

## Pharmaceuticals and Cosmetics Inc., Koprivnica, Croatia **Quality Control Department**

## **BATCH CERTIFICATE**

No. 040000708984

Product/packing/market: Belobaza / á 4 kg / SI

**Batch No** Code

: 27144037 : 7280

Quantity : 125 pcs Manuf. date

: 03.2017

**Expiry date** 

: 03.2021

| Test  | Requirement                 |            |                 | Paguit                         |
|---|-----------------------------|------------|-----------------|--------------------------------|
|   |                             |            |                 | Result                         |
| Appearance  | white, smooth               | and homoge | eneous cream wi | thout clots and foreign matter |
| рН  |                             | Ü          |                 | complies                       |
| Loss on drying  | 4,5                         | 5,5        |                 | 5.0                            |
| Hydroxyl value  | 65                          | 75         | %               | 73,5                           |
| lodine value  | max                         | 10.0       |                 | 6.8                            |
|   | max                         | 2.0        |                 | 0 4                            |
| dentification of benzyl alcohol   | Rt (sample) ≈ Rt (standard) |            |                 | 0.4                            |
| Content of benzyl alcohol   |                             |            |                 | complies                       |
| Content of benzyl alcohol   | 9.0                         | 11,0       | mg/g            | 9 61                           |
| MICROBIOLOGICAL PURITY  | 90,0                        | 110.0      | %               | 96.05                          |
| otal aerobic microbial count (TAMC) +<br>otal combined yeasts/moulds count (TYMC) |                             |            |                 |                                |
|   | max                         | 100        | cfu/g           | <10                            |
| scherichia coli in 0,5 g  | absence                     |            |                 |                                |
| taphylococcus aureus in 0,5 g   | absence                     |            |                 | absence                        |
| seudomonas aeruginosa in 0,5 g  | absence                     |            |                 | absence                        |
| andida albicans in 0,5 g  | absence                     |            |                 | absence                        |
|   |                             |            |                 | absence                        |

I hereby certify that the above information is authentic and accurate

This batch of product has been produced and released at the above mentioned site in full compliance with the GMP requirements and with the specifications in the Marketing Authorisation of the importing country

The batch records were reviewed and found to be in compliance with GMP

Released by:

KRISTINA JANEKOVIĆ PETRAS, MPharm.Univ.M.Spec.

Qualified Person

This document contains e-signature

27.03.2017