

Certificate of Analysis

Productname: Vaselineum album

Inspection No: H03970/0520/536

Batchnumber: 20B26-T13-079491

Expiration date: 28.02.2023

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

Original Manuf. Date: 20.2.2020

Sample Unit: 1 x 20 g

Batch Size: 50 x 5 kg

Identification of producer: V00230

Batch no. of vendor: 1331780

| | 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 | 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 |
| Acidity or alkalinity | <=0,5 | 0,1 | ml | 0.01 M NaOH | Fagron CZ |
| Consistency | 60 - 300 | 60 | | | Contract Lab |
| Polycyclic aromatic hydrocarbons | Conform | Conform | | | Contract Lab |
| Sulfated ash | <=0,05 | 0 | % | | 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 |

INCI: Petrolatum

Performed by: Bc. Andrea Šmídová

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

Date: 29.05.2020

Conclusion: APPROVED

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