



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 226177**

Product:	HYDROCORTISONE ACETATE
Lot:	226177
Expiry date:	31/08/2027
Reference:	Cumple PhEur10.8
Synonyms:	
Formula:	C <sub>23</sub> H <sub>32</sub> O <sub>6</sub>
Molecular weight:	404,5 g/mol

Assay	Result	Specification	
Identification	Conform (A,B)	Test PhEur (A,B)	
Organoleptic properties	Conform	PhEur	
Specific rotation	+166	(+158) - (+167)	
Related substances (HPLC)	Conform	Test PhEur	
Loss on drying	0,03 %	<= 0,5%	
Assay (HPLC)	97,5 %	97,0-102,0%	
Elemental impurities	Conform	Test PhEur	#
Impurity A	0,12 %	<= 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	0,12 %	<= 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: 19/12/2022

Judgement:  
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00023 HENAN LIHUA PHARMACEUTICAL CO. LTD.

Manufacturer batch: K06M20221003

Product	Name	Capacity	Batch
1150502	HIDROCORTISONA ACETATO (INACTIVO)	1 g	226177-D-4
1150503	HIDROCORTISONA ACETATO	5 g	226177-E-2
1150503	HIDROCORTISONA ACETATO	5 g	226177-E-4
1150503	HIDROCORTISONA ACETATO	5 g	226177-E-5
1150503	HIDROCORTISONA ACETATO	5 g	226177-E-6
1150503	HIDROCORTISONA ACETATO	5 g	226177-E-8
1150505	HIDROCORTISONA ACETATO	25 g	226177-G-1
1150505	HIDROCORTISONA ACETATO	25 g	226177-G-2
1150505	HIDROCORTISONA ACETATO	25 g	226177-G-3
1150505	HIDROCORTISONA ACETATO	25 g	226177-G-4
1150508	HIDROCORTISONA ACETATO	250 g	226177-N-1
1150508	HIDROCORTISONA ACETATO	250 g	226177-N-2
1150508	HIDROCORTISONA ACETATO	250 g	226177-N-3
1370208	HIDROCORTISONA ACETATO (FLB)	1 g	226177-D-1
1370208	HIDROCORTISONA ACETATO (FLB)	1 g	226177-D-2
1370208	HIDROCORTISONA ACETATO (FLB)	1 g	226177-D-3
1370209	HIDROCORTISONA ACETATO (FLB)	5 g	226177-E-1
1370209	HIDROCORTISONA ACETATO (FLB)	5 g	226177-E-3
1370209	HIDROCORTISONA ACETATO (FLB)	5 g	226177-E-7
1370217	HIDROCORTISONA ACETATO (FLB)	1 kg	226177-P-1
1370217	HIDROCORTISONA ACETATO (FLB)	1 kg	226177-P-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

ACOFARMA DISTRIBUCIÓN, S.A.  
 C/ Llobregat, 20 - 08223 Terrassa (Barcelona)  
 Tel./ 93-736.00.88  
[www.acofarma.com](http://www.acofarma.com)

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