



Certificate of Analysis

Productname: Vaselinum album

Inspection No: K10076/0124/536
Batchnumber: 23I05-T11-110148
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: 1,402 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: 15.01.2024

Conclusion: **APPROVED**

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