



Certificate of Analysis

Productname: Cineolum (Eucalyptolum)

Inspection No: J02433/0322/536
Batchnumber: 22A27-T02-093453
Expiration date: 13.09.2023
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 13.9.2021

Sample Unit: 1 x 10 ml
Batch Size: 742 x 250 ml

Identification of producer: V01586
Batch no. of vendor: 000029

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear colourless liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	1,456 - 1,460	1,457		Refractive index	Fagron CZ
Identification B	Conform	Conform		TLC	Fagron CZ
Identification C	Conform	Conform		Defined discoloration	Fagron CZ
Appearance of solution	Clear and colourless	Conform			Fagron CZ
Chiral impurities	-0,10 - +0,10	-0,05	°		Fagron CZ
Refractive index	1,456 - 1,460	1,457			Fagron CZ
Related substances	Conform	Conform		GC	Contract Lab
Total impurities	<=2	<2	%		Contract Lab
Residue on evaporation	<=0,1	0,0	%	100-105°C	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

Quality: Excipient

Performed by: Pavla Šlézarová

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

Date: 28.03.2022

Conclusion: APPROVED

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

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