



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 251997**

Product:	BETAMETHASONE 17-VALERATE
Lot:	251997
Expiry date:	30/06/2030
Reference:	Cumple PhEur11.8
Synonyms:	
Formula:	C <sub>27</sub> H <sub>37</sub> FO <sub>6</sub>
Molecular weight:	476,58 g/mol

Assay	Result	Specification	
Identification	Conform (A,C)		
Organoleptic properties	Conform		
Melting point	191 ° C		
Specific rotation	+79,7°	(+77,0°)-(+83,0°)	
Related substances (HPLC)	Conform		
Loss on drying	0,06 %	<= 0,5 %	
Assay	97,1 %	97,0-103,0%	
Impurity A	< 0,05 %	<= 0,7 %	
Impurity C	< 0,05 %	<= 0,15 %	
Impurity E	< 0,05 %	<= 0,3 %	
Impurity G	< 0,05 %	<= 0,3 %	
Impurity H	< 0,05 %	<= 0,15 %	
Impurity I	< 0,05 %	<= 0,15 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	< 0,05 %	<= 1,5 %	
Residual solvent: Methanol	<= 3000 ppm	<= 3000 ppm	#
Residual solvent: methylene chloride	<= 600 ppm	<= 600 ppm	#
Residual solvent: Ethyl acetate	<= 5000 ppm	<= 5000 ppm	#
Residual solvent: acetone	<= 5000 ppm	<= 5000 ppm	#
Elemental impurities	Conform	Test PhEur	#
Nitrosamine impurities	Conform	Test PhEur	#

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 13/11/2025

Judgement:  
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00056 SYMBIOTICA SPECIALITY INGREDIENTS SDN BHD

Manufacturer batch: BV120-0725

Product	Name	Capacity	Batch
1115214	BETAMETASONA 17-VALERATO	1 g	251997-D-1
1115215	BETAMETASONA 17-VALERATO	5 g	251997-E-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: 26/05/2026

