

INNER MONGOLIA GLINT PHARMACEUTICAL CO., LTD.

North Weixin Road, Hongshan Economic Development Zone, Chifeng, Inner Mongolia, China

CERTIFICATE OF ANALYSIS

Product: Griseofulvin		
Batch No.: HH-210706	Reference Standard: BP2018/EP9.6	
Batch Size: 500 Kg	MFG. Date: Jul. 03, 2021	
Shipped Quantity: 500 Kg	EXP. Date: Jul. 02, 2025	
Tests	Specifications	Results
Description	A white or yellowish-white, microfine powder.	A white, microfine powder
Solubility	Practically insoluble in water, freely soluble in dimethylformamide and in tetrachloroethane, slightly soluble in anhydrous ethanol and in methanol.	Conforms
Particle size	The particles of which are generally up to 5um in max. dimension	Conforms
	Larger particles which may occasionally exceed 30um	Conforms
Melting range	217°C to 224°C	222.1°C
Identification	The infrared absorbance spectrum is concordant with the reference spectrum	Conforms
	A wine-red color is produced.	Conforms
Appearance of solution	The solution is clear and not more intensely coloured than reference solution Y ₄ .	Conforms
Acidity	Not more than 1.0ml of 0.02M sodium hydroxide is required	0.39ml
Specific optical rotation	+352° to +364°	+358.7°
Related Substances (GC)	-Cl: <3.0(0.6R)	0.13
	-H: < 0.75(0.15R)	0.05
Substance soluble in light petroleum	≤0.2%	0.09%
Loss on Drying	≤1.0%	0.07%
Sulfated Ash	≤0.2%	0.09%
Residual Solvents	Ethanol not more than 0.5%	0.005
	Acetone not more than 0.5%	0.004
	Dionloromctane not more than 0.06%	0.006
Abnormal Toxicity	Five mice orals, none of the mice dies Within 48h	Conforms
Assay(dried substance)	97.0% to 102.0%	100.3%
Conclusion: The above analytical results conform to BP2018/EP9.6		

内蒙古格林特制药有限责任公司
INNER MONGOLIA GLINT PHARMACEUTICAL CO., LTD