



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 221419**

Product:	HYDROCORTISONE BASE
Lot:	221419
Expiry date:	31/10/2026
Reference:	Cumple PhEur10.7
Synonyms:	17-Hidroxicorticosterona.
Formula:	C <sub>21</sub> H <sub>30</sub> O <sub>5</sub>
Molecular weight:	362,5 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	+166	(+162°)-(+168°)	
Loss on drying	0,0 %	<= 1,0 %	
Assay	97,6 %	97,0-103,0%	
Impurity A	<= 0,05 %	<= 0,2 %	
Impurity B	<= 0,05 %	<= 0,2 %	
Impurity C	<= 0,05 %	<= 0,5 %	
Impurity D	<= 0,05 %	<= 0,5 %	
Impurity E	<= 0,05 %	<= 0,5 %	
Impurity F	NDT	<= 0,3 %	
Impurity G	0,19%	<= 0,4 %	
Impurity H	NDT	<= 0,15 %	
Impurity I	<= 0,05 %	<= 0,5 %	
Impurity N	<= 0,05 %	<= 0,15 %	
Unspecified Impurities	<= 0,05 %	<= 0,10 %	
Total impurities	0,19 %	<= 2,0 %	
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: methylene chloride	< 600 ppm	<= 600 ppm	#
Elemental impurities	Conform	Test PhEur	#

Organoleptic characteristics: White or almost white, crystalline powder. Practically insoluble in water, sparingly soluble in acetone and in ethanol (96 per cent), slightly soluble in methylene chloride.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 05/04/2022

Responsible: M. Mesa

Judgement:  
APPROVED

Technical director: Montserrat Enrique

Manufacturer: F00023 HENAN LIHUA PHARMACEUTICAL CO. LTD.

Manufacturer batch: K05M20211103

Product	Name	Capacity	Batch
1150552	HIDROCORTISONA BASE	1 g	221419-D-1
1150553	HIDROCORTISONA BASE	5 g	221419-E-1
1150554	HIDROCORTISONA BASE	25 g	221419-G-1
1150554	HIDROCORTISONA BASE	25 g	221419-G-2
1150556	HIDROCORTISONA BASE	100 g	221419-J-1
1200177	HIDROCORTISONA BASE	250 g	221419-N-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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Date of edition: 24/06/2026

