



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 215214

Product:	PREDNISONONE
Lot:	215214
Expiry date:	01/03/2026
Reference:	Cumple PhEur10.5
Synonyms:	
Formule:	C ₂₁ H ₂₆ O ₅
Poids moléculaire:	358,4 g/mol

Assay	Result	Specification	
Identification	Conform (A,C)		
Organoleptic properties	Conform	PhEur	
Specific rotation	+186	(+183) - (+191)	
Related substances (HPLC)	Conform	Test PhEur	
Loss on drying	0,06 %	<= 1,0 %	
Assay	100,5 %	97,0 - 102,0 %	
Elemental impurities	Conform	Test PhEur	#
Impurity A	0,1 %	<= 0,5 %	
Impurity D	NDT	<= 0,15 %	
Impurity E	<= 0,05 %	<= 0,2 %	
Unspecified Impurities	0,05 %	<= 0,10 %	
Total impurities	0,2 %	<= 1,0 %	
Residual solvent: Methanol	<= 3000 ppm	<= 3000 ppm	#
Residual solvent: acetone	<= 5000 ppm	<= 5000 ppm	#
Residual solvent: Chloroform	<= 60 ppm	<= 60 ppm	#

Organoleptic characteristics: White or almost white crystalline powder. Practic. insoluble in water, slightly soluble in ethanol 96% and in methylene chloride.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 20/10/2021

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00023 HENAN LIHUA PHARMACEUTICAL CO. LTD.

Manufacturer batch: K03C20210501M

Produit	Nom	Capacité	Lot
1166837	PREDNISONA	5 g	215214-E-1
1166837	PREDNISONA	5 g	215214-E-2

1166839	PREDNISONA	25 g	215214-G-1
1166839	PREDNISONA	25 g	215214-G-2

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

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C/ Llobregat, 20 - 08223 Terrassa (Barcelona)

Tel./ 93-736.00.88

www.acofarma.com

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