

Certificate of Analysis

Productname: Vaselineum album

Inspection No: H06186/0620/536

Batchnumber: 20F02-T02-077218

Expiration date: 31.05.2023

Analysed according to: ČL 2017, Ph.Eur.10.0

Original Manuf. Date: 26.5.2020

Sample Unit: 1 x 20 g

Batch Size: 1 464 x 1 kg

Identification of producer: V00230

Batch no. of vendor: 1345093

| | 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 | 57 | °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 |
| Acidity or alkalinity | <=0,5 | 0,1 | ml | 0.01 M NaOH | Fagron CZ |
| Consistency | 60 - 300 | 73 | | | Contract Lab |
| Polycyclic aromatic hydrocarbons | Conform | Conform | | | Contract Lab |
| Sulfated ash | <=0,05 | 0,00 | % | | Fagron CZ |
| Microbiology | Conform | Conform | | | Contract Lab |
| TAMC | <=2 x 10 ³ | Conform | CFU/g | | Contract Lab |
| TYMC | <=2 x 10 ² | Conform | 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 |

Performed by: Lucie Kubáňová

Responsible: Mgr. Kateřina Jokešová, QC
PharmDr. Ivana Urbánková, QA

Date: 10.07.2020

Conclusion: APPROVED

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