



Certificate of Analysis

Productname: Paraffinum perliquidum

Inspection No: J02560/0422/536
Batchnumber: 22A31-T05-093706
Expiration date: 31.01.2025
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 31.1.2022

Sample Unit: 1 x 125 ml
Batch Size: 447 x 100 ml

Identification of producer: V00230
Batch no. of vendor: 1439781

	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	31	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	0,852			Fagron CZ
Viscosity	25 - 80	31	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

Quality: Excipient

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	Kontrolní laboratoř č. 536	Post Code	779 00	Fax No.	+420 585 226 521

Performed by: Ludmila Stochlebová

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

Date: 04.04.2022

Conclusion: **APPROVED**

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