

## Certificate of Analysis

**Product name:** **Diclofenacum natricum**  
**Batch number / Weight:** **21I29-B06-217363 / 100 G**  
**Analysed according to:** **Ph. Eur.**

| Tests                  | Requirement  | Result  | Unit | Standard remark |
|------------------------|--|---------|------|-----------------|
| Appearance             | White or pale yellow, crystalline powder, slightly hygroscopic | Conform |      |                 |
| Melting point          | about 280  | 278,2   | °C   |                 |
| Identification A       | Conform  | Conform |      |                 |
| Identification D       | Conform  | Conform |      |                 |
| Clarity of solution    | Clear  | Conform |      |                 |
| Absorbance             | <=0,05   | Conform |      |                 |
| Related substances     | Conform  | Conform |      |                 |
| Impurity A             | <=0,2  | 0,00    | %    |                 |
| Impurity F             | <=0,15   | <0,05   | %    |                 |
| Unspecified impurities | <=0,10   | <0,05   | %    |                 |
| Total impurities       | <=0,4  | 0,00    | %    |                 |
| Loss on drying         | <=0,5  | 0,02    | %    |                 |
| Metallic residues      | CHMP/ICH/353369/2013   | Conform |      | Data producer   |
| Residual solvents      | CPMP/ICH/82 260/06   | Conform |      | Data producer   |
| Assay                  | 99,0 - 101,0   | 99,82   | %m/m |                 |
| TSE/BSE-statement:     | No contamination with TSE/BSE-risk materials                   | Conform |      | Data producer   |

Analysis performed by the authorized lab.

Release:  
 Agnieszka Pszczółka  
 Qualified Person

09-03-2022

Expiration: 31-07-2026

Conclusion: APPROVED

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