



## Certificate of Analysis

**Productname:** Acidum aceticum glaciale

**Inspection No:** J09280/1222/536  
**Batchnumber:** 22E20-T06-099550  
**Expiration date:** 31.05.2027  
**Analysed according to:** ČL 2017, Ph.Eur.10.0  
**Original Manuf. Date:** 3.5.2022

**Sample Unit:** 1 x 25 ml  
**Batch Size:** 20 x 100 ml

**Identification of producer:** V01106  
**Batch no. of vendor:** 96210

	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	$\geq 14,8$	15,0	°C		Fagron CZ
Reducing substances	Conform	Conform			Fagron CZ
Chlorides	$\leq 25$	$< 25$	mg/l		Fagron CZ
Sulfates	$\leq 50$	$< 50$	mg/l		Fagron CZ
Iron	$\leq 5$	$< 5$	µg/g		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	99,3	%		Fagron CZ

Quality: Excipient

**Performed by:** Pavla Šlézarová

**Responsible:** Ing. Pavel Mišák, QC  
 MVDr. Zdenka Borská, QP

**Date:** 10.11.2022

**Conclusion:** APPROVED

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

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