

Hegno

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CERTIFICATE OF ANALYSIS

No.: ZL-QC251-02

Product: Griseofulvin		
Batch No.: HH150111	Reference standard: BP2011/EP7/COS	
MFG. Date: Jan.07,2015	Batch Size: 500kg	
EXP. Date: Jan.07,2019		
Tests	Specifications	Results
Characters	White or yellowish-white, microfine powder.	yellowish-white, microfine powder.
Solubility	Practically insoluble in water, freely soluble in dimethylformamide and in tetrachloroethane, slightly soluble in anhydrous ethanol and in methanol.	Meets the requirements
Identification	A: IR	Meets the requirements
	B: Color Test	Meets the requirements
Particle size	$\leq 5\mu\text{m} \geq 87.0\%$	89.05%
	$\leq 10\mu\text{m} \geq 90.0\%$	98.48%
	$\leq 30\mu\text{m} \geq 99.0\%$	100.00%
Melting point	About 220°C	218.2°C—219.3°C
Acidity	0.25g consumed 0.02M Sodium Hydroxide not more than 1.0mL.	0.6ml
Appearance of solution	The solution is clear and not more intensely coloured than reference solution Y ₄ .	Clear, Y ₅ -Y ₆
Specific optical rotation	+354°~+364°	+ 356°
Substances soluble in light petroleum	$\leq 0.2\%$	0.1%
Sulphated ash	$\leq 0.2\%$	0.1%
Loss on drying	$\leq 1.0\%$	0.11%
Related substances (GC)	Dechlorogriseofulvin ≤ 0.60	0.46
	Dehydrogriseofulvin ≤ 0.15	0.11
Related substances (HPLC)	Griseofulvic acid $\leq 0.75\%$	Not detected
	Any other detectable impurity $\leq 0.10\%$	Not detected
	Total impurities $\leq 4.0\%$	2.6%
Residual Ethanol (GC)	$\leq 5000\text{ppm}$	25ppm
Abnormal toxicity	None mice dies within 48h	Meets the requirements
Assay (on dried basis)	97.0%~102.0%	99.1%
Conclusion: The above analytical results conform to BP2011/EP7/COS R1-CEP 2002-143-Rev 00.		

QA Manager:

王杨 楚
 2015年11月14日

QC Manager:

Analyst: 31222
 2015年11月14日