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桂林南药股份有限公司
GUILIN PHARMACEUTICAL CO., LTD.
检验报告单
CERTIFICATE OF ANALYSIS

检验编号 Analysis No.: 15126001

检品名称 Product Name	盐酸莫西沙星工作对照品 Moxifloxacin hydrochloride Reference Standard		
批号 Batch No.	MX151201	检品数量 Quantity of Sample	7g
检品规格 Strength of sample	原料药 Raw materials	检品来源 Source of sample	技术开发部 Technology Development Department
请验单号 Request sheet No.	0146909	本批数量 Batch Size	32.4g
检验目的 Purpose of analysis	全检 All items	请验日期 Date of Request	2015.12.08
检验依据 Analytical criterion	内控标准 In-house specification	报告日期 Date of Report	2016.01.07
生产日期 Date of manufacturing	2015.12.04	复验期 Re-test period	2016.12.03

检验结果 Test results

检验项目 Items		标准规定 Specification	检验结果 Results
【性状】 Description		应为黄色粉末或浅黄色结晶性粉末 A yellow powder or slight yellow crystalline powder	为浅黄色粉末 A slight yellow powder
比旋度 Specific rotation		应为-125° ～ -138° Should be -125° to -138°	-135°
【鉴别】 Identification	（1）液相色谱 HPLC	在含量测定项下记录的色谱图中，供试品溶液主峰的保留时间应与对照品溶液主峰的保留时间一致 In the chromatogram obtained from the Assay, the retention time of principal peak obtained from the test solution should be concordant with that obtained from the reference solution	在含量测定项下记录的色谱图中，供试品溶液主峰的保留时间与对照品溶液主峰的保留时间一。In the chromatogram obtained from the Assay, the retention time of principal peak obtained from the test solution is concordant with that obtained from the reference solution
	（2）IR	本品的红外吸收光谱应与对照品图谱一致 The IR spectrum obtained from the sample is concordant with that of the reference.	与对照品图谱一致 Correspond to the spectrum obtain from the reference
	（3）氯化物的鉴别反应 Reaction of chloride	应显正反应 Positive	显正反应 Positive

NATIONAL QUALITY CONTROL LABORATORY
RECEIVED
04 FEB 2016
TEL: 2726963 / 3546525/30
FAX: 2718073
P.O. Box 29726 - 00202, NAIROBI

【检查】 Test	酸度 Acidity	pH 值应为 3.9~4.6 pH value should be 3.9~4.6	4.3
	溶液的澄清度与颜色 Clarity and color of solution	应不得深于 1 号浊度标准液 The solution is not more opalescent than reference suspension Ⅰ	浅于 1 号浊度标准液 Less than that of the reference suspension Ⅰ
		颜色应不得深于黄绿色 8 号标准比色液 The solution is not more intensely colored than reference solution GY8	颜色浅于黄绿色 8 号标准比色液 。Less than that of the reference solution GY8
	有关物质 Related substance	杂质 A 应不得过 0.1% Impurity A should be not more than 0.1%	<0.05%
		杂质 B 应不得过 0.1% Impurity b should be not more than 0.1%	<0.05%
		杂质 C 应不得过 0.1% Impurity C should be not more than 0.1%	<0.05%
		杂质 D 应不得过 0.1% Impurity D should be not more than 0.1%	<0.05%
		杂质 E 应不得过 0.1% Impurity E should be not more than 0.1%	<0.05%
		杂质 I 应不得过 0.1% Impurity I should be not more than 0.1%	<0.05%
		其他单个杂质应不得过 0.1% Other single impurity should be not more than 0.1%	<0.05%
		总杂质应不得过 0.3% Total impurities should be not more than 0.3%	<0.05%
	残留溶剂 Residue solvent	乙腈 ≤410ppm Acetonitrile ≤410ppm	未检出 Not detected
		甲醇 ≤3000ppm Methanol ≤3000ppm	未检出 Not detected
		乙醇 ≤5000ppm Ethanol ≤5000ppm	35ppm
	水分 Moisture	应不得过 4.5% Not more than 4.5%	3.8%
	炽灼残渣 Residue on ignition	应不得过 0.1% Not more than 0.1%	0.06%
【含量测定】 Assay		按无水物计算，含莫西沙星($C_{21}H_{24}FN_3O_4$)应为 89.9%~93.4% Calculated on anhydride basis, it contains moxifloxacin ($C_{21}H_{24}FN_3O_4$) should be 89.9%~93.4%	91.7%
		含莫西沙星($C_{21}H_{24}FN_3O_4$) it contains moxifloxacin ($C_{21}H_{24}FN_3O_4$)	88.2%

结论 Conclusion：

本品按内控标准检验，结果符合规定。 The quality of the above product complies with the in-house specification.	备注 Remarks：

报告人/日期：[signature]/2016.01.07
Reported by/date

复核人/日期：[signature]/2016.01.07
Reviewed by/date

批准人/日期：[signature]/2016.01.07
Approved by/date

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