



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 241687

Product:	BECLOMETHASONE 17,21-DIPROPIONATE
Lot:	241687
Expiry date:	05/02/2029
Reference:	Cumple PhEur11.5
Synonyms:	Beclometasona dipropionato anhidro.
Formule:	C ₂₈ H ₃₇ ClO ₇
Poids moléculaire:	521,05 g/mol

Assay	Result	Specification	
Identification	Conform (A,B,C)		
Organoleptic properties	Conform		
Related substances (HPLC)	Conform		
Specific rotation	+110	(+108) - (+115)	
Loss on drying	0,39 %	<= 0,5 %	
Assay	97,5 %	96,0 - 102,0 %	
Impurity A	0,09 %	<= 0,2 %	
Impurity B	< 0,05 %	<= 0,5 %	
Impurity C	< 0,05 %	<= 0,15 %	
Impurity D	< 0,05 %	<= 0,2 %	
Impurity F	< 0,05 %	<= 0,5 %	
Impurity L	< 0,05 %	<= 0,6 %	
Impurity M	< 0,05 %	<= 0,5 %	
Impurity N	< 0,05 %	<= 0,2 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	0,09 %	<= 1,5 %	
Residual solvent: Ethyl acetate	< 5000 ppm	<= 5000 ppm	#
Residual solvent: methylene chloride	< 600 ppm	<= 600 ppm	#
Residual solvent: Tetrahydrofuran	< 720 ppm	<= 720 ppm	#
Residual solvent: Pyridine	< 200 ppm	<= 200 ppm	#
Elemental impurities	Conform	Test PhEur	#
Nitrosamine impurities	Conform	Test PhEur	#

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 17/09/2024

Responsible: B. Chia

Judgement:
APPROVED

Technical director: Montserrat Enrique
Manufacturer: F01002 FARMABIOS SpA
Manufacturer batch: 2106DM4-B0052422

Produit	Nom	Capacité	Lot
1114572	BECLOMETASONA 17,21-DIPROPIONATO	1 g	241687-D-1
1114572	BECLOMETASONA 17,21-DIPROPIONATO	1 g	241687-D-2
1114572	BECLOMETASONA 17,21-DIPROPIONATO	1 g	241687-D-3

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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