

Certificate of Analysis

Product name: **Betamethasoni dipropionas micr**

Batch number / Weight: **21H18-B04-213332 / 1 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, (almost) white powder	Conform		
Identification A	Conform	Conform		
Particle size	99% < 25 µm / 90% < 10 µm	Conform		
Specific optical rotation	+ 84 - + 88	+85		
Related substances	Conform	Conform		
Impurity C	<=0,5	0,06	%	
Impurity B	<=0,3	<0,05	%	
Impurity H	<=0,3	<0,05	%	
Impurity D	<=0,2	0,06	%	
Impurity E	<=0,2	<0,05	%	
Impurity G	<=0,2	<0,05	%	
Impurity I	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	0,09	%	
Total impurities	<=1,0	0,27	%	
Loss on drying	<=1,0	0,10	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	97,0 - 102,0	97,3	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents		Conform		
Methanol	<= 3000	18	ppm	
Methylene chloride	<=600	3	ppm	
Acetone	<5000 ppm	18	ppm	
Ethyl acetate	<=5000	<100	ppm	
Isopropanol	<=5000	41	ppm	
Pyridine	<=200	<4	ppm	

Analysis performed by the authorized lab.

Release:

Dominika Soltysik

Qualified Person

23-12-2021

Expiration: 30-04-2026

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.