

Certificate of Analysis

Product name: **Chlorobutanolum hemihydricum**

Batch number / Weight: **21E13-B01-227549 / 25 G**

Analysed according to: **Ph.Eur.11.0**

Number of analysis / Inspection Code **21E13-B01 / INS-21-3090**

Reference Code / No.: **V01511 / 27000917**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform	%	
Appearance of solution	<=ref. susp. II <=BY5	Conform		
Acidity	Conform	Conform	ml	
Impurity A	<=60	<60	ppm	
Impurity B	<=0,10	<0,10	%	
Chlorides	<=100	<100	ppm	
Water (Karl Fischer)	4,5 - 5,5	4,6	%	
Sulphated ash	<=0,1	0,03	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	98,0 - 101,0	99,0	%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, ElSpol

Release:
Dominika Soltysik
Qualified Person

27-01-2023

Expiration: 30-04-2025

Conclusion: APPROVED

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