

Certificate of Analysis

Product name: **Dexamethasoni natrii phosphas**

Batch number / Weight: **22E27-B01-225758 / 1 G**

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

Number of analysis / Inspection Code **22E27-B01-224294 / INS-22-7820**

Reference Code / No.: **V01631 / NC0323**

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	8,06		
Specific optical rotation	+75 - +83	+78		
Related substances	Conform	C		
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	0,06	%	
Unspecified impurities	<=0,10	<0,05		
Total impurities	<=1,0	0,06	%	
Inorganic phosphates	<=1	<1	%	
Ethanol	<=1,5	0,2	ppm	
Water	<=10,0	5,39	%	
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	100,3	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Tetrahydrofurane	<=720	<720	ppm	
2-propanol	<=5000	<5000	ppm	
Dichlorometan	<=600	<600	ppm	

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Acetone	<=5000	<5000	ppm
Ethyl acetate	<=5000	<5000	ppm
Methanol	<=3000	<3000	ppm

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 EL Spol

Release:

Ewelina Gadzinowska

Qualified Person

09-11-2022

Expiration: 28-02-2025

Conclusion: APPROVED

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