

Certificate of Analysis

Productname: ETHER

Inspection No: L01945/0524/536
Batchnumber: 24C06-T01-110807
Expiration date: 28.02.2026
Analysed according to: Ph.Eur.11.2
Original Manuf. Date: 29.2.2024

Sample Unit: 1 x 125 ml
Batch Size: 267 x 5 l

Identification of producer: V00528
Batch no. of vendor: 117

	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	35,0	°C	Distillation range	Fagron CZ
TESTS					
Acidity	<=0,4	0,05	ml	0,02 M NaOH	Fagron CZ
Relative density	0,714 - 0,716	0,716			Fagron CZ
Distillation range	34,0 - 35,0	35,0	°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
Water	<=2	0,9	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

DEV-2024-0367. The raw material was released without the results of the contract laboratory analyses.

Performed by: QC Fagron a.s. (CZ)

Responsible: Mgr. Barbora Vránová, QC
Ing. Martina Zemanová,

Date: 18.03.2024

Conclusion: APPROVED

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