

Certificate of Analysis

Productname: Cineolum (Eucalyptolum)

Inspection No: I06476/0921/536

Batchnumber: 21D21-T10-089574

Expiration date: 15.01.2023

Analysed according to: ČL 2017, Ph.Eur.10.0

Original Manuf. Date: 15.1.2021

Sample Unit: 1 x 10 ml

Batch Size: 1 x 500 ml

Identification of producer: V01586

Batch no. of vendor: 000027

	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	0,0	°		Fagron CZ
Refractive index	1,456 - 1,460	1,457			Fagron CZ
Related substances	dle zkoušky	Conform			Contract Lab
Total impurities	<=2	<2	%		Contract Lab
Residue on evaporation	<=0,1	0	%	100-105°C	Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 ³	Conform	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	Conform	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: Lucie Kubáňová DiS.

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

Date: 17.09.2021

Conclusion: APPROVED

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

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