

Certificate of Analysis

Productname: Rosae aetheroleum artificiale

Inspection No: I09798/1221/536
Batchnumber: 21K10-T09-088386
Expiration date: 28.10.2024
Analysed according to: Interní předpis, Internal
Original Manuf. Date: 29.10.2021

Sample Unit: 0 x
Batch Size: 60 x 25 ml

Identification of producer: V00201
Batch no. of vendor: 1283953

	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	1,515		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

The product conforms to Interní předpis, Internal.

Performed by: Lucie Kubáňová DiS.

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

Date: 10.12.2021

Conclusion: I certify that the above-mentioned batch of pharmaceutical raw material has been manufactured and tested in accordance with the requirements of Marketing Authorization (License) and requirements of Good Manufacturing Practice.

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

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