



Basic Pharma Life Science Pvt. Ltd.

Manufacturers of Bulk Drugs, Drug Intermediates and Fine Chemicals

Plot No. 146/B, Opp. New Fire Station, GIDC Estate, Ankleshwar - 393 002. Gujarat. India

NAME OF PRODUCT	CHLORHEXIDINE GLUCONATE 20% SOLUTION BP CHLORHEXIDINE DIGLUCONATE 20% SOLUTION EP		
BATCH NO.	: 20BPLS/CHG051	A.R. NO.	: 20FP151
MANUFACTURING DATE	: APR - 2020	BATCH SIZE	: 8800 Kg
EXPIRY DATE	: MAR - 2023	QTY. SAMPLED	: 150 g
ALL TEST AS PER	: BP/EP	H S CODE	: 29251900
CERTIFICATE OF ANALYSIS			
TEST	REQUIREMENTS	RESULTS	
Description	Almost colourless or pale- yellowish liquid.	Almost colourless liquid.	
Solubility	Miscible with water, with Not more than 3 parts of acetone and with Not more than 5 parts of ethanol (96%).	Miscible with water, with Less than 3 parts of acetone and with Less than 5 parts of ethanol (96%).	
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	5.80	
Imp. P (Chloroaniline)	Maximum 500 ppm, calculated with reference to chlorhexidine digluconate solution.	Less than 50 ppm	

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AN ISO 9001:2015 COMPANY

Quantity is Must but Quality is First

Ph. : +91-2646-226037 / +91-7622800080 • Telefax: +91-2646-226037

Email : sales@basicpharma.in, info@basicpharma.in

Skype ID : bplspl, Web : <http://www.basicpharma.in>

CIN : U24230GJ2005PTC046278



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TEST	REQUIREMENTS		RESULTS
Related substances			
Impurity L	Not more than 0.2%		0.11%
Impurity Q	Not more than 0.2%		Not detected
Impurity G	Not more than 0.3%		Below disregard limit
Impurity N	Not more than 1.0%		0.09 %
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%		0.23%
Sum of Impurity I and O	Not more than 0.4%		Below disregard limit
Impurity J	Not more than 0.4%		Below disregard limit
Impurity K	Not more than 0.4%		Below disregard limit
Each Unspecified impurity	Not more than 0.10%		Below disregard limit
Total impurities	Not more than 3.0%		0.43 %
Assay	Aqueous solution of 1, 1'-(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.		200.1 g/l
Additional test :			
Colour Test	Absorbance not more than 0.03 at 480 nm		0.007Abs
REMARKS: The material complies with respect to the above specifications.			
Prepared by	: <i>Zays</i>	Checked by	: <i>(n)</i>
Approved by	: <i>dm</i>		
Date	: 08/04/2020	Date	: 08/04/2020
Date	: 08/04/2020	Date	: 08/04/2020

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