

Certificate of Analysis

Product name: **Acidum salicylicum (90)**

Batch number / Weight: **22A12-B06-225310 / 1 KG**

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

Number of analysis / Inspection Code **22A12-B06 / INS-22-3951**

Reference Code / No.: **V00585 / RAS2009500**

| Tests | Requirement | Result | Unit | Standard remark |
|---------------------------------|--|---------|------|-----------------|
| Appearance | Fine, white powder 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 | 0,03 | % | |
| Impurity B | <=0,05 | 0,03 | % | |
| Impurity C | <=0,02 | <0,02 | % | |
| Any other impurity | <=0,05 | <0,03 | % | |
| Total impurities | <=0,2 | 0,06 | % | |
| Chlorides | <=100 | <100 | ppm | |
| Sulphates | <=200 | <200 | ppm | |
| Loss on drying | <=0,5 | 0,02 | % | |
| Sulphated ash | <=0,1 | 0,03 | % | |
| Assay | 99,0 - 100,5 (dried substance) | 99,60 | %m/m | |
| Additional requirements for man | | | | |
| Particle size | >=97% < 90 µm | Conform | % | |
| Particle size | X50 (D50) | 8,2 | 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 |

fagron.pl

Fagron Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail: biuro@fagron.pl

fagron.pl

Fagron sp. z o.o.
ul. Pasternik 26, 31-354 Kraków, Poland
tel.: +48 12 3343 512
e-mail: biuro@fagron.pl

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

Release:

Agnieszka Pszczółka

Qualified Person

28-12-2022

Expiration: 04-04-2025

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

fagron.pl

Fagron Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:biuro@fagron.pl