



Certificate of Analysis

Productname: **Benzocainum**
Number of analysis/Inspection Code: **1 / KEUR-85463B**
Batchnumber: **10L08-B03-271571** ✓
Reference code / No.: **2471 / BZ-19/10-11**
Analysed according to: **PH.EUR.+** 12.15 ✓

FARMADENT d.o.o.
Minarikova ul. 6
2000 Maribor
Prejel: FARM DRAGO

Datum prejema: 10.3.14
Prejedal: MAROLT Robert, mag. farm. spec.
Datum pregleda: 11.3.2014

| Tests | Requirement | Result | Unit | Standard remark |
|------------------------|--|---------|------|-------------------|
| Appearance | White, crystalline powder | Conform | | |
| Particle size | 75% < 250 µm | 79 | % | Sieve analysis |
| Identification A | 89 - 92 | 90 | °C | Melting point |
| Identification B | Conform | Conform | | IR-spectrum |
| Appearance of solution | Clear and colourless | Conform | | 5% m/V in alcohol |
| Acidity or alkalinity | Conform | Conform | | |
| Loss on drying | <=0,5 | <0,1 | % | In vacuo |
| Sulphated ash | <= 0,1 | Conform | % | |
| Residual solvents | CPMP/ICH/283/95 | Conform | | |
| Assay Benzocaine | 99,0 - 101,0 | 100,1 | %m/m | Dried |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | |

Release:
Drs. M.V. Garcia Alia
Pharmacist - QA Manager / QP

04-07-12

Expiration: 12-2015

Conclusion: APPROVED

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