Fagron personalizing medicine

Certificate of Analysis

Productname: **Chlorhexidini digluconat. sol. 20%**

Inspection No: H11293/0121/536
Batchnumber: **20L02-T01-077176**
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: 150 x 50 ml

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 impurites 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 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					
Chlorohexidine digluconate	190 - 210	195	g/l		Contract Lab
Chlorhexidine digluconate	178 - 198	184	g/kg		Contract Lab

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

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

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