



Certificate of Analysis

Productname: Lanolin/Lanolinum

Inspection No: G11226/1119/536

Batchnumber: 19H12-T03-070773

Expiration date: 30.11.2021

Analysed according to: DAB 2008

Sample Unit: 2 x 100 g

Batch Size: 550 x 250 g

| | Requirement | Result | Unit | Standard remark | Insp. Site |
|---------------------------------------|---|---------|------|-----------------|------------|
| CHARACTERS | | | | | |
| Appearance | Pale yellow, unctuous substance. | Conform | | | |
| Odour (2.3.4) | Slight characteristic odour. | Conform | | | |
| IDENTIFICATION | | | | | |
| Identification A | Conform | Conform | | Cholesterol | |
| TESTS | | | | | |
| Water-soluble acid or alkaline subst. | Conform | Conform | | | |
| Saponification value (2.5.6) | 58 - 69 | 66 | | | |
| Soap | Conform | Conform | | | |
| Water - soluble oxidisable substances | Conform | Conform | | | |
| Water soluble substances | <=0,1 | 0,0 | % | | |
| Chlorides | <=100 | Conform | µg/g | | |
| Water (2.5.12, KF) | 18,0 - 21,0 | 19,9 | % | | |
| Rancidity | Conform | Conform | | | |
| Peroxide value (2.5.5) | <=15 | 1,1 | | | |
| Water - absorption capacity | dle zkoušky | Conform | % | | |
| TSE/BSE | No contamination with TSE/BSE-risk materials. | Conform | | | |
| Residual solvents | CPMP/ICH/82 260/2006 | Conform | | | |

Performed by: Jitka Spáčilová

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

Date: 04.12.2019

Conclusion: APPROVED

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