



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 251580

Product:	CLOBETASOL 17-PROPIONATE
Lot:	251580
Expiry date:	30/12/2028
Reference:	Cumple PhEur11.8
Synonyms:	
Formula:	C ₂₅ H ₃₂ ClFO ₅
Molecular weight:	467,0 g/mol

Assay	Result	Specification	
Identification	Conform	Test PhEur	
Organoleptic properties	Conform	PhEur	
Related substances (HPLC)	Conform	Test PhEur	
Specific rotation	(+114,5)	(+112,0) - (+118,0)	
Loss on drying	0,01 %	<= 0,5 %	
Sulphated ashes	0,01 %	<= 0,1%	
Assay (HPLC)	100,4 %	97,0-102,0%	
Impurity A	< 0,05 %	<= 0,2 %	
Impurity B	< 0,05 %	<= 0,3 %	
Impurity D	< 0,05 %	<= 0,2 %	
Impurity E	< 0,05 %	<= 0,3 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	< 0,05 %	<= 1,0 %	
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: methylene chloride	< 600 ppm	<= 600 ppm	#
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Dimethylformamide	< 880 ppm	<= 880 ppm	#
Nitrosamine impurities	Conform		#
Elemental impurities	Conform		#

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

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 01/09/2025

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F01052 HENAN LIHUA PHARMACEUTICAL CO. LTD.

Manufacturer batch: 39A20250101

Product	Name	Capacity	Batch
1119582	CLOBETASOL 17-PROPIONATO	1 g	251580-D-1
1119583	CLOBETASOL 17-PROPIONATO	5 g	251580-E-1
1119583	CLOBETASOL 17-PROPIONATO	5 g	251580-E-2
1119585	CLOBETASOL 17-PROPIONATO	100 g	251580-J-1
1119585	CLOBETASOL 17-PROPIONATO	100 g	251580-J-2
1119586	CLOBETASOL 17-PROPIONATO	25 g	251580-G-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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