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Certificate of Analysis for Moxifloxacin Hydrochloride/MOF（U）

Test sheet NO.: C_{89}-200143

Product Code	MOF(U)	Batch No.	MOF-2009033
Batch Size	126.69kg	Type of Product	API
Manufacture Date	Sep.20,2020	Package size	15.0Kg/Drum
Report Date	Oct.13,2020	Retest date	Sep.19,2022
Standard	The Current Edition of USP		

Tests	Acceptance criteria	Results
【Appearance 】	Light yellow or yellow powder or crystals	Light yellow powder
【Identification 】		
A、Infrared absorption	Infrared-Spectrum is concordant with that of the reference standard	Conforms
B、HPLC	The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay	Conforms
C、Chloride	Positive reaction of chloride	Conforms
D、XRPD	The XRPD spectrum should be concordant with that form II in the patent and should have main diffraction peaks in the following 2θ（±0.2°range）5.8°，8.5°，10.1°，14.5°，17.0°，17.4°。	Conforms (Contract testing)
【Tests 】		
pH	3.9～4.6	4.5
Water	Not more than 4.5%	3.9%
Residue on ignition	Not more than 0.1 %	0.02%
Sulfate	Not more than 0.04 %	Conforms
【related compound】		
Moxifloxacin related compound A（RRT≈1.1）	Not more than 0.1%	ND
Moxifloxacin related compound B（RRT≈1.34）	Not more than 0.1%	ND
Moxifloxacin related compound C（RRT≈1.46）	Not more than 0.1%	ND
Moxifloxacin related compound D（RRT≈1.63）	Not more than 0.1%	ND
Moxifloxacin related compound E （RRT≈1.77）	Not more than 0.1%	ND
Moxifloxacin related compound F （RRT≈0.9）	Not more than 0.15%	Less than ignore limit (<0.05%)
Any other individual impurities	Not more than0.10%	Less than ignore limit (<0.05%)
Total impurities	Not more than 0.5%	Less than ignore limit (<0.05%)
【Enantiomeric purity/ Moxifloxacin related compound G】	Not more than 0.10%	Less than ignore limit (<0.05%)
【Residual solvent 】		
Ethanol	Not more than 5000 ppm	ND
【Microbial limit】		
Total aerobic microbial count	Not more than 10^3cfu/g	<100cfu/g
Total combined yeasts and molds count	Not more than10^2cfu/g	<10cfu/g
Escherichia coli	No detected/g	ND
【Assay】	$C_{21}H_{24}FN_3O_4$ • HCl content should be 98.0% to 102.0% (On the anhydrous basis)	100.4%

Conclusion: The Test Results Comply With Current Edition of USP.

Approved by: 2020.10.13 Reviewed by: 2020.10.13 Printed by: 2020.10.13

HANGZHOU HUARONG PHARMACEUTICAL CO., LTD. 杭州华荣医药有限公司 QC

*Means the document is under process

Product under patent is for R&D purpose.