

CERTIFICATE OF ANALYSIS

No.: ZL-QC1857-01

Product: Griseofulvin			
Batch No.: HH230315		Reference standard: BP2021/EP 10	
Manufacturing Date:Mar .15,2023		Batch Size: 500kg	
Expiry Date:Mar .14,2027			
Tests		Specifications	Results
Characters	Appearance	White or yellowish-white powder.	White powder.
	Solubility	Practically insoluble in water,freely soluble in dimethylformamide,slightly soluble in anhydrous ethanol and in methanol.	Conform
	Melting point	About 220℃	222℃
Identification [IR]		The infrared absorption spectrum of the sample corresponds to that of the Griseofulvin RS.	Conform
Tests	Appearance of solution	7.5% (w/v) solution is clear and not more intensely coloured than reference solution Y ₄ .	Conform
	Acidity	Suspend 0.25g in 20mL of ethanol (96 per cent) 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.	0.52mL
	Specific optical rotation	+354° ~ +364°	+361°
	Related substances [HPLC]	Impurity A: ≤2.0%	Not detected
		Impurity B: ≤3.0%	2.4%
		Impurity C: ≤0.75%	0.39%
		Unspecified impurities : for each impurity: ≤0.15%	Not detected
		Total: ≤5.0%	2.6%
	Loss on drying	≤1.0%	0.12%
Sulfated ash	≤0.2%	0.1%	
Particle size	≤5μm ≥87.0%	91.7%	
	≤10μm ≥90.0%	98.9%	
	≤30μm ≥99.0%	100.0%	
Assay(dried substance)[HPLC]		94.0% ~ 102.0%	98.4%
Conclusion: The above analytical results conform to BP2021/EP 10			

QA: 徐正东
2023年4月11日

QC Manager: 张生
2023年4月11日

Analyst: 鲍晓 2023年4月11日

