



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 212601

Product:	PREDNISOLONE
Lot:	212601
Expiry date:	01/02/2026
Reference:	Cumple PhEur10.4
Synonyms:	
Formula:	C ₂₁ H ₂₈ O ₅
Molecular weight:	360,5 g/mol

Assay	Result	Specification	
Identification	Conform (A,B)	Test PhEur (A,B)	
Organoleptic properties	Conform	PhEur	
Related substances (HPLC)	Conform	Test PhEur	
Specific rotation	+117	(+113) - (+119)	
Loss on drying	0,12 %	<= 1,0 %	
Assay (HPLC)	99,9 %	96,5-102,0%	
Elemental impurities	Conform	Test PhEur	#
Impurity A	0,66 %	<= 1,0 %	
Impurity B	0,06 %	<= 0,3 %	
Impurity C	NDT	<= 0,3 %	
Impurity F	NDT	<= 0,5 %	
Impurity J	<= 0,05 %	<= 0,3 %	
Unspecified Impurities	<= 0,05 %	<= 0,10 %	
Total impurities	0,72 %	<= 1,5 %	
Residual solvent: Methanol	<= 3000 ppm	<= 3000 ppm	#
Residual solvent: methylene chloride	<= 600 ppm	<= 600 ppm	#

Organoleptic characteristics: White or nearly white crystalline powder, hygroscopic. Very slightly soluble in water, soluble in 96% ethanol and in methanol, fairly soluble in acetone, slightly soluble in methylene chloride.

Conservation: In tightly closed containers. Protect from light and moisture.

Date of analysis: 07/07/2021

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00023 HENAN LIHUA PHARMACEUTICAL CO. LTD.

Manufacturer batch: K04I20210402

Product	Name	Capacity	Batch
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1166803	PREDNISOLONA (INACTIVO)	5 g	212601-E-1
1166803	PREDNISOLONA (INACTIVO)	5 g	212601-E-2
1166803	PREDNISOLONA (INACTIVO)	5 g	212601-E-3
1166805	PREDNISOLONA	25 g	212601-G-1
1166805	PREDNISOLONA	25 g	212601-G-2
1166805	PREDNISOLONA	25 g	212601-G-3
1166808	PREDNISOLONA	250 g	212601-N-1
1166810	PREDNISOLONA	1 kg	212601-P-1

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

ACOFARMA DISTRIBUCIÓN, S.A.

C/ Llobregat, 20 - 08223 Terrassa (Barcelona)

Tel./ 93-736.00.88

www.acofarma.com

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