



Certificate of Analysis

Productname: Vaselinum album

Inspection No: K09208/0124/536
Batchnumber: 23I05-T11-109505
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: 1,000 x 1 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 ³	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 ³	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	<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: 11.12.2023

Conclusion: **APPROVED**

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