



Certificate of Analysis

Productname: Chlorhexidini digluconat. sol.

Inspection No: K09126/0124/536

Sample Unit: 1 x 200 ml

Batchnumber: 23I15-T01-109509

Batch Size: 274 x 50 ml

Expiration date: 02.05.2025

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

Original Manuf. Date: 3.5.2023

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 ³	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	<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

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

Performed by: Ludmila Stochlebová

Responsible: Mgr. Zdeňka Šinclová, QC
Ing. Martina Zemanová, QA

Date: 06.12.2023

Conclusion: **APPROVED**

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



Certificate of Analysis

Productname: Chlorhexidini digluconat. sol.

Inspection No: K09126/0124/536

Sample Unit: 1 x 200 ml

Batchnumber: 23I15-T01-109509

Batch Size: 274 x 50 ml

Expiration date: 02.05.2025

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

Original Manuf. Date: 3.5.2023

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			
Solubility	Conform	Conform			
IDENTIFICATION					
Identification A	Conform	Conform		IR-spectrum	
Identification B	Conform	Conform		TLC	
TESTS					
Relative density	1,06 - 1,07	1,06			
pH	5,5 - 7,0	6,0			
Impurity P-Chloroaniline	<= 500	193	ppm		
Related substances	Conform	Conform		HPLC	
Impurity N	<= 1,0	<1,0	%		
Impurity H	<= 0,5	<0,5	%		
Impurity A	<= 0,4	<0,05	%		
Impurity J	<= 0,4	<0,05	%		
Impurity K	<= 0,4	<0,4	%		
Sum of impurities I and O	<= 0,4	<0,05	%		
Impurity G	<= 0,3	<0,3	%		
Impurity B	<= 0,2	<0,2	%		
Impurity F	<= 0,2	<0,05	%		
Impurity L	<= 0,2	<0,2	%		
Impurity Q	<= 0,2	<0,05	%		
Unspecified impurities	<= 0,10	<0,10	%		
Total impurities	<= 3,0	<3,0	%		
Microbiology	Conform	Conform			
TAMC	<=2 x 10 ³	<10	CFU/g		
TYMC	<=2 x 10 ²	<10	CFU/g		
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			
Residual solvents	CPMP/ICH/82 260/2006	Conform			
Metallic residues	ICH Q3D on elemental impurities	Conform			
ASSAY					
Chlorohexidine digluconate	190 - 210	201	g/l		
Chlorohexidine digluconate	178 - 198	190	g/kg		

Quality: API

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

Performed by: Ludmila Stochlebová

Responsible: Mgr. Zdeňka Šinclová, QC
Ing. Martina Zemanová, QA

Date: 06.12.2023

Conclusion: **APPROVED**

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