



## Certificate of Analysis

**Productname:** Cineolum (Eucalyptolum)

**Inspection No:** J07689/0922/536

**Sample Unit:** 1 x 10 ml

**Batchnumber:** 22G26-T24-097554

**Batch Size:** 541 x 1 l

**Expiration date:** 28.07.2024

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

**Original Manuf. Date:** 13.9.2021

**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	1,458		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	0,00	°		Fagron CZ
Refractive index	1,456 - 1,460	1,458			Fagron CZ
Related substances	Conform	Conform		GC	Contract Lab
Total impurities	<=2	<2	%		Contract Lab
Residue on evaporation	<=0,1	0,04	%	100-105°C	Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 <sup>3</sup>	< 10	CFU/g		Contract Lab
TYMC	<=2 x 10 <sup>2</sup>	< 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 Šlězarová

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

**Date:** 31.08.2022

**Conclusion:** APPROVED

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

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