

Certificate of Analysis

Productname: Phenobarbitalum
Number of analysis/Inspection Code: 1 / KEUR-183492B
Batchnumber: 19G23-B01-370866
Reference code / No.: 4131 / PBT/1920029
Analysed according to: PH.EUR 9.8

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colorless crystals	Conform		
Identification A	About 176 / $\leq 2^{\circ}\text{C}$	Conform	$^{\circ}\text{C}$	Melting point
Identification B	Conform	Conform		IR-spectrum
Appearance of solution	Clear / $\leq Y_6$	Conform		1 g / 10 ml dil. NaOH
Acidity	Conform	Conform		
Related substances	Conform	Conform		HPLC
Impurity A	$\leq 0,15$	n.d.	%	
Impurity B	$\leq 0,15$	n.d.	%	
Unspecified impurities	$\leq 0,10$	$\leq 0,05$	%	
Total impurities	$\leq 0,2$	$\leq 0,05$	%	
Loss on drying	$\leq 0,5$	0,1	%	105 $^{\circ}\text{C}$
Sulphated ash	$\leq 0,1$	$\leq 0,1$	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Phenobarbital	99,0 - 101,0	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.

Release:
Wai Lung Chung
Pharmacist - Qualified Person

06/18/20

Expiration: 05-2024

Conclusion: APPROVED

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