

## Certificate of Analysis

**Product name:** **Betamethasoni dipropionas micr**

**Batch number / Weight:** **21E18-B04-213909 / 5 G**

**Analysed according to:** **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, (almost) white powder	Conform		
Particle size	99% < 25 µm / 90% < 10 µm	Conform		
Identification B	Conform	Conform		
Specific optical rotation	+ 84 - + 88	+85	Å°	
Related substances	Conform	Conform		
Impurity C	<=0,5	0,06	%	
Impurity B	<=0,3	0,07	%	
Impurity H	<=0,3	<0,05	%	
Impurity D	<=0,2	0,09	%	
Impurity E	<=0,2	0,10	%	
Impurity G	<=0,2	<0,05	%	
Impurity I	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=1,0	0,32	%	
Loss on drying	<=1,0	0,19	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	97,0 - 102,0	100,9	%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: 31-05-2025

Conclusion: APPROVED

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