

Certificate of Analysis

Productname: Vaselineum album 1712

Inspection No: I02597/0421/536
Batchnumber: 19L06-T13-086889
Expiration date: 30.11.2022
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 30.11.2019

Sample Unit: 0 x 25 kg
Batch Size: 2 x 25 kg

Identification of producer: V00230
Batch no. of vendor: 1317557

| | 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 | 56 | °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 | 0,07 | ml | | Fagron CZ |
| Consistency | 60 - 300 | 177 | | | Data Producer |
| Polycyclic aromatic hydrocarbons | Conform | Conform | | | Data Producer |
| 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 |
| BHT <50 µg/g | | | | | |

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

Performed by: Mgr. Zdeňka Šinclová

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

Date: 21.04.2021

Conclusion: APPROVED

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

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