



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 223815

Product:	CLOBETASOL 17-PROPIONATE
Lot:	223815
Expiry date:	30/09/2026
Reference:	Cumple PhEur10.8
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	+114,1	(+112,0)-(+118,0)	
Loss on drying	0,09 %	<= 0,5 %	
Sulphated ashes	0,01 %	<= 0,1%	
Assay (HPLC)	98,8 %	97,0-102,0%	
Impurity A	0,05 %	<= 0,2 %	
Impurity B	0,06 %	<= 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	#

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: 27/07/2022

Judgement:
APPROVED

Responsible: C. Codina

Technical director: Montserrat Enrique

Manufacturer: F00056 SYMBIOTICA SPECIALITY INGREDIENTS SDN BHD

Manufacturer batch: CLO124-1021

Product	Name	Capacity	Batch
1119581	CLOBETASOL 17-PROPIONATO (INACTIVO)	0.5 g	223815-C-1
1119581	CLOBETASOL 17-PROPIONATO (INACTIVO)	0.5 g	223815-C-2
1119581	CLOBETASOL 17-PROPIONATO (INACTIVO)	0.5 g	223815-C-3
1119582	CLOBETASOL 17-PROPIONATO	1 g	223815-D-1
1119582	CLOBETASOL 17-PROPIONATO	1 g	223815-D-2
1119582	CLOBETASOL 17-PROPIONATO	1 g	223815-D-3
1119583	CLOBETASOL 17-PROPIONATO	5 g	223815-E-1
1119583	CLOBETASOL 17-PROPIONATO	5 g	223815-E-2
1119583	CLOBETASOL 17-PROPIONATO	5 g	223815-E-3
1119585	CLOBETASOL 17-PROPIONATO	100 g	223815-J-1
1119585	CLOBETASOL 17-PROPIONATO	100 g	223815-J-2
1119585	CLOBETASOL 17-PROPIONATO	100 g	223815-J-3
1119586	CLOBETASOL 17-PROPIONATO	25 g	223815-G-1
1119586	CLOBETASOL 17-PROPIONATO	25 g	223815-G-2
1200129	CLOBETASOL 17-PROPIONATO (INACTIVO)	0,25 g	223815-B-1
1200129	CLOBETASOL 17-PROPIONATO (INACTIVO)	0,25 g	223815-B-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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Date of edition: 19/05/2026

