

FAGRON

Hegno

Griseofulvin

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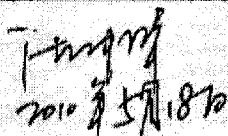
CERTIFICATE OF ANALYSIS

No.: ZL-QC251-01

Product: Griseofulvin		
Batch No.: 100512	Reference standard: BP2009/EP6/COS	
Batch Size: 500kg	MFG. Date: May 08, 2010	
Quantity: 60kg	EXP. Date: May 08, 2014	
Tests	Specifications	Results
Characteristics	White or yellowish-white, microfine powder, tasteless.	yellowish-white, microfine powder, tasteless.
Identification	A, B	Meets the requirements
Particle size	According to BP2009/EP6	Meets the requirements
Melting point	About 220°C	218.3°C - 219.3°C
Acidity	0.25g consumed 0.02M NaOH not more than 1.0mL.	0.6ml
Appearance of solution	Clear and not more intensely coloured than reference solution Y ₄ .	Clear, Y ₅ -Y ₆
Specific optical rotation	+354° ~ +364°	+358°
Substances soluble in light petroleum	≤0.2%	0.13%
Sulphated ash	≤0.2%	0.10%
Loss on drying	≤1.0%	0.10%
Related substances (GC)	Dechlorogriseofulvin ≤0.60% Dehydrogriseofulvin ≤0.15%	0.43 0.03
Related substances (HPLC)	Griseofulvic acid ≤0.75% Any other detectable impurity ≤0.10% Total impurities ≤4.0%	Not detected Not detected 2.4%
Residual Ethanol (GC)	≤5000ppm	13ppm
Abnormal toxicity	None mices dies within 48h	Meets the requirements
Assay (dried basis)	97.0% ~ 102.0%	99.2%
Conclusion: The above analytical results conform to BP2009/EP6/COS R1-CEP 2002-143-Rev 00.		

QA Manager: Shen Zhonghua

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