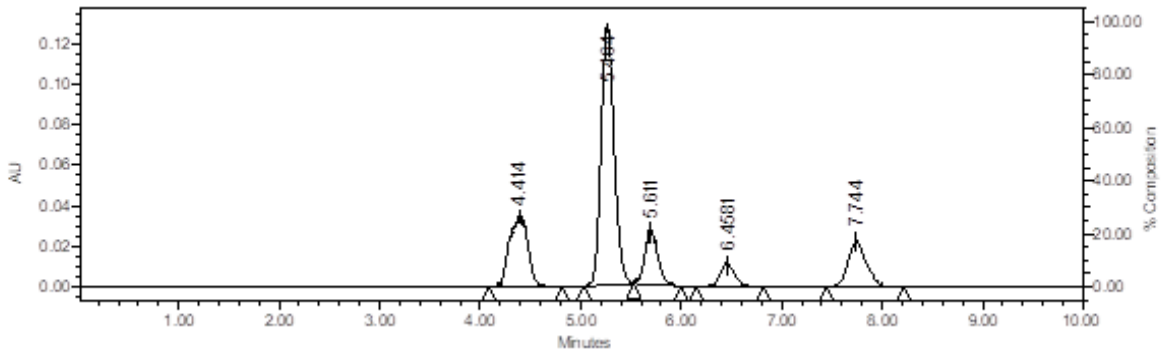

Fig 4: Specificity chromatogram of moxifloxacin.

2.6.6 Placebo interference

The purpose of this study is to evaluate the interference from placebo. Samples were prepared in duplicate by taking placebo equivalent to the amount present in the test preparation and analyzed as indicated by the test method. Chromatograms of placebo preparations are not showing any peak at the retention time of analyte peak i.e., MOXI.

Placebo interference is shown in table 7 and Fig 5 shows the typical chromatogram of placebo.

Table 7: Placebo interference.

Sample No.	Peak found at RT of analyte peak (Yes/No)	Acceptance criteria
1	No	Placebo should not show any peak at the retention time of moxifloxacin.
2	No	

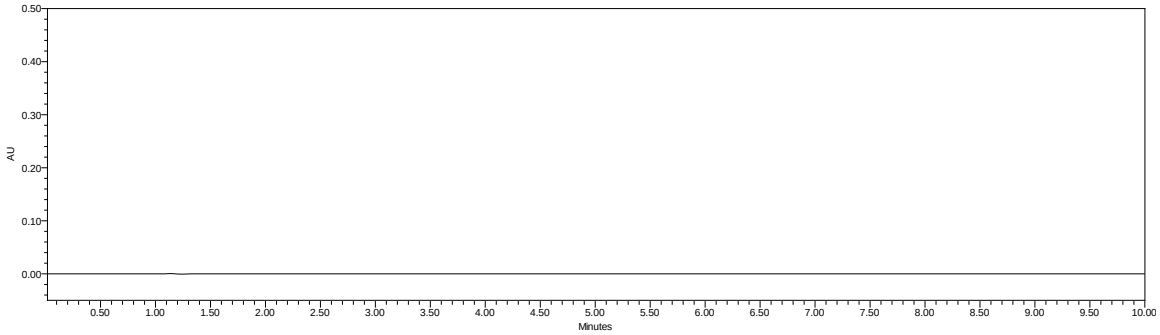

Fig 5: Typical chromatogram of placebo.

2.6.6 Robustness

Robustness of the method was determined by varying the method parameters such as change in flow rate (± 0.2 ml/min), wavelength (± 1 nm) and mobile phase composition. Table 8 represents the studies of moxifloxacin.

Table 8: Robustness studies of Moxifloxacin.

S. No	Parameter	Optimized	Used	Retention time (Rt), min	Plate count	Tailing factor	% RSD
1	Flow rate (± 0.2 ml/min)	1.2 ml/min	1.0 ml/min	5.595	9442	1.1	0.11
			1.2 ml/min	5.495	9348	1.06	0.12
			1.4 ml/min	5.392	9341	1.1	0.14
2	Detection wavelength (± 1 nm)	295.5 nm	294.5 nm	5.495	9344	1.12	0.13
			295.5 nm	5.495	9348	1.06	0.12
			296.5 nm	5.495	9392	1.06	0.22
3	Mobile phase composition (± 5%)	Methanol : Phosphate buffer (pH 2.5)	55:45 %	5.493	9345	1.1	0.11
			60:40 %	5.495	9348	1.06	0.12
			65:50 %	5.491	9320	1.1	0.25

Acceptance criteria: Plate count NLT 2000, tailing factor NMT 1.5, % RSD NMT 2.0.

2.6.7 Limit of Detection (LOD) and Limit of Quantification (LOQ).

A limit of detection (LOD) and a limit of quantification (LOQ) were calculated according to the formulae:

LOD = 3.3* σ/s

LOQ = 10* σ/s

Where, 'σ' is the standard deviation of 'y' intercept of regression line and 's' is the slope of the calibration curve. Table 9 shows LOD and LOQ results of moxifloxacin.

Table 9: LOD and LOQ results of Moxifloxacin.

Limit of Detection (LOD)	0.001 µg/mL.
Limit of Quantitation (LOQ)	0.003 µg/mL.

2.7 Forced degradation studies

To conduct the forced degradation study, 10 mg MOXI was subjected to acidic, alkaline, oxidation, thermal, UV light, humidity and photolytic conditions. For acidic degradation, 10 mg MOXI was dissolved in 5 ml of mobile phase to which 5 ml of 0.1 N HCl was added and heated under reflux at 40 °C for 3 days. The mixture was neutralized by the addition of 0.1 N NaOH. For alkaline degradation, 10 mg drug was dissolved in 5 ml of mobile phase to which 5 ml of 0.1 N NaOH was added and heated under reflux at 40 °C for 3 days before the mixture was neutralized by the addition of 0.1 N HCl.

For degradation under oxidising conditions the drug was heated under reflux with 30 % H_2O_2 (v/v) at 40 °C for 3 days. For thermal degradation the powdered drug was exposed at 105 °C for 72 hours. Regarding UV light degradation, powdered MOXI was exposed to UV light for 3 days. Pharmaceutical MOXI dosage forms were also subjected to the same stress conditions to determine whether any peaks arose from the degraded excipients. After completing the treatments, the MOXI solutions were left to return to room temperature diluted with solvent mixture to obtain 10 µg/ml solutions. Stressed samples were analyzed as per test method with PDA detector. Chromatograms of stressed samples were determined for peak purity. For all forced degradation samples the purity angle is less than purity threshold with no purity flag for MOXI which indicates that there is no interference from degradants in estimation of MOXI. Table 10 shows the stability studies of moxifloxacin. Fig 6-11 represents the different sorts of degradation studies.

Table 10: Stability studies of Moxifloxacin.

Sr. No.	Stress Conditions	Observation	Moxifloxacin			Purity Flag
			Type	Purity Angle	Purity Threshold	
1.	Treated with 0.1 N HCl (5 ml) solution for 3 days (sonicated at 40°C)	No degradation of drug is seen	Standard	0.180	0.380	No
			Sample	0.160	0.365	
2.	Treated with 0.1 N NaOH (5 ml) solution for 3 days (sonicated at 40°C)	No degradation of drug is seen	Standard	0.187	0.370	No
			Sample	0.150	0.360	
3.	Treated with 30 % H_2O_2 (5 ml) solution for 3 days	No degradation of drug is seen	Standard	0.175	0.310	No
			Sample	0.148	0.420	
4.	Kept in oven at 105 °C for 72 hours	No degradation of drug is seen	Standard	0.168	0.290	No
			Sample	0.170	0.420	
5.	Kept in humidity chamber for five days	No degradation of drug is seen	Standard	0.165	0.360	No
			Sample	0.155	0.420	
6.	Kept in photolytic chamber for 3 days	No degradation of drug is seen	Standard	0.160	0.260	No
			Sample	0.158	0.420	

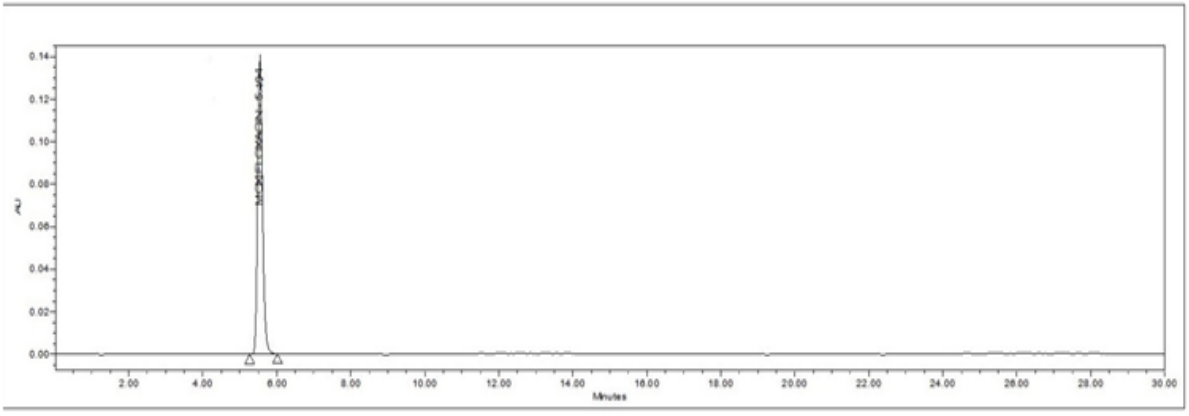

Figure 6: Typical chromatogram of Acid Condition Sample.

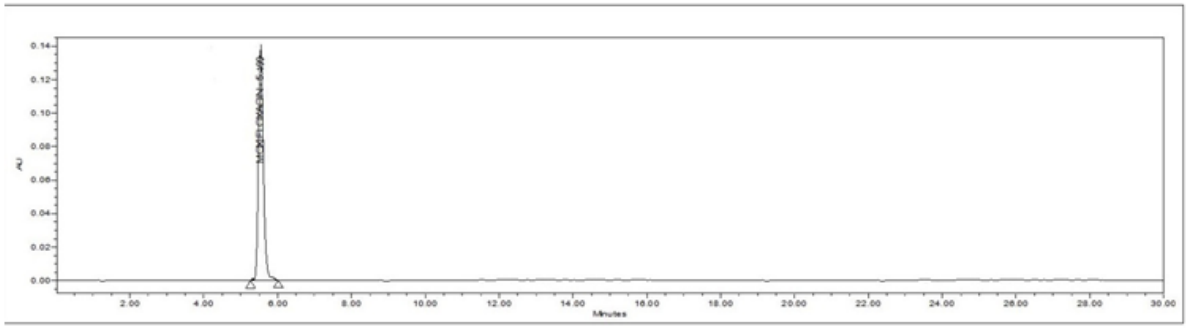

Figure 7: Typical basic degradation of sample.

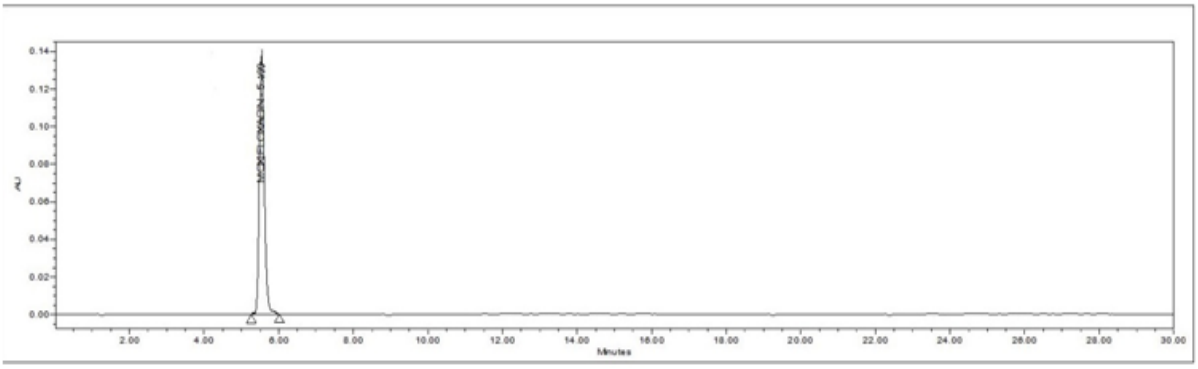

Figure 8: Typical chromatogram of oxidative condition of sample.

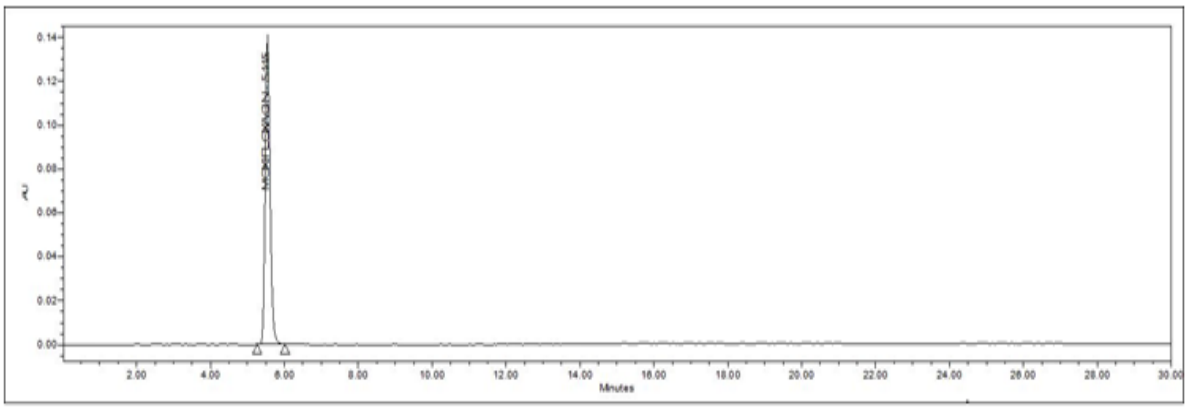

Figure 9: Typical chromatogram of high temperature condition sample.

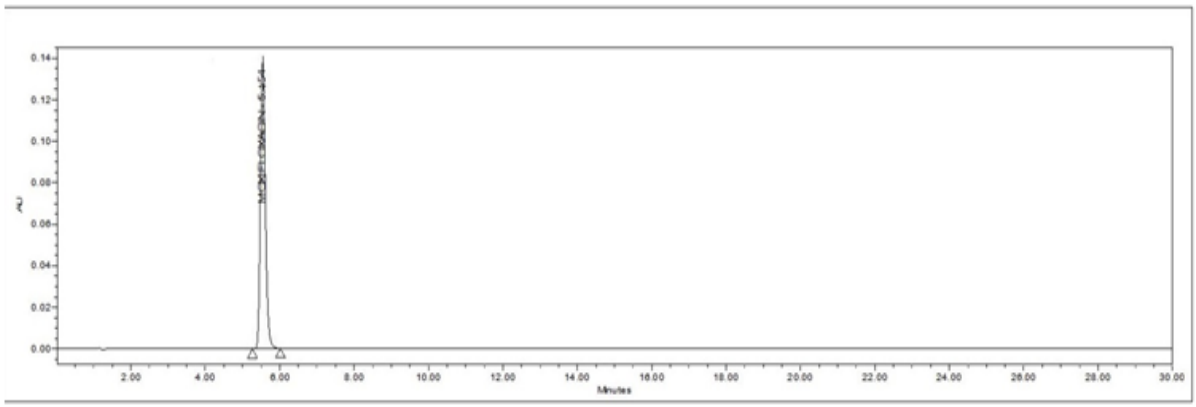

Figure 10: Typical chromatogram of photolytic condition sample.

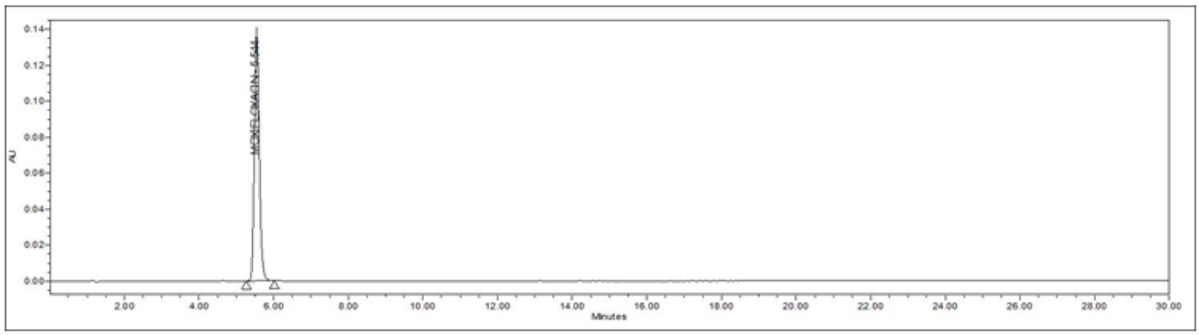

Figure 11: Typical chromatogram of humidity condition sample.

2.8 Assay of marketed formulation

Twenty Avelox® (MOXI) tablets were weighed, average weight was calculated, and was made to fine powder. MOXI powder proportionate to 10 mg was taken in a 10 ml volumetric flask to which small amount of mobile phase was added. The flask is then ultra-sonicated for 15 minutes and volume is made up with the mobile phase. The tablet MOXI solution is then filtered through whatmann filter paper (No. 42) to get rid of insoluble materials. From the above solution 10 ml is added to 100 ml with diluent so as to attain concentration of 100 µg/ml for the assay. It was further diluted according to the need and then analyzed following the proposed procedure. The content of the Avelox was calculated either from the previously plotted calibration graph or utilizing regression equation. Standard chromatogram and standard peak purity chromatogram of moxifloxacin are shown in Fig 12 and 13. Sample chromatogram of moxifloxacin is shown in Fig 14.

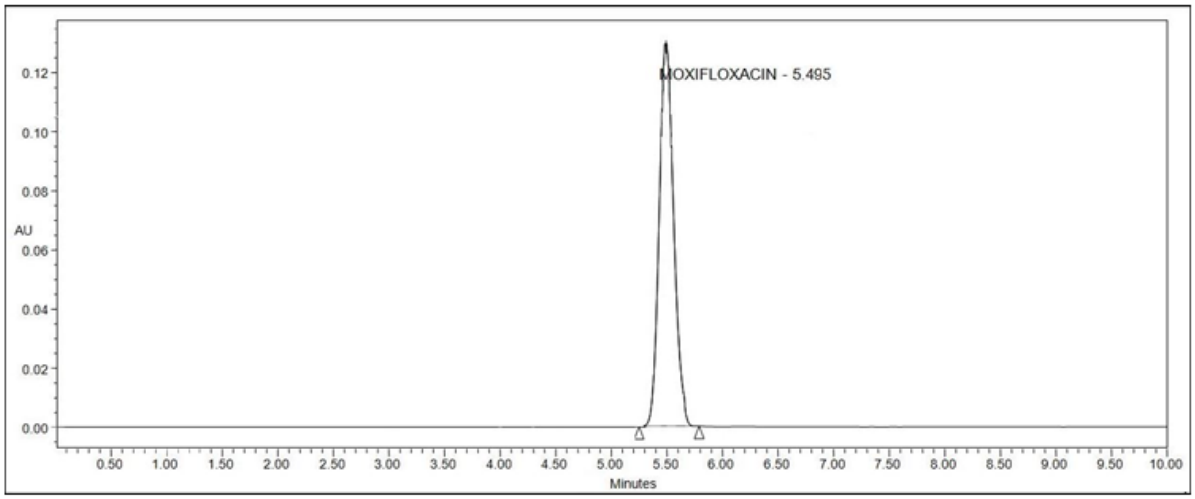

Figure 12: Standard chromatogram of Moxifloxacin.

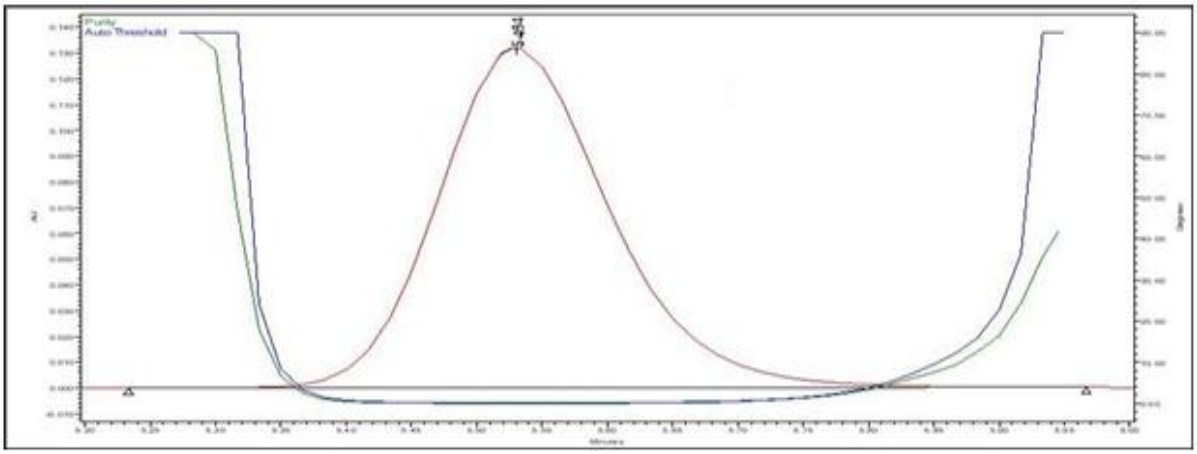

Figure 13: Standard peak purity chromatogram of Moxifloxacin.

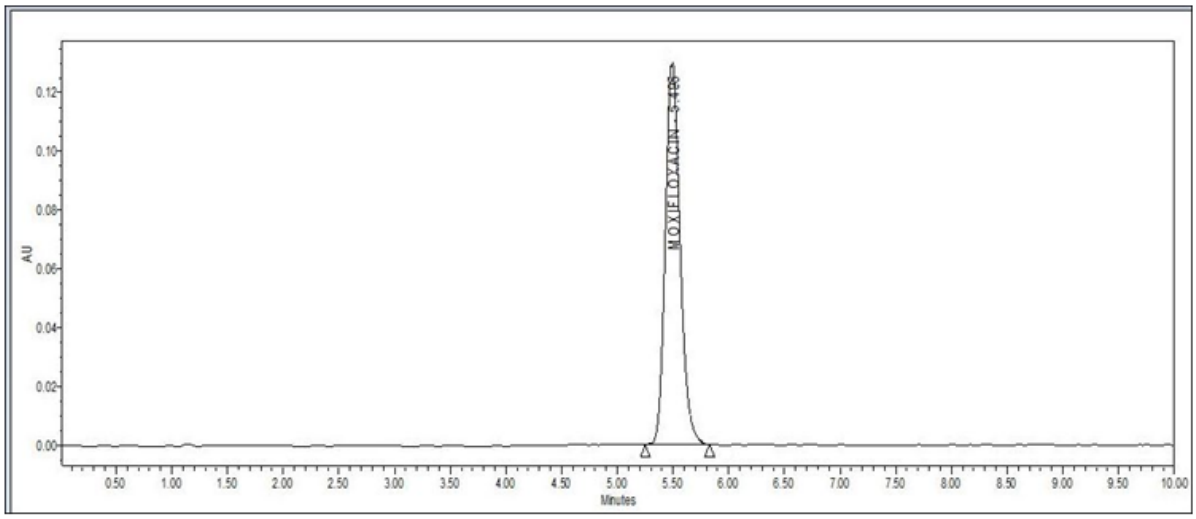

Figure 14: Sample chromatogram of Moxifloxacin.

III. RESULTS AND DISCUSSION

At first for collecting the data on the physico-chemical properties of the drug such as solubility and pKa which are very important for the selection of mobile phase. By utilizing Henderson Hasselbalch equation pH of the buffer is selected. Development of the method is based on the trial and error basis. Several mobile phases of different compositions were tested so as to develop an optimization of chromatographic conditions such as tailing factor, decorous peak shape, and theoretical plates. For the selection of the mobile phase primarily methanol, acetonitrile, CH_3OH : water, ACN : water has been tried in different compositions. MOXI is a polar drug and in RP- HPLC generally C_8, C_{18} column are used. Degradation studies, separation of the impurities formed during the degradation process is noted. Eventually optimizing HPLC method with information was obtained. Methanol and phosphate buffer (pH 2.5) used at a flow rate of 1.2 ml/min was found to be satisfactorily and decorous system suitability parameters. The average retention time (Rt) got for MOXI was at 5.495 min. The tailing factor and theoretical plates for MOXI were found to be 1.1 and 8348 respectively. After words validation parameters were carried out. Accuracy of MOXI was determined by calculating the % recovery. The method was found to be accurate with % recovery between 99.68-99.90 %. Intra and inter-day precision was calculated. Infact the method was precise with percentage RSD < 2%. Intra and inter-day precision are shown in tables 2b and 2c respectively. The % RSD value of robustness which is less than 2% for Moxifloxacin reveals that the proposed method is robust (table 3) (Change in flow rate, wavelength and mobile phase composition). The % RSD values of ruggedness for Moxifloxacin reveal that the proposed method is quite rugged. The LOD and LOQ of Moxifloxacin were found to be 0.001 µg/ml and 0.003 µg/ml **respectively**. The % assay of the bulk was found to be 99.97 ± 3.05. The average content of MOXI was 99.95 ± 2.92, which was in good agreement with labelled claim. The method was specific and has no interference observed when the MOXI were estimated in presence of excipients.

Degradation behaviour of MOXI under various stress conditions are shown in table 4. The assay method of MOXI in pharmaceutical formulation was successfully developed and validated for its intended purpose. Infact there was no particular precaution necessary during manufacturing and storage of MOXI formulation because there was no degradation studied at room temperature.

IV. CONCLUSION

The current research deals with the development of a stability indicating RP-HPLC method for determination of MOXI in bulk as well as pharmaceutical dosage form. The values of accuracy, precision, robustness, ruggedness, LOD and LOQ were within the limits. Infact stressed samples were evaluated as per test method with PDA detector. When the chromatograms of stressed samples were analysed for peak purity of peak utilizing Agilent empower software. For all forced degradation samples the purity angle was less than purity threshold with no purity flag for MOXI peak which indicates that there is no interference from degradants in estimation of MOXI in MOXI sample. As a matter of fact the results of the study shows that the developed method was found to be simple, accurate, sensitive, rapid and reproducible and have short run time and only requires low cost technology which makes this method economically good for all most all clinical laboratories hence this study of novel RP-HPLC method for the determination of MOXI in a bulk and tablet formulation can be successfully utilized for its intended purpose.

ACKNOWLEDGMENT

The authors are thankful to Hetero Labs for providing the sample of Moxifloxacin. We are highly grateful to Dr. L. Rathaiah, honourable chairman, Vignan group of institutions, Vadlamudi, Guntur for providing the necessary laboratory facilities to carry out the present investigation.

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IOSR Journal of Pharmacy (IOSR-PHR) is UGC approved Journal with Sl. No. 3365, Journal No-62875

P. Ravi Sankar. "Development and Validation of a Stability-Indicating Method for Assay of Moxifloxacin in Oral Pharmaceutical Dosage Forms by HPLC.". IOSR Journal of Pharmacy (IOSRPHR), vol. 9, no. 04, 2019, pp. 30-41.