

HiCulture[®] 0.9% Saline, w/0.5% Tween 80 & 0.07% Soya lecithin

MS5328

Intended use

Recommended for transportation of aerobes and fungi.

Directions

Using the capped swab provided along with the tube containing 0.9% Saline with 0.5% Tween 80 and 0.07% Soya lecithin, collect the sample or specimen from surface. Discard the cap of the tube and insert the capped swab with the sample till the bottom of the medium containing tube. Tighten the cap firmly. The specimen will be preserved during transportation and also the viability of the organisms will be maintained but it will diminish over the time. Some growth of contaminants may occur during longer period of transport. After the transportation, the specimen should be inoculated in proper medium as soon as possible. The cultures on transport swabs must not be kept at room temperature for more than 24 hours.

Principle And Interpretation

Environmental monitoring describes the processes and activities that need to take place to characterize and monitor the quality of the environment, which can help to determine the effectiveness of cleaning and bio-contamination. Environmental sampling program will not only allow a pharmaceutical laboratory to know whether it is within the recommended action levels, but will also provide valuable information for determining sources of potential contamination and counteracting them (1). Lecithin and polysorbate 80 (Tween 80) are neutralizers reported to inactivate residual disinfectants from where the sample is collected. Lecithin neutralizes quaternary ammonium compounds and polysorbate 80 neutralizes phenolic disinfectants, hexachlorophene, formalin and with lecithin ethanol (2).

Type of specimen

Environmental samples

Specimen Collection and Handling

For Environmental samples follow appropriate techniques for handling specimens as per established guidelines (3,4). 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. Individual organisms differ in their growth requirement and may show variable growth patterns on the medium
2. Each lot of the medium has been tested for the organisms specified on the COA. It is recommended to users to validate the medium for any specific microorganism other than mentioned in the COA based on the user's unique requirement.
3. Further biochemical and serological tests must be carried out for complete 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 0.9% Saline with 0.5% Tween 80 and 0.07% Soya lecithin in tubes with sterile viscous swabs

Colour

Colorless to pale yellow opalescent solution

Quantity of Medium

8 ml of medium in polypropylene tubes

pH

6.00 - 8.00

Sterility Check

Passes release criteria

Cultural response

Viability of following was established for a period of 18-24 hours for bacterial cultures and 48-72 hours for fungal cultures. Organisms grew luxuriantly when recovered on Tryptone Soya Agar (M290) and incubated at 30-35°C for 18-24 hours for bacterial cultures and 48-72 hours for fungal cultures.

Organism	Recovery
<i>Escherichia coli</i> ATCC 8739 (00012*)	luxuriant
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 6538 (00032*)	luxuriant
^ <i>Pseudomonas paraeruginosa</i> ATCC 9027 (00026*)	luxuriant
<i>Salmonella</i> Typhimurium ATCC 14028 (00031*)	luxuriant
<i>Salmonella</i> Abony NCTC 6017 (00029*)	luxuriant
<i>Candida albicans</i> ATCC 10231 (00054*)	luxuriant
<i>Candida albicans</i> ATCC 2091	luxuriant
** <i>Bacillus spizizenii</i> ATCC 6633 (00003*)	luxuriant
# <i>Aspergillus brasiliensis</i> ATCC 16404 (00053*)	luxuriant
Key (*) Corresponding WDCM numbers, (#) - Formerly known as <i>Aspergillus niger</i>	**Formerly known as <i>Bacillus subtilis</i> subsp. <i>spizizenii</i> ^ Formerly known as <i>Pseudomonas aeruginosa</i>

Storage and Shelf Life

Store between 5-30°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. The United States Pharmacopoeia-National Formulary (USP-NF), 2022.
2. Favero (Chairman), 1967, Biological Contamination Control Committee, a state of the art report., Am. Assoc. for contamination control
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. Vol. 1.

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Disclaimer :

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