

## Certificate of Analysis

**Productname:** Phenobarbitalum natricum  
**Number of analysis/Inspection Code:** 1 / KEUR-198226B  
**Batchnumber:** 22K16-F03-385026  
**Reference code / No.:** 2021 / AVL1049  
**Analysed according to:** PH.EUR11.0

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	Not detected	%	
Impurity B	<=0,15	Not detected	%	
Unspecified impurities	<=0,10	0,06	%	
Total impurities	<=0,2	0,1	%	
Loss on drying	<=7,0	6,7	%	4 h 150 °C
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Phenobarbital-sodium	98,0 - 102,0	99,7	%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

10/11/23

Expiration: 30-09-26

Conclusion: APPROVED

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