



## Certificate of Analysis

**Productname:** Cineolum (Eucalyptolum)

**Inspection No:** K05873/0923/536

**Sample Unit:** 1 x 10 ml

**Batchnumber:** 23G28-T09-105534

**Batch Size:** 40 x 100 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 <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	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**

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