Linden grain Medium

M1916

Intended Use:

Recommended for Media Fill process simulation for beverage bottling, to test for low acid beverage spoiling bacteria.

Composition**

Ingredients	Gms / Litre
Dextrose (Glucose)	20.000
Yeast extract	3.500
Casitose ▲	2.000
Ammonium sulphate	2.000
Potassium dihydrogen phosphate	1.000
Magnesium sulphate	1.000
Final pH (at 25°C)	4.2±0.2

**Formula adjusted, standardized to suit performance parameters
▲ - Equivalent to Casein peptone

Directions

Suspend 29.50 grams in 1000 ml purified / distilled water. Heat if necessary to dissolve the medium completely. Dispense as desired and sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes.

Principle And Interpretation

Linden Grain Medium is for media fill process simulation for beverage bottling. Media fill is the performance of an aseptic manufacturing procedure using a sterile microbiological growth medium in place of the drug solution. It is a part of validation of an aseptic manufacturing (3). The medium allows the growth of the contaminant flora in the environment, indicated by turbid growth in the broth.

Casitose provides amino acids and other complex nitrogenous substances. Yeast extract supplies. Vitamin B complex. Glucose is the carbohydrate source. Ammonium sulphate and magnesium sulphate acts as nitrogen source. Phosphate buffers the medium.

Type of specimen

Pharmaceutical samples.

Specimen Collection and Handling

For pharmaceutical samples follow appropriate techniques for handling specimens as per established guidelines (3).
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. Further biochemical and serological test must be carried out 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

Cream to yellow homogeneous free flowing powder

Colour and Clarity of prepared medium

Light amber coloured clear solution in tubes

Reaction

pH of 2.95% w/v aqueous solution at 25°C. pH : 4.2±0.2

pH

4.00-4.40

Cultural Response

Cultural characteristics was observed after an incubation at 20-25°C for 3-5 days.

Organism	Growth
Candida albicans ATCC 10231 (00054)*	luxuriant
# Aspergillus brasiliensis ATCC 16404 (00053)*	luxuriant
Saccharomyces cerevisiae ATCC 9763 (00058*)	luxuriant
Candida albicans ATCC 2091 (00055*)	luxuriant

Key : (*) Corresponding WDCM numbers. (#) - Formerly known as *Aspergillus niger*

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 15-25°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use. 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 clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (1,2).

Reference

1. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition.

2. 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.

3. U.S. Department of Health and Human sevices Food & Drug Administration, Centre for drug evaluations and Research, April 2012

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