

## Certificate of Analysis

**Product name:** Acidum salicylicum  
**Batch number / Weight:** 21G30-B03-213783 / 250 G  
**Analysed according to:** Ph.Eur. + Monogr.

| Tests                  | Requirement                                                     | Result  | Unit | Standard remark |
|------------------------|-----------------------------------------------------------------|---------|------|-----------------|
| Appearance             | Fine, white powder<br>or white or colourless, acicular crystals | Conform |      |                 |
| Identification A       | 158 - 161                                                       | 160,8   | °C   |                 |
| Identification B       | Conform                                                         | Conform |      |                 |
| Appearance of solution | Clear / colourless                                              | Conform |      |                 |
| Related substances     | Conform                                                         | Conform |      |                 |
| Impurity A             | <=0,1                                                           | 0,052   | %    |                 |
| Impurity B             | <=0,05                                                          | 0,036   | %    |                 |
| Impurity C             | <=0,02                                                          | 0,00    | %    |                 |
| Any other impurity     | <=0,05                                                          | <0,03   | %    |                 |
| Total impurities       | <=0,2                                                           | 0,088   | %    |                 |
| Chlorides              | <=100                                                           | Conform | ppm  |                 |
| Sulphates              | <=200                                                           | Conform | ppm  |                 |
| Loss on drying         | <=0,5                                                           | 0,02    | %    |                 |
| Sulfated ash           | <=0,1                                                           | 0,01    | %    |                 |
| Assay Salicylic acid   | 99,0 - 100,5 (dried substance)                                  | 100,23  | %m/m |                 |
| Particle size          | >=97% < 180 µm                                                  | Conform | %    |                 |
| Particle size          | >=90% < 150 µm                                                  | Conform | %    |                 |
| Particle size          | X50 (D50)                                                       | 27,601  | µm   |                 |
| Metallic residues      | CHMP/ICH/353369/2013                                            | Conform |      | Data producer   |
| Residual solvents      | CPMP/ICH/82 260/06                                              | Conform |      | Data producer   |
| TSE/BSE-statement:     | No contamination with TSE/BSE-risk materials                    | Conform |      | Data producer   |

Analysis performed by the authorized lab.

Release:  
 Ewelina Gadzinowska  
 Qualified Person

10-12-2021

Expiration: 21-10-2024

Conclusion: APPROVED

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