



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 226549**

Product:	BUDESONIDE
Lot:	226549
Expiry date:	31/10/2026
Reference:	Cumple PhEur11.0
Synonyms:	
Formula:	C <sub>25</sub> H <sub>34</sub> O <sub>6</sub>
Molecular weight:	430,53 g/mol

Assay	Result	Specification	
Identification	Conform (A)	Test PhEur (A)	
Organoleptic properties	Conform	PhEur	
Related substances (HPLC)	Conform		
Epimer A	48,6 %	Test PhEur	
Loss on drying (1 g, 105°C)	0,12 %	<= 0,5 %	
Assay (HPLC)	99,7 %	97,5-102,0%	
Impurity A	0,1 %	<= 0,2 %	
Impurity D	< 0,05 %	<= 0,2 %	
Impurity K	< 0,05 %	<= 0,2 %	
Impurity L	< 0,05 %	<= 0,2 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	0,1 %	<= 0,5 %	
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: Isopropyl ether	< 500 ppm	<= 500 ppm	#
Residual solvent: Pyridine	< 200 ppm	<= 200 ppm	#
Residual solvent: Tetrahydrofuran	< 720 ppm	<= 720 ppm	#
Residual Solvent: Butyric aldehyde	< 170 ppm	<= 170 ppm	#

Organoleptic characteristics: White or almost white, crystalline powder. Practically insoluble in water, freely soluble in methylene chloride, sparingly soluble in ethanol 96%.

Conservation: n tightly closed containers. Protect from light.

Date of analysis: 13/01/2023

Judgement:  
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00174 NEWCHEM SPA

Manufacturer batch: NB2836M

Product	Name	Capacity	Batch
1114879	BUDESONIDA	1 g	226549-D-1
1114879	BUDESONIDA	1 g	226549-D-2
1114879	BUDESONIDA	1 g	226549-D-3
1114880	BUDESONIDA	5 g	226549-E-1
1114880	BUDESONIDA	5 g	226549-E-2
1114880	BUDESONIDA	5 g	226549-E-3
1114885	BUDESONIDA	50 g	226549-I-1
1114885	BUDESONIDA	50 g	226549-I-2
1370229	BUDESONIDA (FLB)	1 g	226549-D-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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