

Certificate of Analysis

Productname: Betamethasonum micronisatum
Number of analysis/Inspection Code: 1 / KEUR-184023B
Batchnumber: 20A27-F07-369316
Reference code / No.: 2509 / BT-191101
Analysed according to: PHEUR10.0+

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, (almost) white powder	Conform		
Particle size	99% <25 µm and 90%<10 µm	Conform		
Identification B	Conform	Conform		IR-spectrum
Identification C	Conform	Conform		TLC
Specific optical rotation	+118 - +126	+121	°	0,5% <i>m/V</i> in methanol; dried
Related substances	Conform	Conform		HPLC
Impurity A	<=1,0	<0,05	%	
Impurity B	<=1,0	<0,05	%	
Impurity C	<=1,0	<0,05	%	
Impurity D	<=1,0	<0,05	%	
Impurity E	<=1,0	<0,05	%	
Impurity F	<=1,0	<0,05	%	
Impurity G	<=1,0	<0,05	%	
Impurity H	<=1,0	<0,05	%	
Impurity I	<=1,0	<0,05	%	
Impurity J	<=1,0	<0,05	%	
Impurity A to J	Max. 1 peak >=0,5	0		
Total impurities	<=2,0	0,2	%	
Loss on drying	<=0,5	0,4	%	105 °C 4h
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Betamethasone (base)	97,0 - 103,0	98,9	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:

P. Hofman

Pharmacist - Qualified Person

07/07/20

Expiration: 11-2022

Conclusion: APPROVED

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