

Certificate of Analysis

Product name: **Acidum acetylsalicylicum**
Batch number / Weight: **20D01-B08-200895 / 1 KG**
Analysed according to: **Ph. Eur.**

| Tests | Requirement | Result | Unit | Standard remark |
|----------------------------|--|---------|------|-----------------|
| Appearance | Fine,(almost) white, crystalline powder | Conform | | |
| Appearance | or colorless crystals | c | | |
| Identification A | Conform | Conform | | |
| Identification B | 156 - 161 | 159,1 | °C | |
| Appearance of solution | Clear / colourless | Conform | | |
| Related substances | Conform | Conform | | |
| Impurity A | <=0,15 | <0,03 | % | |
| Impurity B | <=0,15 | 0,00 | % | |
| 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 | % | |
| 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 Acetylsalicylic acid | 99,5 - 101,0 | 99,65 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized lab.

Release:
Dorota Sutkowska
Qualified Person

25-06-2020

Expiration: 21-10-2022

Conclusion: APPROVED

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