

Certificate of Analysis

Product name: **Beclometason diprop. anh. mic.**
Batch number / Weight: **19J02-F03-217111 / 1 G**
Analysed according to: **Ph.Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, (almost) white kristallines powder	Conform		
Particle size	99%<25 µm / 90%<10 µm	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	<=0,5	Conform	%	
Specific optical rotation	+108 - +115	+114	°	
Related substances	Conform	Conform		
Impurity A	<=0,2	<0,1	%	
Impurity B	<=0,5	<0,1	%	
Impurity C	<=0,15	<0,05	%	
Impurity D	<=0,2	<0,1	%	
Impurity F	<=0,5	<0,1	%	
Impurity L	<=0,6	<0,1	%	
Impurity M	<=0,5	<0,1	%	
Impurity N	<=0,2	<0,1	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=1,5	<0,1	%	
Loss on drying	<=0,5	0,4	%	
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	101,1	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
 Ewelina Gadzinowska
 Qualified Person

24-11-2021

Expiration: 30-04-2024

Conclusion: APPROVED

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