



# Certificate of Analysis

**Productname:** Vaselineum flavum

**Inspection No:** F10312/1118/536  
**Batchnumber:** 18H22-T15-060101  
**Expiration date:** 31.08.2021  
**Analysed according to:** ČL 2017, Ph.Eur.9.0

**Sample Unit:** 0 x 50 g  
**Batch Size:** 30 x 5 kg

**Identification of producer:** V00230  
**Batch no. of vendor:** 1249173

	Requirement	Result	Unit	Standard remark	Insp. Site
<b>CHARACTERS</b>					
Appearance	(Pale) yellow translucent mass.	Conform			Fagron CZ
Solubility	Conform	Conform			
<b>IDENTIFICATION</b>					
Identification A	40 - 60	58	°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			
Acidity or alkalinity	≤0,5	Conform			Fagron CZ
Consistency	100 - 300	Conform	ml	0,01 mol/l NaOH	Data Producer
Polycyclic aromatic hydrocarbons	Conform	173			Data Producer
Sulfated ash	≤ 0,05	Conform			Data Producer
Microbiology	Conform	≤0,05	%		Data Producer
TAMC	≤2 x 10 <sup>3</sup>	Conform			Contract Lab
TYMC	≤2 x 10 <sup>2</sup>	Conform	CFU/g		Contract Lab
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform	CFU/g		Contract Lab
Residual solvents	CPMP/ICH/82 260/06	Conform			Data Producer
Metallic residues	CHMP/SWP/4446/2000	Conform			Data Producer

**Performed by:** Alena Poláchová

**Responsible:** Lenka Morávková, QC  
 PharmDr. Hana Běhalová, QP

**Date:** 23.11.2018

**Conclusion:** APPROVED

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