

PRODUCT	CHLORHEXIDINE DIGLUCONATE SOLUTION EP	
Manufacturing Date	January 21, 2023	Lot No. 104230022
Retest date	January 20, 2025	

TEST	SPECIFICATION	RESULT
Description	Almost colourless or pale-yellowish liquid	Conforms
IDENTIFICATION		
Identification by IR	IR spectrum is concordant with the reference spectrum of the standard	Conforms
Identification by TLC	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	Conforms
pH	5.5 - 7.0	6.2
Relative density	1.06 - 1.07	1.065
RELATED SUBSTANCES		
Impurity A	Less than, or equal to, 0.4 %	Less than 0.05 %
Impurity B	Less than, or equal to, 0.2 %	Less than 0.05 %
Impurity F	Less than, or equal to, 0.2 %	Less than 0.05 %
Impurity G	Less than, or equal to, 0.3 %	Less than 0.05 %
Impurity H	Less than, or equal to, 0.5 %	0.19 %
Impurities I+O	Less than, or equal to, 0.4 %	0.06 %
Impurity J	Less than, or equal to, 0.4 %	Less than 0.05 %
Impurity K	Less than, or equal to, 0.4 %	Less than 0.05 %
Impurity L	Less than, or equal to, 0.2 %	0.11 %
Impurity N	Less than, or equal to, 1.0 %	0.10 %
Impurity Q	Less than, or equal to, 0.2 %	Less than 0.05 %
Any unspecified impurity	Less than, or equal to, 0.10 %	0.06 %
Total impurities	Less than, or equal to, 3.0 %	0.52 %
^A Impurity P (chloroaniline)	Less than, or equal to, 100 ppm	11 ppm
Assay by titration	19.0 - 21.0 %	19.8 %
RESIDUAL SOLVENTS		
Methanol	Less than, or equal to, 3000 ppm	Less than 100 ppm
MICROBIAL QUALITY NON-STERILE PRODUCTS		
Total Aerobic Microbial Count (TAMC)	Not more than 10 ³ CFU/g	Conforms
Total Combined Yeasts/Moulds Count (TYMC)	Not more than 10 ² CFU/g	Conforms
Bile-tolerant gram-negative bacteria	Absence (CFU/g)	Conforms

ADDITIONAL INFORMATION
^A at release (EP NMT 500ppm)

TESTED ACCORDING TO R1-CEP 2017-128 REV 00.CUSTOMER'S MATERIAL CODE: APPH3.

Printing Date: 20/02/23

Reviewed and approved by SONIA IBORRA (Head of QC Transformation) 2023-02-16

Electronically signed in compliance with 21 CFR Part 11.

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