

Certificate of Analysis

Product name: **Phenytoinum natricum**

Batch number / Weight: **21I21-B03-223714 / 25 G**

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

Number of analysis / Inspection Code **21I21-B03 / INS-22-4096**

Reference Code / No.: **V01799 / 456159 (U3983)**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white crystalline powder, slightly hygroscopic	Conform		
Identification A	Conform	Conform		
Identification C	Conform	Conform		
Appearance of solution	Clear, <=BY6	Conform		
Related substances	Conform	Conform		
Impurity E	<=0,3	<0,05	%	
Impurity C	<=0,2	0,06	%	
Impurity D	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	<0,05		
Total impurities	<=0,5	0,06	%	
Free phenytoin	Conform	Conform		
Water (Karl Fischer)	<=3,0	0,18	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Phenytoinum natricum	98,5 - 100,5	98,89	%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:

Ewelina Gadzinowska

Qualified Person

18-10-2022

Expiration: 01-08-2026

Conclusion: APPROVED

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