



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 200837

Product:	PREDNISONA
Lot:	200837
Expiry date:	01/02/2025
Reference:	Cumple PhEur10.2
Synonyms:	
Formula:	C ₂₁ H ₂₆ O ₅
Molecular weight:	358,4 g/mol

Assay	Result	Specification	
Identification	Conform(A,C)		
Organoleptic properties	Conform	PhEur	
Specific rotation	+188°	(+183°) - (+191°)	
Related substances (HPLC)	Conform	Test PhEur	
Loss on drying	0,02 %	<= 1,0 %	
Assay	100,6 %	97,0 - 102,0 %	
Impurity A	0,08 %	<= 0,5 %	
Impurity D	0,01%	<= 0,15 %	
Impurity E	0,03 %	<= 0,2 %	
Unspecified Impurities	<=0,10 %	<= 0,10 %	
Total impurities	0,23 %	<= 1,0 %	
Residual solvent: Methanol	<=3000ppm	<= 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: 20/07/2020

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00023 HENAN LIHUA PHARMACEUTICAL CO. LTD.

Manufacturer batch: K03C20200404M

Product	Name	Capacity	Batch
1166837	PREDNISONA	5 g	200837-E-1
1166837	PREDNISONA	5 g	200837-E-2
1166837	PREDNISONA	5 g	200837-E-3

1166837	PREDNISONA	5 g	200837-E-4
1166839	PREDNISONA	25 g	200837-G-1
1166839	PREDNISONA	25 g	200837-G-2
1166842	PREDNISONA (INACTIVO)	250 g	200837-N-1
1166844	PREDNISONA	1 kg	200837-P-1
1166844	PREDNISONA	1 kg	200837-P-2
1370133	PREDNISONA (FLB) (INACTIVO)	1 g	200837-D-1
1370133	PREDNISONA (FLB) (INACTIVO)	1 g	200837-D-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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