

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

18A 23-H04-00724

INNER MONGOLIA GLINT PHARMACEUTICAL CO., LTD.

North Weixin Road, Hongshan Economic Developing Zone, Chifeng, Inner Mongolia, China

024000-CHINA

CERTIFICATE OF ANALYSIS

Director Técnico

Product: Griseofulvin		
Batch No.: BP/EP-170222	Reference standard: BP2013/EP8	
Batch Size : 500 Kg	MFG. Date: FEB. 10, 2017	
Shipped Quantity : 100 Kg	EXP. Date: FEB. 10, 2021	
Tests	Specifications	Results
Description	A white or yellowish-white, microfine powder.	A white, microfine powder
Particle size	The particles of which are generally up to 5um in max dimension Larger particles which may occasionally exceed 30um	≤5μm: ≥87.0% ≤10μm: ≥90.0% ≤30μm: ≥99.0%
Melting point	About 220°C	221.4°C
Identification	The infrared absorbance spectrum is concordant with the reference spectrum	Conforms
	A wine-red color develops	Conforms
Appearance of solution	The solution is clear and not more intensely coloured than reference solution Y ₄ .	Clear, < Y ₄
Acidity	Not more than 1.0ml of 0.02M sodium hydroxide is required	0.38ml
Specific optical rotation	+354° to +364°	+359.1°
Related substances	-Cl: < 0.60	1.53% (0.31)
	-H: < 0.15	0.26% (0.05)
Substance soluble in light petroleum	≤0.2%	0.14%
Loss on drying	≤1.0%	0.04%
Sulfated ash	≤0.2%	0.07%
Abnormal toxicity	Five mice orals, none of the mice dies within 48h	Conforms
Assay(dried substance)	97.0% to 102.0%	98.5%
Conclusion: The above analytical results conform to BP2013/EP8		

Analyzer: Feng Qinglei

checked by: Song Ge

Manager: Ren Xiaogui

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