Griseofulvinum

Hegno

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CERTIFICATE OF ANALYSIS

No.:ZL-QC251-01

Product: Griseofulvin		
Batch No.: 120617	Reference standard: BP2011/EP7/COS	
MFG. Date: Jun.16, 2012	Batch Size: 500kg	
EXP. Date: Jun.16, 2016		

Tests	Specifications	Results
Characters	White or yellowish-white, microfine powder, tasteless.	yellowish-white, microfine powder, tasteless.
Identification	A: IR	Meets the requirements
	B: Color Test	Meets the requirements
Particle size	≤ 5μm ≥ 87.0%	95.89%
	≤ 10μm ≥ 90.0%	99.91%
	≤ 30μm ≥ 99.0%	100.00%
Melting point	About 220℃	218.5℃—219. 4℃
Acidity	0.25g consumed 0.02M Sodium Hydroxide not more than 1.0mL.	0.5ml
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	≤0.2%	0.1%
Sulphated ash	≤0.2%	0.1%
Loss on drying	≤1.0%	0.12%
Related substances (GC)	Dechlorogriseofulvin ≤0.60 Dehydrogriseofulvin ≤0.15	0.33 0.07
Related substances (HPLC)	Griseofulvic acid ≤0.75% Any other detectable impurity ≤0.10% Total impurities ≤4.0%	Not detected Not detected 2.2%
Residual Ethanol (GC)	≤5000ppm	12ppm
Abnormal toxicity	None mices dies within 48h	Meets the requirements
Assay (on dried basis)	97.0%～102.0%	98.8%

Conclusion: The above analytical results conform to BP2011/EP7/COS R1-CEP 2002-143-Rev 00.

QA Manager: 王炳楚 2012年8月9日

QC Manager: 樊光珠 2012年8月9日

Analyst: 刘娜 2012年8月9日

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Corresponde al lote de Fagron:
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Director Técnico