



## Certificate of Analysis

**Productname:** ETHER

**Inspection No:** J09303/0922/536  
**Batchnumber:** 22I30-T06-098579  
**Expiration date:** 23.09.2024  
**Analysed according to:** ČL 2017, Ph.Eur.10.0  
**Original Manuf. Date:** 23.9.2022

**Sample Unit:** 1 x 125 ml  
**Batch Size:** 12,504 x 100 ml

**Identification of producer:** V00528  
**Batch no. of vendor:** 658

	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	0,716		Relative density	Fagron CZ
Identification B	34,0 - 35,0	34,2	°C	Distillation range	Fagron CZ
TESTS					
Acidity	<=0,4	0,4	ml	0,02 M NaOH	Fagron CZ
Relative density	0,714 - 0,716	0,716			Fagron CZ
Distillation range	34,0 - 35,0	34,2	°C	100%	Fagron CZ
Aldehydes	Conform	Conform			Fagron CZ
Peroxides	Conform	Conform			Fagron CZ
Non-volatile matter	<=20	0,018	mg/l		Fagron CZ
Substances with a foreign odour	Conform	Conform			Fagron CZ
Water	<=2	0,7	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:** Pavla Šlězarová

**Responsible:** Ing. Pavel Mišák, QC  
 MVDr. Zdenka Borská, QP

**Date:** 11.11.2022

**Conclusion:** APPROVED

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

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