

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

## **BATCH CERTIFICATE**

No. 040000553068

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

**Batch No** 

: 23408075

Code

:7280

Manuf. date

: 07.2015

**Expiry date** 

: 07.2019

Quantity : 125 pcs

| Test                                                                             | Requirement  white, smooth and homogeneous cream without clots and |       |          | Result                                         |
|----------------------------------------------------------------------------------|--------------------------------------------------------------------|-------|----------|------------------------------------------------|
| Appearance                                                                       |                                                                    |       |          | n without clots and foreign matter<br>complies |
| рН                                                                               | 4,5                                                                | 5,5   |          | 5,0                                            |
| Loss on drying                                                                   | 65                                                                 | 75    | %        | 72,42                                          |
| Hydroxyl value                                                                   | max                                                                | 10,0  |          | 4,7                                            |
| lodine value                                                                     | max                                                                | 2,0   |          | 0,32                                           |
| Identification of benzyl alcohol                                                 | Rt (sample) ≈ Rt (standard)                                        |       |          |                                                |
| Content of benzyl alcohol                                                        | 9,0                                                                | 11,0  | mg/g     | complies 9,87                                  |
| Content of benzyl alcohol                                                        | 90,0                                                               | 110,0 | %        | 98,7                                           |
| 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                                                            |       | <u>-</u> | . •                                            |
| Staphylococcus aureus in 0,5 g                                                   | absence                                                            |       |          | absence                                        |
| Pseudomonas aeruginosa in 0,5 g                                                  | absence                                                            |       |          | absence                                        |
|                                                                                  |                                                                    |       |          | absence                                        |
| Candida albicans in 0,5 g                                                        | 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.

Qualified Person

20.07.2015

This document contains e-signature.