TM 1269 – NEUTRALISING FLUID (as per BP/EP)

INTENDED USE

For neutralising the activity of antimicrobial agents.

PRODUCT SUMMARY AND EXPLANATION

Neutralising fluid is used to neutralize the activity of antimicrobial agents generally present in pharmaceutical materials. This fluid 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.

COMPOSITION

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

PRINCIPLE

The neutralising agents present in the medium neutralizes 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.

INSTRUCTION FOR USE

- Dissolve 18.64 grams in 1000 ml distilled water containing 30 gm of polysorbate 80.
- Heat if necessary to dissolve the medium completely.
- Sterilize by autoclaving at 15 psi pressure (121°C) for 15 minutes.

QUALITY CONTROL SPECIFICATIONS

Appearance of Powder : Cream to yellow homogeneous free flowing powder.
Appearance of prepared medium : Light yellow coloured opalescent solution in tubes.
pH (at 25°C) : 7.0 ± 0.2

INTERPRETATION

Cultural characteristics observed after incubation when subcultured on Tryptone Soya Agar.

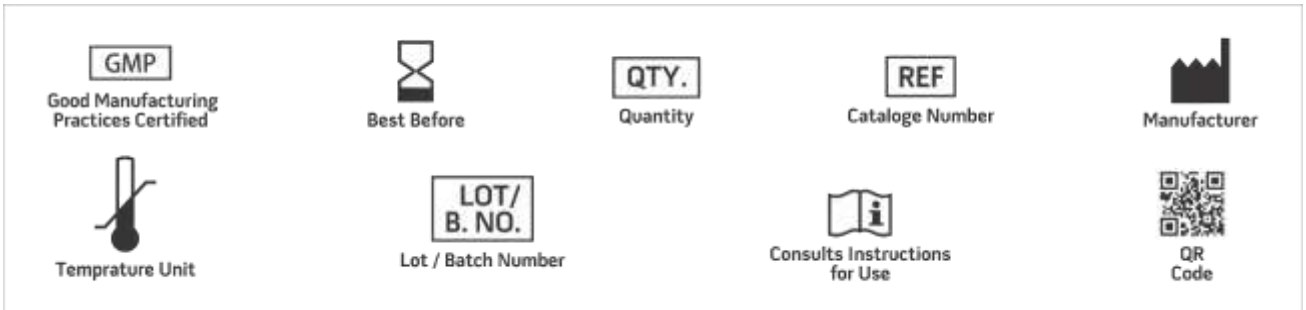
Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Incubation Temperature	Incubation Period
Staphylococcus aureus	25923	50-100	Good	35-37°C	40- 48 Hours
Salmonella Typhimurium	14028	50-100	Good	35-37°C	40- 48 Hours
Pseudomonas aeruginosa	27853	50-100	Good	35-37°C	40- 48 Hours
Escherichia coli	25922	50-100	Good	35-37°C	40- 48 Hours
Bacillus subtilis	6633	50-100	Good	35-37°C	40- 48 Hours

PACKAGING:
In pack size of 500 gm bottles.

STORAGE
Dehydrated powder, hygroscopic in nature, store in a dry place, in tightly-sealed containers between 25-30°C and protect from direct sunlight. Under optimal conditions, the medium has a shelf life of 4 years. When the container is opened for the first time, note the time and date on the label space provided on the container. After the desired amount of medium has been taken out replace the cap tightly to protect from hydration.
Product Deterioration: Do not use if they show evidence of microbial contamination, discoloration, drying or any other signs of deterioration.

DISPOSAL
After use, prepared plates, specimen/sample containers and other contaminated materials must be sterilized before discarding.

REFERENCES
1. European Pharmacopoeia, 2005, European Department, Directorate for the Quality of Medicines of the Council of Europe, Vol. 5, pp -161.
2. British Pharmacopoeia, 2004, The Stationery Office British Pharmacopoeia.



NOTE: Please consult the Material Safety Data Sheet for information regarding hazards and safe handling Practices.

***For Lab Use Only**

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