



Certificate of Analysis

Productname: Rosmarini etheroleum

Inspection No: J11992/0323/536
Batchnumber: 22C08-T04-101007
Expiration date: 21.02.2025
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 22.2.2022

Sample Unit: 1 x 100 ml
Batch Size: 5 x 30 ml

Identification of producer: V00201
Batch no. of vendor: 1297456

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear, mobile, colourless or pale yellow liquid. Characteristic odour.	Conform			Fagron CZ
IDENTIFICATION					
Identification B	Conform	Conform		Chromatographic profile, GC	Contract Lab
TESTS					
Relative density	0,895 - 0,920	0,909			Fagron CZ
Refractive index	1,464 - 1,473	1,466			Fagron CZ
Optical rotation	-5 - +8	+1,3	°		Fagron CZ
Acid value	<=1,0	0,36			Fagron CZ
Chromatographic profile	Conform	Conform		GC	Contract Lab
alpha-pinene	9,0 - 14,0	12,4	%		Contract Lab
camphene	2,5 - 6,0	4,5	%		Contract Lab
beta-pinene	4,0 - 9,0	7,1	%		Contract Lab
beta-myrcene	1,0 - 2,0	1,6	%		Contract Lab
limonene	1,5 - 4,0	2,5	%		Contract Lab
cineole	38,0 - 55,0	47,2	%		Contract Lab
p-cymene	0,8 - 2,5	1,3	%		Contract Lab
camphor	5,0 - 15,0	9,3	%		Contract Lab
bornyl acetate	0,1 - 1,5	0,5	%		Contract Lab
alpha-terpineol	1,0 - 2,6	1,5	%		Contract Lab
borneol	1,5 - 5,0	2,6	%		Contract Lab
verbenone	<=0,4	<0,4	%		Contract Lab
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 ³	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	<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

Rosemary oil, Moroccan and Tunisian type.

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: Pavla Šlězarová

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

Date: 30.01.2023

Conclusion: **APPROVED**

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