



Certificate of Analysis

Productname: ETHER

Inspection No: K03490/0523/536
Batchnumber: 23E17-T06-104055
Expiration date: 22.03.2025
Analysed according to: ČL 2017, Ph.Eur.11.0
Original Manuf. Date: 22.3.2023

Sample Unit: 1 x 125 ml
Batch Size: 2,670 x 250 ml

Identification of producer: V00528
Batch no. of vendor: 230

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear colourless liquid, volatile.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	0,714 - 0,716	0,715		Relative density	Fagron CZ
Identification B	34,0 - 35,0	34,6	°C	Distillation range	Fagron CZ
TESTS					
Acidity	<=0,4	0,1	ml	0,02 M NaOH	Fagron CZ
Relative density	0,714 - 0,716	0,715			Fagron CZ
Distillation range	34,0 - 35,0	34,6	°C	100%	Fagron CZ
Aldehydes	Conform	Conform			Fagron CZ
Peroxides	Conform	Conform			Fagron CZ
Non-volatile matter	<=20	0,0	mg/l		Fagron CZ
Substances with a foreign odour	Conform	Conform			Fagron CZ
Water	<=2	0,9	g/l		Fagron CZ
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			Data Producer
Residual solvents	CPMP/ICH/82 260/06	Conform			Data Producer
Metallic residues	ICH Q3D on elemental impurities	Conform			Data Producer

Quality: Excipient

Performed by: Ludmila Stochlebová

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

Date: 31.05.2023

Conclusion: APPROVED

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

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