Fagron personalizing medicine

Certificate of Analysis

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

Inspection No: I07643/1021/536
Batchnumber: **21A27-T08-090064**
Expiration date: 31.08.2023
Analysed according to: ČL 2017-Dopl.2018,Ph.Eur.10.0
Original Manuf. Date: 28.9.2020

Sample Unit: 0 x
Batch Size: 500 x 25 ml

Identification of producer: V00572
Batch no. of vendor: B/136/20

	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	6,2			Fagron CZ
Impurity P-Chloroaniline	<= 500	200	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 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	<0,2	%		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					
Chlorohexidine digluconate	190 - 210	207	g/l		Contract Lab
Chlorhexidine digluconate	178 - 198	193	g/kg		Contract Lab

Name Fagron a.s. (CZ)
Kontrolní laboratoř č. 536
Address Holická 1098/31m, Olomouc
Post Code 779 00
Phone No. +420585222590
Fax No. +420 585 226 521

The product conforms to ČL 2017-Dopl.2018,Ph.Eur.10.0.

Performed by: Lucie Kubáňová DiS.

Responsible: Ing. Pavel Mišák, QC
MVDr. Zdenka Borská, QA

Date: 05.10.2021

Conclusion: **I certify that the above-mentioned batch of pharmaceutical raw material has been manufactured and tested in accordance with the requirements of Marketing Authorization (License) and requirements of Good Manufacturing Practice.**

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

Name	Fagron a.s. (CZ) Kontrolní laboratoř č. 536	**Address** **Post Code**	Holická 1098/31m, Olomouc 779 00	**Phone No.** **Fax No.**	+420585222590 +420 585 226 521