



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 223684

Product:	PREDNISONNE
Lot:	223684
Expiry date:	30/04/2027
Reference:	Cumple PhEur10.8
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	+183	(+183) - (+191)	
Related substances (HPLC)	Conform	Test PhEur	
Loss on drying	0,14 %	<= 1,0 %	
Assay	99,5 %	97,0 - 102,0 %	
Elemental impurities	Conform	Test PhEur	#
Impurity A	0,07 %	<= 0,5 %	
Impurity D	< 0,05 %	<= 0,15 %	
Impurity E	< 0,05 %	<= 0,2 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	0,07 %	<= 1,0 %	
Residual solvent: Methanol	ND	<= 3000 ppm	#
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Chloroform	ND	<= 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: 21/07/2022

Judgement:
APPROVED

Responsible: C. Codina

Technical director: Montserrat Enrique

Manufacturer: F00023 HENAN LIHUA PHARMACEUTICAL CO. LTD.

Manufacturer batch: K03C20220507M

Produit	Nom	Capacité	Lot
1166837	PREDNISONA	5 g	223684-E-2
1166837	PREDNISONA	5 g	223684-E-4

1166839	PREDNISONA	25 g	223684-G-1
1166839	PREDNISONA	25 g	223684-G-2
1166844	PREDNISONA	1 kg	223684-P-1
1166844	PREDNISONA	1 kg	223684-P-2
1370133	PREDNISONA (FLB) (INACTIVO)	1 g	223684-D-1
1370133	PREDNISONA (FLB) (INACTIVO)	1 g	223684-D-2
1370244	PREDNISONA (FLB)	5 g	223684-E-1
1370244	PREDNISONA (FLB)	5 g	223684-E-3

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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