

Certificate of Analysis

Productname: Paraffinum liquidum

Inspection No: I01733/0321/536

Sample Unit: 0 x

Batchnumber: 20L18-T04-085057

Batch Size: 45 x 1 l

Expiration date: 31.12.2023

Analysed according to: ČL 2017-Dopl.2018,Ph.Eur.10.0

Original Manuf. Date: 16.12.2020

Identification of producer: V00230

Batch no. of vendor: 1379164

	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	186	mPa.s	Viscosity	Fagron CZ
TESTS					
Acidity or alkalinity	<=0,1	0,04	ml		Fagron CZ
Relative density	0,827 - 0,890	0,868			Fagron CZ
Viscosity	110 - 230	186	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/82 260/2006	Conform			Data Producer
Metallic residues	ICH Q3D on elemental impurities	Conform			Data Producer

Performed by: Bc. Andrea Šmidová

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


Date: 19.03.2021

Conclusion: APPROVED

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