

Certificate of Analysis

Product name: **Natrii salicylas**
Batch number / Weight: **22J18-B04-222063 / 250 G**
Analysed according to: **Ph. Eur. 10.8**
Number of analysis / Inspection Code **22J18-B04 / INS-22-9016**
Reference Code / No.: **V01380 / 102072210**

| Tests | Requirement | Result | Unit | Standard remark |
|-------------------------|---|---------|------|-----------------|
| Appearance | (almost) White, crystalline powder or flakes małe, bezbarwne kryształy lub błyszczące płatki | conform | | |
| Identification A, C | Conform | Conform | | |
| Appearance of solution | Clear <=BY6 | Conform | | |
| Acidity | Conform | Conform | | |
| Chlorides | <=200 | <200 | ppm | |
| Sulphates | <=600 | <600 | ppm | |
| Loss on drying | <=0,5 | 0,03 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | |
| Assay Sodium salicylate | 99,0 -101,0 (dried) | 100,08 | % | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | |
| Residual solvents | | | | |
| Methanol | <= 3000 | <3000 | ppm | |
| Benzene | <= 2 | <2 | ppm | |

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:
Ewelina Gadzinowska
Qualified Person

28-11-2022

Expiration: 31-07-2025

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