

Certificate of Analysis

Productname: **Menthae piperitae etheroleum**

Inspection No: L02334/0524/536
Batchnumber: **24B28-T21-110756**
Expiration date: 20.02.2027
Analysed according to: ČL 2023, Ph. Eur. 11.0
Original Manuf. Date: 21.2.2024

Sample Unit: 1 x 5 ml
Batch Size: 27 x 25 ml

Identification of producer: V00201
Batch no. of vendor: 1388053

	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	0,903			Fagron CZ
Refractive index	1,457 - 1,467	1,461			Fagron CZ
Optical rotation	-30 - -10	-22	°		Fagron CZ
Acid value	<=1,4	0,32			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	2,2	%		Contract Lab
1,8-Cineole	3,5 - 8,0	4,3	%		Contract Lab
Menthone	14,0 - 32,0	28,8	%		Contract Lab
Menthofuran	1,0 - 8,0	2,9	%		Contract Lab
Isomenthone	1,5 - 10,0	4,7	%		Contract Lab
Menthyl acetate	2,8 - 10,0	5,2	%		Contract Lab
Isopulegol	<=0,2	<0,05	%		Contract Lab
Menthol	30,0 - 55,0	36,8	%		Contract Lab
Pulegone	<=3,0	1,7	%		Contract Lab
Carvone	<=1,0	0,2	%		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

Quality: Excipient

Name	Fagron a.s. (CZ)	Address	Holická 1098/31m, Olomouc	Phone No.	+420585222590
	Kontrolní laboratoř č. 536	Post Code	779 00	Fax No.	+420 585 226 521

Performed by: QC Fagron a.s. (CZ)

Responsible: Mgr. Barbora Vránová, QC
MVDr. Zdenka Borská, QA/ QP

Date: 15.04.2024

Conclusion: **APPROVED**

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