

## Certificate of Analysis

**Productname:** Diclofenacum natricum  
**Number of analysis/Inspection Code:** 1 / KEUR-186901B  
**Batchnumber:** 20J01-F09-374503  
**Reference code / No.:** 3718 / RDS/2001/0043A  
**Analysed according to:** PH.EUR10.2

| Tests                   | Requirement                                  | Result  | Unit         | Standard remark       |
|-------------------------|--|---------|--------------|-----------------------|
| Appearance              | White or pale yellow, crystalline powder     | Conform |              | Slightly hygroscopic  |
| Identification A        | Conform                                      | Conform |              | IR-spectrum           |
| Identification D        | Conform                                      | Conform |              | Sodium                |
| Appearance of solution  | Conform                                      | Conform |              | 5% <i>m/V</i> in MeOH |
| Related substances      | Conform                                      | Conform |              | HPLC                  |
| Impurity A              | <=0,2  | 0,0     | %            |                       |
| Impurity F              | <=0,15                                       | 0,00    | %            |                       |
| Unspecified impurities  | <=0,10                                       | 0,05    | %            |                       |
| Total impurities        | <=0,4  | 0,1     | %            |                       |
| Loss on drying          | <=0,5  | 0,1     | %            | 3H 105°C              |
| Metallic residues       | CHMP/ICH/353369/2013                         | Conform |              | Data producer         |
| Residual solvents       | CHMP/ICH/82260/2006                          | Conform |              | Data producer         |
| Assay Diclofenac sodium | 99,0 - 101,0                                 | 99,9    | % <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

11/09/20

Expiration: 12-2024

Conclusion: APPROVED

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