

江西大地制药有限责任公司
JIANGXI DADI PHARMACEUTICAL CO., LTD
INDUSTRY AREA, LIANHUA COUNTY, JIANGXI PROVINCE, CHINA

检验报告
CERTIFICATE OF ANALYSIS

名称 Product Name: 盐酸莫西沙星 MOXIFLOXACIN HYDROCHLORIDE
规格 Packing: 1×25Kg
批号 Batch No.: 230525-1
检验依据 Examined Basis: USP38
生产日期 Mfg. Date: 2023.05.21
有效日期 Exp. Date: 2027.05.20

检验项目 (Tests)		标准 (Acceptance Criteria)	结果 (Results)
性状 Description		黄色结晶性粉末 Yellow colour crystalline powder	符合规定 Conform
鉴别 (Identification)	红外吸收 光谱(IR)	供试品红外吸收图谱与对照品一致 Conforms to the spectrum of MOXIFLOXACIN HYDROCHLORIDE	符合规定 Conform
	HPIC	供试品与对照溶液主峰保留时间一致 The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.	符合规定 Conform
酸度 PH		3.9~4.6	4.45
比旋度 (α) _D ²⁰ Specific rotation		-125° ~ -138°	-129.5°
有关物质 Related substance		≤0.5%	0.29%
干燥失重 Dry weightlessness		≤4.5%	3.5%
炽灼残渣 Residue on ignition		≤0.1%	0.10%
重金属 Heavy metals		≤0.001%	符合规定 Conform
含量 Assay (by HPLC)		98.0%~102%	99.62%
结论: 本品按 USP38 标准检验, 结果符合规定 Conclusion: Conforms to USP38 specification for moxifloxacin hydrochloride.			

Chief Inspection 主检: 李小林

Checking Officer 复核: 林小艳

