

Certificate of Analysis

Product name: **Natrii hydrogenocarbonas**

Batch number / Weight: **22J11-B04-224718 / 5 KG**

Analysed according to: **Ph.Eur.10.8**

Number of analysis / Inspection Code **22J11-B04 / INS-22-9570**

Reference Code / No.: **V00611 / 41221005/2**

| Tests | Requirement | Result | Unit | Standard remark |
|---------------------------|--|---------|------|-----------------|
| Appearance | (Almost) White, crystalline powder | Conform | | |
| Identification A | Pink / red | Conform | | |
| Identification B | Conform | Conform | | |
| Identification C | Conform | Conform | | |
| Solubility | acc. to Ph. Eur. | Conform | | |
| Appearance of solution | Clear / colourless | Conform | | |
| Carbonates | $\leq 8,6$ | 8,08 | | |
| Chlorides | ≤ 150 | Conform | ppm | |
| Sulphates | ≤ 150 | Conform | ppm | |
| Ammonium | ≤ 20 | Conform | ppm | |
| Calcium | ≤ 100 | Conform | ppm | |
| Iron | ≤ 20 | Conform | ppm | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Sodium hydrogen carbonate | 99,0 - 101,0 | 100,16 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

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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,CBMiA

Release:

Agnieszka Pszczółka

Qualified Person

13-12-2022

Expiration: 05-10-2024

Conclusion: APPROVED

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