



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 250688

Product:	CLOBETASOL 17-PROPIONATE
Lot:	250688
Expiry date:	30/11/2029
Reference:	Cumple PhEur11.7
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	(+116,0)	(+112,0) - (+118,0)	
Loss on drying	0,00 %	<= 0,5 %	
Sulphated ashes	0,01 %	<= 0,1%	
Assay (HPLC)	100,1 %	97,0-102,0%	
Impurity A	< 0,05 %	<= 0,2 %	
Impurity B	0,07 %	<= 0,3 %	
Impurity D	< 0,05 %	<= 0,2 %	
Impurity E	< 0,05 %	<= 0,3 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	0,07 %	<= 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: 08/04/2025

Responsible: B.Chia

Technical director: Montserrat Enrique

Judgement:
APPROVED

Manufacturer: F00056 SYMBIOTICA SPECIALITY INGREDIENTS SDN BHD

Manufacturer batch: CLO116-1224

Produit	Nom	Capacité	Lot
1119582	CLOBETASOL 17-PROPIONATO	1 g	250688-D-1
1119583	CLOBETASOL 17-PROPIONATO	5 g	250688-E-1
1119585	CLOBETASOL 17-PROPIONATO	100 g	250688-J-1
1119586	CLOBETASOL 17-PROPIONATO	25 g	250688-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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