



## BATCH CERTIFICATE

No. 040001209921

**Product/packing/market:** Beloderm 0,5 mg/g cream / á 1 kg / SI

**Batch No** : 21579013  
**Code** : 3772  
**Quantity** : 945 pcs

**Manuf. date** : 01.2023  
**Expiry date** : 01.2026

| Test  | Requirement   |                 |       | Result   |
|---|---|-----------------|-------|----------|
| Appearance  | white, homogenous cream without mechanical impurities |                 |       | complies |
| pH  | 4,5   | 5,5             |       | 5,0      |
| Identification of betamethasone dipropionate (HPLC) | Rt (sample) = Rt (standard)                           |                 |       | complies |
| Identification of chlorocresol (HPLC)               | Rt (sample) = Rt (standard)                           |                 |       | complies |
| RELATED SUBSTANCES (HPLC)                           |   |                 |       |          |
| Betamethasone-17-propionate                         | not more than   | 0,5             | %     | <LOQ     |
| Betamethasone-21-propionate                         | not more than   | 0,5             | %     | 0,119    |
| Individual unknown related substance                | not more than   | 0,5             | %     | <LOQ     |
| The sum of all known and unknown related substances | not more than   | 2,5             | %     | 0,119    |
| Content of betamethasone (HPLC)                     | 0,475   | 0,525           | mg/g  | 0,499    |
| Content of betamethasone (HPLC)                     | 95,0  | 105,0           | %     | 99,8     |
| Content of chlorocresol (HPLC)                      | 0,9   | 1,1             | mg/g  | 1,000    |
| Content of chlorocresol (HPLC)                      | 90,0  | 110,0           | %     | 100,0    |
| MICROBIOLOGICAL PURITY                              |   |                 |       |          |
| Total aerobic microbial count (TAMC)                | not more than   | 10 <sup>2</sup> | cfu/g | <10      |
| Total combined yeasts/moulds count (TYMC)           | not more than   | 10 <sup>1</sup> | cfu/g | <10      |
| Pseudomonas aeruginosa in 1g                        | absence   |                 |       | absence  |
| Staphylococcus aureus in 1g                         | absence   |                 |       | absence  |



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

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|------|-------------|--------|
|------|-------------|--------|

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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.

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**Released by:** KRISTINA JANEKOVIĆ PETRAS, MPharm.Univ.M.Spec.  
Qualified Person  
23.01.2023

This document contains e-signature.