

## Certificate of Analysis

**Productname:** Paraffinum perliquidum

**Inspection No:** I07434/1021/536

**Batchnumber:** 21C26-T06-090275

**Expiration date:** 31.03.2024

**Analysed according to:** ČL 2017, Ph.Eur.10.0

**Original Manuf. Date:** 31.3.2021

**Sample Unit:** 1 x 125 ml

**Batch Size:** 209 x 1 l

**Identification of producer:** V00230

**Batch no. of vendor:** 1393476

	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	0,07	ml	0,1 mol/l NaOH	Fagron CZ
Relative density	0,810 - 0,875	0,845			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>	Conform	CFU/g		Contract Lab
TYMC	<=2 x 10 <sup>2</sup>	Conform	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

**Name** Fagron a.s. (CZ)  
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**Performed by:** Ing. Petra Drábková

**Responsible:** Ing. Pavel Mišák, QC  
PharmDr. Ivana Urbánková, QA

**Date:** 08.10.2021

**Conclusion:** **APPROVED**

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

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