



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 214635

Product:	HYDROCORTISONE BASE
Lot:	214635
Expiry date:	01/12/2025
Reference:	Cumple PhEur10.5
Synonyms:	17-Hidroxicorticosterona.
Formula:	C ₂₁ H ₃₀ O ₅
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	165	(+162°)-(+168°)	
Loss on drying	0,05 %	<= 1,0 %	
Assay	100,3 %	97,0-103,0%	
Impurity A	0,05 %	<= 0,2 %	
Impurity B	<= 0,05 %	<= 0,2 %	
Impurity C	0,07 %	<= 0,5 %	
Impurity D	<= 0,05 %	<= 0,5 %	
Impurity E	<= 0,05 %	<= 0,5 %	
Impurity F	<= 0,05 %	<= 0,3 %	
Impurity G	<= 0,05 %	<= 0,4 %	
Impurity H	NDT	<= 0,15 %	
Impurity I	NDT	<= 0,5 %	
Impurity N	<= 0,05 %	<= 0,15 %	
Unspecified Impurities	0,07 %	<= 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: 01/09/2021

Responsible: M. Mesa

Judgement:
APPROVED

Technical director: Montserrat Enrique

Manufacturer: F00023 HENAN LIHUA PHARMACEUTICAL CO. LTD.

Manufacturer batch: K05M20210104M

Product	Name	Capacity	Batch
1150552	HIDROCORTISONA BASE	1 g	214635-D-1
1150552	HIDROCORTISONA BASE	1 g	214635-D-2
1150553	HIDROCORTISONA BASE	5 g	214635-E-1
1150553	HIDROCORTISONA BASE	5 g	214635-E-2
1150554	HIDROCORTISONA BASE	25 g	214635-G-1
1150554	HIDROCORTISONA BASE	25 g	214635-G-2
1150556	HIDROCORTISONA BASE	100 g	214635-J-1
1150556	HIDROCORTISONA BASE	100 g	214635-J-2
1200177	HIDROCORTISONA BASE	250 g	214635-N-1
1200177	HIDROCORTISONA BASE	250 g	214635-N-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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