Neutralizing Fluid EP

Intended Use
Neutralizing Fluid is recommended for neutralizing the activity of antimicrobial agents in accordance with EP.

Summary
Neutralizing Fluid is used to neutralize the activity of antimicrobial agents generally present in pharmaceutical materials. This is required to neutralize the effect of antimicrobials while testing the sterility of such materials. The neutralizing agents present in the medium neutralize the activity of antimicrobial agents present in various pharmaceutical products which may interfere with microbial limit tests or sterility testing analysis. 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.

Principle
Peptone (meat or casein) provides carbon, nitrogen compounds, vitamins, minerals and other essential growth nutrients. Egg lecithin act as neutralizing agent. Sodium chloride maintains osmotic equilibrium and phosphates serve as buffering agents.

Formula*
Ingredients	**g/L**
Peptone (Meat or Casein)	1.0
Egg Lecithin	3.0
Histidine Hydrochloride	1.0
Sodium Chloride	4.3
Potassium Dihydrogen Phosphate	3.6
Disodium Hydrogen Phosphate Dihydrate	7.2
Final pH (at 25°C)	7.0 ± 0.2

*Adjusted to suit performance parameters.

Storage and Stability
Store dehydrated medium below 30°C in tightly closed container and the prepared medium at 2°C-8°C. Avoid freezing and overheating. Use before expiry date on the label. Once opened keep powdered medium closed to avoid hydration.

Type of specimen
Pharmaceutical samples

Specimen Collection and Handling
Ensure that all samples are properly labelled. Follow appropriate techniques for handling samples as per established guidelines. Some samples may require special handling, such as immediate refrigeration or protection from light, follow the standard procedure. The samples must be stored and tested within the permissible time duration. After use, contaminated materials must be sterilized by autoclaving before discarding.

Directions
1. Suspend 20.10 g (the equivalent weight of dehydrated medium per litre) of the powder in 1000 mL purified / distilled water containing 30.00 g of polysorbate 80.
2. Heat if necessary, to dissolve the powder completely.
3. Distribute into tubes or flasks as desired.
4. Sterilize by autoclaving at 121°C (15 psi) for 15 minutes as per validated cycle.

Quality Control

Dehydrated Appearance Light yellow coloured, homogeneous, free flowing powder with a tendency to form lumps.
Prepared Appearance: Light yellow coloured, clear to slightly opalescent solution.
Growth Promotion Test: Growth promotion is carried out in accordance with the harmonized method of USP/EP/JP/IP and growth is observed after an incubation at 30°C-35°C for 18-24 hours for bacterial and <= 2 days for fungal.
Growth Promoting Properties: The test results observed are within the specified temperature and shortest period of time, inoculating ≤ 100 cfu (at 30°C-35°C for 18 hours for bacterial and 24 hours for fungal).

Organism (ATCC)	**Growth**
Staphylococcus aureus subsp. *aureus* (6538)	Good
Pseudomonas aeruginosa (9027)	Good
Bacillus spiizenii (6633)	Good
Candida albicans 3147 (10231)	Good
Escherichia coli (8739)	Good
Salmonella enterica subsp. *enterica* serovar *Typhimurium* (14028)	Good

Growth Promotion Test in presence of Quaternary Ammonium Compound and Aldehyde

Organism (ATCC)	**Test* I**	**Test* II**	**Control** I**	**Control** II**
Staphylococcus aureus subsp. *aureus* (6538)	Good	Good	Inhibited	Inhibited
Bacillus spizizenii (6633)	Good	Good	Inhibited	Inhibited

* Neutralizing Fluid
** Soyabean Casein Digest Medium
I: With Quaternary Ammonium Compound.
II: With Aldehyde.

Note: Inoculum cfu for good growth is 10 -100.

Performance and Evaluation

Performance of the product is dependent on following parameters as per product label claim:

1. Directions
2. Storage
3. Expiry

Warranty

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

Reference

1. European Pharmacopoeia, 2008, European Department, Directorate for the Quality of Medicines of the Council of Europe
2. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:

Cat No.	**Product description**	**Pack Size**
201140020500	Dehydrated Culture Media	500 g