



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 221422

Product:	BETAMETHASONE 17,21-DIPROPIONATE
Lot:	221422
Expiry date:	30/09/2029
Reference:	Cumple PhEur10.7
Synonyms:	
Formula:	C ₂₈ H ₃₇ FO ₇
Molecular weight:	504,59 g/mol

Assay	Result	Specification	
Identification	Conform (A)		
Organoleptic properties	Conform	PhEur	
Specific rotation	+85,8 °	(+84,0) - (+88,0)	
Related substances (HPLC)	Conform	Test PhEur	
Loss on drying	0,25 %	<= 1,0 %	
Assay (HPLC)	100,3 %	97,0-102,0%	
Elemental impurities	Conform	Test PhEur	#
Impurity B	0,1 %	<= 0,3 %	
Impurity C	0,2 %	<= 0,5 %	
Impurity D	<= 0,05 %	<= 0,2 %	
Impurity E	<= 0,05 %	<= 0,2 %	
Impurity G	<= 0,05 %	<= 0,2 %	
Impurity H	<= 0,05 %	<= 0,3 %	
Impurity I	<= 0,05 %	<= 0,15 %	
Unspecified Impurities	<= 0,10 %	<= 0,10 %	
Total impurities	0,4 %	<= 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: Pyridine	< 200ppm	<= 200 ppm	#
Residual solvent: Isopropanol	< 5000 ppm	<= 5000 ppm	#

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 06/04/2022

Responsible: C. Codina

Judgement:
APPROVED

Technical director: Montserrat Enrique

Manufacturer: F00056 SYMBIOTICA SPECIALITY INGREDIENTS SDN BHD

Manufacturer batch: BDP108-1021

Product	Name	Capacity	Batch
1115192	BETAMETASONA 17,21-DIPROPIONATO	1 g	221422-D-1
1115193	BETAMETASONA 17,21-DIPROPIONATO	5 g	221422-E-1
1115195	BETAMETASONA 17,21-DIPROPIONATO	25 g	221422-G-1
1115197	BETAMETASONA 17,21-DIPROPIONATO	100 g	221422-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: 08/06/2026

