



## Certificate of Analysis

**Productname:** Vaselinum album

**Inspection No:** K09211/0124/536  
**Batchnumber:** 23I05-T11-109514  
**Expiration date:** 31.08.2026  
**Analysed according to:** Ph.Eur.11.0  
**Original Manuf. Date:** 31.8.2023

**Sample Unit:** 1 x 20 g  
**Batch Size:** 18 x 5 kg

**Identification of producer:** V01479  
**Batch no. of vendor:** 1528204

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	(Almost) white, translucent, soft unctuous mass, transparent in thin layer even after cooling to 0 °C.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	35 - 70	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
Density	Conform	0,818	g/cm <sup>3</sup>	60°C, USP	Data Producer
Acidity or alkalinity	<=0,5	0,03	ml	0.01 M NaOH	Fagron CZ
Consistency	60 - 300	79			Contract Lab
Polycyclic aromatic hydrocarbons	<= 75	<75	ppm		Contract Lab
Sulfated ash	<=0,05	0,00	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 <sup>3</sup>	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 <sup>2</sup>	<10	CFU/g		Contract Lab
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			Data Producer
Residual solvents	ICH Q3C	Conform			Data Producer
Metallic residues	ICH Q3D	Conform			Data Producer

Quality: Excipient

**Performed by:** Ludmila Burianová

**Responsible:** Mgr. Zdeňka Šinclová, QC  
MVDr. Zdenka Borská, QP

**Date:** 08.12.2023

**Conclusion:** **APPROVED**

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