

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-220105	Reference Standard: BP2018/EP9.7	
Batch Size: 500 Kg	MFG. Date: Dec. 24, 2021	
Shipped Quantity: 60 Kg	EXP. Date: Dec. 23, 2025	
Tests	Specifications	Results
Description	White or yellowish-white powder.	White or yellowish-white powder.
Solubility	Practically insoluble in water, freely soluble in dimethylformamide, slightly soluble in anhydrous ethanol and in methanol.	Conforms
Particle size	The particles of which are generally up to 5µm in max. dimension	Conforms
	Larger particles which may occasionally exceed 30µm	Conforms
Melting range	217°C to 224°C	221.7°C
Identification	The Infrared absorbance spectrum is concordant with the reference spectrum	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	0.28ml
Specific optical rotation	+354° to +364°	+361.8°
Related Substances (HPLC)	Impurity A: ≤2.0% Impurity B: ≤3.0% Impurity C: ≤0.75% Unspecified Impurities: for each impurity: ≤0.15% Total: ≤5.0%	0.1% 0.6% 0.15% N.D. 1.0%
Loss on Drying	≤1.0%	0.05%
Sulphated Ash	≤0.2%	0.06%
Residual Solvents	Ethanol not more than 0.5%	0.0023%
	Acetone not more than 0.5%	ND
	Dichloromethane not more than 0.05%	0.0009%
Abnormal Toxicity	Five mice orals, none of the mice dies Within 48h	Conforms
Assay(dried substance)	97.0% to 102.0%	99.0%

Conclusion: The above analytical results conform to BP2018

EP9.7 上海格林特制药有限公司

Analyzer: *Dia Lian*

Checked by: *Shang Chengle*

QC Manager: *Li Yipian*