



Certificate of Analysis

FARMADENT d.o.o. Minarikova ul. 6 2000 Maribor Prejel: FUJS DRAGO ZA: <i>Keleno</i>
Datum prejema: <i>23. 1. 14</i>
Pregledal: <i>MAROLT Robert mag. farm. spec.</i>
Datum pregleda: <i>23. 1. 2014</i>

Productname: **Chlorhexidini diglucon. sol.**
Number of analysis/Inspection Code: 3 / KEUR-101366B
Batchnumber: **13H19-B01-287348** ✓
Reference code / No.: 2133 / BK13-CG-011
Analysed according to: **PH.EUR 7.8**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) colourless or yellowish and (almost) clear liquid	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification B	Conform	Conform		TLC
Relative density	1,06 - 1,07	1,07		
pH	5,5 - 7,0	6,8		5%V/V
Impurity P	<=500	41	ppm	
Related substances	Conform	Conform		HPLC
Impurity N	<=1,0	0,2	%	
Impurity H	<=0,5	0,3	%	
Impurity A	<=0,4	<0,05	%	
Impurity J	<=0,4	0,1	%	
Impurity K	<=0,4	<0,05	%	
Sum of impurities I and O	<=0,4	0,1	%	
Impurity G	<=0,3	0,1	%	
Impurity B	<=0,2	0,1	%	
Impurity F	<=0,2	<0,05	%	
Impurity L	<=0,2	0,1	%	
Impurity Q	<=0,2	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=3,0	0,9	%	
Residual solvents	CPMP/ICH/283/95	Conform		Data producer
Assay Chlorohexidine digluconate	190 - 210	207	g / l	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analyse performed by the authorized lab Proxylabs.

Release:
Drs. M.V. Garcia Alia
Pharmacist - QA Manager / QP

13-11-13

Expiration: 02-2015 ✓

Conclusion: APPROVED

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