

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

## **BATCH CERTIFICATE**

No. 040000705401

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

**Batch No** 

: 27018027

Code Quantity : 7279

: 249 pcs

Manuf. date

: 02.2017

**Expiry date** 

: 02.2021

| Test   | Requirement                 |            |               | Result                           |
|--|-----------------------------|------------|---------------|----------------------------------|
| Appearance   | white, smooth               | and homoge | neous cream v | vithout clots and foreign matter |
| Hq   |                             |            |               | complies                         |
|  | 4,5                         | 5,5        |               | 4,9                              |
| Loss on drying   | 65                          | 75         | %             |                                  |
| Hydroxyl value   | 05                          | 75         | 70            | 72,1                             |
|  | max                         | 10,0       |               | 4,0                              |
| lodine value   | max                         | 2,0        |               | 0,3                              |
| Identification of benzyl alcohol   | Rt (sample) ≈ Rt (standard) |            |               | 0,3                              |
| Content of benzyl alcohol  |                             |            |               | complies                         |
| •  | 9,0                         | 11,0       | mg/g          | 9,77                             |
| Content of benzyl alcohol  | 00.0                        | 1100       | •             |                                  |
| MICROBIOLOGICAL PURITY   | 90,0                        | 110,0      | %             | 97,75                            |
| Total aerobic microbial count (TAMC) + total combined yeasts/moulds count (TYMC) |                             |            |               |                                  |
|  | 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.

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.

01.03.2017

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.