



Certificate of Analysis

Productname: Terebinthinae etheroleum

Inspection No: J01651/0322/536

Batchnumber: 22B01-T07-092960

Expiration date: 20.01.2025

Analysed according to: ČL 2017,Dopl.2018,Ph.Eur.10.0

Original Manuf. Date: 21.1.2022

Sample Unit: 1 x 10 ml

Batch Size: 74 x 1 l

Identification of producer: V00201

Batch no. of vendor: 1296342

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear,colourless or pale yellow liquid of characteristic odour of alfa-pinen and beta-pinen.	Conform			Fagron CZ
IDENTIFICATION					
Identification B	Conform	Conform		Chromatographic profile, GC	Fagron CZ
TESTS					
Relative density	0,856 - 0,872	0,867			Fagron CZ
Refractive index	1,465 - 1,475	1,470			Fagron CZ
Optical rotation	-40 - -28	-30	°		Fagron CZ
Acid value	<=1,0	0,95			Fagron CZ
Peroxide value	<=20	19			Fagron CZ
Fatty oils and resinified essential oils	Conform	Conform			Fagron CZ
Chromatographic profile	Conform	Conform		GC	Contract Lab
Alfa-pinene	70,0 - 85,0	77,6	%		Contract Lab
Camphene	0,5 - 2,0	1,0	%		Contract Lab
beta-Pinene	5,0 - 20,0	13,3	%		Contract Lab
Car-3-ene	<=1,0	<1,0	%		Contract Lab
β-Myrcene	0,4 - 1,5	0,6	%		Contract Lab
Liimonene	1,0 - 7,0	2,0	%		Contract Lab
Longifolene	0,2 - 4,0	1,3	%		Contract Lab
β-Caryophyllene	0,1 - 3,0	2,0	%		Contract Lab
Caryophyllene oxide	<=1,0	0,1	%		Contract Lab
Residue on evaporation	<=2,5	1,3	%		Fagron CZ
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	Conform ICH Q3C	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: 17.03.2022

Conclusion: **APPROVED**

This document has been produced electronically from our quality system and is valid without signature.