


# Kalchem International


## Chemicals & Compounding Supplies

### CERTIFICATE OF ANALYSIS

No.: ZI-QC260-02

Product: Griseofulvin		
Batch No.: HH150932	Reference standard: BP2015/EP8	
MFG Date: Oct.01,2015	Batch Size: 500kg	
EXP Date: Oct 01,2019		
Tests	Specifications	Results
Appearance	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	$\leq 5\mu\text{m} \geq 87.0\%$	92.96%
	$\leq 10\mu\text{m} \geq 90.0\%$	97.67%
	$\leq 30\mu\text{m} \geq 99.0\%$	99.94%
Melting point	About 220°C	218.3°C - 219.4°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 <sub>s</sub> .	Clear Y <sub>s</sub> -Y <sub>6</sub>
Specific optical rotation	+354° to +364°	+359°
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	Dechlorogriseofulvin: $\leq 0.60$	0.40
	Dehydrogriseofulvin: $\leq 0.15$	0.07
Abnormal toxicity	According to BP2015/EP8	Meets the requirements
Content (on dried basis)	97.0% to 102.0%	98.6%
Conclusion: The above analytical results conform to BP2015/EP8.		

QA Manager: 

QC Manager: 

Analyst: 

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