



R. N. LABORATORIES PVT. LTD.
Plot No.1 & 86, Sursez, Diamond Park, Sachin, Surat, Gujarat, India.

Certificate of Analysis

Product Name	Chlorhexidine Gluconate 20 % Solution (BPR/Excipient grade)		
Reference	USP/EP/BP	Inspection Lot	40000003 661
Batch No.	CGX2024099	Batch Size	8000.00 Kg.
Mfg. Date	09/09/2024	Exp. Date	08/09/2027
Release Date	14/09/2024		

Section-A: Chemical testing

Sr. No.	Tests	Specification	Reference	Results
1.	Description	Almost colorless or pale yellowish, clear liquid.	USP/EP/BP	Complies
2.	Solubility	Miscible with glacial acetic acid and with water; miscible with three times its volume of acetone and with five times its volume of dehydrated alcohol; further addition of acetone or dehydrated alcohol yields a white turbidity.	USP	Complies
		Miscible with water, with not more than 3 parts of acetone and with not more than 5 parts of ethanol (96%).	EP/BP	Complies
3.	IDENTIFICATION:			
	A. IR	The IR Spectrum obtained with sample should correspond with that of standard.	USP/EP/BP	Complies
	B. Thin Layer Chromatography	The principal spot in the chromatogram obtained with the test solution should be similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution.	USP/EP/BP	Complies
	C. Residual melting point	132°C to 136°C.	EP/BP	133.3°C
	D. Chemical Test	A deep red color should be produced.	EP/BP	Complies

	PREPARED BY	CHECKED BY	APPROVED BY
NAME	Mr. Sandip Zalavadiya	Mr. Prakash Patel	Mr. Sohail Shaikh
DESIGNATION	Sr.Executive QC	Manager QC	Manager QA
SIGNATURE			
DATE	14/09/2024	14/09/2024	15/09/2024



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Sr. No.	Tests	Specification	Reference	Results
4.	Specific gravity/ Relative density	1.06 to 1.07	USP/EP/BP	1.065
5.	pH(5% v/v)	5.5 to 7.0	USP/EP/BP	6.16
6.	Organic impurities (Related substances)			
	Chlorhexidineoxazinoneanalog (Impurity L)	NMT 0.2 %	USP/EP/BP	BDL
	Specified unidentifiedimpurity 1 (Impurity Q)	NMT 0.2 %	USP/EP/BP	0.10 %
	Chlorhexidine amine (Impurity G)	NMT 0.3 %	USP/EP/BP	BDL
	Chlorhexidine guanidine (Impurity N)	NMT 1.0 %	USP/EP/BP	0.09%
	Chlorhexidine urea (Impurity B)	NMT 0.2 %	USP/EP/BP	0.06%
	p-Chlorophenyl urea (Impurity F)	NMT 0.2 %	USP/EP/BP	ND
	Chlorhexidine nitrile (Impurity A)	NMT 0.4 %	USP/EP/BP	BDL
	Chlorhexidine dimer (Impurity H)	NMT 0.5 %	USP/EP/BP	0.27%
	o-Chlorhexidineandspecifiedunidenti fiedimpurity 2 (Sum of Impurity I & O)	NMT 0.4 %	USP/EP/BP	0.06%
	Chlorhexidineglucityl Triazine (Impurity J)	NMT 0.4 %	USP/EP/BP	BDL
	Chlorhexidine	-	USP/EP/BP	-
	Oxochlorhexidine (Impurity K)	NMT 0.4 %	USP/EP/BP	0.05%

	PREPARED BY	CHECKED BY	APPROVED BY
NAME	Mr. Sandip Zalavadiya	Mr. Prakash Patel	Mr. Sohail Shaikh
DESIGNATION	Sr.Executive QC	Manager QC	Manager QA
SIGNATURE			
DATE	14/09/2024	14/09/2024	15/09/2024



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Plot No.1 & 86, Sursez, Diamond Park, Sachin, Surat, Gujarat, India.

Certificate of Analysis

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Reference	USP/EP/BP	Inspection Lot	40000003 661
Batch No.	CGX2024099	Batch Size	8000.00 Kg.
Mfg. Date	09/09/2024	Exp. Date	08/09/2027
Release Date	14/09/2024		

Sr. No.	Tests	Specification	Reference	Results
	Any individual unspecified impurity	NMT 0.10 %	USP/EP/BP	BDL
	Total impurities	NMT 3.0 %	USP/EP/BP	0.63%
7.	p –Chloroaniline	Not more than 500 ppm	USP	7.27 ppm
8.	Assay	NLT 19.0 % (w/v) and NMT 21.0 % (w/v)	USP	20.34% w/v
		NLT 190 g/L and NMT 210 g/L	EP/BP	207.6 g/L
Residual Solvent				
9.	Methanol	Not more than 3000 ppm	Inhouse	183 ppm
10.	Butanol	Not more than 5000 ppm	Inhouse	66 ppm
11.	Colour absorbance test by UV at 480nm	NMT 0.05	Inhouse	0.018

BDL= below disregard limit; ND= Not detected

If present, o-chlorhexidine and specified unidentified impurity 2 may not be completely resolved by the method. These peaks are integrated together to determine conformance.

Report: In the opinion of the undersigned, the above batch complies with the standards of specifications Mentioned under current monographs of USP/EP/BP

	PREPARED BY	CHECKED BY	APPROVED BY
NAME	Mr. Sandip Zalavadiya	Mr. Prakash Patel	Mr. Sohail Shaikh
DESIGNATION	Sr.Executive QC	Manager QC	Manager QA
SIGNATURE			
DATE	14/09/2024	14/09/2024	18/09/2024



R. N. LABORATORIES PVT. LTD.
Plot No.1 & 86, Sursez, Diamond Park, Sachin, Surat, Gujarat, India.

Certificate of Analysis

Product Name	Chlorhexidine Gluconate 20 % Solution		
Reference	In house	AR. No.	MT/I/24/0303
Batch No.	CGX2024099	Batch Size	8000.00 Kg
Mfg. Date	09/09/2024	Exp. Date	08/09/2027
Release Date	16/09/2024		

Section-B: Microbial testing

Sr. No.	Tests	Specification	Reference	Results
1.	Microbial Enumeration Test			
	A. Total aerobic microbial count	NMT 10^2 CFU/mL	In house	Nil
	B. Total yeasts and molds count	NMT 10^2 CFU/mL	In house	Nil
	C. Other specific micro Organisms (<i>S.aureus</i> , <i>P.aeruginosa</i> , <i>E.coli</i> , <i>Salmonella spp.</i> , <i>B.cepacia</i> , <i>S. marcescens</i>)	Should be Absent/10 mL	In house	Absent/10 mL

Note: The batch is released based on chemical analysis reported in Section - A, on completion of microbial tests results are reported in this Section -B.

Report: In the opinion of the undersigned, the above batch complies with the Current In house Specification.

	PREPARED BY	CHECKED BY	APPROVED BY
NAME	Mr. Akash Dhangar	Mr. Prakash Patel	Mr. Sohail Shaikh
DESIGNATION	Sr. Executive - MB	Manager - QC	Manager QA
SIGNATURE			
DATE	16/09/2024	16/09/2024	16/09/2024