

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

## **BATCH CERTIFICATE**

No. 040000706149

Product/packing/market: Belobaza / á 2 kg / SI

**Batch No** 

: 27060027

Code : 7279 Quantity : 249 pcs Manuf. date

: 02.2017

**Expiry date** 

: 02.2021

| Test   | Requirement                 |            |               | Result                           |
|--|-----------------------------|------------|---------------|----------------------------------|
| Appearance   |                             |            |               |                                  |
| Appearance   | white, smooth               | and homoge | neous cream v | vithout clots and foreign matter |
| pH   |                             |            |               | complies                         |
| Loss on draine   | 4.5                         | 5.5        |               | 5,0                              |
| Loss on drying   | 65                          | 75         | %             | 72 3                             |
| Hydroxyl value   |                             |            | 70            | 723                              |
|  | max                         | 10.0       |               | 6.1                              |
| lodine value   |                             |            |               |                                  |
| tale tree in   | max                         | 2.0        |               | 0.3                              |
| Identification of benzyl alcohol   | Rt (sample) ≈ Rt (standard) |            |               |                                  |
| Content of benzyl alcohol  |                             |            |               | complies                         |
| -  | 9.0                         | 11 0       | mg/g          | 9.70                             |
| Content of benzyl alcohol  | 90.0                        | 110.0      | %             | 20.07                            |
| MICROBIOLOGICAL PURITY   | 30.0                        | 110.0      | 70            | 96.97                            |
| Total aerobic microbial count (TAMC) + total combined yeasts/moulds count (TYMC) |                             |            |               |                                  |
| or years mondo dount (11110)   | max                         | 100        | cfu/g         | <10                              |
| Escherichia coli in 0.5 g  | absence                     |            |               |                                  |
| Staphylococcus aureus in 0 5 g   | absence                     |            |               | absence                          |
| Pseudomonas aeruginosa in 0,5 g  | absence                     |            |               | absence                          |
| Candida 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:

TAMARA TETEC, MPharm. Univ. Master

Qualified Person

This document contains e-signature

16.03.2017