



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 240791

Product:	PREDNISONONE
Lot:	240791
Expiry date:	30/04/2027
Reference:	Cumple PhEur11.4
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	(+187)	(+183) - (+191)	
Related substances (HPLC)	Conform	Test PhEur	
Loss on drying	0,10 %	<= 1,0 %	
Assay	99,6 %	97,0 - 102,0 %	
Elemental impurities	Conform	Test PhEur	#
Impurity A	0,06 %	<= 0,5 %	
Impurity D	< 0,05 %	<= 0,15 %	
Impurity E	< 0,05 %	<= 0,2 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	0,06 %	<= 1,0 %	
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Chloroform	< 60 ppm	<= 60 ppm	#
Nitrosamine impurities	Conform	Test PhEur	#

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: 11/06/2024

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F00023 HENAN LIHUA PHARMACEUTICAL CO. LTD.

Manufacturer batch: K03C20220507M

Product	Name	Capacity	Batch
1166837	PREDNISONA	5 g	240791-E-1

1166837	PREDNISONA	5 g	240791-E-2
1166837	PREDNISONA	5 g	240791-E-3
1166837	PREDNISONA	5 g	240791-E-4
1166839	PREDNISONA	25 g	240791-G-1
1166839	PREDNISONA	25 g	240791-G-2
1166839	PREDNISONA	25 g	240791-G-3
1166839	PREDNISONA	25 g	240791-G-4

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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