

Certificate of Analysis

Productname: Menthae piperitae etheroleum

Inspection No: I08122/1021/536

Batchnumber: 21117-T08-089122

Expiration date: 05.09.2024

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

Original Manuf. Date: 6.9.2021

Sample Unit: 0 x

Batch Size: 18 x 1 l

Identification of producer: V00201

Batch no. of vendor: 1275880

	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, GC	Contract Lab
TESTS					
Relative density	0,900 - 0,916	0,902			Fagron CZ
Refractive index	1,457 - 1,467	1,461			Fagron CZ
Optical rotation	-30 - -10	-23	°		Fagron CZ
Acid value	≤1,4	0,43			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	2,3	%		Contract Lab
1,8-Cineole	3,5 - 8,0	4,7	%		Contract Lab
Menthone	14,0 - 32,0	28,9	%		Contract Lab
Menthofuran	1,0 - 8,0	3,4	%		Contract Lab
Isomenthone	1,5 - 10,0	5,0	%		Contract Lab
Menthyl acetate	2,8 - 10,0	4,9	%		Contract Lab
Isopulegol	≤0,2	<0,2	%		Contract Lab
Menthol	30,0 - 55,0	40,3	%		Contract Lab
Pulegone	≤3,0	0,9	%		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 103	<10	CFU/g		Contract Lab
TYMC	≤2 x 102	<10	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)
Kontrolní laboratoř č. 536

Address

Post Code

 Holická 1098/31m, Olomouc
779 00

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The product conforms to ČL 2017-Dopl.2019,Ph.Eur.10.0.

Performed by: Lucie Kubáňová DiS.

Responsible: Ing. Pavel Mišák, QC
MVDr. Zdenka Borská, QA

Date: 21.10.2021



Conclusion: I certify that the above-mentioned batch of pharmaceutical raw material has been manufactured and tested in accordance with the requirements of Marketing Authorization (License) and requirements of Good Manufacturing Practice.

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

Name Fagron a.s. (CZ)
Kontrolní laboratoř č. 536

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