

## Certificate of Analysis

**Productname:** Clobetasoli propionas micron.  
**Number of analysis/Inspection Code:** 1 / KEUR-186263B  
**Batchnumber:** 20B18-F06-373275  
**Reference code / No.:** 3989 / CLO 118/0919  
**Analysed according to:** PHEUR10.0+

| Tests                          | Requirement                                  | Result  | Unit         | Standard remark                 |
|--------------------------------|--|---------|--------------|---------------------------------|
| Appearance                     | Fine, (almost) white powder                  | Conform |              |                                 |
| Particle size                  | 99%<25 µm / 90% <10 µm                       | Conform |              |                                 |
| Identification IR-spectrum     | Conform                                      | Conform |              |                                 |
| Specific optical rotation      | +112 - +118                                  | +115    |              | 1% <i>m/V</i> in acetone; dried |
| Related substances             | Conform                                      | Conform |              | HPLC                            |
| Impurity E                     | <=0,3  | <0,1    | %            |                                 |
| Impurity D                     | <=0,2  | 0,1     | %            |                                 |
| Impurity B                     | <=0,3  | 0,2     | %            |                                 |
| Impurity C                     | <=0,3  | <0,1    | %            |                                 |
| Impurity A                     | <=0,2  | <0,1    | %            |                                 |
| Impurity L                     | <=0,2  | <0,1    | %            |                                 |
| Impurity M                     | <=0,2  | <0,1    | %            |                                 |
| Unspecified impurities         | <=0,10                                       | <0,05   | %            |                                 |
| Total impurities               | <=1,0  | 0,2     | %            |                                 |
| Loss on drying                 | <=0,5  | 0,0     | %            | 3H 105°C                        |
| Sulphated ash                  | <=0,1  | Conform | %            |                                 |
| Metallic residues              | CHMP/ICH/353369/2013                         | Conform |              | Data producer                   |
| Residual solvents              | CHMP/ICH/82260/2006                          | Conform |              | Data producer                   |
| Assay Clobetasol 17-propionate | 97,0 - 102,0                                 | 98,3    | % <i>m/m</i> | Dried                           |
| TSE/BSE-statement:             | No contamination with TSE/BSE-risk materials | Conform |              | Data producer                   |

Analysis performed by the authorized laboratory Steris.

Release:  
Paul Hofman  
Pharmacist - Qualified Person

10/12/20

Expiration: 08-2024

Conclusion: APPROVED

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