



Certificate of Analysis

Productname: Benzalkonii chloridum

Inspection No: J01272/0322/536

Batchnumber: 21K05-T02-094639

Expiration date: 30.04.2024

Analysed according to: Ph.Eur.10.4

Original Manuf. Date: 1.5.2021

Sample Unit: 1 x 5 g

Batch Size: 32 x 25 g

Identification of producer: V00499

Batch no. of vendor: BCCF7723

| | 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 | | | Fagron CZ |
| Solubility | Conform | Conform | | | Fagron CZ |
| IDENTIFICATION | | | | | |
| Identification B | Conform | Conform | | Chromatotograms | Contract Lab |
| Identification E | Conform | Conform | | Chlorides | Fagron CZ |
| TESTS | | | | | |
| Appearance of solution | Clear,<=Y6 | Conform | | | Fagron CZ |
| Acidity or alkalinity | Conform | Conform | | | Fagron CZ |
| Aver.rel.mol.mass, rat. of alkyl.com. | Conform | 350 | | HPLC | Contract Lab |
| C12 homologue | >=40 | 66 | % | | Contract Lab |
| C14 homologue | >=20 | 32 | % | | Contract Lab |
| sum of C12 and C14 homologues | >=70 | 98 | % | | 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 | 5,0 | % | | Fagron CZ |
| Sulfated ash | <=0,1 | 0,0 | % | | Fagron CZ |
| 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 | 98,7 | % | Anhydrous | Fagron CZ |

Quality: Excipient

Performed by:

Responsible: Ing. Pavel Mišák, QC
PharmDr. Ivana Urbánková, QA

Date: 04.04.2022

Conclusion: **APPROVED**

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

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|-------------|----------------------------|------------------|---------------------------|------------------|------------------|
| Name | Fagron a.s. (CZ) | Address | Holická 1098/31m, Olomouc | Phone No. | +420585222590 |
| | Kontrolní laboratoř č. 536 | Post Code | 779 00 | Fax No. | +420 585 226 521 |