BUFFERED SODIUM CHLORIDE SOLUTION, PH 7,0 W/O TWEEN 80 (90 ML)

INTENDED USE:

Buffered Sodium Chloride Solution pH 7.0 w/o Tween 80 is a diluent recommended by the Harmonised European Pharmacopoeia for the microbiological examination of non-sterile pharmaceutical producs.

PRINCIPLE AND INTERPRETATION:

Buffered Sodium Chloride Solution pH 7.0 is used to make suspensions of organisms for testing growth promoting and inhibitory properties of media when examining non-sterile pharmaceutical products for specified microorganisms. This fluid provides osmotic stability, a stable pH value and maintains the viability of microorganisms during preparation of samples. Phosphates are the buffering agents in the solution. Sodium chloride provides osmotic stability. A low peptone content provides basic nutrients such as amino acids to maintain organism viability.

COMPOSITION:

Ingredients	Gr/Liter
Peptone	1 gr
Potassium dihydrogen phosphate	3,6 gr
Disodium hydrogen phosphate	7,2 gr
Sodium chloride	4,3 gr

***Formula adjusted, standardized to suit performance parameters.
pH: 7,0 ± 0,2

PRECAUTIONS:

For professional use only. Do not use tubes if they show evidence of microbial contamination, discoloration or other signs of deterioration.

TEST PROCEDURE:

Refer to the USP for details on sample collection and preparation for testing of nonsterile products.

QUALITY CONTROL:

1.Sterility Control:

Incubation 48 hours at 30-35ºC and 72 hours at 20-25ºC: NO GROWTH

2.Phsical/Chemical Control

pH: 7,0 ± 0,2
Apperance: Clear and colourless

3.Microbiological Control: Incubation at a temperature of 35±2ºC and observed after 18-24 hours.

Microorganism	Inoculum (CFU)	Results
		Growth
Staphlococcus aureus ATCC 6538	10-100	Good
Pseudomonas aeruginosa ATCC 9027	10-100	Good
Bacillus subtilis ATCC 6633	10-100	Good
Escherichia coli ATCC 8739	10-100	Good
Salmonella typhimurium ATCC 14028	10-100	Good
Candida albicans ATCC 10231	10-100	Good

LIMITATIONS OF THE PROCEDURE:

Buffered Sodium Chloride-Peptone Solution pH 7.0 is not a culture medium. The minimal nutrient content does not allow significant growth of more fastidious microorganisms. Instead, transfer aliquots of the processed solutions or the inoculated filter membranes to suitable culture media.

STORAGE CONDITIONS AND SHELF LIFE:

Store the prepared medium at 2 - 12°C or 2-25°C. Use before expiry date on the label. Do not use beyond stated expiry date.

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DISPOSAL:

Incubated medium may contain active bacteria and micro-organisms. Do not open infected medium. Infected tube should be autoclaved, incinerated or opened and soaked in a chlorine-based disinfectant (liquid bleach) for 20 minutes prior to disposal.

PACKAGING:

Katalog Number: 01139
Content/Packaging: Screw cap x 20 piece /box

REFERENCES:

1. United States Pharmacopeial Convention, Inc. 2008. The United States pharmacopeia 31/The national formulary 26, Supp. 1, 8-1-08, online. United States Pharmacopeial Convention, Inc., Rockville, Md.
2. European Directorate for the Quality of Medicines and Healthcare. 2008. The European pharmacopoeia,6th ed., Supp. 1, 4-1-2008, online. European Directorate for the Quality of Medicines and Healthcare, Council of Europe, 226 Avenue de Colmar BP907-, F-67029 Strasbourg Cedex 1, France.