

Certificate of Analysis

Productname: Betamethasoni dipropionas micr
Number of analysis/Inspection Code: 1 / KEUR-179617B
Batchnumber: 19J31-F02-366804
Reference code / No.: 3989 / BDP 101/0419
Analysed according to: PH.EUR9.8+

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, (almost) white powder	Conform		
Particle size	99% < 25 µm / 90% < 10 µm	Conform		Microscopy
Identification B	Conform	Conform		IR-spectrum
Specific optical rotation	+ 84 - + 88	+88		1% <i>m/V</i> EtOH; dried
Related substances	Conform	Conform		HPLC
Impurity C	<=0,5	0,3	%	
Impurity B	<=0,3	0,1	%	
Impurity H	<=0,3	<0,05	%	
Impurity D	<=0,2	0,1	%	
Impurity E	<=0,2	<0,05	%	
Impurity G	<=0,2	0,1	%	
Impurity I	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	0,09	%	
Total impurities	<=1,0	0,7	%	
Loss on drying	<=1,0	0,2	%	105°C
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Betamethasone dipropionate	97,0 - 102,0	99,4	% <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:
 dr. M.J. Vincenten - van Maanen
 Pharmacist - Qualified Person

01/15/20

Expiration: 03-2024

Conclusion: APPROVED

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