METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

1490-TDS-ENG-2025

PREDNISOLONA BASE (EUR. PH.)		
DESCRIPTION DCI: PREDNISOLONE	DESCRIPTION DOE: PREDNISOLONA	
CAS Nº: 50-24-8	EC Nº: 200-021-7	AEMPS CODE: 887A
MOL. WEIGHT: 360,45	MOL. FORMULA: C21H28O5	ARTICLE CODE: 1490

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline, hygroscopic powder
Solubility	Very slightly soluble in water, soluble in ethanol (96 %) and in methanol, sparingly soluble in acetone, slightly soluble in methylene chloride
Identification A	Complies
Identification B	Complies
Specific optical rotation	+113 / +119
Related substances	
Impurity A	=< 1.0 %
Impurity F	=< 0.5 %
Impurity B	=< 0.3 %
Impurity C	=< 0.3 %
Impurity J	=< 0.3 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 1.5 %
Loss on drying	=< 1.0 %
Assay	96.5 - 102.0 %

COMPLIES WITH

Eurepean Pharmacopoeia 11.4

STORAGE

Keep the container tightly closed, in a cool, dry place. Protected from air and light.

REMARKS

It shows polymorphism.

Prednisolone 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.