

TECHNICAL DATA SHEET

1084-TDS-ENG-2026

HIDROCORTISONA BASE (EUR. PH.)		
DESCRIPTION DCI: HYDROCORTISONE		DESCRIPTION DOE: HIDROCORTISONA
CAS Nº: 50-23-7	EC Nº: 200-020-1	AEMPS CODE: 54A
MOL. WEIGHT: 362,47	MOL. FORMULA: C ₂₁ H ₃₀ O ₅	ARTICLE CODE: 1084

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Practically insoluble in water, sparingly soluble in acetone and in ethanol (96 %), slightly soluble in methylene chloride
Identification A	Complies
Identification B	Complies
Specific optical rotation	+162 / +168
Related substances	
Impurity C	=< 0.5 %
Impurity D	=< 0.5 %
Impurity E	=< 0.5 %
Impurity I	=< 0.5 %
Impurity G	=< 0.4 %
Impurity F	=< 0.3 %
Impurity A	=< 0.2 %
Impurity B	=< 0.2 %
Impurity H	=< 0.15 %
Impurity N	=< 0.15 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 2.0 %
Loss on drying	=< 1.0 %
Assay	97.0 - 103.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Protect from the light. Keep the container tightly closed in a dry and well-ventilated place.

REMARKS

Hydrocortisone is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

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,

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which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.