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Research Article

Degradation Studies of Different Brands of Moxifloxac in Available in the Market

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ABSTRACT

Moxifloxacin is the wide range antibiotic effective against the (-ve) bacteria and (+ve) bacteria .The forced degradation studies conducted for the determination of degradation of durg product. According to ICH guide line moxifloxacin exposed to different condition. Degradation amount of the drug product can be calculated with the help of UV spectrophotometer. According to USP /BP the official test limits should not less then (%) and should not more then (%). On exposure to acidic and basic medium of avelox ,izilone and Moxiget the forced degradation studies conducted . Observed negligible difference in availability on exposure to UV and heat during the forced degradation studies of the drug substance. This method is simple, less time consuming and cost effective. For the simultaneous quantitative analysis of the Avelox, izilone and Moxiget this method also can be successfully employed.

INTRODUCTION

Moxifloxacin hydrochloride , a floroquinolones , is considerabily yellow crystalline salt is 1-cyclopropyl -6-fluoro-1.4dihydro -8- methoxy -7-[(4as,7as)-octahydro-6H-pyrrolo[3,4-b]pyridine-6-yl]-4-oxo-3 quinoline carboxylic acid .[1] Chemical formula of moxifloxacin is $C_{21}H_{24}F{\cdot}N_3O_4$.Hcl and have molecular weight of moxifloxacin is 437.9. Moxifloxacin is a wide ranging spectrum antimicrobial agent. It is effective for (-ve) bacteria and (+) bacteria. Moxifloxacin produces action by subsiding DNA gyrase , topoisomerase type 2 and 4

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topoisomerase , enzymes essential to split bacterial DNA , this further subsiding the cell replication .[2] Moxifloxacin mostly used for the treatment of skin and skin structure infections , community acquired pneumonia acute bacterial exacerbation of chronic bronchitis, acute bacterial sinusitis . Moxifloxacin commercially accessible as IV diffusions in plastic container, oral tablets and ophthalmic solution [1]

Mostly small scaled industries used spectrophotometery method as maintenance problems are economical and less cost of equipment. Through this analytical technique is absorption of monochromatic light determined by colorless complex in the near (UV) ultraviolet region (200-300). UV spectroscopy can also be used for moxifloxacin stress degradation studies .According to ICH guideline the forced degradation states of active pharmaceutical substance include acidic, basic and photo condition. [3]

Parameters for forced degradation: For drug degradation studies basic parameters included are acid/base stress testing, photo degradation, humidity and with temperature.

Acid /base stress testing: By acid/base stress testing forced degradation of drug is determined in contact with acidic and basic condition to its basic degradation product drug product results degradation .by carbonyl functional groups in which include carbamates , alcohol , amides (lactam),esters (lactones) , aryl amine , imines and imides then acid/base hydrolysis is carried out .

Thermal/humidity testing: On introducing the drug substance to thermal / humidity environment over long time results to degrade forcefully drug substance to its primary components. By this process thermal/ humidity stress testing is carried out.

UVdegradation: many drug substance which is synthetically and naturally polymer prepared on exposing to sunlight become crack.

EXPERIMENTATION:

Moxifloxacin : Moxifloxacin brands used were Avelox 400mg tablets of bayer Pakistan Ltd, izilone 400mg tablets of bosch pharmaceutical (pvt)Ltd ,Moxiget 400mg tablet of Getz pharma (pvt) Ltd.

Reagents: 1N Hcl and 1 N NaOH analytical reagent were used and deionized filtered and double distilled water were used.

Glass ware : pyrex type stirrer , pipette , measuring cylinder , beaker , funnel , volumetric flask were used . After washing the glass ware with chromic acid rinsed with freshly laboratory prepared deionized or double distilled water.

Instrumentation:

- Weighing balance.
- Water bath.
- Spectrophotometer.
- Uv lamp.

Preparation of 1N NaOH : Dissolved accurately weigh 40gm NaOH in 100ml volumetric flask and deionized water add for make up the volume .

Preparation of 1N Hcl : in 100ml volumetric flask take 8.36ml hydrochloric acid (37% 12N) analytical grade and deionized H_2O added to make up the volume .

Preparation of moxifloxacin solution: individually weigh the intact tablets of each of the brands. Tablets of each brands triturates individually in mortar pestle. Powder equalent to 20mg of moxifloxvacin . Weigh accurately that is avelox (37.74mg), moxiget (30.905) izilone(33.12mg) .All of 03 brands powders weigh sample individually pure into the 100ml volumetric flask . Dissolve this powder sample by shaking with the help of water and finally add more water to makeup the 100ml volume for each sample respectively. Preferably 200ppm concentration solution obtained. Individually all brands absorbance determine by using spectrophotometer at 294nm wavelength.

Procedure For Degradation Studies:

For acid: Individually take 5ml of 200ppm of avelox . izilone and moxiget in 3 separated test tubes then in each test tubes add 5ml of 1N HCL . Left the samples for 30 min. After the time period completion transferred solution to a separated cuvette and at the 294 nm wavelength Uv absorbance of the solution was measured.

For base : In 3 separated test tube take 5ml of 200ppm solution of avelox, moxiget and izilone then in each test tube 5ml of water added and at 294nm wavelength absorbance of solution was measured .

For heat : In 03 separated test tubes takes 5ml of 200ppm solution of avelox , izilone and moxiget then in each test tube 5ml of watewr added and at 294 nm waveleght Uv absorbance of solution was measured .

For UV: take 5 ml of 200ppm solution of avelox , izilone and moxiget in 03 separated test tubes then add 5ml of water in each test tube , exposing these test tubes to 30 min to UV light measured the UV absorbance at 294 nm wave length .

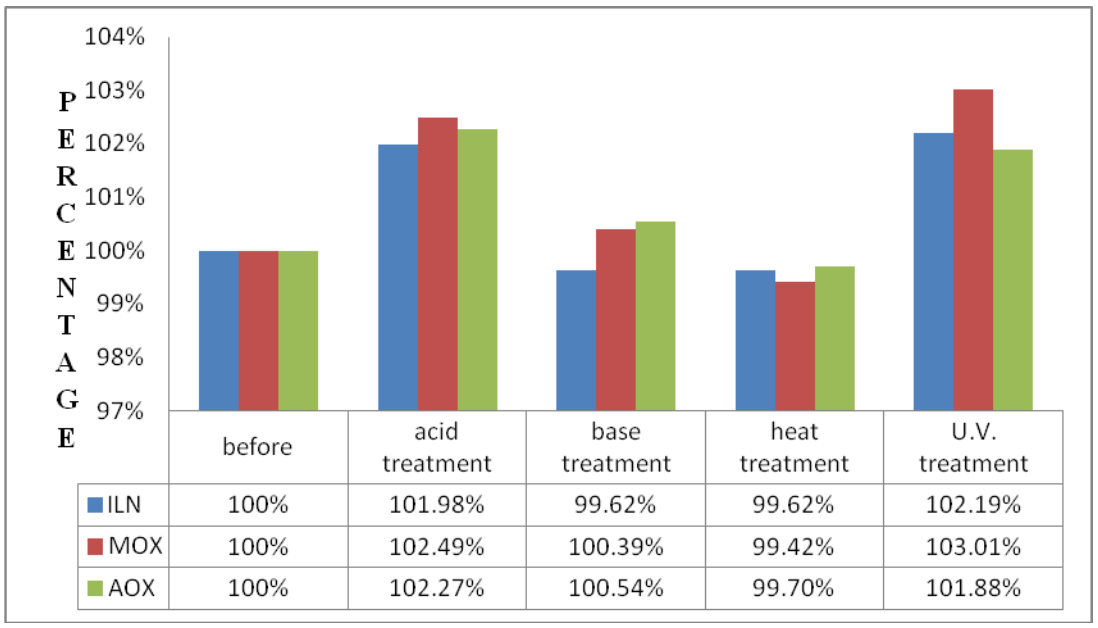

Fig. 1: graphical representation of percentage degradation

Table 1: absorbance of different brands of moxifloxacin

TREATMENTS	1	2	3	AVERAGE
			ILN	
Before	2.844	2.843	2.836	2.841
after acid	2.891	2.909	2.892	2.897
after base	2.585	2.850	2.851	2.762
after heat	2.821	2.835	2.835	2.830
after U.V	2.916	2.897	2.897	2.903
			MOX	
Before	2.820	2.815	2.826	2.820
after acid	2.885	2.882	2.905	2.891
after base	2.835	2.834	2.825	2.831
after heat	2.792	2.811	2.809	2.804
after U.V	2.914	2.896	2.906	2.905
			AOX	
Before	2.834	2.812	2.813	2.820
after acid	2.883	2.892	2.859	2.878
after base	2.833	2.839	2.833	2.835
after heat	2.814	2.813	2.807	2.811
after U.V	2.860	2.890	2.868	2.873

RESULTS AND DISCUSSION

We have conducted the degradation study on three brands of moxifloxacin used were Avelox 400mg tablets of bayer Pakistan Ltd, izilone 400mg tablets of bosch pharmaceutical (Pvt) Ltd, Moxiget 400mg tablet of Getz pharma (Pvt) Ltd. when moxifloxacin brands are treated with the 1N HCL shows availability absorbance and percentage given respectively in the table 2. When moxifloxacin brands are treated with the 1N NaOH drugs shows the increased availability and absorbance respectively . when subjected to heat for 30min then moxifloxacin shows no changes. When exposed to Uv light negligible changes has been observed respectively.

We conluded according to our results that when we introducd ILN into acidic medium 1N HCL shows degradation to major extend that is (101.98%) , MOX shows degradation to major extend that is (102.49%) while AOX give major results on expose to acidic medium (102.27%) respectively. Similarly on exposure to 1N NaOH basic medium the ILN shows the

Table 2: Percentages of different brands (before and after treatments)

			ILN		
S.No.	**Before**	**Acid Treatment**	**Base Treatment**	**Heat Treatment**	**U.V. Treatment**
1	100.11	101.76	99.30	99.30	102.64
2	100.07	102.39	99.79	99.79	101.97
3	99.82	101.80	99.79	99.79	101.97
average	100.00	101.98	99.62	99.62	102.19
			MOX		
1	99.99	102.29	100.52	99.00	103.32
2	99.81	102.19	100.48	99.67	102.68
3	100.20	103.00	100.17	99.60	103.04
AVERAGE	100.00	102.49	100.39	99.42	103.01
			AOX		
	100.51	102.25	100.47	99.80	101.43
	99.73	102.57	100.69	99.76	102.49
	99.76	101.39	100.47	99.55	101.71
AVERAGE	100.00	102.07	100.54	99.70	101.88

(99.62%) degradation where as MOX shows degradation to (minor) extend that is (100.39%) while calpol give results on expose to basic medium (%) respectively.

When panado, disprol and calpol heated for 30 min and evaluated for degradation studies shows negligible changes in concentration respectively for degradation studies .

When panado, disprol and calpol exposed to UV light for 30 min and evaluated for degradation studies shows negligible changes in concentration respectively for degradation studies .Our research group had done this types of activity for different drugs[4-8].

CONCLUSION

According to USP and BP specification the official limit of the content should NLT (%) and NMT (%) of the labeled amount. We have concluded from our studies that paracetamole more degrades in acidic and basic medium where as little degradation also arise with time , while in UV and heat paracetamole shows negligible degradation effect .

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