



Certificate of Analysis

Productname: Chlorhexidini digluconat. sol.

Inspection No: H10938/1220/536

Batchnumber: 20K24-T04-080122

Expiration date: 31.08.2023

Analysed according to: ČL 2017-Dopl.2018, Ph.Eur. 10.0

Original Manuf. Date: 30.9.2020

Sample Unit: 0 x

Batch Size: 1 436 x 50 ml

Identification of producer: V00572

Batch no. of vendor: B/127/20

	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	5,7			Fagron CZ
Impurity P-Chloroaniline	<= 500	71,4	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	<0,05	%		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	<0,2	%		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 103	Conform	CFU/g		Contract Lab
TYMC	<=2 x 102	Conform	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					
Chlorhexidine digluconate	190 - 210	207	g/l		Contract Lab
Chlorhexidine digluconate	178 - 198	193	g/kg		Contract Lab

Performed by: Lenka Morávková
Responsible: Ing. Mgr. Kateřina Jokešová, QC
Ing. Martina Zemanová, QP
Date: 16.12.2020
Conclusion: **APPROVED**

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