

Certificate of Analysis

Productname: **Natrii acetat trihydricus**
Number of analysis/Inspection Code: 1 / KEUR-187554B
Batchnumber: **20J06-F10-374647**
Reference code / No.: 1987 / 3079240
Analysed according to: **PH.EUR10.2**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder of colourless crystals	Conform		
Identification A	Conform	Conform		Acetate
Identification B	Conform	Conform		Sodium
Identification C	39,0 - 40,5	Conform	%	Loss on drying
Appearance of solution	Clear Colourless	Conform		10% <i>m/V</i>
pH	7,5 - 9,0	8,3		5% <i>m/V</i>
Reducing substances	Conform	Conform		
Chlorides	<= 200	Conform	ppm	
Sulphates	<= 200	Conform	ppm	
Aluminium	<= 0,2	Conform	ppm	
Arsenic	<= 2	Conform	ppm	
Calcium and magnesium	<= 50	Conform	ppm	Als Ca
Iron	<= 10	Conform	ppm	
Loss on drying	39,0 - 40,5	39,8	%	130 °C
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Sodium acetat trihydrate	99,0 - 101,0	99,8	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Proxylabs.

Release:
 Paul Hofman
 Pharmacist - Qualified Person

12/07/20

Expiration: 04-2023

Conclusion: APPROVED

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