

Certificate of Analysis

Productname: **Menthae piperitae etheroleum**

Inspection No: I02379/0421/536
Batchnumber: **20L14-T10-087041**
Expiration date: 23.11.2023
Analysed according to: ČL 2017-Dopl.2019,Ph.Eur.10.0
Original Manuf. Date: 24.11.2020

Sample Unit: 0 x
Batch Size: 45 x 100 ml

Identification of producer: V00201
Batch no. of vendor: 1234249

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Colourless, pale yellow or pale greenish-yellow liquid, with characteristic odour.	Conform			Contract Lab
Solubility	Conform	Conform			Contract Lab
IDENTIFICATION					
Identification B	Conform	Conform		Chromatographic profile	Contract Lab
TESTS					
Relative density	0,900 - 0,916	0,902			Contract Lab
Refractive index	1,457 - 1,467	1,460			Contract Lab
Optical rotation	-30 - -10	-24	°		Contract Lab
Acid value	≤1,4	0,3			Contract Lab
Fatty oils and resinified essential oils	Conform	Conform			Contract Lab
Mint oil	Conform	Conform			Contract Lab
Chromatographic profile	Conform	Conform		GC	Contract Lab
Limonene	1,0 - 3,5	2,3	%		Contract Lab
1,8-Cineole	3,5 - 8,0	4,5	%		Contract Lab
Menthone	14,0 - 32,0	29,9	%		Contract Lab
Menthofuran	1,0 - 8,0	2,9	%		Contract Lab
Isomenthone	1,5 - 10,0	4,8	%		Contract Lab
Menthyl acetate	2,8 - 10,0	5,5	%		Contract Lab
Isopulegol	≤0,2	0,15	%		Contract Lab
Menthol	30,0 - 55,0	39,5	%		Contract Lab
Pulegone	≤3,0	1,1	%		Contract Lab
Carvone	≤1,0	0,1	%		Contract Lab
Ratio of 1,8- cineole content to limonen	≥2	2			Contract Lab
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

Name Fagron a.s. (CZ)
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Performed by: External + SVÚ

Responsible: Lenka Morávková, QC
Ing. Martina Zemanová, QP

Date: 30.04.2021

Conclusion: APPROVED

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