

Certificate of Analysis

Productname: Rosae aetheroleum artificiale

Inspection No: I07133/0921/536

Batchnumber: 20H26-F02-085622

Expiration date: 06.08.2023

Analysed according to: Interní předpis, Internal

Original Manuf. Date: 7.8.2020

Sample Unit: 1 x 1 ml

Batch Size: 65 x 25 ml

Identification of producer: V00201

Batch no. of vendor: 1217757

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Light yellow liquid with characteristic odour.	Conform			Fagron CZ
IDENTIFICATION					
Identification	Conform	Conform		TLC	Fagron CZ
TESTS					
Refractive Index	1,500 - 1,530	1,511		30 °C	Fagron CZ
Relative density	0,975 - 1,075	0,987			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

Performed by: Bc. Andrea Šmídová

Responsible: Ing. Pavel Mišák, QC
 PharmDr. Ivana Urbánková, QA

Date: 03.09.2021

Conclusion: APPROVED

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