



## Certificate of Analysis

**Productname:** Chlorhexidini digluconat. sol.

**Inspection No:** K05095/0723/536

**Batchnumber:** 23F27-T06-103776

**Expiration date:** 21.04.2025

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

**Original Manuf. Date:** 22.4.2022

**Sample Unit:** 1 x 25 ml

**Batch Size:** 277 x 100 ml

**Identification of producer:** V01918

**Batch no. of vendor:** CGE2022023

	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	6,1			Fagron CZ
Impurity P-Chloroaniline	<= 500	49,4	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	<0,4	%		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	<0,05	%		Contract Lab
Unspecified impurities	<= 0,10	<0,05	%		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	199	g/l		Contract Lab
Chlorohexidine digluconate	178 - 198	186	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:** Bc. Andrea Šmídová

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

**Date:** 17.08.2023

**Conclusion:** **APPROVED**

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