



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 252083

Product:	METHYLPREDNISOLONE
Lot:	252083
Expiry date:	30/03/2028
Reference:	Cumple PhEur11.8
Synonyms:	6-alfa-Metilprednisolona.
Formula:	C ₂₂ H ₃₀ O ₅
Molecular weight:	374,5 g/mol

Assay	Result	Specification	
Identification	Conform (A,B)		
Organoleptic properties	Conform		
Related substances (HPLC)	Conform		
Specific rotation	+99,8	(+97,0) - (+103,0)	
Loss on drying	0,10 %	<= 1,0 %	
Assay	99,3 %	97,0 - 102,0 %	
Impurity A	< 0,05 %	<= 0,3 %	
Impurity B	0,05 %	<= 0,2 %	
Impurity C	< 0,05 %	<= 0,15 %	
Impurity D	0,14 %	<= 0,5 %	
Impurity E	< 0,05 %	<= 0,15 %	
Impurity F	< 0,05 %	<= 0,15 %	
Impurity H	< 0,05 %	<= 0,2 %	
Sum of impurities G and I	0,07 %	<= 0,3 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	0,26 %	<= 2,0 %	
Residual solvent: methylene chloride	< 600 ppm	<= 600 ppm	#
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Elemental impurities	Conform	Test PhEur	#
Nitrosamine impurities	Conform		#

Organoleptic characteristics: White or almost white, crystalline powder. Practically insoluble in water, sparingly soluble in ethanol (96 per cent), slightly soluble in acetone and in methylene chloride. It shows polymorphism. FRIDGE (2-8°C)

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 24/11/2025

Responsible: B. Chia

Judgement:
APPROVED

Technical director: Montserrat Enrique

Manufacturer: F01052 HENAN LIHUA PHARMACEUTICAL CO. LTD.

Manufacturer batch: 15D20250402

Product	Name	Capacity	Batch
1160249	METILPREDNISOLONA	1 g	252083-D-2
1160250	METILPREDNISOLONA	5 g	252083-E-1
1160253	METILPREDNISOLONA	50 g	252083-I-1
1160254	METILPREDNISOLONA	500 g	252083-O-1
1370116	METILPREDNISOLONA (FLB)	1 g	252083-D-1

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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