



## Certificate of Analysis

**Productname:** Paraffinum liquidum

**Inspection No:** K04892/0923/536

**Batchnumber:** 23C09-T11-106810

**Expiration date:** 28.02.2026

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

**Original Manuf. Date:** 28.2.2023

**Sample Unit:** 1 x 125 ml

**Batch Size:** 96 x 5 l

**Identification of producer:** V00230

**Batch no. of vendor:** 1501902

	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	201	mPa.s	Viscosity	Fagron CZ
TESTS					
Acidity or alkalinity	<=0,1	0,04	ml		Fagron CZ
Relative density	0,827 - 0,890	0,867			Fagron CZ
Viscosity	110 - 230	201	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 <sup>3</sup>	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 <sup>2</sup>	<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

<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

**Performed by:** Ludmila Burianová

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

**Date:** 05.09.2023

**Conclusion:** **APPROVED**

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