



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 212613

Product:	CLOBETASOL 17-PROPIONATE
Lot:	212613
Expiry date:	01/05/2025
Reference:	Cumple PhEur10.4
Synonyms:	
Formula:	C ₂₅ H ₃₂ ClFO ₅
Molecular weight:	467,0 g/mol

Assay	Result	Specification	
Residual solvent: Pyridine	<= 200 ppm	<= 200 ppm	#
Residual solvent: Ethyl acetate	<= 500 ppm	<= 5000 ppm	#
Residual solvent: Dimethylformamide	<= 880 ppm	<= 880 ppm	#
Residual solvent: methylene chloride	<= 600 ppm	<= 600 ppm	#
Residual solvent: acetone	<= 5000 ppm	<= 5000 ppm	#
Sulphated ashes	0,01 %	<= 0,1%	
Assay (HPLC)	99,2 %	97,0-102,0%	
Residual solvent: Methanol	<= 3000 ppm	<= 3000 ppm	#
Specific rotation	+115,1	(+112,0)-(+118,0)	
Loss on drying	0,13 %	<= 0,5 %	
Organoleptic properties	Conform	PhEur	
Unspecified Impurities	<= 0,05 %	<= 0,10 %	
Related substances (HPLC)	Conform	Test PhEur	
Total impurities	0,17 %	<= 1,0 %	
Impurity D	<= 0,05 %	<= 0,2 %	
Identification	Conform	Test PhEur	
Impurity E	NDT	<= 0,3 %	
Impurity A	<= 0,05 %	<= 0,2 %	
Impurity B	0,17 %	<= 0,3 %	

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 25/05/2021

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00056 SYMBIOTICA SPECIALITY INGREDIENTS SDN BHD

Manufacturer batch: CLO112-0620

Product	Name	Capacity	Batch
1119581	CLOBETASOL 17-PROPIONATO (INACTIVO)	0.5 g	212613-C-1
1119581	CLOBETASOL 17-PROPIONATO (INACTIVO)	0.5 g	212613-C-2
1119582	CLOBETASOL 17-PROPIONATO	1 g	212613-D-1
1119582	CLOBETASOL 17-PROPIONATO	1 g	212613-D-2
1119583	CLOBETASOL 17-PROPIONATO	5 g	212613-E-1
1119583	CLOBETASOL 17-PROPIONATO	5 g	212613-E-2
1119585	CLOBETASOL 17-PROPIONATO	100 g	212613-J-1
1119585	CLOBETASOL 17-PROPIONATO	100 g	212613-J-2
1119586	CLOBETASOL 17-PROPIONATO	25 g	212613-G-1
1119586	CLOBETASOL 17-PROPIONATO	25 g	212613-G-2
1200129	CLOBETASOL 17-PROPIONATO (INACTIVO)	0,25 g	212613-B-1
1200129	CLOBETASOL 17-PROPIONATO (INACTIVO)	0,25 g	212613-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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