

Certificate of Analysis

Productname: Chlorhexidini digluconat. sol.

Inspection No: G10820/1219/536

Batchnumber: 19109-T07-071041

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: 120 x 1 l

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 impurities 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

Performed by: Dominika Stropková

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

Date: 16.01.2020

Conclusion: **APPROVED**



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