

## Certificate of Analysis

**Productname:** Betamethasoni dipropionas micr  
**Number of analysis/Inspection Code:** 1 / KEUR-187315B  
**Batchnumber:** 20C10-F02-373261  
**Reference code / No.:** 3989 / BDP 103/1019  
**Analysed according to:** PHEUR10.1+

| Tests                            | Requirement                                  | Result  | Unit         | Standard remark           |
|----------------------------------|--|---------|--------------|---------------------------|
| Appearance                       | Fine, (almost) white powder                  | Conform |              |                           |
| Particle size                    | 99% < 25 µm / 90% < 10 µm                    | Conform |              | Microscopy                |
| Identification B                 | Conform                                      | Conform |              | IR-spectrum               |
| Specific optical rotation        | + 84 - + 88                                  | +87     |              | 1% <i>m/V</i> EtOH; dried |
| Related substances               | Conform                                      | Conform |              | HPLC                      |
| Impurity C                       | <=0,5  | 0,1     | %            |                           |
| Impurity B                       | <=0,3  | <0,05   | %            |                           |
| Impurity H                       | <=0,3  | <0,05   | %            |                           |
| Impurity D                       | <=0,2  | 0,1     | %            |                           |
| Impurity E                       | <=0,2  | <0,05   | %            |                           |
| Impurity G                       | <=0,2  | <0,05   | %            |                           |
| Impurity I                       | <=0,15                                       | <0,05   | %            |                           |
| Unspecified impurities           | <=0,10                                       | 0,05    | %            |                           |
| Total impurities                 | <=1,0  | 0,3     | %            |                           |
| Loss on drying                   | <=1,0  | 0,2     | %            | 105°C                     |
| Metallic residues                | CHMP/ICH/353369/2013                         | Conform |              | Data producer             |
| Residual solvents                | CHMP/ICH/82260/2006                          | Conform |              | Data producer             |
| Assay Betamethasone dipropionate | 97,0 - 102,0                                 | 98,6    | % <i>m/m</i> | Dried                     |
| TSE/BSE-statement:               | No contamination with TSE/BSE-risk materials | Conform |              | Data producer             |

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:  
Paul Hofman  
Pharmacist - Qualified Person

11/25/20

Expiration: 09-2024

Conclusion: APPROVED

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