

Certificate of Analysis

Product name: **Benzocainum**
Batch number / Weight: **21J21-B01-216135 / 100 G**
Analysed according to: **Ph. Eur.**

| Tests | Requirement | Result | Unit | Standard remark |
|--|---|---------|-------|-----------------|
| Appearance | White, crystalline powder or colorless crystals | Conform | | |
| Identification | Conform | Conform | | |
| Related substances | Conform | Conform | | |
| Unspecified impurities for each impurity | $\leq 0,10$ | $<0,05$ | % | |
| Total impurities | $\leq 0,2$ | 0,00 | % | |
| Loss on drying | $\leq 0,5$ | 0,025 | % | |
| Sulphated ash | $\leq 0,1$ | 0,005 | % | |
| Assay Benzocaine | 99,0 - 101,0 (dried substance) | 100,25 | % m/m | |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized lab.

Release:
 Dominika Sołtysik
 Qualified Person

22-12-2021

Expiration: 07-06-2024

Conclusion: APPROVED

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