



Certificate of Analysis

Productname: Eugenolum

Inspection No: J02656/0422/536

Batchnumber: 22A11-T04-093763

Expiration date: 08.12.2024

Analysed according to: ČL 2017-Dopl.2020,Ph.Eur.10.0

Original Manuf. Date: 9.12.2021

Sample Unit: 1 x 1 ml

Batch Size: 92 x 100 ml

Identification of producer: V00201

Batch no. of vendor: 1289975

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Colourless or pale yellow, clear liquid, darkening on exposure to air.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification B	Conform	Conform		IR-spectrum	Fagron CZ
TESTS					
Relative density	1,066 - 1,070	1,068			Fagron CZ
Refractive index	1,540 - 1,542	1,540			Fagron CZ
Dimeric and oligomeric compounds	<=0,25	0,10		330 nm	Fagron CZ
Related substances	Conform	Conform		GC	Contract Lab
Any impurity	<=0,5	<0,5	%		Contract Lab
sum of imp.with a rel.ret.gr.>2,0	<=1,0	<1,0	%		Contract Lab
Total impurities	<=3,0	<3,0	%		Contract Lab
Hydrocarbons	Conform	Conform			Fagron CZ
Sulfated ash	<=0,1	0,05	%		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	ICH Q3C	Conform			Data Producer
Metallic residues	ICH Q3D	Conform			Data Producer

Quality: Excipient

Performed by: Ludmila Stochlebová

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

Date: 02.05.2022

Conclusion: **APPROVED**

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