

## Certificate of Analysis

**Product name:** **Dexamethasoni natrii phosphas**

**Batch number / Weight:** **21H04-B11-213745 / 1 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, (almost) white powder, very hygroscopic	Conform		
Identification B	Conform	Conform		
Identification G	Conform	Conform		
Appearance of solution	Clear ≤B7	Conform		
pH	7,5 - 9,5	8,01		
Specific optical rotation	+75 - +83	+78,4		
Related substances	Conform	Conform		
Impurity A	≤0,5	<0,05	%	
Impurity G	≤0,3	<0,05	%	
Impurity B	≤0,2	<0,05	%	
Impurity C	≤0,2	<0,05	%	
Impurity D	≤0,2	<0,05	%	
Impurity E	≤0,2	<0,05	%	
Impurity F	≤0,2	<0,05	%	
Unspecified impurities	≤0,10	<0,05	%	
Total impurities	≤1,0	0,00	%	
Inorganic phosphates	≤1	<1	%	
Ethanol	≤1,5	0,15	%	
Water	≤10,0	4,85	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Dexamethasone disodium	97,0 - 102,0	101,85	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:

Ewelina Gadzinowska

Qualified Person

21-01-2022

Expiration: 31-03-2024

Conclusion: APPROVED

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