



FINISHED PRODUCT SPECIFICATIONS

CHLOREXOL[®] unscented

Antiseptic and disinfectant hydro-alcoholic solution 5L

Date: 13/03/2020

No. FP / OTC / 52

A - DESCRIPTION

A.1 **NAME OF PRODUCT:** CHLOREXOL UNSCENTED 5L

A.2 **CODE:** 35-92500

A.3 **REFERENCE:** CA/50000275

A.4 **DOSAGE FORM:** Antiseptic and disinfectant Solution

A.5 **PACKAGE DETAILS:** Rigid Plastic Gallon of 5 L

B - FORMULA

Each 100 mL contains:

<u>Active ingredients</u>	<u>Dosage</u>
Chlorhexidine Gluconate 20%	1 mL
Isopropyl Alcohol	75 mL

Active ingredients
Humectants

C – QUALITATIVE & QUANTITATIVE REQUIREMENTS

TESTS	REFERENCE	ACCEPTABLE LIMITS
APPEARANCE OF SOLUTION	IN HOUSE	Clear and colorless solution
FILLING VOLUME (L)	IN HOUSE	5.0 – 5.1
TOTAL COUNT	USP 36 chapter <61>	Total Aerobic Microbial Count (< 1cfu/mL) (after incubation at 30 ⁰ – 35 ⁰ C for 3 days) Total Combined Yeast/Molds Count (< 1cfu/mL) (after incubation at 20 ⁰ – 25 ⁰ C for 5 days)
EFFICACY	EN 1040: 2005	Efficacy against Staphylococcus Aureus, Pseudomonas Aeruginosa : log reduction > 5
	EN 1650:2016	Efficacy against Aspergillus brasiliensis, Candida albicans: log reduction > 4
	EN 1500:2016	The mean reduction of the release of the test organism <i>Escherichia coli</i> K12 achieved by the hygienic handrub with Chlorexol $\geq$ to that achieved by 60 % (v/v) propan-2-ol
pH	IN-HOUSE	5.0 – 9.0
ASSAY FOR CHLORHEXIDINE GLUCONATE	USP 36	$0.18 \leq 0.2 \text{ g\%} \leq 0.22$
ASSAY for Isopropyl Alcohol	IN-HOUSE	$67.5 < 75 \% < 82.5$
ORGANIC IMPURITIES	USP 36	NMT 500 ppm

D - STORAGE CONDITIONS

Store below 25⁰C

E - PROTECTIVE MEASURES

NO REQUIREMENTS BEYOND STANDARD INDUSTRIAL HYGIENE PRACTICES

F - SHELF LIFE

2 Years.

QC pharmacist
Dr. Elissa El Kassir