

Certificate of Analysis

Productname: Unguentum emulsificans/Hydrophile Salbe DAB

Inspection No: I00718/0121/536
Batchnumber: 20J14-T12-083291
Expiration date: 31.01.2024
Analysed according to: DAB 2008
Original Manuf. Date: 14.1.2021

Sample Unit: 1 x 250 g
Batch Size: 191 x 250 g

Identification of producer: V00929
Batch no. of vendor: 20J14-T12

| | Requirement | Result | Unit | Standard remark | Insp. Site |
|------------------------|---|---------|-------|-------------------------|------------|
| CHARACTERS | | | | | |
| Appearance | Soft ointment. | Conform | | | |
| Odour | Slight characteristic odour. | Conform | | | |
| IDENTIFICATION | | | | | |
| Identification A | Conform | Conform | | Crystalline precipitate | |
| Identification B | Conform | Conform | | Hydrophilic ointment | |
| TESTS | | | | | |
| Acidity or alkalinity | Conform | Conform | | | |
| Hydroxyl value | 55 - 70 | 68 | | | |
| Microbiology | Conform | Conform | | | |
| TAMC | $\leq 2 \times 10^2$ | Conform | CFU/g | | |
| TYMC | $\leq 2 \times 10^1$ | Conform | CFU/g | | |
| Pseudomonas aeruginosa | negative/1g | Conform | | | |
| Staphylococcus aureus | negative/1g | Conform | | | |
| TSE/BSE | No contamination with TSE/BSE-risk materials. | Conform | | | |
| Residual solvents | CPMP/ICH/82 260/2006 | Conform | | | |

Performed by: Mgr. Zdeňka Šinclová

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



Date: 17.02.2021

Conclusion: APPROVED

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