

Certificate of Analysis

Productname: Paraffinum liquidum

Inspection No: I04671/0621/536
Batchnumber: 21E21-T17-085713
Expiration date: 31.05.2024
Analysed according to: ČL 2017-Dopl.2018,Ph.Eur.10.0
Original Manuf. Date: 31.5.2021

Sample Unit: 1 x 200 ml
Batch Size: 935 x 1 l

Identification of producer: V00230
Batch no. of vendor: 1401349

	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	155	mPa.s	Viscosity	Fagron CZ
TESTS					
Acidity or alkalinity	<=0,1	0,03	ml		Fagron CZ
Relative density	0,827 - 0,890	0,867			Fagron CZ
Viscosity	110 - 230	155	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	Conform	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	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) Kontrolní laboratoř č. 536	Address	Holická 1098/31m, Olomouc	Phone No.	+420585222590
		Post Code	779 00	Fax No.	+420 585 226 521

Performed by: Lucie Kubáňová DiS.
Responsible: Ing. Pavel Mišák, QC
PharmDr. Ivana Urbánková, QA
Date: 16.06.2021
Conclusion: **APPROVED**

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Name	Fagron a.s. (CZ) Kontrolní laboratoř č. 536	Address	Holická 1098/31m, Olomouc	Phone No.	+420585222590
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