Certificate of Analysis

Product name: **Prednisoloni natrii phosphas**

Batch number / Weight: **24A29-B02-237954 / 1 G**

Analysed according to: **Ph.Eur.11.3**

Number of analysis / Inspection Code **24A29-B02 / INS-24-1309**

Reference Code / No.: **V00858 / PSP/N/046/23**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Appearance of solution	Clear / colour <=B7	Conform		
pH	7,5 - 9,0	7,96		
Specific optical rotation	+94 - +100	+94,9		
Related substances	Conform	Conform		
Any impurity	<=2	0,4	%	
Max. 1 impurity	>=1%	Conform		
Total impurities	<=3	1,3	%	
Inorganic phosphates	<=1	Conform	%	
Water (Karl Fischer)	<=8,0	5,77	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Prednisolone disodium phosphat	96,0 - 103,0	97,17	%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 Fagron PL lab

Release:
Dominika Sołtysik
Qualified Person

05-03-2024

Expiration: 31-05-2027

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

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