Certificate of Analysis

Product name: **Dexamethasoni natrii phosphas**

Batch number / Weight: **21L03-B06-216880 / 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	8,13		
Specific optical rotation	+75 - +83	+80,1		
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	0,06	%	
Impurity D	<=0,2	<0,05	%	
Impurity E	<=0,2	0,06	%	
Impurity F	<=0,2	0,10	%	
Unspecified impurities	<=0,10	0,053	%	
Total impurities	<=1,0	0,42	%	
Inorganic phosphates	<=1	<1	%	
Ethanol	<=1,5	0,17	%	
Water	<=10,0	6,60	%	
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	100,75	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Tetrahydrofurane		<720	ppm	
2-propanol	<=5000	<5000	ppm	
Dichlorometan	<=600	<600	ppm	
Acetone	not more than 3000 ppm	<5000	ppm	
Ethyl acetate	<=5000	0,0	ppm	
Methanol		<3000	ppm	

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Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

27-05-2022

Expiration: 31-01-2024

Conclusion: APPROVED

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