



## Certificate of Analysis

**Productname:** Citri etheroleum

**Inspection No:** K07731/1023/536

**Batchnumber:** 23H09-T01-108728

**Expiration date:** 27.07.2026

**Analysed according to:** ČL 2017-Dopl.2022, Ph.Eur. 11.0

**Original Manuf. Date:** 28.7.2023

**Sample Unit:** 1 x 1 ml

**Batch Size:** 15 x 25 ml

**Identification of producer:** V00201

**Batch no. of vendor:** 1358496

	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, GC	Contract Lab
TESTS					
Relative density	0,850 - 0,858	0,854			Fagron CZ
Refractive index	1,473 - 1,476	1,474			Fagron CZ
Optical rotation	+5,7 - +7,0	6,3	°		Data Producer
Absorbance	0,20 - 0,96	0,33			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	12,6	%		Contract Lab
sabinene	1,0 - 3,0	1,7	%		Contract Lab
limonene	56,0 - 78,0	67,7	%		Contract Lab
gamma-terpinene	6,0 - 12,0	8,1	%		Contract Lab
beta-caryophyllene	<=0,5	0,1	%		Contract Lab
neral	0,3 - 1,5	0,6	%		Contract Lab
alfa-terpineol	<=0,6	0,1	%		Contract Lab
neryl-acetate	0,2 - 0,9	0,2	%		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>	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 <sup>2</sup>	<10	CFU/g		Contract Lab
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			Data Producer
Residual solvents	ICH Q3C	Conform			Data Producer
Metallic residues	ICH Q3D	Conform			Data Producer

Quality: Excipient

<b>Name</b>	Fagron a.s. (CZ)	<b>Address</b>	Holická 1098/31m, Olomouc	<b>Phone No.</b>	+420585222590
	Kontrolní laboratoř č. 536	<b>Post Code</b>	779 00	<b>Fax No.</b>	+420 585 226 521

**Performed by:** Ludmila Burianová

**Responsible:** Mgr. Zdeňka Šinclová, QC  
MVDr. Zdenka Borská, QP

**Date:** 18.10.2023

**Conclusion:** **APPROVED**

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