

CERTIFICATE OF ANALYSIS

No.: ZL-QC1857-01

Product: Griseofulvin			
Batch No.: HH220808		Reference Standard: BP2019/EP9.6	
MFG Date: Aug.05,2022		Batch Size: 500kg	
EXP Date: Aug.04,2026			
Tests		Specifications	Results
Charact ers	Appearance	White or yellowish-white , microfine powder.	white , microfine powder.
	Solubility	Practically insoluble in water , freely soluble in dimethylformamide and in tetrachloroethane , slightly soluble in anhydrous ethanol and in methanol.	conform
	Melting point	About 220°C	222°C
Identifi cation	A [IR]	Meets the requirements	Meets the requirements
	B (Color test)	Dissolve about 5mg in 1mL of sulfuric acid R and add about 5mg of powdered potassium dichromate R . A dark red colour develops.	conform
Test	Appearance of solution	The solution is clear and not more intensely coloured than reference solution Y ₄ .	Meets the requirements
	Acidity	Suspend 0.25g in 20mL of ethanol (96 percent) R and add 0.1mL of phenolphthalein solution R. Not more than 1.0mL of 0.02M sodium hydroxide is required to change the colour of the indicator.	0.56ml
	Specific optical rotation	+354°~+364°	364°
	Related substances [GC]	Dechloro-griseofulvin: ≤0.60R	0.40R
		Dehydrogriseofulvin: ≤0.15R	0.031R
	Substances soluble in light petroleum	≤0.2%	0.1%
	Loss on drying	≤1.0%	0.094%
	Sulfated ash	≤0.2%	0.1%
Assay [UV] (dried substance)		97.0%~102.0%	98.5%
Particle size		≤5μm: ≥87.0%	90.6%
		≤10μm: ≥90.0%	98.2%
		≤30μm: ≥99.0%	100.0%
Conclusion: The above analytical results conform to BP2019/EP9.6.			

QA:

徐杰
2022年8月28日

QC Manager:

王俊杰
2022年8月11日

Analyst:

鲍国政

2022年8月11日