

Hegno

C7-003-11-0083

Griseofulvinum

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CERTIFICATE OF ANALYSIS

No.: ZL-QC251-01

Product: Griseofulvin		
Batch No.: 130630	Reference standard: BP2011/EP7/COS	
MFG. Date: Jun.30,2013	Batch Size: 500kg	
EXP. Date: Jun.30,2017		
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	$\leq 5\mu\text{m} \geq 87.0\%$	93.96%
	$\leq 10\mu\text{m} \geq 90.0\%$	99.26%
	$\leq 30\mu\text{m} \geq 99.0\%$	100.00%
Melting point	About 220°C	218.3°C – 219.4°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°	+357°
Substances soluble in light petroleum	$\leq 0.2\%$	0.1%
Sulphated ash	$\leq 0.2\%$	0.1%
Loss on drying	$\leq 1.0\%$	0.12%
Related substances (GC)	Dechlorogriseofulvin ≤ 0.60	0.38
	Dehydrogriseofulvin ≤ 0.15	0.05
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)	$\leq 5000\text{ppm}$	37ppm
Abnormal toxicity	None mice dies within 48h	Meets the requirements
Assay (on dried basis)	97.0% ~ 102.0%	98.7%
Conclusion: The above analytical results conform to BP2011/EP7/COS R1-CEP 2002-143-Rev 00.		

QA Manager:

王树楚
2013年7月12日

QC Manager: U

FAGRON IDENTIFICATION
Corresponde al lote de Fagron:

13G-30-806

Director Técnico S.

Analyst: 张亚娟
2013年7月12日

2013年7月