

## Certificate of Analysis

**Product name:** **Acidum salicylicum**  
**Batch number / Weight:** **20E21-B03-217215 / 250 G**  
**Analysed according to:** **Ph.Eur. + Monogr.**

| Tests                  | Requirement                                  | Result  | Unit | Standard remark |
|------------------------|----------------------------------------------|---------|------|-----------------|
| Appearance             | Fine, white powder                           | Conform |      |                 |
| Identification A       | 158 - 161                                    | 160,3   | °C   |                 |
| Identification B       | Conform                                      | Conform |      |                 |
| Appearance of solution | Clear / colourless                           | Conform |      |                 |
| Related substances     | Conform                                      | C       |      |                 |
| Impurity A             | <=0,1                                        | 0,043   | %    |                 |
| Impurity B             | <=0,05                                       | 0,042   | %    |                 |
| Impurity C             | <=0,02                                       | 0,00    | %    |                 |
| Any other impurity     | <=0,05                                       | <0,03   | %    |                 |
| Total impurities       | <=0,2                                        | 0,085   | %    |                 |
| Chlorides              | <=100                                        | C       | ppm  |                 |
| Sulphates              | <=200                                        | C       | ppm  |                 |
| Loss on drying         | <=0,5                                        | 0,00    | %    |                 |
| Sulfated ash           | <=0,1                                        | 0,00    | %    |                 |
| Assay Salicylic acid   | 99,0 - 100,5 (dried substance)               | 99,33   | %m/m |                 |
| Particle size          | >=97% < 180 µm                               | 99      | %    |                 |
| Particle size          | >=90% < 150 µm                               | 98      | %    |                 |
| Particle size          | X50 (D50)                                    | 27,972  | 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

09-12-2021

Expiration: 21-10-2024

Conclusion: APPROVED

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