

## Certificate of Analysis

**Product name:** **Acidum acetylsalicylicum**

**Batch number / Weight:** **22J18-B02-229345 / 250 G**

**Analysed according to:** **Ph.Eur.11**

**Number of analysis / Inspection Code** **22J18-B02 / INS-22-8960**

**Reference Code / No.:** **V00581 / 22287**

| Tests                      | Requirement  | Result  | Unit | Standard remark |
|----------------------------|--|---------|------|-----------------|
| Appearance                 | White or almost white, crystalline powder or colourless crystals | Conform |      |                 |
| Identification A           | Conform  | Conform |      |                 |
| Identification B           | 156 - 161  | 160,2   | °C   |                 |
| Melting point              | About 143  | 139,7   | °C   |                 |
| Appearance of solution     | Clear / colourless   | Conform |      |                 |
| Related substances         | Conform  | Conform |      |                 |
| Impurity A                 | <=0,15   | <0,03   | %    |                 |
| Impurity B                 | <=0,15   | <0,03   | %    |                 |
| Impurity C                 | <=0,15   | <0,03   | %    |                 |
| Impurity D                 | <=0,15   | <0,03   | %    |                 |
| Impurity E                 | <=0,15   | <0,03   | %    |                 |
| Impurity F                 | <=0,15   | <0,03   | %    |                 |
| Unspecified impurities     | <=0,05   | <0,03   | %    |                 |
| Total impurities           | <=0,25   | 0,00    | %    |                 |
| Loss on drying             | <=0,5  | 0,11    | %    |                 |
| Sulfated 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 Acetylsalicylic acid | 99,5 - 101,0 (dried substance)                                   | 99,68   | %m/m |                 |
| TSE/BSE-statement:         | No contamination with TSE/BSE-risk materials                     | Conform |      | Data producer   |
| Residual solvents          |  |         |      |                 |
| Acetic acid                | <=0,5% (LOD)   | Conform |      |                 |

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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,CBMiA

Release:

Agnieszka Pszczółka

Qualified Person

12-04-2023

Expiration: 28-02-2025

Conclusion: APPROVED

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