



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 217241

Product:	CLOBETASOL 17-PROPIONATE
Lot:	217241
Expiry date:	01/09/2026
Reference:	Cumple PhEur10.6
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	+116,0	(+112,0)-(+118,0)	
Loss on drying	0,12 %	<= 0,5 %	
Sulphated ashes	0,00 %	<= 0,1%	
Assay (HPLC)	99,3 %	97,0-102,0%	
Impurity A	0,07 %	<= 0,2 %	
Impurity B	0,15 %	<= 0,3 %	
Impurity D	<= 0,05 %	<= 0,2 %	
Impurity E	NDT	<= 0,3 %	
Unspecified Impurities	<= 0,05 %	<= 0,10 %	
Total impurities	0,22 %	<= 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: 17/02/2022

Judgement:
APPROVED

Responsible: C. Codina

Technical director: Montserrat Enrique

Manufacturer: F00056 SYMBIOTICA SPECIALITY INGREDIENTS SDN BHD

Manufacturer batch: CLO121-1021

Product	Name	Capacity	Batch
1119581	CLOBETASOL 17-PROPIONATO (INACTIVO)	0.5 g	217241-C-1
1119582	CLOBETASOL 17-PROPIONATO	1 g	217241-D-1
1119582	CLOBETASOL 17-PROPIONATO	1 g	217241-D-2
1119583	CLOBETASOL 17-PROPIONATO	5 g	217241-E-1
1119585	CLOBETASOL 17-PROPIONATO	100 g	217241-J-1
1119586	CLOBETASOL 17-PROPIONATO	25 g	217241-G-1
1200129	CLOBETASOL 17-PROPIONATO (INACTIVO)	0,25 g	217241-B-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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