



## Certificate of Analysis

**Productname:** ETHER

**Inspection No:** K01892/0523/536  
**Batchnumber:** 23B15-T03-102505  
**Expiration date:** 13.02.2025  
**Analysed according to:** ČL 2017, Ph.Eur.11.0  
**Original Manuf. Date:** 13.2.2023

**Sample Unit:** 1 x 125 ml  
**Batch Size:** 5,166 x 250 ml

**Identification of producer:** V00528  
**Batch no. of vendor:** 123

	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	0,714		Relative density	Fagron CZ
Identification B	34,0 - 35,0	35,0	°C	Distillation range	Fagron CZ
TESTS					
Acidity	<=0,4	0,1	ml	0,02 M NaOH	Fagron CZ
Relative density	0,714 - 0,716	0,714			Fagron CZ
Distillation range	34,0 - 35,0	35,0	°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	1	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:** 05.05.2023

**Conclusion:** APPROVED

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

<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