

Certificate of Analysis

Product name: **Beclometason diprop. anh. mic.**

Batch number / Weight: **21K15-B03-230916 / 1 G**

Analysed according to: **Ph.Eur.11.1**

Number of analysis / Inspection Code **21K15-B03 / INS-22-0776**

Reference Code / No.: **V00858 / BMD/M/011/21**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, (almost) white crystallin powder	Conform		
Particle size	99%<25 µm / 90%<10 µm	Conform		
Identification	Conform	Conform		
Identification C	<=0,5	Conform	%	
Specific optical rotation	+108 - +115	+112	°	
Related substances	Conform	Conform		
Impurity A	<=0,2	<0,05	%	
Impurity B	<=0,5	<0,05	%	
Impurity C	<=0,15	<0,05	%	
Impurity D	<=0,2	<0,05	%	
Impurity F	<=0,5	<0,05	%	
Impurity L	<=0,6	<0,05	%	
Impurity M	<=0,5	<0,05	%	
Impurity N	<=0,2	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=1,5	<0,05	%	
Loss on drying	<=0,5	0,09	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Beclometason diprop.	96,0 - 102,0	99,2	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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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 EL Spol

Release:
Dominika Soltysik
Qualified Person

27-06-2023

Expiration: 31-08-2026

Conclusion: APPROVED

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