

**BAJAJ****BAJAJ HEALTHCARE LTD. [UNIT-II]**Head Office: 6<sup>th</sup> Floor, Bhoomi Velocity Infotech Park, Above ICICI Bank,

Road No.: 23, Wagle Industrial Estate, Thane (W)- 400 604,

Tel: +91 22 66177400 Website: www.bajajhealth.com

Manufacturing Site: Block No. 588, Savli, Karachia Road,

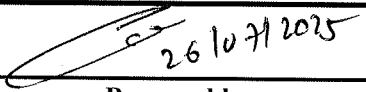
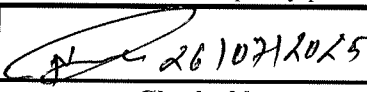
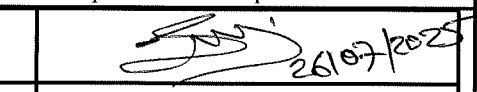
At &amp; Post: Gothada – 391 776. Tal. Savli, Dist: Vadodara, Gujarat, India.

☎ 02667 – 220100, Fax: +91 02667 619135 E-mail: bajajhealth@bajajhealth.com

FORMAT NO: QA030/F/06-07

**CERTIFICATE OF ANALYSIS**

Product	: Chlorhexidine Gluconate Solution USP	A.R. No.	: EFM252600491
Batch No.	: CS-00510725	Batch Size	: 4000kg
Mfg. Date	: JUL-2025	Sampled on	: 21/07/2025
Retest / Exp. Date	: JUN-2028	Page No.	: 01 of 01

TEST	LIMITS	RESULT	
Description	Almost colorless or pale-yellow, Clear liquid	Clear colorless liquid	
Solubility	Miscible with glacial acetic acid and with water, miscible with three parts its volume of acetone and with five times its volume of dehydrated alcohol, further addition of acetone or dehydrated alcohol yield a white turbidity.	Complies	
Identification:			
A. IR	IR spectrum of the test sample should be concordant with that of Chlorhexidine working standard.	Complies	
B. TLC	The principal spot of the sample solution corresponds in color, size and R <sub>f</sub> value to that of the standard solution.	Complies	
C. By HPLC	The retention time of the major peak from the sample solution corresponds to that of the standard solutions obtained in the Assay.	Complies	
Specific Gravity	1.06 - 1.07	1.066	
pH	5.5 - 7.0	6.17	
Limit of p-Chloroaniline	Not more than 500 ppm	14ppm	
Organic impurities (by HPLC):			
Chlorhexidine oxazinone analog	Not more than 0.2 %	0.169%	
Specified unidentified impurity-1	Not more than 0.2 %	0.067%	
Chlorhexidine Amine	Not more than 0.3 %	0.003%	
Chlorhexidine guanidine	Not more than 1.0 %	0.181%	
Chlorhexidine urea	Not more than 0.2 %	0.027%	
p-Chlorophenyl urea	Not more than 0.2 %	0.011%	
Chlorhexidine nitrile	Not more than 0.4 %	0.022%	
Chlorhexidine dimer	Not more than 0.5 %	0.242%	
o- Chlorhexidine and specified unidentified impurity-2	Not more than 0.4 %	0.042%	
Chlorhexidine glucityl triazine	Not more than 0.4 %	0.043%	
Oxochlorhexidine	Not more than 0.4 %	0.022%	
Any individual Unspecified imp.	Not more than 0.10 %	0.045%	
Total impurities	Not more than 3.0 %	0.977%	
Assay (by HPLC)	Not less than 19.0 % and Not more than 21.0 % (w/v)	20.0% w/v	
Residual Solvent (By GC) :			
Methanol	NMT 3000 ppm	39ppm	
n-Butanol	NMT 5000 ppm	52ppm	
Conclusion: The sample complies / Does not comply with the standard of quality prescribed in specification as per USP 46.			
Sign/Date	 26/07/2025	 26/07/2025	 26/07/2025
	Prepared by QC	Checked by QC	Approved by QA