



Certificate of Analysis

Productname: Menthae piperitae etheroleum
Inspection No: L02395/0524/536
Batchnumber: 24B28-T21-110876
Expiration date: 20.02.2027
Analysed according to: Ph.Eur.11.0
Customer: FAGRON a.s.
Sample Unit: 0 x
Batch Size: 75 x 25 ml
Batch no. of vendor: 1388053

	Requirement	Result	Unit	Standard remark
Appearance	Colourless, pale yellow or pale greenish-yellow liquid. with characteristic odour.	Conform		
Solubility	Conform	Conform		
Identification B	Conform	Conform		Chromatographic profile, GC
Relative density	0,900 - 0,916	0,903		
Refractive index	1,457 - 1,467	1,461		
Optical rotation	-30 - -10	-22	°	
Acid value	<=1,4	0,32		
Fatty oils and resinified essential oils	Conform	Conform		
Mint oil	Conform	Conform		
Chromatographic profile	Conform	Conform		GC
Limonene	1,0 - 3,5	2,2	%	
1,8-Cineole	3,5 - 8,0	4,3	%	
Menthone	14,0 - 32,0	28,8	%	
Menthofuran	1,0 - 8,0	2,9	%	
Isomenthone	1,5 - 10,0	4,7	%	
Menthyl acetate	2,8 - 10,0	5,2	%	
Isopulegol	<=0,2	<0,05	%	
Menthol	30,0 - 55,0	36,8	%	
Pulegone	<=3,0	1,7	%	
Carvone	<=1,0	0,2	%	
Ratio of 1,8- cineole content to limonene	>=2	2		
TAMC	<=2 x 103	<10	CFU/g	
TYMC	<=2 x 102	<10	CFU/g	
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform		
Residual solvents	CPMP/ICH/82 260/2006	Conform		
Metallic residues	ICH Q3D on elemental impurities	Conform		

Quality: Excipient

Name	Fagron a.s. (CZ) Kontrolní laboratoř č. 536	Address	Holická 1098/31m, Olomouc	Phone No.	+420585222590
		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: 18.04.2024

Conclusion: **APPROVED**

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