



Certificate of Analysis

Productname: Paraffinum liquidum

Inspection No: K09203/0124/536

Batchnumber: 23I05-T13-109511

Expiration date: 31.08.2026

Analysed according to: ČL 2017-Dopl.2018,Ph.Eur.11.0

Original Manuf. Date: 31.8.2023

Sample Unit: 1 x 125 ml

Batch Size: 96 x 5 l

Identification of producer: V00230

Batch no. of vendor: 1527106

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Colourless,transparent,oily liquid, free from fluorescence in daylight.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	Conform	Conform		IR-spectrum	Fagron CZ
Identification C	110 - 230	207	mPa.s	Viscosity	Fagron CZ
TESTS					
Acidity or alkalinity	<=0,1	0,03	ml		Fagron CZ
Relative density	0,827 - 0,890	0,867			Fagron CZ
Viscosity	110 - 230	207	mPa.s		Fagron CZ
Polycyclic aromatic hydrocarbons	Conform	Conform			Fagron CZ
Readily carbonisable substances	Conform	Conform			Fagron CZ
Solid paraffins	Conform	Conform			Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 ³	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	<10	CFU/g		Contract Lab
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: Ludmila Burianová

Responsible: Mgr. Zdeňka Šinclová, QC
MVDr. Zdenka Borská, QP

Date: 04.12.2023

Conclusion: **APPROVED**

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