METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

1067-TDS-ENG-2023

GRISEOFULVINA - EP		
DESCRIPTION DCI: GRISEOFULVIN	DESCRIPTION DOE: GRISEOFULVINA	
CAS Nº: 126-07-8	EC Nº: 204-767-4	AEMPS CODE: 1683A
MOL. WEIGHT: 352.77	MOL. FORMULA: C17H17ClO6	ARTICLE CODE: 1067

ATTRIBUTES	SHOULD BE
Appearance	White or yellowish-white, microfine powder
Solubility	Practically insoluble in water, freely soluble in DMF and tetrachloroethane, slightly soluble in anhydrous ethanol and in methanol
Melting point	About 220 ºC
Identification	Complies
Appearance of solution	Clear and not mor intensely coloured than ref. sol. Y4
Acidity	=< 1.0 mL of 0.02 M NaOH 0.02 M
Specific optical rotation	+354 / +364
Related substances	
Impurity B	=< 3.0 %
Impurity A	=< 2.0 %
Impurity C	=< 0.75 %
Unspecified impurities	=< 0.15 %
Total impurities	=< 5.0 %
Loss on drying	=< 1.0 %
Sulfated ash	=< 0.2 %
Assay	94.0 - 102.0 %
Residual solvents	
Ethanol	=< 0.5 %
Acetone	=< 0.5 %
Methylene Chloride	=< 0.06 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep the containers tightly closed.

REMARKS

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

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.