

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

## **BATCH CERTIFICATE**

No. 040000647839

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

**Batch No** 

Quantity

: 25692076

Code

: 7279

: 249 pcs

Manuf. date

: 07.2016

**Expiry date** 

: 07.2020

| Test | Requirement | Result |
|------|-------------|--------|
|      | Requirement | Nesuit |

| Appearance                                | white, smooth and homogeneous cream without clots and foreign matter |       |       |           |
|---|--|-------|-------|-----------|
| pH  | 4.5  |       |       | complies  |
| Loss on drying                            | 4,5  | 5,5   |       | 4,87      |
| Loss on drying                            | 65   | 75    | %     | 71,0      |
| Hydroxyl value                            | max  | 10,0  |       | 5,4       |
| lodine value                              |  |       |       |           |
|   | max  | 2,0   |       | 0,3       |
| Identification of benzyl alcohol          | Rt (sample) ≈ Rt (standard)  |       |       |           |
| Content of benzyl alcohol                 |  |       |       | complies  |
|   | 9,0  | 11,0  | mg/g  | 9,90      |
| Content of benzyl alcohol                 | 90,0   | 110,0 | %     | 99,02     |
| MICROBIOLOGICAL PURITY                    |  |       |       |           |
| 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   |
| i secucinorias acruginosa in 0,0 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.

14.07.2016

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.