



Neutralizing Fluid

LQ124C

Intended Use

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

Composition**

Ingredients	g / L
HMC peptone #	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
Polysorbate 80 (Tween 80)	30.000

**Formula adjusted, standardized to suit performance parameters

Equivalent to Peptone (meat or casein)

Directions

Label the ready to use LQ124C bottle. Inoculate the sample and Incubate at specified temperature and time.

Principle And Interpretation

Neutralizing fluid is used to neutralize the activity of antimicrobial agents generally present in pharmaceutical materials (1,2). 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 neutralizing 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. HMC peptone provides carbon, nitrogen compounds, vitamins, minerals and other essential growth nutrients. Egg lecithin and polysorbate 80 act as neutralizing agents. Histidine hydrochloride is the source of amino acid. Sodium chloride maintains osmotic equilibrium and phosphates serve as buffering agents.

Type of specimen

Pharmaceutical samples

Specimen Collection and Handling

For pharmaceutical samples, follow appropriate techniques for sample collection, processing as per pharmaceutical guidelines (1,2). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. Biochemical characterization is necessary to be performed on colonies from pure cultures for further identification.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Sterile clear neutralizing fluid in glass bottle.

Colour

Light yellow opalescent solution

Quantity of Medium

100 ml of medium in glass bottle.

Sterility Check

Passes release criteria

Cultural Response

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

Organism	Inoculum (CFU)	Growth
** <i>Bacillus spizizenii</i> ATCC 6633 (00003*)	50-100	good
<i>Escherichia coli</i> ATCC 25922 (00013*)	50-100	good
<i>Pseudomonas aeruginosa</i> ATCC 27853 (00025*)	50-100	good
<i>Staphylococcus aureus</i> <i>subsp. aureus</i> ATCC 25923 (00034*)	50-100	good
<i>Salmonella</i> Typhimurium ATCC 14028 (00031*)	50-100	good

Key : (*) Corresponding WDCM numbers

**Formerly known as *Bacillus subtilis* subsp. *spizizenii*

Storage and Shelf Life

On receipt store between 15-30°C. Use before expiry date on the label. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with sample must be decontaminated and disposed of in accordance with current laboratory techniques (3,4).

Reference

1. European Pharmacopoeia, 2022, 10 th volume, European Directorate for the quality of medicines & Healthcare.
2. The British Pharmacopoeia, 2022, Medicines and Healthcare products Regulatory Agency.
3. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition.
4. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition.

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