

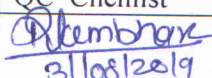
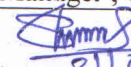
**OREX**

**OREX PHARMA PVT. LTD.**  
**THANE (W)**  
**CERTIFICATE OF ANALYSIS**

Product	<b>MOXIFLOXACIN HYDROCHLORIDE USP</b>		
Batch no.	ORX/MOX-L/1908019	A.R. No.	FP/2019/0179
Batch Size	240.0 Kg	Sample Date	20/08/2019
Mfg. Date	August- 2019	Exp. Date	July - 2022

Sr. No.	TEST	SPECIFICATION	RESULT
1	Appearance	Light yellow to yellow crystalline powder, slightly hygroscopic.	Light yellow to yellow crystalline powder, slightly hygroscopic.
2	Solubility	Soluble in 0.1N NaOH, sparingly soluble in water and methanol, slightly soluble in 0.1N HCl, DMF, and alcohol, practically insoluble in MDC, acetone, ethyl acetate, toluene, insoluble in tert-butyl methyl ether and n-heptane.	Complies
3	Identification by		
	a) By IR	Should comply with working standard	Complies
	b) By HPLC	RT of main peak in sample solution should match with RT of Moxifloxacin peak in std. solution	Complies
	c) Test for chloride	Should be positive	Complies
4	pH (0.2% solution in water)	Between 3.9 and 4.6	4.1
5	Specific optical rotation (On anhydrous basis)	-125 <sup>0</sup> to -138 <sup>0</sup>	-130.2 <sup>0</sup>
6	Related Substances (by HPLC)	Moxifloxacin Related comp A: NMT 0.10% 6,8-Dimethoxy : NMT 0.10% 8-Ethoxy : NMT 0.10% 6-Methoxy-8-fluoro : NMT 0.10% 8-Hydroxy : NMT 0.10% Other individual Impurity : NMT 0.10% Total Impurities : NMT 0.50%	ND ND 0.01% ND ND 0.04% 0.06%
7	Water content by KF	Not More Than 4.5%	3.51%
8	Residue of ignition	Not more than 0.10%	0.06%
9	Chloride /sulfate	Not more than 0.04%	Complies
10	Assay by HPLC (On anhydrous basis)	NLT 98.0% NMT 102.0%	99.40%
11	Residual Solvent	Dichloromethane : NMT 600 PPM Methanol : NMT 3000 PPM IPA : NMT 5000 PPM	Complies Complies Complies
12	Microbiology Test	Total aerobic Microbial Count /g : NMT 10 <sup>3</sup> cfu/g Total combined Yeasts & Moulds Count /g : NMT 10 <sup>2</sup> cfu/g	Absent Absent

**Remark:- The product Complies as per USP - 39 specification.**

	<b>Prepared by</b>	<b>Approved by</b>
<b>Name</b>	Miss . Reshama Kumbhare	Mr. S.S. Gouda
<b>Designation</b>	QC Chemist	Manager , QC /QA
<b>Sign &amp; Date</b>	 31/08/2019	 31/08/2019

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