

Certificate of Analysis

Productname: Betamethasoni valeras micr.
Number of analysis/Inspection Code: 1 / KEUR-179842B
Batchnumber: 19I26-F02-364983
Reference code / No.: 3989 / BV 109/0519
Analysed according to: PH.EUR9.8+

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white crystalline powder	Conform		
Particle size	99% <25 µm / 90% <10 µm	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification B	Conform	Conform		HPLC
Specific optical rotation	+77 - +83	+80		1% <i>m</i> /V EtOH; dried
Related substances	Conform	Conform		HPLC
Impurity A	<=0,7	<0,05	%	
Impurity C	<=0,15	<0,05	%	
Impurity E	<=0,3	<0,05	%	
Impurity G	<=0,3	<0,05	%	
Impurity H	<=0,15	<0,05	%	
Impurity I	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=1,5	<0,05	%	
Loss on drying	<=0,5	0,1	%	105°C
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Betamethasone valerate	97,0 - 103,0	101,7	% <i>m</i> /m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Quercus BE.

Release:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

01/28/20

Expiration: 04-2024

Conclusion: APPROVED

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