

## Certificate of Analysis

**Productname:** Vaselinum flavum

**Inspection No:** I08793/1221/536  
**Batchnumber:** 21C05-T01-091198  
**Expiration date:** 28.02.2024  
**Analysed according to:** ČL 2017, Ph.Eur.10.0  
**Original Manuf. Date:** 28.2.2021

**Sample Unit:** 0 x 50 g  
**Batch Size:** 10 x 1 kg

**Identification of producer:** V00230  
**Batch no. of vendor:** 1387482

	Requirement	Result	Unit	Standard remark	Insp. Site
<b>CHARACTERS</b>					
Appearance	Yellow, translucent, unctuous mass, slightly fluorescent in daylight when melted.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
<b>IDENTIFICATION</b>					
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
<b>TESTS</b>					
Appearance	Conform	Conform			Fagron CZ
Acidity or alkalinity	<=0,5	0,1	ml	0.01 M NaOH	Fagron CZ
Consistency	100 - 300	167			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 <sup>3</sup>	Conform	CFU/g		Contract Lab
TYMC	<=2 x 10 <sup>2</sup>	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

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The product conforms to ČL 2017, Ph.Eur.10.0.

Performed by: Ing. Petra Drábková

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

Date: 08.12.2021 

Conclusion: I certify that the above-mentioned batch of pharmaceutical raw material has been manufactured and tested in accordance with the requirements of Marketing Authorization (License) and requirements of Good Manufacturing Practice.

This document has been produced electronically from our quality system and is valid without signature.

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