

## Certificate of Analysis

Productname: Citri etheroleum

Inspection No: 102256/0321/536  
 Batchnumber: **20L14-T05-085587**  
 Expiration date: 23.11.2023  
 Analysed according to: ČL 2017, Ph.Eur.10.0  
 Original Manuf. Date: 24.11.2020

Sample Unit: 1 x 1 ml  
 Batch Size: 82 x 25 ml

Identification of producer: V00201  
 Batch no. of vendor: 1234253

	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 CZ
IDENTIFICATION					
Identification B	Conform	Conform		Chromatographic profile	Contract Lab
TESTS					
Relative density	0,850 - 0,858	0,852			Fagron CZ
Refractive index	1,473 - 1,476	1,474			Fagron CZ
Optical rotation	+57 - +70	+62	°		Fagron CZ
Absorbance	0,20 - 0,96	0,43			Fagron CZ
Fatty oils and resinified essential oils	Conform	Conform			Fagron CZ
Chromatographic profile	Conform	Conform		GC	Contract Lab
beta-pinene	7,0 - 17,0	13,5	%		Contract Lab
sabinene	1,0 - 3,0	1,7	%		Contract Lab
limonene	56,0 - 78,0	63,8	%		Contract Lab
gamma-terpinene	6,0 - 12,0	8,1	%		Contract Lab
beta-caryophyllene	<=0,5	0,2	%		Contract Lab
neral	0,3 - 1,5	0,8	%		Contract Lab
alfa-terpineol	<=0,6	0,2	%		Contract Lab
neryl-acetate	0,2 - 0,9	0,3	%		Contract Lab
geranial	0,5 - 2,3	1,3	%		Contract Lab
geranyl acetate	0,1 - 0,8	0,2	%		Contract Lab
Residue on evaporation	1,8 - 3,6	2,4	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 <sup>3</sup>	Conform	CFU/g		Contract Lab
TYMC	<=2 x 10 <sup>2</sup>	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

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	Kontrolní laboratoř č. 536	Post Code	779 00	Fax No.	+420 585 226 521

**Performed by:** Lucie Kubáňová DiS.

**Responsible:** Ing. Mgr. Kateřina Jokešová, QC  
PharmDr. Ivana Urbánková, QA

**Date:** 09.04.2021

**Conclusion:** **APPROVED**

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