



Neutralizing Fluid

ME1420

This medium is recommended for neutralizing the activity of antimicrobial agents in accordance with EP.

Composition**

Ingredients	Gms / Litre
Peptone (meat and casein)	1.000
Lecithin (egg)	3.000
Histidine hydrochloride	1.000
Sodium chloride	4.300
Potassium dihydrogen phosphate	3.600
Disodium hydrogen phosphate dihydrate	7.200

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 18.64 grams (the equivalent weight of dehydrated medium per litre) in 1000 ml distilled water containing 30 gm of polysorbate 80. Heat if necessary to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes.

Principle And Interpretation

Neutralising fluid is used to neutralize the activity of antimicrobial agents generally present in pharmaceutical materials(1). This is required to neutralize the effect of antimicrobials while testing the sterility of such materials. This medium may be added to Buffered Sodium Chloride Peptone Solution, pH 7.0 before sterilization. If utilized their efficacy and non-toxicity towards microorganisms are demonstrated (1).

The neutralising agents present in the medium neutralises the activity of antimicrobial agents present in various pharmaceutical products which may interfere with microbial limit tests or sterility testing analysis. Egg lecithin and polysorbate 80 act as neutralising agents. Sodium chloride maintains osmotic equilibrium and phosphates serve as buffering agents.

Quality Control

Appearance

Cream to yellow homogeneous free flowing powder

Colour and Clarity of prepared medium

Light yellow coloured opalescent solution in tubes

Cultural Response

Cultural characteristics observed when subcultured on Tryptone Soya Agar (M290), after an incubation at 35-37°C for 40-48 hours

Cultural Response

Organism	Inoculum (CFU)	Growth
Cultural Response		
<i>Bacillus subtilis</i> ATCC 6633	50-100	good
<i>Escherichia coli</i> ATCC 8739	50-100	good
<i>Pseudomonas aeruginosa</i> ATCC 9027	50-100	good
<i>Staphylococcus aureus</i> ATCC 6538	50-100	good
<i>Salmonella</i> Typhimurium ATCC 14028	50-100	good

Storage and Shelf Life

Store below 30°C in tightly closed container and the prepared medium at 2 - 8°C. Use before expiry date on the label.

Reference

1. European Pharmacopoeia, 2008, European Department, Directorate for the Quality of Medicines of the Council of Europe

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