



Certificate of Analysis

Productname: Vaselineum album 1712

Inspection No: G03012/0619/536
Batchnumber: 18K01-T06-065454
Expiration date: 31.10.2021
Analysed according to: ČL 2017, Ph.Eur.9.0
Original Manuf. Date: 31.10.2018

Sample Unit: 0 x 50 g
Batch Size: 15 x 10 kg

Identification of producer: V00230
Batch no. of vendor: 1260333

| | Requirement | Result | Unit | Standard remark | Insp. Site |
|----------------------------------|--------------------------------------------------|---------|-------|-----------------|---------------|
| CHARACTERS | | | | | |
| Appearance | (Almost) white, translucent, soft unctuous mass. | 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 | Conform | ml | | Data Producer |
| Consistency | 60 - 300 | 169 | | | Data Producer |
| Polycyclic aromatic hydrocarbons | Conform | Conform | | | Data Producer |
| Sulfated ash | <=0,05 | <0,05 | % | | Data Producer |
| 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/82 260/06 | Conform | | | Data Producer |
| Metallic residues | CHMP/SWP/4446/2000 | Conform | | | Data Producer |

BHT 45,6 mg/kg

Performed by: Kamila Wisnerová

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

Date: 20.06.2019

Conclusion: APPROVED

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