

Hegno

FAGRON IBÉRICA, S.A.U

Corresponde al lote de Fagron:

84 YiDong Street, Hongshan District, Chifeng, Inner Mongolia 024001 China

Tel: +86 (21) 60753300 Fax: +86 (21) 60753311 www.hegno.com

Chifeng Pharmaceutical Co., Ltd.

CERTIFICATE OF ANALYSIS

Director Técnico

No.:ZL-QC251-02

Product: Griseofulvin		
Batch No.: HH150528	Reference standard: BP2015/EP8/COS	
MFG. Date: May24,2015	Batch Size: 500kg	
EXP. Date: May24,2019		
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	$\leq 5\mu\text{m} \geq 87.0\%$	94.92 %
	$\leq 10\mu\text{m} \geq 90.0\%$	99.88%
	$\leq 30\mu\text{m} \geq 99.0\%$	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° ~ +364°	+ 358°
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	0.34
	Dehydrogriseofulvin ≤ 0.15	0.08
Related substances (HPLC)	Griseofulvic acid $\leq 0.75\%$	Not detected
	Any other detectable impurity $\leq 0.10\%$	Not detected
	Total impurities $\leq 4.0\%$	1.8%
Residual Ethanol (GC)	$\leq 5000\text{ppm}$	29ppm
Abnormal toxicity	None mices dies within 48h	Meets the requirements
Assay (on dried basis)	97.0% ~ 102.0%	99.1%
Conclusion: The above analytical results conform to BP2015/EP8/COS R1-CEP 2002-143-Rev 00.		

QA Manager:

QC Manager:

Analyst: 320208 2015年5月29日

2015年5月29日

2015年5月29日