



Certificate of Analysis

Productname: Chlorhexidini digluconat. sol. 20%

Inspection No: H11292/0121/536
 Batchnumber: 20L02-T01-077172
 Expiration date: 17.09.2022
 Analysed according to: ČL 2017-Dopl.2018,Ph.Eur.10.0
 Original Manuf. Date: 17.9.2020

Sample Unit: 0 x
 Batch Size: 100 x 1 l

Identification of producer: V01483
 Batch no. of vendor: A-200604

	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	5,6			Fagron CZ
Impurity P-Chloroaniline	<= 500	<50	µg/g		Fagron CZ
Related substances	Conform	Conform		HPLC	Contract Lab
Impurity N	<= 1,0	<1,0	%		Contract Lab
Impurity H	<= 0,5	<0,05	%		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	<0,05	%		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	Conform	CFU/g		Contract Lab
TYMC	<= 2 x 10 ²	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	195	g/l		Contract Lab
Chlorhexidine digluconate	178 - 198	184	g/kg		Contract Lab

Performed by: Lucie Kubáňová DiS.
Responsible: Ing. Mgr. Kateřina Jokešová, QC
PharmDr. Ivana Urbánková, QA
Date: 14.01.2021
Conclusion: APPROVED

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