

BUFFERED SODIUM CHLORIDE SOLUTION, PH 7.0 W/NEUTRALISANT (100 ML)

INTENDED USE:

Buffered Sodium Chloride Solution pH 7.0 is a diluent recommended by the Harmonised European Pharmacopoeia for the microbiological examination of non-sterile pharmaceutical products.

PRINCIPLE AND INTERPRETATION:

This medium is recommended for preparation of stable test strain suspension employed for validating the microbiological testing procedures of non-sterile products. The standardized stable suspensions are used so that the suitability of this test to detect microorganism in presence of product can be established. Non-fatty products insoluble in water and watersoluble products are diluted/dissolved using this solution. Peptone (meat or casein) serves as nutrient source and maintains the cell viability. Phosphates in the medium act as good buffering agents. Sodium chloride maintains the osmotic balance and cell integrity. The combination of lecithin, polysorbate 80 and histidine neutralizes aldehydes and phenolic compounds. This medium supports the repair of injured cells that have sensitivity to low pH. It is also recommended for pre-enrichment and repair of injured cells

COMPOSITION:

Ingredients	Gr/Liter
Peptone	1 gr
Potassium dihydrogen phosphate	3,6 gr
Disodium hydrogen phosphate	5,77 gr
Sodium chloride	4,3 gr
Lecithine	3 gr
Tween 80 (polysorbate 80)	30 gr
L-Histidine	1 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.

For details on test methods for the examination of nonsterile pharmaceutical products using Buffered Sodium Chloride Peptone Solution pH 7.0, refer to USP General Chapter <62>

QUALITY CONTROL:
1. Sterility Control:

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

2. Physical/Chemical Control

pH: 7,0 ± 0,2

Appearance: Light amber

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

Microorganism	Inoculum (CFU)	Results
		Growth
<i>Staphylococcus aureus</i> ATCC 6538	10-100	Good
<i>Pseudomonas aeruginosa</i> ATCC 9027	10-100	Good
<i>Bacillus subtilis</i> ATCC 6633	10-100	Good
<i>Escherichia coli</i> ATCC 8739	10-100	Good
<i>Salmonella typhimurium</i> ATCC 14028	10-100	Good
<i>Candida albicans</i> 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.

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: 01141

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.
3. Japanese Ministry of Health, Labour and Welfare. 2006. The Japanese pharmacopoeia, 15th ed., online. Japanese Ministry of Health, Labour and Welfare



Aseptic Sterile



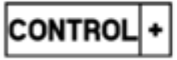
Batch Code



Catalogue Number



Negative Controls



Positive Controls



Use by



Temperature
Limitation



Do not reuse



Contains sufficient
for <n> tests



Look at user manual



Manufacturer