

Certificate of Analysis

Productname: Vaselineum flavum

Inspection No: L02469/0524/536

Batchnumber: 112547

Expiration date: 31.12.2026

Analysed according to: ČL 2023, Ph. Eur. 11.0

Customer: FAGRON a.s.

Sample Unit: 1 x 1 kg

Batch Size: 250 x 1 kg

Batch no. of vendor: 1547081

	Requirement	Result	Unit	Standard remark
CHARACTERS				
Appearance	Yellowish or light amber, unctuous mass, slightly fluorescent in daylight even when melted, transparent in thin layers.	Conform		
Solubility	Conform	Conform		
IDENTIFICATION				
Identification A	35 - 70	57	° C	Drop point
Identification B	Conform	Conform		IR-spectrum
Identification D	Conform	Conform		Appearance
TESTS				
Appearance	Conform	Conform		
Acidity or alkalinity	<=0,5	0,05	ml	0.01 M NaOH
Consistency	100 - 300	139		
UV abs. limit for poly.arom.hydrocarb.	<=75	<75	ppm	
Sulfated ash	<=0,05	0,0	%	
Microbiology	Conform	Conform		
TAMC	<=2 x 10 ³	<10	CFU/g	
TYMC	<=2 x 10 ²	<10	CFU/g	
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform		
Residual solvents	ICH Q3C	Conform		
Metallic residues	ICH Q3D	Conform		

Quality: Excipient

Performed by: QC Fagron a.s. (CZ)

Responsible: Mgr. Zdeňka Šinclová, QC
Mgr. Barbora Agatha Halouzková, QA/ QP

Date: 18.04.2024

Conclusion: APPROVED

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