



Certificate of Analysis

Productname: Vaselinum album

Inspection No: J01051/0322/536
Batchnumber: 21K23-T02-093433
Expiration date: 30.11.2024
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 30.11.2021

Sample Unit: 1 x 20 g
Batch Size: 310 x 1 kg

Identification of producer: V00230
Batch no. of vendor: 1432115

| | Requirement | Result | Unit | Standard remark | Insp. Site |
|----------------------------------|--|---------|-------------------|-----------------|---------------|
| CHARACTERS | | | | | |
| Appearance | (Almost) white, translucent, soft unctuous mass, slightly fluorescent in daylight when melted. | Conform | | | Fagron CZ |
| Solubility | Conform | Conform | | | Fagron CZ |
| IDENTIFICATION | | | | | |
| Identification A | 35 - 70 | 53 | °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 | 0,825 | g/cm ³ | 60°C, USP | Data Producer |
| Acidity or alkalinity | <=0,5 | 0,1 | ml | 0.01 M NaOH | Fagron CZ |
| Consistency | 60 - 300 | 276 | | | Contract Lab |
| Polycyclic aromatic hydrocarbons | Conform | Conform | | | Contract Lab |
| Sulfated ash | <=0,05 | 0,0 | % | | 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 | CPMP/ICH/82 260/2006 | Conform | | | Data Producer |
| Metallic residues | ICH Q3D on elemental impurities | Conform | | | Data Producer |

Quality: Excipient

| | | | | | |
|-------------|----------------------------|------------------|---------------------------|------------------|------------------|
| Name | Fagron a.s. (CZ) | Address | Holická 1098/31m, Olomouc | Phone No. | +420585222590 |
| | Kontrolní laboratoř č. 536 | Post Code | 779 00 | Fax No. | +420 585 226 521 |

Performed by: Ludmila Stochlebová

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

Date: 14.03.2022

Conclusion: **APPROVED**

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