

Certificate of Analysis

Productname: Diclofenacum natricum
Number of analysis/Inspection Code: 1 / KEUR-183148B
Batchnumber: 19L02-F02-370430
Reference code / No.: 3718 / RDS/1908/0264A
Analysed according to: PH.EUR10.0

| 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 |
| Clarity of solution | Helder | Conform | | 5% <i>m/V</i> in MeOH |
| Absorbance | <=0,05 | Conform | | E 440 nm; 5% <i>m/V</i> MeOH |
| Related substances | Conform | Conform | | HPLC |
| Impurity A | <=0,2 | 0,0 | % | |
| Impurity F | <=0,15 | <0,05 | % | |
| Unspecified impurities | <=0,10 | <0,05 | % | |
| Total impurities | <=0,4 | 0,0 | % | |
| 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 | 100,2 | % <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:
Wai Lung Chung
Pharmacist - Qualified Person

06/05/20

Expiration: 07-2024

Conclusion: APPROVED

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