

Certificate of Analysis

Product name: Chlorali hydras

Batch number / Weight: 24A24-B10-233217 / 250 G

Analysed according to: Ph.Eur.11.3

Number of analysis / Inspection Code 24A24-B10 / INS-24-0872

Reference Code / No.: V01085 / 10224/2311B066

Tests	Requirement	Result	Unit	Standard remark
Appearance	Colourless, transparent crystals	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Appearance of solution	Clear / colourless	Conform		
рН	3,5 - 5,5	5,13		
Chloralalcoholate	Conform	Conform		
Chlorides	<=100	<100	ppm	
Residue on evaporation	<=0,1	0,02	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	98,5 - 101,0	100,03	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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

13-02-2024

Expiration: 30-11-2025

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

fagron.pl Fagron Services Northern Europe Sp. z o.o.

ul. Armii Krajowej 3 32-540 Trzebinia, Poland e-mail:fsne@fagron.pl

fagron.pl Fagron sp. z o.o.

ul. Pasternik 26, 31-354 Kraków, Poland

tel.: +48 12 3343 512 e-mail: biuro@fagron.pl