

Certificate of Analysis

Productname: **Phenobarbitalum natricum**
Number of analysis/Inspection Code: 1 / KEUR-196223B
Batchnumber: **21K11-F03-382699**
Reference code / No.: 2021 / AVJ0866
Analysed according to: **PH.EUR10.6**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white crystalline powder	Conform		Hygroscopic
Identification A	Difference <= 2C	0	°C	
Identification B	Conform	Conform		IR-spectrum
Identification E	Conform	Conform		Na
Appearance of solution	Clear / <=Y7	Conform		10%m/V in alcohol 50%V/V
pH	<=10,2	9,8		10%m/V
Related substances	Conform	Conform		HPLC
Impurity A	<=0,15	n.d.	%	
Impurity B	<=0,15	n.d.	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,2	<0,05	%	
Loss on drying	<=7,0	6,8	%	4 h 150 °C
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Phenobarbital-sodium	98,0 - 102,0	100,1	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Proxylabs.

Manufacturer / Country : Alkaloida Chemical Company ZRT / HU
CEP :

Release:
 Anthony Amoureux
 Qualified Person

11/30/22

Expiration: 30-06-24

Conclusion: APPROVED

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