

Certificate of Analysis

Productname:	Phenytoinum natricum
Number of analysis/Inspection Code:	1 / KEUR-185418B
Batchnumber:	20G01-F07-372996
Reference code / No.:	4121 / 453247
Analysed according to:	PH.EUR10.2

Appearance(Almost) white crystalline powder; slightly hygroscopicConformIR-spectrumIdentification AConformConformIR-spectrumIdentification CConformConformSodiumAppearance of solutionClear, <=BY6ConformConformS% m/V in verdund NaOHRelated substancesConformConformConformHPLCImpurity E<=0,3<0,05%Impurity CImpurity D<=0,10<0,05%Impurity CInspecified impurities<=0,5<0,05%Impurity CTotal impurities<=0,5ConformData producerKaft Fischer)<=3,00,4%Impurity CMetallic residuesCHMP/ICH/353369/2013ConformData producerAssay Phenytoinum natricum98,0 - 102,099,5%m/mAnhydrousTSE/BSE-statement:No contamination with TSE/BSE-risk materialsConformData producerCEPCEP availableCEPData producerData producer	Tests	Requirement	Result	Unit	Standard remark
Identification AConformConformR-spectrumIdentification CConformConformSodiumAppearance of solutionClear, <=BY6					
Identification CConformConformSodiumAppearance of solutionClear, <=BY6	Appearance	(Almost) white crystalline powder; slightly hygroscopic	Conform		
Appearance of solutionClear, <=BY6Conform5% m/V in verdund NaOHRelated substancesConformConformHPLCImpurity E<=0,3	Identification A	Conform	Conform		IR-spectrum
Related substancesConformConformHPLCImpurity E<=0,3	Identification C	Conform	Conform		Sodium
Impurity E<=0,3<0,05%Impurity C<=0,2	Appearance of solution	Clear, <=BY6	Conform		5% m/V in verdund NaOH
Impurity C<=0,2<0,05%Impurity D<=0,15	Related substances	Conform	Conform		HPLC
Impurity D<=0,15<0,05%Unspecified impurities<=0,10	Impurity E	<=0,3	<0,05	%	
Unspecified impurities<=0,10<0,05%Total impurities<=0,5	Impurity C	<=0,2	<0,05	%	
Total impurities<=0,5<0,5%Free phenytoinConformConformConformWater (Karl Fischer)<=3,0	Impurity D	<=0,15	<0,05	%	
Free phenytoinConformConformWater (Karl Fischer)<=3,0	Unspecified impurities	<=0,10	<0,05	%	
Water (Karl Fischer)<=3,00,4%Metallic residuesCHMP/ICH/353369/2013ConformData producerResidual solventsCHMP/ICH/82260/2006ConformData producerAssay Phenytoinum natricum98,0 - 102,099,5%m/mAnhydrousTSE/BSE-statement:No contamination with TSE/BSE-risk materialsConformData producer	Total impurities	<=0,5	<0,5	%	
Metallic residuesCHMP/ICH/353369/2013ConformData producerResidual solventsCHMP/ICH/82260/2006ConformData producerAssay Phenytoinum natricum98,0 - 102,099,5%m/mAnhydrousTSE/BSE-statement:No contamination with TSE/BSE-risk materialsConformData producer	Free phenytoin	Conform	Conform		
Residual solventsCHMP/ICH/82260/2006ConformData producerAssay Phenytoinum natricum98,0 - 102,099,5%m/mAnhydrousTSE/BSE-statement:No contamination with TSE/BSE-risk materialsConformData producer	Water (Karl Fischer)	<=3,0	0,4	%	
Assay Phenytoinum natricum98,0 - 102,099,5%m/mAnhydrousTSE/BSE-statement:No contamination with TSE/BSE-risk materialsConformData producer	Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
TSE/BSE-statement: No contamination with TSE/BSE-risk materials Conform Data producer	Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
	Assay Phenytoinum natricum	98,0 - 102,0	99,5	%m/m	Anhydrous
CEP CEP available Conform Data producer	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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