METAPHARMACEUTICAL IND SL
Josep Plà, 163, 2n 5a / Tel. 933 089 976 / info@metapharmaceutical.com

PREDNISOLONA BASE (EUR. PH.)

PRODUCT CODE: 1490	CAS Nº: 50-24-8	ANALYSIS Nº: 073/24	
MANUFACTURER BATCH:	K04I20231222	CERTIFICATE ID:	41.535
SUPPLIER BATCH:	BT24005	MANUFACTURING DATE:	29/12/2023
METAPH BATCH:	0260324	RETEST DATE:	30/11/2028

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline, hygroscopic powder	White, crystalline, hygroscopic powder
Identification A	Complies	Complies
Identification B	Complies	Complies
Specific optical rotation	+113 / +119	+115
Related substances		
Impurity A	=< 1.0 %	0.05 %
Impurity F	=< 0.5 %	< 0.05 %
Impurity B	=< 0.3 %	< 0.05 %
Impurity C	=< 0.3 %	< 0.05 %
Impurity J	=< 0.3 %	< 0.05 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 1.5 %	0.05 %
Loss on drying	=< 1.0 %	0.03 %
Assay	96.5 - 102.0 %	100.0 %

COMPLIES WITH

Eurepean Pharmacopoeia 11.0

REMARKS

It shows polymoprphism (5.9).

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

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

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

Analysis date: 08/04/2024
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