内蒙古格林特制药有限责任公司 Inner Mongolia Glint Pharmaceutical Co., Ltd.	编号 Serial No.	SOR-ZL-QC-15200-03
检验报告单 Certificate of Analysis	替代 Replacement	无 No
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品名 Name: 灰黄霉素 Griseofulvin　　来源 Source: 101 车间
批号 Lot №: C007-240910　　数量 Quantity: 500kg
报告单编号 Report №: HH-2409087　　包装规格 Packaging: 20kg/桶
生产日期 Manufacture Date: 2024 年 07 月 29 日　　有效期至 Expiry Date: 2028 年 07 月 28 日
检验依据 Specification: BP2021/EP10.0

Test item 测试项目	Specification 质量标准	Test results 结果
Description 性状	A white or yellowish-white microfine powder 白色至微黄色微细粉末	Complies 本品为白色微细粉末。
	Practically insoluble in water, freely soluble in dimethylformamide . slightly solublein anhydrous ethanol and in methanol 本品不溶于水、易溶于N，N－二甲基甲酰胺、微溶于无水乙醇、甲醇。	Complies 符合规定
Particle size 颗粒长度	The particles of which are generally up to 5μm in max. dimension 一般 5μm 以下	Complies 符合规定
	larger particles which may occasionally exceed 30μm 偶见 30μm 以上大颗粒	
Melting point 熔点	It melts at about 220℃ 约 220℃	221.3℃
Identification 鉴别	The infrared absorbance spectrum is concordant with the reference spectrum 供试品的红外光吸收图谱应与对照品图谱一致（IR）	The infrared absorbance spectrum is concordant with the reference spectrum 供试品的红外光吸收图谱与对照品图谱一致。
Appearance of solution 溶液外观	The solution is clear 溶液应澄清	Complies 符合规定
	Not more intensely coloured than reference solution Y4 色泽：应＜Y_4对照溶液	Complies 符合规定
Acidity 酸度	Not more than 1.0ml of 0.02M sodium hydroxide is required 消耗 0.02mol/L NaOH 应＜1.0ml	0.30ml
Specific optical rotation 比旋度	Calculated with reference to the dried substance +354° ~ +364°（按干燥品计算）	+358°
Related substances 有关物质	Impurity B is not more than3.0% 杂质 B 应＜3.0%	0.93%
	Impurity C is not more than0.75% 杂质 C 应＜0.75%	0.29%
	Impurity A is not more than 2.0% 杂质 A 应＜2.0%	0.07%
	Other Single Unkown Impurity is not more than 0.15% 未知单一杂质应＜0.15%	Not Detected 未检出
	Total impurities is not more than 5.0% 杂质总和应＜5.0%	1.3%
Loss on drying 干燥失重	Loses not more than 1.0% of its weight 减失重量应＜1.0%	0.12%
Residue on ignition 炽灼残渣	Not more than 0.2% ＜0.2%	0.05%
Residual solvents 残留溶剂	Ethanol not more than0.5%　乙醇＜0.5%	0.0033%
	Acetone not more than0.5%　丙酮＜0.5%	0.0004%
	Dichloromethane not more than 0.06%　二氯甲烷＜0.06%	0.0012%
Assay 含量	Calculated with reference to the dried substance 94.0%~102.0%（按干燥品计算）	97.3%

Conclusion: Tested according to BP2021/EP10.0,the results meet the standard requirements。
结论 Result: 本品经检验符合 BP2021/EP10.0 质量标准规定。

检验者 Analyzer: 张成福　　报告日期 Report date: 2024年09月21日
复核者 Checked by: 李[illegible]　　复核日期 Check date: 2024年09月21日
QC 经理 QC Manager: 刘[illegible]　　批准日期 Approved date: 2024年9月21日

METAPHARMACEUTICAL

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15/11/2024.