



Certificate of Analysis

Productname: Acidum aceticum glaciale

Inspection No: K09833/0124/536

Sample Unit: 1 x 25 ml

Batchnumber: 22K02-T01-108273

Batch Size: 15 x 100 ml

Expiration date: 31.10.2027

Analysed according to: ČL 2017, Ph.Eur.10.0

Original Manuf. Date: 11.10.2022

Identification of producer: V01106

Batch no. of vendor: 98134

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Crystalline mass or clear, colourless, volatile liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	Conform	Conform		Strongly acid solution	Fagron CZ
Identification B	Conform	Conform		Acetates	Fagron CZ
TESTS					
Appearance	Clear, colourless	Conform			Fagron CZ
Freezing point	$\geq 14,8$	16,0	°C		Fagron CZ
Reducing substances	Conform	Conform			Fagron CZ
Chlorides	≤ 25	< 25	mg/l		Fagron CZ
Sulfates	≤ 50	< 50	mg/l		Fagron CZ
Iron	≤ 5	< 5	ppm		Fagron CZ
Residue on evaporation	$\leq 0,01$	0,00	%		Fagron CZ
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			Data Producer
Residual solvents	CPMP/ICH/82 260/2006	Conform			Data Producer
Metallic residues	ICH Q3D on elemental impurities	Conform			Data Producer
ASSAY					
Acetic acid	99,0 - 100,5	100,2	%		Fagron CZ

Quality: Excipient

Performed by: Pavla Šlězarová

Responsible: Mgr. Zdeňka Šinclová, QC
MVDr. Zdenka Borská, QP

Date: 12.01.2024

Conclusion: APPROVED

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