



Certificate of Analysis

Productname: Cineolum (Eucalyptolum)

Inspection No: K05875/0923/536

Sample Unit: 1 x 10 ml

Batchnumber: 23G28-T09-105536

Batch Size: 32 x 500 ml

Expiration date: 03.07.2025

Analysed according to: Ph.Eur.11.0

Original Manuf. Date: 4.7.2023

Identification of producer: V01586

Batch no. of vendor: 000034

	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
TESTS					
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	0,0	%	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	ICH Q3C	Conform			Data Producer
Metallic residues	ICH Q3D	Conform			Data Producer

Quality: Excipient

Performed by: Bc. Andrea Šmídová

Responsible: Mgr. Zdeňka Šinclová, QC
MVDr. Zdenka Borská, QP

Date: 05.10.2023

Conclusion: **APPROVED**

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