



Certificate of Analysis

Productname: Citronellae etheroleum

Inspection No: J01251/0222/536
Batchnumber: 22A19-T04-093082
Expiration date: 04.01.2025
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 5.1.2022

Sample Unit: 1 x 1 ml
Batch Size: 108 x 100 ml

Identification of producer: V00201
Batch no. of vendor: 1294093

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Light yellow or brownish yellow liquid.	Conform			Fagron CZ
IDENTIFICATION					
Identification B	Conform	Conform		Chromatographic profile, GC	Contract Lab
TESTS					
Relative density	0,881 - 0,895	0,888			Fagron CZ
Refractive index	1,463 - 1,475	1,471			Fagron CZ
Optical rotation	-4 - +1,5	-3,2	°		Fagron CZ
Chromatographic profile	Conform	Conform		GC	Contract Lab
limonene	1,0 - 5,0	4,4	%		Contract Lab
citronellal	30,0 - 45,0	37,5	%		Contract Lab
citronellyl-acetate	2,0 - 4,0	2,6	%		Contract Lab
neral	<=2,0	0,2	%		Contract Lab
geranial	<=2,0	0,8	%	Geranial	Contract Lab
geranyl-acetate	3,0 - 8,0	3,4	%		Contract Lab
citronellol	9,0 - 15,0	14,4	%		Contract Lab
geraniol	20,0 - 25,0	22,6	%		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

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: Bc. Andrea Šmídová

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

Date: 17.02.2022

Conclusion: **APPROVED**

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