

Certificate of Analysis

Productname: Phenytoinum natricum
Number of analysis/Inspection Code: 1 / KEUR-185409B
Batchnumber: 20G01-F07-372995
Reference code / No.: 4121 / 453247
Analysed according to: PH.EUR10.2

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white crystalline powder; slightly hygroscopic	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification C	Conform	Conform		Sodium
Appearance of solution	Clear, <=BY6	Conform		5% m/V in verdund NaOH
Related substances	Conform	Conform		HPLC
Impurity E	<=0,3	<0,05	%	
Impurity C	<=0,2	<0,05	%	
Impurity D	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,5	<0,5	%	
Free phenytoin	Conform	Conform		
Water (Karl Fischer)	<=3,0	0,4	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Phenytoinum natricum	98,0 - 102,0	99,5	%m/m	Anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
CEP	CEP available	Conform		Data producer

Analysis performed by the authorized laboratory Eurofins.

Release:
Paul Hofman
Pharmacist - Qualified Person

09/01/20

Expiration: 06-2024

Conclusion: APPROVED

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