

Certificate of Analysis

Product name: **Betamethasoni valeras micr.**

Batch number / Weight: **21G28-B02-213543 / 5 G**

Analysed according to: **Ph. Eur.07/2008:1367**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, (almost) white crystalline powder	Conform		
Particle size	99% <25 µm / 90% <10 µm	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Specific optical rotation	+77 - +83	+79,4		
Related substances	Conform	Conform		
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	0,06	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Betamethasone valerate	97,0 - 103,0	102,8	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Agnieszka Pszczółka
Qualified Person

21-12-2021

Expiration: 30-04-2026

Conclusion: APPROVED

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