



Certificate of Analysis

Productname: Vaselinum flavum

Inspection No: I09964/0122/536
Batchnumber: 21I10-T01-091795
Expiration date: 31.08.2024
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 31.8.2021

Sample Unit: 1 x 20 g
Batch Size: 112 x 1 kg

Identification of producer: V00230
Batch no. of vendor: 1419049

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Yellow, translucent, unctuous mass, slightly fluorescent in daylight when melted.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	40 - 60	55	°C	Drop point	Fagron CZ
Identification B	Conform	Conform		IR-spectrum	Fagron CZ
Identification D	Conform	Conform		Appearance	Fagron CZ
TESTS					
Appearance	Conform	Conform			Fagron CZ
Density	dle zkoušky	0,818	g/cm3	60°C, USP	Data Producer
Acidity or alkalinity	<=0,5	0,3	ml	0.01 M NaOH	Fagron CZ
Consistency	100 - 300	113			Contract Lab
Polycyclic aromatic hydrocarbons	Conform	Conform			Contract Lab
Sulfated ash	<=0,05	0	%		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	ICH Q3C	Conform			Data Producer
Metallic residues	ICH Q3D	Conform			Data Producer

Performed by: Lucie Kubáňová DiS.

Responsible: Ing. Pavel Mišák, QC
MVDr. Zdenka Borská, QA

Date: 19.01.2022

Conclusion: **APPROVED**

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