

Certificate of Analysis

Productname: Ether solvens

Inspection No: L02587/0424/536
Batchnumber: 24D10-T01
Expiration date: 28.03.2026
Analysed according to: Ph.Eur.11.2

Customer: FAGRON a.s.
Sample Unit: 1 x 500 ml
Batch Size: 1,250 x kg

Batch no. of vendor: 215

	Requirement	Result	Unit	Standard remark
CHARACTERS				
Appearance	Clear colourless liquid, volatile.	Conform		
Solubility	Conform	Conform		
IDENTIFICATION				
Identification A	0,714 - 0,716	0,716		Relative density
Identification B	34,0 - 35,0	34,9	°C	Distillation range
TESTS				
Acidity	<=0,4	0,1	ml	0,02 M NaOH
Relative density	0,714 - 0,716	0,716		
Distillation range	34,0 - 35,0	34,9	°C	100%
Acetone and aldehydes	Conform	Conform		
Peroxides	Conform	Conform		
Non-volatile matter	<=20	0,0	mg/l	
Water	<=2	1	g/l	
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform		
Residual solvents	ICH Q3C	Conform		
Metallic residues	ICH Q3D on elemental impurities	Conform		

Quality: Excipient

DEV-2024-0367. Surovina propuštěna bez výsledků analýz smluvní laboratoře.

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

Responsible: Mgr. Barbora Vránová, QC
 MVDr. Zdenka Borská, QA/ QP

Date: 10.04.2024

Conclusion: APPROVED

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Relative density	0,714 - 0,716	0,716		
Distillation range	34,0 - 35,0	34,9	°C	100%
Acetone and aldehydes	Conform	Conform		
Peroxides	Conform	Conform		
Non-volatile matter	<=20	0,0	mg/l	
Volatile impurities	Conform	Conform		
Unspecified impurities	<=0,05	<0,03	%	
Total impurities	<=0,1	<0,03	%	
Water	<=2	1	g/l	
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform		
Residual solvents	ICH Q3C	Conform		
Metallic residues	ICH Q3D on elemental impurities	Conform		

Quality: Excipient

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

Responsible: Mgr. Barbora Vránová, QC
 MVDr. Zdenka Borská, QA/ QP

Date: 18.04.2024

Conclusion: APPROVED

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		Post Code		Fax No.	+420 585 226 521

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