



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 233384

Product:	PREDNISOLONE
Lot:	233384
Expiry date:	31/03/2027
Reference:	Cumple PhEur11.2
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	0,04 %	<= 1,0 %	
Assay (HPLC)	99,3 %	96,5-102,0%	
Elemental impurities	Conform	Test PhEur	#
Impurity A	0,68 %	<= 1,0 %	
Impurity B	< 0,05 %	<= 0,3 %	
Impurity C	< 0,05 %	<= 0,3 %	
Impurity F	< 0,05 %	<= 0,5 %	
Impurity J	< 0,05 %	<= 0,3 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	0,68 %	<= 1,5 %	
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: methylene chloride	< 600 ppm	<= 600 ppm	#
Nitrosamine impurities	Conform	Test PhEur	#

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: 23/10/2023

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00023 HENAN LIHUA PHARMACEUTICAL CO. LTD.

Manufacturer batch: K04I20220403

Product	Name	Capacity	Batch
1166805	PREDNISOLONA	25 g	233384-G-2
1166805	PREDNISOLONA	25 g	233384-G-4
1166808	PREDNISOLONA	250 g	233384-N-1
1166810	PREDNISOLONA	1 kg	233384-P-1
1370246	PREDNISOLONA (FLB)	5 g	233384-E-1
1370246	PREDNISOLONA (FLB)	5 g	233384-E-2
1370246	PREDNISOLONA (FLB)	5 g	233384-E-3
1370247	PREDNISOLONA (FLB)	25 g	233384-G-1
1370247	PREDNISOLONA (FLB)	25 g	233384-G-3
1370247	PREDNISOLONA (FLB)	25 g	233384-G-5

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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