

Certificate of Analysis

Product name: **Dexamethasoni acetat micr.**
Batch number / Weight: **21G27-B10-213233 / 1 G**
Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	white/ almost white crystalline powder	Conform		
Particle size	$\geq 99\% < 25 \mu\text{m}$ / $\geq 90\% < 10 \mu\text{m}$	Conform		
Identification A	Conform	Conform		
Identification D	Conform	Conform		
Specific optical rotation	(+94) - (+99)	+96		
Related substances	Conform	Conform		
Impurity I	$\leq 0,4$	$< 0,05$	%	
Impurity A	$\leq 0,2$	$< 0,05$	%	
	$\leq 0,2$	$< 0,05$	%	
Impurity D	$\leq 0,3$	$< 0,05$	%	
Unspecified impurities	$\leq 0,10$	$< 0,05$	%	
Total impurities	$\leq 0,5$	$< 0,05$	%	
Loss on drying	$\leq 0,5$	0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	97,5 - 102,0	101,1	%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

17-12-2021

Expiration: 26-08-2025

Conclusion: APPROVED

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