

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

BATCH CERTIFICATE

No. 040000880340

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

Batch No : 22027029 Code : 7279

Manuf. date

: 02.2019

: 491 pcs Quantity

Expiry date

: 01.2023

| Test | Requirement white, smooth and homogeneous cream without clots and for | | | Result |
|----------------------------------------------------------------------------------|------------------------------------------------------------------------|---------------|------------|------------------------------------------|
| Арреагалсе | | | | out clots and foreign matter complies |
| рH | 4,5 | 5.5 | | • |
| Loss on drying | | · | | 5,1 |
| Hydroxyl value | 65 | 75 | % | 71,4 |
| fodine value | not more than | 10,0 | | 6,1 |
| | not more than | 2.0 | | 0,3 |
| Identification of benzyl alcohol | Rt (sample) = f | Rt (standard) | | |
| Content of benzyl alcohol | 9,0 | 11,0 | mg/g | complies |
| Content of benzyl alcohol | 90,0 | 110.0 | //g/g % | 9,85 98,5 |
| MICROBIOLOGICAL PURITY | | | | 50,5 |
| Total aerobic microbial count (TAMC) + total combined yeasts/moulds count (TYMC) | | | | |
| | not more than | 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:

IVANA KRAJINA, MPharm.

This document contains e-signature.

Qualified Person

22.02.2019