

## Certificate of Analysis

**Productname:** Acidum lacticum (racemicum)

**Inspection No:** I09983/1221/536  
**Batchnumber:** 21K16-T10-093036  
**Expiration date:** 31.07.2026  
**Analysed according to:** ČL 2017, Ph.Eur.10.0  
**Original Manuf. Date:** 14.7.2021

**Sample Unit:** 1 x 25 ml  
**Batch Size:** 388 x 50 ml

**Identification of producer:** V01709  
**Batch no. of vendor:** L9010714

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Colourless or slightly yellow, syrupy liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	Conform	Conform		Strongly acid solution	Fagron CZ
Identification B	1,20 - 1,21	1,21		Relative density	Fagron CZ
Identification C	Conform	Conform		Lactates	Fagron CZ
TESTS					
Appearance	<= Y6	Conform			Fagron CZ
Ether-insoluble substances	Conform	Conform			Fagron CZ
Sugars and other reducing substances	Conform	Conform			Fagron CZ
Citric, oxalic and phosphoric acid	Conform	Conform			Fagron CZ
Sulfates	<=200	<200	µg/g		Fagron CZ
Calcium	<=200	<200	µg/g		Fagron CZ
Sulfated ash	<=0,1	0,0	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 <sup>3</sup>	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 <sup>2</sup>	<10	CFU/g		Contract Lab
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					
Lactic acid	88,0 - 92,0	91,3	%		Fagron CZ
Food quality					

<b>Name</b>	Fagron a.s. (CZ) Kontrolní laboratoř č. 536	<b>Address</b>	Holická 1098/31m, Olomouc	<b>Phone No.</b>	+420585222590
		<b>Post Code</b>	779 00	<b>Fax No.</b>	+420 585 226 521

**Performed by:** Ing. Petra Drábková

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

**Date:** 13.12.2021

**Conclusion:** **APPROVED**

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

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