FAGRON

Certificate of Analysis

Productname: **Chlorhexidini digluconat. sol.**

Inspection No: G09314/0919/536
Batchnumber: **19I09-T07-071038**
Expiration date: 19.12.2020
Analysed according to: ČL2017-Dopl.2018,Ph.Eur.9.3
Original Manuf. Date: 19.12.2018

Sample Unit: 0 x
Batch Size: 1 150 x 25 ml

Identification of producer: V01483
Batch no. of vendor: A-180630

	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	1,065			Fagron CZ
pH	5,5 - 7,0	5,9			Fagron CZ
Impurity P-Chloroaniline	<= 500	Conform	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	<0,4	%		Contract Lab
Impurity J	<= 0,4	<0,4	%		Contract Lab
Impurity K	<= 0,4	<0,4	%		Contract Lab
Sum of impurites I and O	<= 0,4	<0,4	%		Contract Lab
Impurity G	<= 0,3	<0,3	%		Contract Lab
Impurity B	<= 0,2	<0,2	%		Contract Lab
Impurity F	<= 0,2	<0,2	%		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
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	200	g/l		Contract Lab

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

Performed by:	Dominika Stropková
Responsible:	Mgr. Kateřina Jokešová, QC PharmDr. Ivana Urbánková, QA
Date:	02.12.2019
Conclusion:	**APPROVED**

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

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