Fagron personalizing medicine

# Certificate of Analysis

**Productname:** **Adeps lanae**

**Inspection No:** I07433/1021/536
**Batchnumber:** **21B18-T01-090162**
**Expiration date:** 28.02.2023
**Analysed according to:** ČL 2017-Dopl.2020,Ph.Eur.10.0
**Original Manuf. Date:** 3.2.2021

**Sample Unit:** 0 x 50 g
**Batch Size:** 20 x 1 kg

**Identification of producer:** V00328
**Batch no. of vendor:** L04858

| | Requirement | Result | Unit | Standard remark | Insp. Site |
|---|---|---|---|---|---|
| CHARACTERS | | | | | |
| Appearance | Yellow, unctuous substance. When melted, it is a clear or almost clear, yellow liquid. A solution in light petroleum is opalescent. | Conform | | | Fagron CZ |
| Solubility | Conform | Conform | | | Fagron CZ |
| IDENTIFICATION | | | | | |
| Identification A | Green | Conform | | | Fagron CZ |
| Identification B | Red / strong green fluorescence | Conform | | | Fagron CZ |
| TESTS | | | | | |
| Water-soluble acid or alk. substances | Conform | Conform | | | Fagron CZ |
| Water-absorption capacity | >= 20 | 26 | ml | | Fagron CZ |
| Acid value | <=1,0 | 0,77 | | | Fagron CZ |
| Peroxide value | <=20 | 15 | | | Fagron CZ |
| Saponification value | 90 - 105 | 96 | | | Fagron CZ |
| Water-soluble oxidisable substances | Conform | Conform | | | Fagron CZ |
| Paraffins | <=1,0 | 0,36 | % | | Fagron CZ |
| Pesticide residues | Conform | Conform | | | Contract Lab |
| Chlorides | <=150 | Conform | µg/g | | Fagron CZ |
| Loss on drying | <=0,5 | 0,2 | % | 105 °C | Fagron CZ |
| Sulfated ash | <=0,15 | 0,0 | % | | Fagron CZ |
| Microbiology | Conform | Conform | | | Contract Lab |
| TAMC | <=2 x 103 | Conform | CFU/g | | Contract Lab |
| TYMC | <=2 x 102 | 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 |
| Drop point | 38 - 44 | 43 | °C | | Fagron CZ |

BHT 162,600 µg/g


**Name** Fagron a.s. (CZ) Kontrolní laboratoř č. 536
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**The product conforms to ČL 2017-Dopl.2020,Ph.Eur.10.0.**

| | |
|---|---|
| **Performed by:** | Ing. Petra Drábková |
| **Responsible:** | Ing. Pavel Mišák, QC<br>MVDr. Zdenka Borská, QA |
| **Date:** | 19.10.2021 |
| **Conclusion:** | **I certify that the above-mentioned batch of pharmaceutical raw material has been manufactured and tested in accordance with the requirements of Marketing Authorization (License) and requirements of Good Manufacturing Practice.** |

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


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|---|---|---|---|---|---|
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