

Certificate of Analysis

Productname: Chlorhexidini digluconat. sol.

Inspection No: H02470/0320/536

Batchnumber: 20A17-T01-076649

Expiration date: 08.11.2021

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

Original Manuf. Date: 8.11.2019

Sample Unit:

0 x

Batch Size:

30 x 1 l

Identification of producer: V01483

Batch no. of vendor: A-190527

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Almost colourless or pale-yellowish liquid.	Conform			Contract Lab
Solubility	Conform	Conform			Contract Lab
IDENTIFICATION					
Identification A	Conform	Conform		IR-spectrum	Contract Lab
Identification B	Conform	Conform		TLC	Contract Lab
TESTS					
Relative density	1,06 - 1,07	1,06			Contract Lab
pH	5,5 - 7,0	5,7			Contract Lab
Impurity P-Chloroaniline	<= 500	27	µg/g		Contract Lab
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					
Chlorhexidine digluconate	190 - 210	199	g/l		Contract Lab
Chlorhexidine digluconate	178 - 198	188	g/kg		Contract Lab

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	Kontrolní laboratoř č. 536	Post Code	779 00	Fax No.	+420 585 226 521

Performed by: External/Ekocentrum

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

Date: 09.04.2020 

Conclusion: **APPROVED**

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