

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-221004	Reference Standard: EP10.0/BP2021	
Batch Size: 500 Kg	MFG. Date: Sept. 29, 2022	
Shipped Quantity: 20 Kg Package: 20Kg/Drum	EXP. Date: Sept. 28, 2026	
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	It melts at about 220°C	220.8°C
Identification	The infrared absorbance spectrum is concordant with the reference spectrum	Conforms
Appearance of Solution	The solution is clear	Conforms
	not more intensely coloured than reference solution Y ₄ .	
Acidity	Not more than 1.0ml of 0.02M sodium hydroxide is required	0.36ml
Specific Optical Rotation	Calculated with reference to the dried substance +354° to +364°	+361°
Related Substances	Dechologriseofulvin ≤3.0%	0.58%
	Dehydrogriseofulvin ≤0.75%	0.24%
	Griseofulvin acid ≤2.0%	0.04%
	Other single unknown impurity ≤0.15%	ND
	Total impurities ≤5.0%	0.86%
Residue on Ignition	≤0.2%	0.09%
Loss on Drying	≤1.0%	0.09%
Residual Solvents	Ethanol ≤ 0.5%	0.0012%
	Acetone ≤ 0.5%	0.0006%
	Dichloromethane ≤ 0.06%	ND
Assay	Calculated with reference to the dried substance 94.0% to 102.0%	100.5%
Conclusion: The above analytical results conform to EP10.0/BP2021.		

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12/01/2023

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