

Certificate of Analysis

Productname: Vaselineum flavum

Inspection No: J09995/0123/536
Batchnumber: 22E09-T03-101028
Expiration date: 31.05.2025
Analysed according to: ČL 2017, Ph.Eur.10.0

Customer: FAGRON a.s.
Sample Unit: 1 x 20 g
Batch Size: 80 x 5 kg

Batch no. of vendor: 1456092

	Requirement	Result	Unit	Standard remark
CHARACTERS				
Appearance	Yellow, translucent, unctuous mass, slightly fluorescent in daylight when melted.	Conform		
Solubility	Conform	Conform		
IDENTIFICATION				
Identification A	40 - 60	46	°C	Drop point
Identification B	Conform	Conform		IR-spectrum
Identification D	Conform	Conform		Appearance
TESTS				
Appearance	Conform	Conform		
Acidity or alkalinity	<=0,5	0,3	ml	0.01 M NaOH
Consistency	100 - 300	117		
Polycyclic aromatic hydrocarbons	Conform	Conform		
Sulfated ash	<=0,05	<0,05	%	
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: Ekocentrum

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

Date: 08.12.2022

Conclusion: APPROVED

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