



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 242177

Product:	METHYLPREDNISOLONE
Lot:	242177
Expiry date:	15/03/2026
Reference:	Cumple PhEur11.5
Synonyms:	6-alfa-Metilprednisolona.
Formule:	C ₂₂ H ₃₀ O ₅
Poids moléculaire:	374,5 g/mol

Assay	Result	Specification	
Nitrosamine impurities	Conform		#
Elemental impurities	Conform	Test PhEur	#
Residual solvent: Chloroform	< 60 ppm	<= 60 ppm	#
Related substances (HPLC)	Conform		
Sum of impurities G and I	<= 0,05 %	<= 0,3 %	
Organoleptic properties	Conform		
Impurity H	<= 0,05 %	<= 0,2 %	
Identification	Conform (A,B)		
Impurity F	<= 0,05 %	<= 0,15 %	
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Assay	100,3 %	97,0 - 102,0 %	
Residual solvent: methylene chloride	< 600 ppm	<= 600 ppm	#
Loss on drying	0,24 %	<= 1,0 %	
Total impurities	<= 0,05 %	<= 2,0 %	
Specific rotation	+ 100,1	(+97,0) - (+103,0)	
Unspecified Impurities	<= 0,05 %	<= 0,10 %	
Impurity A	<= 0,05 %	<= 0,3 %	
Impurity E	ND	<= 0,15 %	
Impurity D	<= 0,05 %	<= 0,5 %	
Impurity C	ND	<= 0,15 %	
Impurity B	<= 0,05 %	<= 0,2 %	

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: 19/11/2024

Responsible: B. Chia

Judgement:
APPROVED

Technical director: Montserrat Enrique

Manufacturer: F00101 TIANJIN TIANYAO PHARMACEUTICALS CO., LTD.

Manufacturer batch: NXEMP220407

Produit	Nom	Capacité	Lot
1160249	METILPREDNISOLONA	1 g	242177-D-1
1160249	METILPREDNISOLONA	1 g	242177-D-3
1160250	METILPREDNISOLONA	5 g	242177-E-1
1160250	METILPREDNISOLONA	5 g	242177-E-2
1160253	METILPREDNISOLONA	50 g	242177-I-1
1160253	METILPREDNISOLONA	50 g	242177-I-2
1160253	METILPREDNISOLONA	50 g	242177-I-3
1370116	METILPREDNISOLONA (FLB)	1 g	242177-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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