

Certificate of Analysis

Product name: **Natrii hydroxidum**
Batch number / Weight: **22J06-B02-222473 / 100 G**
Analysed according to: **Ph.Eur.10.8**
Number of analysis / Inspection Code **22J06-B02 / INS-22-8698**
Reference Code / No.: **V00582 / 2022369443**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline mass in the form of pellets, stick or slabs, deliquescent, readily absorbing carbon dioxide	Conform		
Identification A	$\geq 11,0$	Conform		
Identification B	Conform	Conform		
Appearance of solution	Clear / colourless	Conform		
Carbonates	$\leq 2,0$	0,89	%	
Chlorides	≤ 200	<200	ppm	
Sulphates	≤ 200	<200	ppm	
Iron	≤ 10	<10	ppm	
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Assay Sodium hydroxide	97,0 - 100,5	98,54	% m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL lab

Release:

Agnieszka Pszczółka

Qualified Person

26-11-2022

Expiration: 12-11-2023

Conclusion: APPROVED

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