

Certificate of Analysis

Productname: Citri etheroleum

Inspection No: I04914/0621/536
Batchnumber: 20H18-F05-085623
Expiration date: 11.08.2023
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 12.8.2020

Sample Unit: 1 x 1 ml
Batch Size: 88 x 25 ml

Identification of producer: V00201
Batch no. of vendor: 1218058

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear, mobile, pale yellow or greenish-yellow liquid. It may become cloudy at low temperatures. Characteristic odour.	Conform			Fagron PL
IDENTIFICATION					
Identification B	Conform	Conform		Chromatographic profile	Contract Lab
TESTS					
Relative density	0,850 - 0,858	0,852			Fagron PL
Refractive index	1,473 - 1,476	1,474			Fagron PL
Optical rotation	+57 - +70	+63	°		Fagron PL
Absorbance	0,20 - 0,96	0,44			Fagron PL
Fatty oils and resinified essential oils	Conform	Conform			Contract Lab
Chromatographic profile	Conform	Conform		GC	Contract Lab
beta-pinene	7,0 - 17,0	14,6	%		Contract Lab
sabinene	1,0 - 3,0	2,0	%		Contract Lab
limonene	56,0 - 78,0	67,4	%		Contract Lab
gamma-terpinene	6,0 - 12,0	8,8	%		Contract Lab
beta-caryophyllene	<=0,5	0,1	%		Contract Lab
neral	0,3 - 1,5	0,7	%		Contract Lab
alfa-terpineol	<=0,6	0,1	%		Contract Lab
neryl-acetate	0,2 - 0,9	0,3	%		Contract Lab
geranial	0,5 - 2,3	1,1	%		Contract Lab
geranyl-acetate	0,1 - 0,8	0,2	%		Contract Lab
Residue on evaporation	1,8 - 3,6	2,2	%		Fagron PL
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 ³	Conform	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	Conform	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	Holická 1098/31m, Olomouc	Phone No.	+420585222590
		Post Code	779 00	Fax No.	+420 585 226 521

Performed by: Ekocentrum+Fagron PL

Responsible: Ing. Pavel Mišák, QC
PharmDr. Ivana Urbánková, QA

Date: 17.06.2021

Conclusion: **APPROVED**

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