METAPHARMACEUTICAL IND SL
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GRISEOFULVINA (EUR. PH.)

PRODUCT CODE: 1067	CAS Nº: 126-07-8	ANALYSIS Nº: 294/24	
MANUFACTURER BATCH:	C007-240910	CERTIFICATE ID:	44.215
SUPPLIER BATCH:	----	MANUFACTURING DATE:	29/07/2024
METAPH BATCH:	0191124	EXPIRY DATE:	28/07/2028

ATTRIBUTES	SHOULD BE	IS
Appearance	White or yellowish-white, powder	White powder
Solubility	Practically insoluble in water, freely soluble in DMF and tetrachloroethane, slightly soluble in anhydrous ethanol and in methanol	Complies (*)
Melting point	About 220 ºC	221.5 ºC
Identification	Complies	Complies
Appearance of solution	Clear and not mor intensely coloured than ref. sol. Y4	Complies
Acidity	=< 1.0 mL of 0.02 M NaOH 0.02 M	0.7 mL of 0.02 M NaOH
Specific optical rotation	+354 / +364	+358
Related substances		
Impurity B	=< 3.0 %	0.8 %
Impurity A	=< 2.0 %	0.3 %
Impurity C	=< 0.75 %	0.3 %
Unspecified impurities	=< 0.15 %	No Detected
Total impurities	=< 5.0 %	1.4 %
Loss on drying	=< 1.0 %	0.1 %
Sulfated ash	=< 0.2 %	0.1 %
Assay	94.0 - 102.0 %	98.2 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliance with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Griseofulvin is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

(*) Data adapted from the manufacturer's certificate of analysis.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Keep the containers tightly closed.

Analysis date: 13/01/2025
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000906
INNER MONGOLIA GLINT PHARMACEUTICAL CO., LTD
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