

Certificate of Analysis

Product name: **Acidum acetylsalicylicum**

Batch number / Weight: **20114-B04-202395 / 1 KG**

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

| Tests | Requirement | Result | Unit | Standard remark |
|------------------------|---|---------|------|-----------------|
| Appearance | Fine,(almost) white, crystalline powder | Conform | | |
| Identification | Conform | Conform | | |
| Identification A | Conform | Conform | | |
| Identification B | 156 - 161 | 160,2 | °C | |
| Melting point | 156 - 161 | 139,7 | °C | |
| Solubility | According to Ph. Eur. Slightly soluble in water Freely soluble in ethanol (96%) | Conform | | |
| Appearance of solution | Clear / colourless | Conform | | |
| Related substances | Conform | Conform | | |
| Impurity A | <=0,15 | 0,00 | % | |
| 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 | 0,00 | % | |
| Unspecified impurities | <=0,05 | <0,03 | % | |
| Total impurities | <=0,25 | 0,00 | % | |
| Loss on drying | <=0,5 | 0,01 | % | |
| 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 | 99,5 - 101,0 | 100,09 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized lab.

Release:

Ewelina Gadzinowska

Qualified Person

15-10-2020

Expiration: 21-06-2023

Conclusion: APPROVED

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