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FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:

15L 03-B04

Chifeng Pharmaceutical Co., Ltd.

CERTIFICATE OF ANALYSIS Director Técnico

No.: ZL-QC561-02

Product: Griseofulvin		
Batch No.: HH150640	Reference standard: BP2015/EP8/COS	
MFG. Date: Jul. 04, 2015	Batch Size: 100kg	
EXP. Date: Jul. 04, 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	$\leq 5\mu\text{m} \geq 87.0\%$	95.78%
	$\leq 10\mu\text{m} \geq 90.0\%$	99.80%
	$\leq 30\mu\text{m} \geq 99.0\%$	100.00%
Melting point	About 220°C	218.2°C ~ 219.2°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° to +364°	+357°
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: ≤ 0.80	0.28
	Dehydrogriseofulvin: ≤ 0.15	0.09
Related substances (HPLC)	Griseofulvic acid $\leq 0.75\%$	Not detected
	Any other detectable impurity $\leq 0.10\%$	Not detected
	Total impurities $\leq 4.0\%$	1.9%
Abnormal toxicity	According to BP2015/EP8	Meets the requirements
Content (dried substance)	97.0% to 102.0%	99.1%
Residual ethanol	$\leq 5000\text{ppm}$	8ppm
Conclusion: The above analytical results conform to BP2015/EP8/COS R1-CEP 2002-143-Rev 00.		

QA Manager:

王峰 2015年7月21日

QC Manager:

王峰 2015年7月21日

Analyst: 322813

2015年7月21日