

CERTIFICATE OF ANALYSIS

NAME OF PRODUCT	CHLORHEXIDINE BASE		
BATCH NO.	03/09/24	SAMPLE QTY	100 GM
MFG.DATE	SEPTEMBER 2024	EXPIRY DATE	AUGUST 2027

SR NO.	PROPERTIES	SPECIFICATIONS	RESULTS
1	Description	White powder or Granules	White powder
2	IR Spectrum	Complies with master IR spectrum	Complies
3	Melting Point	134 ± 2°C	134.2°C
4	% Residue on Ignition	≤ 0.10%	0.07%
5	% Loss on drying	≤ 0.50%	0.24 %
6	% Assay (Chlorhexidine Base)	100 ±2	99.29%
7	P-Chloroaniline	<500 ppm	Complies
8	Related Substance		
	Chlorhexidine oxazinone analog (Imp.L)	NMT 0.2%	0.09
	Specified unidentified impurity (Imp.Q)	NMT 0.2%	ND
	Chlorhexidine amine (Imp.G)	NMT 0.3%	ND
	Chlorhexidine guanidine (Imp.N)	NMT 1.0%	0.11%
	Chlorhexidine urea (Imp.B)	NMT 0.2%	ND
	p-Chlorophenyl urea (Imp.F)	NMT 0.2%	0.09
	Chlorhexidine nitrile (Imp.A)	NMT 0.4%	0.08%
	Chlorhexidine dimer (Imp.H)	NMT 0.5%	0.37%
	o-Chlorhexidine and specified inidentified impurity 2 (Imp. O+I)	NMT 0.4%	0.08%
	Chlorhexidine glucityl triazine (Imp.J)	NMT 0.4%	ND
	Oxochlorhexidine (Imp.K)	NMT 0.4%	0.13%
	Any individual unspecified impurity	NMT 0.10%	0.07%
	Total impurities	NMT 3.0%	1.02%