HiFill™ Test HiVeg™ Medium, Sterile Powder

Intended use

HiFill™ Test Medium, Sterile powder is a gamma (γ) irradiated sterile powder recommended for the evaluation of sterility in manufacturing process for easy detection of contamination by Media Fill Test.

Composition**

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Gms / Litre</th>
</tr>
</thead>
<tbody>
<tr>
<td>HiVeg™ hydrolysate</td>
<td>17.000</td>
</tr>
<tr>
<td>Soya peptone</td>
<td>3.00</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>5.000</td>
</tr>
<tr>
<td>Dipotassium hydrogen phosphate</td>
<td>2.500</td>
</tr>
<tr>
<td>Dextrose (Glucose)</td>
<td>2.500</td>
</tr>
<tr>
<td>MFT indicator</td>
<td>0.100</td>
</tr>
<tr>
<td>Final pH (at 25°C)</td>
<td>7.3 ± 0.2</td>
</tr>
</tbody>
</table>

**Formula adjusted, standardized to suit performance parameters

Directions

Sterile powder can be used directly for the evaluation of sterility in manufacturing process. For sterile liquid medium aseptically add 30.10 grams in 1000 ml sterile distilled / purified water. DO NOT AUTOCLAVEDispense aseptically in sterile tubes or flasks as desired.

Note: If any fibres are observed in the solution it is recommended to filter the solution through 0.22 micron filter to eliminate any possibility of presence of fibres.

Principle And Interpretation

Soyabean Casein Digest Medium is recommended by various pharmacopoeia as sterility testing medium (1,2,3,4,5,7). HiFill™ Test HiVeg™ Medium, Sterile Powder is prepared by completely replacing animal based peptone with vegetable peptones to avoid BSE/TSE risks associated with animal peptones.

HiVeg™ hydrolysate and Soya peptone in the medium provides nitrogenous and carbonaceous compounds, long chain amino acids, vitamins and other essential nutrients. Sodium chloride maintains the osmotic balance. Phosphate buffers the medium. Dextrose serves as an energy source. In this line the HiFill™ Test Medium with the addition of MFT indicator, helps to verify the microbiological growth in aseptic production process. MFT Indicator is the medium is utilized by all microorganisms and the microbial contamination is indicated by colour change from light yellow to maroon-red. It is an easier method for detection of contamination with no time consumption.

Please refer disclaimer Overleaf.
Type of specimen
Pharmaceutical samples

Specimen Collection and Handling
For pharmaceutical samples follow appropriate techniques for handling samples as per established guidelines (1,2,3,5,7). 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:
NA

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

Quality Control
Appearance
Cream to yellow homogeneous free flowing powder

Colour and Clarity of prepared medium
Yellow coloured clear solution

Reaction
Reaction of 3.01% w/v aqueous solution at 25°C. pH : 7.30±0.20

pH
7.10-7.50

Sterility Testing
No growth is observed after 14 days for Bacteria at 30-35°C and for Fungi at 20-25°C.

Growth Promotion
Cultural characteristics observed after an incubation at 30-35°C for <= 3 days for Bacterial and at 20-25°C for <= 5 days for Fungal (* under anaerobic condition).

Sterility Testing

<table>
<thead>
<tr>
<th>Organism (ATCC)</th>
<th>Inoculum (CFU)</th>
<th>Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staphylococcus aureus subsp. aureus ATCC 6538 (00032*)</td>
<td>50 -100</td>
<td>luxuriant w/red to maroon colour</td>
</tr>
<tr>
<td>Staphylococcus aureus subsp. aureus ATCC 25923 (00034*)</td>
<td>50 -100</td>
<td>luxuriant w/red to maroon colour</td>
</tr>
<tr>
<td>Escherichia coli ATCC 8739 (00012*)</td>
<td>50 -100</td>
<td>luxuriant w/red to maroon colour</td>
</tr>
<tr>
<td>Escherichia coli ATCC 25922 (00013*)</td>
<td>50 -100</td>
<td>luxuriant w/red to maroon colour</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa ATCC 9027 (00026*)</td>
<td>50 -100</td>
<td>luxuriant w/red to maroon colour</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa ATCC 27853 (00025*)</td>
<td>50 -100</td>
<td>luxuriant w/red to maroon colour</td>
</tr>
<tr>
<td>Bacillus subtilis subsp. spizizenii ATCC 6633 (00003*)</td>
<td>50 -100</td>
<td>luxuriant w/red to maroon colour</td>
</tr>
<tr>
<td>Micrococcus luteus ATCC 9341</td>
<td>50 -100</td>
<td>luxuriant w/red to maroon colour</td>
</tr>
<tr>
<td>Salmonella Typhimurium ATCC 14028 (00031*)</td>
<td>50 -100</td>
<td>luxuriant w/red to maroon colour</td>
</tr>
</tbody>
</table>

Please refer disclaimer Overleaf.
**Storage and Shelf Life**

Store between 10-30°C in a tightly closed container and the prepared medium at 2-8°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. 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 (4,6).

**Reference**

2. European Pharmacopoeia, 2016, European Dept. for the quality of Medicines.
3. Indian Pharmacopoeia, 2018 Govt. of India, Ministry of Health and Family Welfare, New Delhi, India.

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**Disclaimer:**

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related HiMedia™ publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate. HiMedia™ Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal or therapeutic use but for laboratory, diagnostic, research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.