



## Certificate of Analysis

**Productname:** Chlorhexidini digluconat. sol.

**Inspection No:** J11987/0323/536

**Batchnumber:** 22J31-T06-101004

**Expiration date:** 31.07.2025

**Analysed according to:** ČL 2017-Dopl.2018, Ph.Eur.10.0

**Original Manuf. Date:** 31.8.2022

**Sample Unit:** 1 x 25 ml

**Batch Size:** 363 x 100 ml

**Identification of producer:** V00572

**Batch no. of vendor:** B/121/22

|                            | Requirement                                   | Result  | Unit  | Standard remark | Insp. Site    |
|----------------------------|---|---------|-------|-----------------|---------------|
| CHARACTERS                 |   |         |       |                 |               |
| Appearance                 | Almost colourless or pale-yellowish liquid.   | Conform |       |                 | Contract Lab  |
| Solubility                 | Conform                                       | Conform |       |                 | Contract Lab  |
| IDENTIFICATION             |   |         |       |                 |               |
| Identification A           | Conform                                       | Conform |       | IR-spectrum     | Contract Lab  |
| Identification B           | Conform                                       | Conform |       | TLC             | Contract Lab  |
| TESTS                      |   |         |       |                 |               |
| Relative density           | 1,06 - 1,07                                   | 1,07    |       |                 | Contract Lab  |
| pH                         | 5,5 - 7,0                                     | 5,8     |       |                 | Contract Lab  |
| Impurity P-Chloroaniline   | <= 500  | 110     | ppm   |                 | Contract Lab  |
| Related substances         | Conform                                       | Conform |       | HPLC            | Contract Lab  |
| Impurity N                 | <= 1,0  | <1,0    | %     |                 | Contract Lab  |
| Impurity H                 | <= 0,5  | <0,5    | %     |                 | Contract Lab  |
| Impurity A                 | <= 0,4  | <0,05   | %     |                 | Contract Lab  |
| Impurity J                 | <= 0,4  | <0,4    | %     |                 | Contract Lab  |
| Impurity K                 | <= 0,4  | <0,4    | %     |                 | Contract Lab  |
| Sum of impurities I and O  | <= 0,4  | <0,4    | %     |                 | Contract Lab  |
| Impurity G                 | <= 0,3  | <0,3    | %     |                 | Contract Lab  |
| Impurity B                 | <= 0,2  | <0,05   | %     |                 | Contract Lab  |
| Impurity F                 | <= 0,2  | <0,05   | %     |                 | Contract Lab  |
| Impurity L                 | <= 0,2  | <0,2    | %     |                 | Contract Lab  |
| Impurity Q                 | <= 0,2  | <0,2    | %     |                 | Contract Lab  |
| Unspecified impurities     | <= 0,10                                       | <0,10   | %     |                 | Contract Lab  |
| Total impurities           | <= 3,0  | <3,0    | %     |                 | Contract Lab  |
| Microbiology               | Conform                                       | Conform |       |                 | Contract Lab  |
| TAMC                       | <=2 x 10 <sup>3</sup>                         | <10     | CFU/g |                 | Contract Lab  |
| TYMC                       | <=2 x 10 <sup>2</sup>                         | <10     | CFU/g |                 | 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                      |   |         |       |                 |               |
| Chlorohexidine digluconate | 190 - 210                                     | 210     | g/l   |                 | Contract Lab  |
| Chlorohexidine digluconate | 178 - 198                                     | 196     | g/kg  |                 | Contract Lab  |

Quality: API

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

**Performed by:** Ekocentrum

**Responsible:** Mgr. Zdeňka Šinclová, QC  
MVDr. Zdenka Borská, QP

**Date:** 30.01.2023

**Conclusion:** **APPROVED**

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