

Certificate of Analysis

Productname: Menthae piperitae etheroleum

Inspection No: I05023/0621/536

Sample Unit:

0 x

Batchnumber: 21E12-T02-086267

Batch Size:

90 x 100 ml

Expiration date: 09.02.2024

Analysed according to: ČL 2017-Dopl.2019, Ph.Eur.10.0

Original Manuf. Date: 10.2.2021

Identification of producer: V00201

Batch no. of vendor: 1257813

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Colourless, pale yellow or pale greenish-yellow liquid. with characteristic odour.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification B	Conform	Conform		Chromatographic profile	Contract Lab
TESTS					
Relative density	0,900 - 0,916	0,901			Fagron CZ
Refractive index	1,457 - 1,467	1,461			Fagron CZ
Optical rotation	-30 - -10	-22	°		Fagron CZ
Acid value	≤1,4	0,29			Fagron CZ
Fatty oils and resinified essential oils	Conform	Conform			Fagron CZ
Mint oil	Conform	Conform			Contract Lab
Chromatographic profile	Conform	Conform		GC	Contract Lab
Limonene	1,0 - 3,5	2,9	%		Contract Lab
1,8-Cineole	3,5 - 8,0	6,9	%		Contract Lab
Menthone	14,0 - 32,0	30,9	%		Contract Lab
Menthofuran	1,0 - 8,0	2,9	%		Contract Lab
Isomenthone	1,5 - 10,0	4,9	%		Contract Lab
Menthyl acetate	2,8 - 10,0	4,7	%		Contract Lab
Isopulegol	≤0,2	<0,1	%		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	2,4			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)	Address	Holická 1098/31m, Olomouc	Phone No.	+420585222590
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Performed by: Lucie Kubáňová DiS.

Responsible: Ing. Pavel Mišák, QC
PharmDr. Ivana Urbánková, QA

Date: 13.07.2021

Conclusion: **APPROVED**



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