



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 251241

Product:	BETAMETHASONE 17,21-DIPROPIONATE
Lot:	251241
Expiry date:	30/09/2029
Reference:	Cumple PhEur11.8
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	85,1	(+84,0) - (+88,0)	
Related substances (HPLC)	Conform	Test PhEur	
Loss on drying	0,14 %	<= 1,0 %	
Assay (HPLC)	98,9 %	97,0-102,0%	
Elemental impurities	Conform	Test PhEur	#
Impurity B	0,10 %	<= 0,3 %	
Impurity C	0,34 %	<= 0,5 %	
Impurity D	< 0,05 %	<= 0,2 %	
Impurity E	0,07 %	<= 0,2 %	
Impurity G	< 0,05%	<= 0,2 %	
Impurity H	< 0,05%	<= 0,3 %	
Impurity I	< 0,05%	<= 0,15 %	
Unspecified Impurities	< 0,05%	<= 0,10 %	
Total impurities	0,51 %	<= 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	<= 200 ppm	<= 200 ppm	#
Residual solvent: Isopropanol	<= 5000 ppm	<= 5000 ppm	#

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 28/07/2025

Responsible: B. Chia

Judgement:
APPROVED

Technical director: Montserrat Enrique

Manufacturer: F00056 SYMBIOTICA SPECIALITY INGREDIENTS SDN BHD

Manufacturer batch: BDP107-1024

Product	Name	Capacity	Batch
1115192	BETAMETASONA 17,21-DIPROPIONATO	1 g	251241-D-1
1115192	BETAMETASONA 17,21-DIPROPIONATO	1 g	251241-D-2
1115192	BETAMETASONA 17,21-DIPROPIONATO	1 g	251241-D-3
1115193	BETAMETASONA 17,21-DIPROPIONATO	5 g	251241-E-1
1115193	BETAMETASONA 17,21-DIPROPIONATO	5 g	251241-E-2
1115193	BETAMETASONA 17,21-DIPROPIONATO	5 g	251241-E-3
1115195	BETAMETASONA 17,21-DIPROPIONATO	25 g	251241-G-1
1115195	BETAMETASONA 17,21-DIPROPIONATO	25 g	251241-G-2
1115195	BETAMETASONA 17,21-DIPROPIONATO	25 g	251241-G-3
1115197	BETAMETASONA 17,21-DIPROPIONATO	100 g	251241-J-1
1115197	BETAMETASONA 17,21-DIPROPIONATO	100 g	251241-J-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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