

Certificate of Analysis

Productname: Acidum lacticum (racemicum)

Inspection No: I09860/1221/536
Batchnumber: 21K16-T10-085613
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: 614 x 250 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 ³	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	<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					

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Performed by: Ing. Petra Drábková

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

Date: 13.12.2021

Conclusion: **APPROVED**

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