

Certificate of Analysis

Product name: Budesonidum micronisatum
Batch number / Weight: 24G22-B05-007134 / 1 g
Producer / Producer Batch Number: Farmabios S.p.A. / 21100M1 B0032421
Analyzed according to: Ph. Eur. 11.6
Number of Analysis / Certificate no.: 24G22-B05 / QO0011901

	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white crystalline powder	Conform		
Identification A	IR spectrum	Conform		
Particle size	100% <10 µm / >=99% <5 µm	Conform		
Related substances	Acc. to Ph. Eur.	Conform		
Impurity A	<=0,2	<0,05	%	
Impurity L	<=0,2	0,10	%	
Impurity D	<=0,2	<0,05	%	
Impurity K	<=0,2	0,11	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,5	0,21	%	
Epimer A	40,0 - 51,0	43,09	%	
Loss on drying	<=0,5	0,13	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
Assay	97,5 - 102,0	99,61	% m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		DP

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FSNE lab

Release:

27-2-2025
 Dominika Sołtysik
 Qualified Person

Expiration: 15-3-2029

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.