

Certificate of Analysis

Product name: **Dexamethasoni natrii phosphas**

Batch number / Weight: **21K16-B14-220796 / 1 G**

Analysed according to: **Ph. Eur. 10.8**

Number of analysis / Inspection Code **21K16-B14 / INS-21-6326**

Reference Code / No.: **V01631 / NB0769**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, (almost) white powder, very hygroscopic	Conform		
Identification A	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

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab CBMiA

Release:
Ewelina Gadzinowska
Qualified Person

24-08-2022

Expiration: 31-03-2024

Conclusion: APPROVED

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