



Certificate of Analysis

Productname: ETHER

Inspection No: L03011/0524/536
Batchnumber: 24D22-T13-112877
Expiration date: 19.04.2026
Analysed according to: Ph.Eur.11.2
Original Manuf. Date: 19.4.2024

Sample Unit: 1 x 125 ml
Batch Size: 6,760 x 100 ml

Identification of producer: V00528
Batch no. of vendor: 251

	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	34,7	°C	Distillation range	Fagron CZ
TESTS					
Acidity	<=0,4	0,08	ml	0,02 M NaOH	Fagron CZ
Relative density	0,714 - 0,716	0,715			Fagron CZ
Distillation range	34,0 - 35,0	34,7	°C	100%	Fagron CZ
Acetone and aldehydes	Conform	Conform			Fagron CZ
Peroxides	Conform	Conform			Fagron CZ
Non-volatile matter	<=20	0,0	mg/l		Fagron CZ
Volatile impurities	Conform	Conform			Contract Lab
Unspecified impurities	<=0,05	<0,03	%		Contract Lab
Total impurities	<=0,1	<0,03	%		Contract Lab
Water	<=2	0,6	g/l		Fagron CZ
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

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: QC Fagron a.s. (CZ)

Responsible: PharmDr. Ivana Urbánková, QA/ QP
MVDr. Zdenka Borská, QA/ QP

Date: 09.05.2024

Conclusion: **APPROVED**

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