



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 214634

Product:	BETAMETHASONE 17,21-DIPROPIONATE
Lot:	214634
Expiry date:	01/05/2025
Reference:	Cumple PhEur10.5
Synonyms:	
Formula:	C ₂₈ H ₃₇ FO ₇
Molecular weight:	504,59 g/mol

Assay	Result	Specification	
Residual solvent: Isopropanol	<= 5000 ppm	<= 5000 ppm	#
Residual solvent: Pyridine	<= 200 ppm	<= 200 ppm	#
Residual solvent: Ethyl acetate	<= 5000 ppm	<= 5000 ppm	#
Residual solvent: acetone	<= 5000 ppm	<= 5000 ppm	#
Related substances (HPLC)	Conform	Test PhEur	
Impurity I	0,06 %	<= 0,15 %	
Specific rotation	+84,7	(+84,0) - (+88,0)	
Impurity H	NDT	<= 0,3 %	
Organoleptic properties	Conform	PhEur	
Impurity G	NDT	<= 0,2 %	
Identification	Conform (A)		
Impurity E	0,05 %	<= 0,2 %	
Residual solvent: methylene chloride	<= 600 ppm	<= 600 ppm	#
Elemental impurities	Conform	Test PhEur	#
Residual solvent: Methanol	<= 3000 ppm	<= 3000 ppm	#
Assay (HPLC)	99,5 %	97,0-102,0%	
Total impurities	0,35 %	<= 1,0 %	
Loss on drying	0,10 %	<= 1,0 %	
Unspecified Impurities	<= 0,05 %	<= 0,10 %	
Impurity D	0,09 %	<= 0,2 %	
Impurity C	0,09 %	<= 0,5 %	
Impurity B	0,05 %	<= 0,3 %	

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 06/09/2021

Responsible: M. Mesa

Judgement:
APPROVED

Technical director: Montserrat Enrique

Manufacturer: F00056 SYMBIOTICA SPECIALITY INGREDIENTS SDN BHD

Manufacturer batch: BDP-105-0620

Product	Name	Capacity	Batch
1115192	BETAMETASONA 17,21-DIPROPIONATO	1 g	214634-D-1
1115193	BETAMETASONA 17,21-DIPROPIONATO	5 g	214634-E-1
1115195	BETAMETASONA 17,21-DIPROPIONATO	25 g	214634-G-1
1115197	BETAMETASONA 17,21-DIPROPIONATO	100 g	214634-J-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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Date of edition: 30/04/2025

