



## Certificate of Analysis

**Productname:** Paraffinum perliquidum

**Inspection No:** K04262/0623/536

**Batchnumber:** 23D21-T12-106384

**Expiration date:** 31.03.2026

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

**Original Manuf. Date:** 31.3.2023

**Sample Unit:** 1 x 125 ml

**Batch Size:** 45 x 100 ml

**Identification of producer:** V00230

**Batch no. of vendor:** 1505391

	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	25 - 80	30	mPa.s	Viscosity	Fagron CZ
TESTS					
Acidity or alkalinity	<=0,1	0,04	ml	0,1 mol/l NaOH	Fagron CZ
Relative density	0,810 - 0,875	0,850			Fagron CZ
Viscosity	25 - 80	30	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	CPMP/ICH/82 260/2006	Conform			Data Producer
Metallic residues	ICH Q3D on elemental impurities	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 Stochlebová

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

**Date:** 04.07.2023

**Conclusion:** **APPROVED**

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