



## Certificate of Analysis

**Productname:** Benzalkonii chloridum

**Inspection No:** K03752/0723/536

**Sample Unit:** 1 x 5 g

**Batchnumber:** 23E15-T13-105206

**Batch Size:** 23 x 25 g

**Expiration date:** 30.06.2025

**Analysed according to:** ČL 2017-Dopl.2021, Ph.Eur. 11.0

**Original Manuf. Date:** 16.7.2022

**Identification of producer:** V00499

**Batch no. of vendor:** BCCH7635

|                                       | Requirement   | Result  | Unit | Standard remark | Insp. Site    |
|---------------------------------------|---|---------|------|-----------------|---------------|
| CHARACTERS                            |   |         |      |                 |               |
| Appearance                            | (Yellowish)white powder or gelatinous, yellowish-white fragments, hygroscopic. On heating it forms a clear molten mass. | Conform |      |                 | Contract Lab  |
| Solubility                            | Conform   | Conform |      |                 | Contract Lab  |
| IDENTIFICATION                        |   |         |      |                 |               |
| Identification B                      | Conform   | Conform |      | Chromatotograms | Contract Lab  |
| Identification E                      | Conform   | Conform |      | Chlorides       | Contract Lab  |
| TESTS                                 |   |         |      |                 |               |
| Appearance of solution                | Clear, <=Y6   | Conform |      |                 | Contract Lab  |
| Acidity or alkalinity                 | Conform   | Conform |      |                 | Contract Lab  |
| Aver.rel.mol.mass, rat. of alkyl.com. | Conform   | Conform |      | HPLC            | Contract Lab  |
| C12 homologue                         | >=40  | 69      | %    |                 | Contract Lab  |
| C14 homologue                         | >=20  | 31      | %    |                 | Contract Lab  |
| sum of C12 and C14 homologues         | >=70  | 100     | %    |                 | Contract Lab  |
| Impurities A, B and C                 | Conform   | Conform |      | HPLC            | Contract Lab  |
| Impurity A                            | <=0,5   | <0,5    | %    |                 | Contract Lab  |
| Impurity B                            | <=0,15  | <0,15   | %    |                 | Contract Lab  |
| Impurity C                            | <=0,05  | <0,05   | %    |                 | Contract Lab  |
| Amines and amine salts                | Conform   | Conform |      |                 | Contract Lab  |
| Water (Karl Fischer)                  | <=10  | 5       | %    |                 | Contract Lab  |
| Sulfated ash                          | <=0,1   | <0,1    | %    |                 | Contract Lab  |
| TSE/BSE                               | No contamination with TSE/BSE-risk materials.   | Conform |      |                 | Data Producer |
| Residual solvents                     | CPMP/ICH/82 260/2006  | Conform |      |                 | Data Producer |
| Metallic residues                     | ICH Q3D on elemental impurities   | Conform |      |                 | Data Producer |
| ASSAY                                 |   |         |      |                 |               |
| Benzalkonium chloride                 | 95,0 - 104,0  | 95,4    | %    | Anhydrous       | Contract Lab  |

Quality: Excipient

**Performed by:** Ekocentrum

**Responsible:** Mgr. Zdeňka Šinclová, QC  
Ing. Martina Zemanová, QA

**Date:** 11.07.2023

**Conclusion:** **APPROVED**

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