

Certificate of Analysis

Productname: Vaselineum flavum

Inspection No: H01181/0320/536

Batchnumber: 19G24-T06-073862

Expiration date: 31.07.2022

Analysed according to: ČL 2017,Ph.Eur.9.0

Original Manuf. Date: 31.7.2019

Sample Unit: 1 x 20 g

Batch Size: 100 x 1 kg

Identification of producer: V00230

Batch no. of vendor: 1300315

	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
Acidity or alkalinity	<=0,5	Conform	ml	0.01 M NaOH	Data Producer
Consistency	100 - 300	166			Data Producer
Polycyclic aromatic hydrocarbons	Conform	Conform			Data Producer
Sulfated ash	<=0,05	<0,05	%		Data Producer
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	CHMP/SWP/4446/2000	Conform			Data Producer

Performed by: Dominika Stropková

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

Date: 08.04.2020

Conclusion: APPROVED

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