

Certificate of Analysis

Product name: **Naproxenum**

Batch number / Weight: **23F19-B01-235905 / 25 G**

Analysed according to: **Ph.Eur.11.4**

Number of analysis / Inspection Code **23F19-B01 / INS-23-5278**

Reference Code / No.: **V01704 / 2-M-C-4751222**

| Tests | Requirement | Result | Unit | Standard remark |
|------------------------|--|---------|------|-----------------|
| Appearance | (Almost) white, crystalline powder | Conform | | |
| Identification A | +59 - +62 | +61,4 | | |
| Identification D | Conform | Conform | | |
| Appearance of solution | Clear / colour <=BY7 | Conform | | |
| Enantiomeric purity | <=2,5 (Impurity G) | 0,22 | % | |
| Related substances | Conform | Conform | | |
| Impurity O | <=0,15 | <0,05 | % | |
| Impurity L | <=0,15 | <0,05 | % | |
| Unspecified impurities | <=0,10 | <0,05 | % | |
| Total impurities | <=0,3 | 0,00 | % | |
| Loss on drying | <=0,5 | 0,14 | % | |
| Sulphated ash | <=0,1 | 0,00 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay Naproxen | 99,0 - 101,0 | 99,81 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL lab

Release:
Dominika Soltysik
Qualified Person

09-04-2024

Expiration: 30-11-2027

Conclusion: APPROVED

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