R. N. LABORATORIES PVT. LTD.

Certificate of Analysis

Product Name	**Chlorhexidine Gluconate 20 % Solution**		
Reference	USP/EP/BP	Inspection Lot No.	40000004238
Batch No.	CGN2024164	Batch Size	8000.00 Kg.
Mfg. Date	24/12/2024	Exp. Date	23/12/2027
Release Date	28/12/2024		

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	132.8°C
	D. Chemical Test	A deep red color should be produced.	EP/BP	Complies
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	6.17

	PREPARED BY	CHECKED BY	APPROVED BY
NAME	Mr. Vikas Pathak	Mr. Prakash Patel	Mr. Sohail Shaikh
DESIGNATION	Sr.Executive QC	Manager QC	Manager QA
SIGNATURE			
DATE	28/12/2024	28/12/2024	30/12/2024

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Sr. No.	Tests	Specification	Reference	Results
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	0.09 %
	Chlorhexidine amine (Impurity G)	NMT 0.3 %	USP/EP/BP	BDL
	Chlorhexidine guanidine (Impurity N)	NMT 1.0 %	USP/EP/BP	0.08%
	Chlorhexidine urea (Impurity B)	NMT 0.2 %	USP/EP/BP	0.05%
	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	0.30 %
	o-Chlorhexidineandspecifiedunidentifiedimpurity 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	BDL
	Any individual unspecified impurity	NMT 0.10 %	USP/EP/BP	BDL
	Total impurities	NMT 3.0 %	USP/EP/BP	0.58 %

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DATE	28/12/2024	28/12/2024	30/12/2024

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Sr. No.	Tests	Specification	Reference	Results
7.	p –Chloroaniline	Not more than 500 ppm	USP	7.04 ppm
8.	Assay	NLT 19.0 % (w/v) and NMT 21.0 % (w/v)	USP	20.09 % w/v
9.	Colour absorbance test by UV at 480nm	NMT 0.1	Inhouse	0.004

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

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NAME	Mr. Vikas Pathak	Mr. Prakash Patel	Mr. Sohail Shaikh
DESIGNATION	Sr.Executive QC	Manager QC	Manager QA
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DATE	28/12/2024	28/12/2024	30/12/2024