



## Certificate of Analysis

**Productname:** Chlorhexidini digluconat. sol.

**Inspection No:** L00792/0324/536

**Batchnumber:** 23I15-T01-110794

**Expiration date:** 02.05.2025

**Analysed according to:** ČL 2017-Dopl.2018, Ph.Eur. 11.0

**Original Manuf. Date:** 3.5.2023

**Sample Unit:** 1 x 25 ml

**Batch Size:** 330 x 100 ml

**Identification of producer:** V01918

**Batch no. of vendor:** CGE2023019

	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	1,06			Fagron CZ
pH	5,5 - 7,0	6,0			Fagron CZ
Impurity P-Chloroaniline	<= 500	193	ppm		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	<0,05	%		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	<0,05	%		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	201	g/l		Contract Lab
Chlorohexidine digluconate	178 - 198	190	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:** Ludmila Stochlebová

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

**Date:** 15.02.2024

**Conclusion:** **APPROVED**

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