



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 223273**

Product:	BETAMETHASONE 17-VALERATE
Lot:	223273
Expiry date:	28/02/2027
Reference:	Cumple PhEur10.8
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,B)	Test PhEur (A,C)	
Organoleptic properties	Conform	PhEur	
Melting point (Mettler)	192 °C	Approx. 192°C	
Specific rotation	+79,9°	(+77,0°)-(+83,0°)	
Related substances (HPLC)	Conform	Test PhEur	
Loss on drying (1 g, 105°C)	0,08 %	<= 0,5%	
Assay	100,9 %	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	0,07 %	<= 0,15 %	
Impurity I	<= 0,05 %	<= 0,15 %	
Unspecified Impurities	0,06 %	<= 0,10 %	
Total impurities	0,13 %	<= 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	#

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 26/09/2022

Judgement:  
APPROVED

Responsible: C. Codina

Technical director: Montserrat Enrique

Manufacturer: F00056 SYMBIOTICA SPECIALITY INGREDIENTS SDN BHD

Manufacturer batch: BV101-0322

Product	Name	Capacity	Batch
1115213	BETAMETASONA 17-VALERATO (INACTIVO)	0,5 g	223273-C-1
1115213	BETAMETASONA 17-VALERATO (INACTIVO)	0,5 g	223273-C-2
1115213	BETAMETASONA 17-VALERATO (INACTIVO)	0,5 g	223273-C-3
1115214	BETAMETASONA 17-VALERATO	1 g	223273-D-1
1115214	BETAMETASONA 17-VALERATO	1 g	223273-D-2
1115214	BETAMETASONA 17-VALERATO	1 g	223273-D-3
1115214	BETAMETASONA 17-VALERATO	1 g	223273-D-4
1115215	BETAMETASONA 17-VALERATO	5 g	223273-E-1
1115215	BETAMETASONA 17-VALERATO	5 g	223273-E-2
1115215	BETAMETASONA 17-VALERATO	5 g	223273-E-3
1115215	BETAMETASONA 17-VALERATO	5 g	223273-E-4

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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