

*Griseofulvinum***Hegno**

Chifeng Pharmaceutical Co., Ltd.

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

Tel: +86 (21) 60753366 Fax: +86 (21) 60753355 www.hegno.com

FAGRON IBERICA, S.A.

n° Cote 12I/03-804

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ANNA VIÑAS

Director Técnico

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	$\leq 5\mu\text{m} \geq 87.0\%$	95.89%
	$\leq 10\mu\text{m} \geq 90.0\%$	99.91%
	$\leq 30\mu\text{m} \geq 99.0\%$	100.00%
Melting point	About 220 °C	218.5 °C – 219.4 °C
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	$\leq 0.2\%$	0.1%
Sulphated ash	$\leq 0.2\%$	0.1%
Loss on drying	$\leq 1.0\%$	0.12%
Related substances (GC)	Dechlorogriseofulvin ≤ 0.60	0.33
	Dehydrogriseofulvin ≤ 0.15	0.07
Related substances (HPLC)	Griseofulvic acid $\leq 0.75\%$	Not detected
	Any other detectable impurity $\leq 0.10\%$	Not detected
	Total impurities $\leq 4.0\%$	2.2%
Residual Ethanol (GC)	$\leq 5000\text{ppm}$	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:

王新强

2012年8月9日

QC Manager:

裴光林

2012年8月9日

Analyst:

刘永华

2012年8月9日