

## Certificate of Analysis

**Productname:** Cineolium (Eucalyptolum)

**Inspection No:** I04556/0621/536  
**Batchnumber:** 21D21-T10-085451  
**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:** 100 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 103	Conform	CFU/g		Contract Lab
TYMC	<=2 x 102	Conform	CFU/g		Contract Lab
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			Data Producer
Residual solvents	CPMP/ICH/82 260/2008	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:** 10.06.2021

**Conclusion:** APPROVED

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

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