

## **Certificate of Analysis**

Productname: Number of analysis/Inspection Code: Batchnumber: Reference code / No.: Analysed according to:

Benzocainum

2 / KEUR-102804B **13L06-B02** 2990 18 2637 / 040 03 13 **PH.EUR 7.8** 

FARMADENT d.o.o. 6 Minariko 2000 Mai RAGO el: F 3 Datum pre Pregledal: MAR mag, farm., spec Roher Datum pregleda:

| Tests                  | Requirement                                  | Result  | Unit | Standard remark  |
|------------------------|--|---------|------|------------------|
|                        |  |         |      |                  |
| Appearance             | White, crystalline powder                    | Conform |      |                  |
| Identification A       | 89 - 92                                      | 89      | °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 Benzocaïne       | 99,0 - 101,0                                 | 100,6   | %m/m | Dried            |
| TSE/BSE-statement:     | No contamination with TSE/BSE-risk materials | Conform |      | Data producer    |

Analyse performed by the authorized lab Proxylabs.

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

12/27/13

Expiration: 02-2018

Conclusion: APPROVED

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