

Certificate of Analysis

Productname: Paraffinum perliquidum

Inspection No: I01854/0321/536
Batchnumber: 20H06-T03-084737
Expiration date: 31.07.2023
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 31.7.2020

Sample Unit: 1 x 200 ml
Batch Size: 100 x 1 l

Identification of producer: V00230
Batch no. of vendor: 1352772

	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	26	mPa.s	Viscosity	Fagron CZ
TESTS					
Acidity or alkalinity	≤0,1	0,05	ml	0,1 mol/l NaOH	Fagron CZ
Relative density	0,810 - 0,875	0,851			Fagron CZ
Viscosity	25 - 80	26	mPa.s		Fagron CZ
Polycyclic aromatic hydrocarbons	Conform	Conform			Fagron CZ
Readily carbonisable substances	Conform	Conform			Fagron CZ
Solid paraffins	Conform	Conform			Fagron CZ
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			Data Producer
Residual solvents	CPMP/ICH/82 280/2006	Conform			Data Producer
Metallic residues	ICH Q3D on elemental impurities	Conform			Data Producer

Performed by: Lucie Kubáňová DiS.

Responsible: Ing. Mgr. Kateřina Jokešová, QC
PharmDr. Ivana Urbánková, QA

Date: 09.04.2021

Conclusion: APPROVED

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

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