

Certificate of Analysis

Productname: Paraffinum liquidum
Inspection No: I07496/1021/536
Batchnumber: 21I01-T05-090021
Expiration date: 31.07.2024
Analysed according to: ČL 2017-Dopl.2018, Ph.Eur.10.0
Original Manuf. Date: 31.7.2021

Sample Unit: 0 x
Batch Size: 49 x 500 ml

Identification of producer: V00230
Batch no. of vendor: 1412578

	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	168	mPa.s	Viscosity	Fagron CZ
TESTS					
Acidity or alkalinity	≤0,1	0,05	ml		Fagron CZ
Relative density	0,827 - 0,890	0,867			Fagron CZ
Viscosity	110 - 230	168	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	CPMP/ICH/82 260/2006	Conform			Data Producer
Metallic residues	ICH Q3D on elemental impurities	Conform			Data Producer

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

The product conforms to ČL 2017-Dopl.2018,Ph.Eur.10.0.

Performed by: Lucie Kubáňová DiS.

Responsible: Lenka Morávková, QC
MVDr. Zdenka Borská, QA

Date: 02.11.2021



Conclusion: I certify that the above-mentioned batch of pharmaceutical raw material has been manufactured and tested in accordance with the requirements of Marketing Authorization (License) and requirements of Good Manufacturing Practice.

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

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