



Certificate of Analysis

Productname: Acidum lacticum (racemicum)

Inspection No: J09397/1022/536
Batchnumber: 22I21-T03-098677
Expiration date: 10.01.2027
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 11.1.2022

Sample Unit: 1 x 25 ml
Batch Size: 1,349 x 50 ml

Identification of producer: V01847
Batch no. of vendor: L9020111

	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	ppm		Fagron CZ
Calcium	<=200	<200	ppm		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	88,9	%		Fagron CZ

Performed by: Pavla Šlězarová

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

Date: 02.11.2022

Conclusion: **APPROVED**

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