

Certificate of Analysis

Product name: **Natrii docusas**
Batch number / Weight: **23I28-B03-230163 / 25 G**
Analysed according to: **Ph.Eur.11.3**
Number of analysis / Inspection Code **23I28-B03 / INS-23-9200**
Reference Code / No.: **V01641 / SD2120960**

| Tests | Requirement | Result | Unit | Standard remark |
|------------------------------|--|---------|------|-----------------|
| Appearance | White, waxy mass or flakes with a characteristic odour | Conform | | |
| Identification A | Conform | Conform | | |
| Identification B | Conform | Conform | | |
| Alcalinity | Conform | Conform | | |
| | <=0,2 ml HCl (0,1M) | 0,05 | ml | |
| Related non-ionic substances | <=0,4 | <0,4 | % | |
| Chlorides | <= 350 | 35,3 | ppm | |
| Sodium sulphate | <= 2 | <2 | % | |
| Water (Karl Fischer) | <= 3,0 | 0,83 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay Docusate sodium | 98,0 - 101,0 | 99,34 | %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 FAPL, Quercus

Release:
Dominika Soltysik
Qualified Person

15-01-2024

Expiration: 08-12-2025

Conclusion: APPROVED

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