

Certificate of Analysis

Product name: Benzocainum

Batch number / Weight: 21J21-B01-216129 / 25 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 | | <0,05 | | |
| for each impurity | <= 0,10 | | % | |
| Total impurities | <=0,2 | 0,00 | % | |
| Loss on drying | <=0,5 | 0,025 | % | |
| Sulphated ash | <= 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

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