

HIDROCORTISONA BASE (EUR. PH.)			
PRODUCT CODE: 1084		CAS Nº: 50-23-7	ANALYSIS Nº: 275/23
MANUFACTURER BATCH:	K05M20230802	CERTIFICATE ID:	40.183
SUPPLIER BATCH:	----	MANUFACTURING DATE:	12/08/2023
METAPH BATCH:	0111123	RETEST DATE:	30/07/2028

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	Almost white, crystalline powder
Identification A	Complies	Complies
Identification B	Complies	Complies
Specific optical rotation	+162 / +168	+166
Related substances		
Impurity C	=< 0.5 %	0.12 %
Impurity D	=< 0.5 %	< 0.05 %
Impurity E	=< 0.5 %	< 0.05 %
Impurity I	=< 0.5 %	0.05 %
Impurity G	=< 0.4 %	< 0.05 %
Impurity F	=< 0.3 %	< 0.05 %
Impurity A	=< 0.2 %	0.06 %
Impurity B	=< 0.2 %	< 0.05 %
Impurity H	=< 0.15 %	< 0.05 %
Impurity N	=< 0.15 %	< 0.05 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 2.0 %	0.2 %
Loss on drying	=< 1.0 %	0.1 %
Assay	97.0 - 103.0 %	100.9 %

COMPLIES WITH

European Pharmacopoeia 11.0

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".

All data controlled by Metapharmaceutical Industrial SL.

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

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

Analysis date: 20/12/2023
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000493
 HENAN LIHUA Ph. Co., Ltd.
 Middle Of Huanghe Street, Hi-Tech Industry
 Development Zone
 455000 Anyang

