



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 230818

Product:	BETAMETHASONE 17,21-DIPROPIONATE
Lot:	230818
Expiry date:	31/05/2027
Reference:	Cumple PhEur11.0
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	+85,7	(+84,0) - (+88,0)	
Related substances (HPLC)	Conform	Test PhEur	
Loss on drying	0,16 %	<= 1,0 %	
Assay (HPLC)	100,1 %	97,0-102,0%	
Elemental impurities	Conform	Test PhEur	#
Impurity B	0,1 %	<= 0,3 %	
Impurity C	0,3 %	<= 0,5 %	
Impurity D	0,05 %	<= 0,2 %	
Impurity E	0,1 %	<= 0,2 %	
Impurity G	0,05 %	<= 0,2 %	
Impurity H	0,05 %	<= 0,3 %	
Impurity I	0,05 %	<= 0,15 %	
Unspecified Impurities	0,08 %	<= 0,10 %	
Total impurities	0,5 %	<= 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: 16/03/2023

Responsible: M. Mesa

Judgement:
APPROVED

Technical director: Montserrat Enrique

Manufacturer: F00056 SYMBIOTICA SPECIALITY INGREDIENTS SDN BHD

Manufacturer batch: BDP104-0622

Product	Name	Capacity	Batch
1115192	BETAMETASONA 17,21-DIPROPIONATO	1 g	230818-D-1
1115192	BETAMETASONA 17,21-DIPROPIONATO	1 g	230818-D-2
1115192	BETAMETASONA 17,21-DIPROPIONATO	1 g	230818-D-3
1115192	BETAMETASONA 17,21-DIPROPIONATO	1 g	230818-D-4
1115192	BETAMETASONA 17,21-DIPROPIONATO	1 g	230818-D-5
1115193	BETAMETASONA 17,21-DIPROPIONATO	5 g	230818-E-1
1115193	BETAMETASONA 17,21-DIPROPIONATO	5 g	230818-E-2
1115193	BETAMETASONA 17,21-DIPROPIONATO	5 g	230818-E-3
1115193	BETAMETASONA 17,21-DIPROPIONATO	5 g	230818-E-4
1115193	BETAMETASONA 17,21-DIPROPIONATO	5 g	230818-E-5
1115193	BETAMETASONA 17,21-DIPROPIONATO	5 g	230818-E-6
1115195	BETAMETASONA 17,21-DIPROPIONATO	25 g	230818-G-1
1115195	BETAMETASONA 17,21-DIPROPIONATO	25 g	230818-G-2
1115195	BETAMETASONA 17,21-DIPROPIONATO	25 g	230818-G-3
1115195	BETAMETASONA 17,21-DIPROPIONATO	25 g	230818-G-4
1115195	BETAMETASONA 17,21-DIPROPIONATO	25 g	230818-G-5
1115195	BETAMETASONA 17,21-DIPROPIONATO	25 g	230818-G-6
1115197	BETAMETASONA 17,21-DIPROPIONATO	100 g	230818-J-1
1115197	BETAMETASONA 17,21-DIPROPIONATO	100 g	230818-J-2
1115197	BETAMETASONA 17,21-DIPROPIONATO	100 g	230818-J-3
1115197	BETAMETASONA 17,21-DIPROPIONATO	100 g	230818-J-4
1115197	BETAMETASONA 17,21-DIPROPIONATO	100 g	230818-J-6

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: 12/04/2026

