

CERTIFICATE OF ANALYSIS:- Chlorhexidine Gluconate Solution, BP

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NAME OF PRODUCT	Chlorhexidine Gluconate Solution, BP	
BATCH NO.	20BPLS/CHG230	
MANUFACTURING DATE		
EXPIRY DATE		
ALL TESTS PER	BP/EP	
CERTIFICATE OF ANALYSIS		
TEST	REQUIREMENT	RESULTS
Description	An almost colorless or pale- yellowish liquid	An almost colorless Liquid
Solubility	Miscible with water, with Not more than 3 parts of acetone and with Not more than 5 parts of ethanol (96%)	Complies
Identification A.By IR B.By TLC	To compare with the Chlorhexidine WRS. The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution.	Complies Complies
Relative density	1.06 to 1.07	1.064
Ph	5.5 to 7.0	5.82
Imp. P(Chloroaniline)	Maximum 500 ppm, calculated with reference to chlorhexidine digluconate solution.	Complies
Related substance		
Impurity L	Not more than 0.2%	0.06 %
Impurity Q	Not more than 0.2%	Below disregard limit
Impurity G	Not more than 0.3%	Below disregard limit
Impurity N	Not more than 1.0%	0.07 %
Impurity B	Not more than 0.2%	Below disregard limit
Impurity F	Not more than 0.2%	Not detected
Impurity A	Not more than 0.4%	Not detected
Impurity H	Not more than 0.5%	0.21%
Impurity I+O	Not more than 0.4%	0.06%
Impurity J	Not more than 0.4%	Not detected
Impurity K	Not more than 0.4%	Below disregard limit
Unspecified impurities	Not more than 0.10%	Below disregard limit
Total Impurity	Not more than 3.0%	0.40%
Assay	Aqueous solution of 1, l'-(hexane-1, 6-diyl) bis[5-(4-chlorophenyl) biguanide]di-D-digluconate contains not less than 190 g/l and not more than 210 g/l.	200.4 g/l
Color test	Absorbent not more than 0.03 at 480 nm	0.004 ABs

REMARKS : THE MATERIAL COMPLIES WITH RESPECT TO THE ABOVE SPECIFICATIONS

