



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 213871

Product:	BUDESONIDE
Lot:	213871
Expiry date:	01/05/2026
Reference:	Cumple PhEur10.5
Synonyms:	
Formula:	C ₂₅ H ₃₄ O ₆
Molecular weight:	430,53 g/mol

Assay	Result	Specification	
Impurity A	<= 0,2 %	<= 0,2 %	=
Residual Solvent: Butyric aldehyde	<= 170 ppm	<= 170 ppm	#
Loss on drying (1 g, 105°C)	0,06 %	<= 0,5%	
Residual solvent: Pyridine	<= 200 ppm	<= 200 ppm	#
Assay (HPLC)	100,0 %	97,5-102,0%	
Residual solvent: Tetrahydrofuran	<= 720 ppm	<= 720 ppm	#
Related substances (HPLC)	Conform		=
Residual solvent: Methanol	<= 3000 ppm	<= 3000 ppm	#
Epimer A	47,2 %	Test PhEur	
Residual solvent: Isopropyl ether	<= 500 ppm	<= 500 ppm	#
Identification	Conform (A)	Test PhEur (A)	
Total impurities	<= 0,5 %	<= 0,5 %	=
Organoleptic properties	Conform	PhEur	
Residual solvent: acetone	<= 5000 ppm	<= 5000 ppm	#
Impurity L	<= 0,2 %	<= 0,2 %	=
Unspecified Impurities	<= 0,10 %	<= 0,10 %	=
Impurity D	<= 0,2 %	<= 0,2 %	=
Impurity K	<= 0,2 %	<= 0,2 %	=

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

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 16/07/2021

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00174 NEWCHEM SPA

Manufacturer batch: NB1506M

Product	Name	Capacity	Batch
1114879	BUDESONIDA	1 g	213871-D-1
1114879	BUDESONIDA	1 g	213871-D-2
1114880	BUDESONIDA	5 g	213871-E-1
1114880	BUDESONIDA	5 g	213871-E-2
1114885	BUDESONIDA	50 g	213871-I-1
1114885	BUDESONIDA	50 g	213871-I-2

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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