

## Certificate of Analysis

**Productname:** Cremor Basalis/Basiscreme

**Inspection No:** H10018/1120/536  
**Batchnumber:** 20J14-T06-083251  
**Expiration date:** 31.10.2023  
**Analysed according to:** DAC 2019

**Sample Unit:** 1 x 500 g  
**Batch Size:** 385 x 1 kg

|                                      | Requirement                                   | Result  | Unit  | Standard remark | Insp. Site |
|--------------------------------------|-----------------------------------------------|---------|-------|-----------------|------------|
| <b>CHARACTERS</b>                    |                                               |         |       |                 |            |
| Appearance                           | White soft creme, washable with water.        | Conform |       |                 |            |
| Odour (2.3.4)                        | Slight odour.                                 | Conform |       |                 |            |
| <b>IDENTIFICATION</b>                |                                               |         |       |                 |            |
| A.TLC (2.2.27)                       | see the test                                  | Conform |       |                 |            |
| B.bluer upper layer                  | see the test                                  | Conform |       |                 |            |
| C.purple colour                      | see the test                                  | Conform |       |                 |            |
| <b>TESTS</b>                         |                                               |         |       |                 |            |
| Saponification value (2.5.6)         | 30 - 42                                       | 35      |       |                 |            |
| Unsaponifiable matter (2.5.7)        | 25,0 - 35,0                                   | 29,3    | %     |                 |            |
| Water (2.5.12, KF)                   | 38,0 - 42,0                                   | 40,9    | %     |                 |            |
| Homogeneous distribution of componen | see the test                                  | Conform |       |                 |            |
| Microbiology                         | Conform                                       | Conform |       |                 |            |
| TAMC                                 | <=2 x 10 <sup>2</sup>                         | Conform | CFU/g |                 |            |
| TYMC                                 | <=2 x 10 <sup>1</sup>                         | 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:** Jitka Spáčilová

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

**Date:** 11.11.2020

**Conclusion:** APPROVED

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