

## Certificate of Analysis

**Productname:** Beclometason diprop. anh. mic.  
**Number of analysis/Inspection Code:** 1 / KEUR-181291B  
**Batchnumber:** 19J02-F03-368343  
**Reference code / No.:** 3511 / BMD/M/021/19  
**Analysed according to:** PH.EUR9.8+

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, (almost) white kristallines powder	Conform		
Particle size	99%<25 µm / 90%<10 µm	Conform		Microscopy
Identification A	Conform	Conform		IR-spectrum
Identification B	Conform	Conform		Chloride
Identification C	<=0,5	Conform	%	Loss on drying
Specific optical rotation	+108 - +115	+114		1% <i>m</i> /V in alcohol; dried
Related substances	Conform	Conform		HPLC
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	%	3h 105 °C
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Beclometason diprop.	96,0 - 102,0	101,1	% <i>m</i> / <i>m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Quercus BE.

Release:  
 Wai Lung Chung  
 Pharmacist - Qualified Person

03/20/20

Expiration: 04-2024

Conclusion: APPROVED

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