

Certificate of Analysis

Productname: Chlorhexidini digluconat. sol. 20%

Inspection No: H10949/1220/536

Sample Unit: 0 x

Batchnumber: 20K24-T04-077122

Batch Size: 70 x 1 l

Expiration date: 31.08.2023

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

Original Manuf. Date: 30.9.2020

Identification of producer: V00572

Batch no. of vendor: B/127/20

| | Requirement | Result | Unit | Standard remark | Insp. Site |
|---------------------------|---|---------|-------|-----------------|---------------|
| CHARACTERS | | | | | |
| Appearance | Almost colourless or pale-yellowish liquid. | Conform | | | Fagron CZ |
| Solubility | Conform | Conform | | | Fagron CZ |
| IDENTIFICATION | | | | | |
| Identification A | Conform | Conform | | IR-spectrum | Fagron CZ |
| Identification B | Conform | Conform | | TLC | Fagron CZ |
| TESTS | | | | | |
| Relative density | 1,06 - 1,07 | 1,07 | | | Fagron CZ |
| pH | 5,5 - 7,0 | 5,7 | | | Fagron CZ |
| Impurity P-Chloroaniline | <= 500 | 71,4 | µg/g | | Fagron CZ |
| 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 | <0,05 | % | | Contract Lab |
| Impurity G | <= 0,3 | <0,3 | % | | Contract Lab |
| Impurity B | <= 0,2 | <0,2 | % | | 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 ³ | Conform | CFU/g | | Contract Lab |
| TYMC | <= 2 x 10 ² | Conform | 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 | | | | | |
| Chlorhexidine digluconate | 190 - 210 | 207 | g/l | | Contract Lab |
| Chlorhexidine digluconate | 178 - 198 | 193 | g/kg | | Contract Lab |

Name Fagron a.s. (CZ)
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Performed by: Lenka Morávková

Responsible: Ing. Mgr. Kateřina Jokešová, QC
PharmDr. Ivana Urbánková, QA

Date: 15.12.2020

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) Kontrolní laboratoř č. 536 | Address | Holická 1098/31m, Olomouc | Phone No. | +420585222590 |
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