



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 251080

Product:	HYDROCORTISONE ACETATE
Lot:	251080
Expiry date:	31/12/2029
Reference:	Cumple PhEur11.7
Synonyms:	
Formula:	C ₂₃ H ₃₂ O ₆
Molecular weight:	404,5 g/mol

Assay	Result	Specification	
Identification	Conform (A,B)	Test PhEur (A,B)	
Organoleptic properties	Conform	PhEur	
Specific rotation	(+165)	(+158) - (+167)	
Related substances (HPLC)	Conform	Test PhEur	
Loss on drying	0,05 %	<= 0,5%	
Assay (HPLC)	99,2 %	97,0-102,0%	
Elemental impurities	Conform	Test PhEur	#
Impurity A	0,10 %	<= 0,5 %	
Impurity B	< 0,05 %	<= 0,3 %	
Impurity C	0,05 %	<= 0,6 %	
Impurity D	< 0,05 %	<= 0,3 %	
Impurity E	< 0,05 %	<= 0,3 %	
Impurity G	< 0,05 %	<= 0,15 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	0,15 %	<= 1,5 %	
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: methylene chloride	< 600 ppm	<= 600 ppm	#

Organoleptic characteristics: White or almost white, crystalline powder. Practically insoluble in water, slightly soluble in anhydrous ethanol and in methylene chloride.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 04/06/2025

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00023 HENAN LIHUA PHARMACEUTICAL CO. LTD.

Manufacturer batch: K06M20250116

Product	Name	Capacity	Batch
1150503	HIDROCORTISONA ACETATO	5 g	251080-E-2
1150505	HIDROCORTISONA ACETATO	25 g	251080-G-1
1150505	HIDROCORTISONA ACETATO	25 g	251080-G-2
1150508	HIDROCORTISONA ACETATO	250 g	251080-N-1
1370208	HIDROCORTISONA ACETATO (FLB)	1 g	251080-D-1
1370208	HIDROCORTISONA ACETATO (FLB)	1 g	251080-D-2
1370209	HIDROCORTISONA ACETATO (FLB)	5 g	251080-E-1
1370209	HIDROCORTISONA ACETATO (FLB)	5 g	251080-E-3

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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