



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 260592

Product:	CLOBETASOL 17-PROPIONATE
Lot:	260592
Expiry date:	30/01/2031
Reference:	Cumple PhEur12.2
Synonyms:	
Formule:	C ₂₅ H ₃₂ O ₅
Poids moléculaire:	467,0 g/mol

Assay	Result	Specification	
Identification	Conform	Test PhEur	
Organoleptic properties	Conform	PhEur	
Related substances (HPLC)	Conform	Test PhEur	
Specific rotation	+117	(+112) - (+118)	
Loss on drying	0,01 %	<= 0,5 %	
Sulphated ashes	0,02 %	<= 0,1%	
Assay (HPLC)	100,2 %	97,0-102,0%	
Impurity A	< 0,05 %	<= 0,2 %	
Impurity B	0,11 %	<= 0,3 %	
Impurity D	< 0,05 %	<= 0,2 %	
Impurity E	< 0,05 %	<= 0,3 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	0,11 %	<= 1,0 %	
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: methylene chloride	< 600 ppm	<= 600 ppm	#
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Ethyl acetate	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Dimethylformamide	< 880 ppm	<= 880 ppm	#
Residual solvent: Pyridine	< 200 ppm	<= 200 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: 13/05/2026

Responsible: B. Chia

Technical director: Montserrat Enrique

Judgement:
APPROVED

Manufacturer: F01058 GREAT PACIFIC EXPORTS PVT LTD.

Manufacturer batch:

Produit	Nom	Capacité	Lot
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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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