Soyabean HiVeg™ Medium, Sterile powder

Intended use

Recommended for validation. Gamma irradiated sterile powders from 3 different manufacturing lots. Each lot is tested for GPT, Sterility & Filterability for the evaluation of sterility of manufacturing process. Soyabean HiVeg™ Medium, Sterile powder is prepared by completely replacing animal based peptones with vegetable peptones. It is a gamma irradiated sterile powder recommended for the evaluation of sterility in manufacturing process.

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>3.000</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>5.000</td>
</tr>
<tr>
<td>Dipotassium phosphate</td>
<td>2.500</td>
</tr>
<tr>
<td>Dextrose</td>
<td>2.500</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 grams in 1000 ml sterile distilled / purified water. Heat if necessary to dissolve the medium completely. DO NOT AUTOCLAVE OR OVERHEAT. Excessive heating is detrimental. Dispense aseptically in sterile tubes or flasks as desired.

Principle And Interpretation

Soyabean HiVeg™ Medium, Sterile powder is prepared by completely replacing animal based Tryptone of Soyabean Casein Digest Medium, Sterile powder with vegetable based HiVeg™ hydrolysate. This makes the medium free of BSE/ TSE associated risks. This medium can be used for the same purpose of Soyabean Casein Digest Medium, which is recommended by various pharmacopoeias as sterility testing medium (1, 2). It is also used for the sensitivity testing by the tube dilution method for antimicrobial agents (3).

The combination of HiVeg™ hydrolysate and Soya peptone makes this medium nutritious by providing amino acids and long chain peptides for the growth of microorganisms. Dextrose serves as the carbon source and dipotassium phosphate buffers the medium. Sodium chloride maintains the osmotic balance of the medium.

Type of specimen

Pharmaceutical samples

Specimen Collection and Handling

For pharmaceutical samples, follow appropriate techniques for sample collection, processing as per pharmaceutical guidelines (1). 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.
2. This medium is general purpose medium and may not support the growth of fastidious organisms.
**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 may have green tinge homogeneous free flowing powder

**Colour and Clarity of prepared medium**
Light amber coloured clear solution

**Reaction**
Reaction of 3.0% w/v aqueous solution at 25°C. pH : 7.3±0.2

**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.

**Stability test**
Light yellow coloured clear solution without any precipitation or sedimentation at room temperature for 7 days

**Growth promoting properties**
Clearly visible growth of microorganism comparable to that previously obtained with previously tested and approved lot of medium occurs at the specified temperature for not more than the shortest period of time specified inoculating not more than 100 cfu (at 30-35°C for 18-24 hours for bacteria and 5 days for fungal) Growth promotion is carried out as per USP/EP/BP/JP/IP.

<table>
<thead>
<tr>
<th>Organism</th>
<th>Inoculum (CFU)</th>
<th>Growth</th>
<th>Incubation period</th>
<th>Incubation temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Salmonella Typhimurium</em> ATCC 14028 (00031*)</td>
<td>50 -100</td>
<td>luxuriant</td>
<td>18 -24 hrs</td>
<td>30 -35 °C</td>
</tr>
<tr>
<td><em>Salmonella Abony NCTC 6017</em> (00029*)</td>
<td>50 -100</td>
<td>luxuriant</td>
<td>18 -24 hrs</td>
<td>30 -35 °C</td>
</tr>
<tr>
<td><em>Pseudomonas aeruginosa</em> ATCC 9027* (00026*)</td>
<td>50 -100</td>
<td>luxuriant</td>
<td>18 -24 hrs</td>
<td>30 -35 °C</td>
</tr>
<tr>
<td><em>Streptococcus pneumoniae</em> ATCC 6305</td>
<td>50 -100</td>
<td>luxuriant</td>
<td>18 -24 hrs</td>
<td>30 -35 °C</td>
</tr>
<tr>
<td><em>Staphylococcus aureus</em> subsp. aureus ATCC 6538 (00032*)</td>
<td>50 -100</td>
<td>luxuriant</td>
<td>18 -24 hrs</td>
<td>30 -35 °C</td>
</tr>
<tr>
<td><em>Escherichia coli</em> ATCC 25922 (00013*)</td>
<td>50 -100</td>
<td>luxuriant</td>
<td>18 -24 hrs</td>
<td>30 -35 °C</td>
</tr>
<tr>
<td><em>Escherichia coli</em> NCTC 9002</td>
<td>50 -100</td>
<td>luxuriant</td>
<td>18 -24 hrs</td>
<td>30 -35 °C</td>
</tr>
<tr>
<td><em>Escherichia coli</em> ATCC 8739 (00012*)</td>
<td>50 -100</td>
<td>luxuriant</td>
<td>18 -24 hrs</td>
<td>30 -35 °C</td>
</tr>
<tr>
<td><em>Bacillus subtilis</em> subsp. spizizenii ATCC 6633 (00003*)</td>
<td>50 -100</td>
<td>luxuriant</td>
<td>18 -24 hrs</td>
<td>30 -35 °C</td>
</tr>
<tr>
<td><em>Micrococcus luteus</em> ATCC 9341</td>
<td>50 -100</td>
<td>luxuriant</td>
<td>18 -24 hrs</td>
<td>30 -35 °C</td>
</tr>
<tr>
<td><em>Pseudomonas aeruginosa</em> ATCC 27853 (00025*)</td>
<td>50 -100</td>
<td>luxuriant</td>
<td>18 -24 hrs</td>
<td>30 -35 °C</td>
</tr>
<tr>
<td><em>Candida albicans</em> ATCC 10231 (00054*)</td>
<td>50 -100</td>
<td>luxuriant</td>
<td>&lt;=5 d</td>
<td>20 -25 °C</td>
</tr>
<tr>
<td><em>Staphylococcus aureus</em> subsp. aureus ATCC 25923 (00034*)</td>
<td>50 -100</td>
<td>luxuriant</td>
<td>18 -24 hrs</td>
<td>30 -35 °C</td>
</tr>
</tbody>
</table>

**Sterility Testing- Growth promotion+Validation**

*Staphylococcus aureus* subsp. aureus ATCC 6538 (00032*)

50 -100 luxuriant <=3 d 20 -25 °C

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*Please refer disclaimer Overleaf.*
# Aspergillus brasiliensis ATCC 16404 (00053*)
50 -100 luxuriant <=5 d 20 -25 °C

Candida albicans ATCC 2091 (00055*)
50 -100 luxuriant <=5 d 30 -35 °C

Staphylococcus aureus subsp. aureus ATCC 25923 (00034*)
50 -100 luxuriant <=3 d 20 -25 °C

Escherichia coli ATCC 25922 (00013*)
50 -100 luxuriant <=3 d 20 -25 °C

Pseudomonas aeruginosa ATCC 9027 (00026*)
50 -100 luxuriant <=3 d 20 -25 °C

Bacillus subtilis subsp. spizizenii ATCC 6633 (00003*)
50 -100 luxuriant <=3 d 20 -25 °C

Salmonella Typhimurium ATCC 14028 (00031*)
50 -100 luxuriant <=3 d 20 -25 °C

Salmonella Abony NCTC 6017 (00029*)
50 -100 luxuriant <=3 d 20 -25 °C

Streptococcus pneumoniae ATCC 6305
50 -100 luxuriant <=3 d 20 -25 °C

Escherichia coli ATCC 8739 (00012*)
50 -100 luxuriant <=3 d 20 -25 °C

Escherichia coli NCTC 9002
50 -100 luxuriant <=3 d 20 -25 °C

Pseudomonas aeruginosa ATCC 27853 (00025*)
50 -100 luxuriant <=3 d 20 -25 °C

Micrococcus luteus ATCC 9341
50 -100 luxuriant <=3 d 20 -25 °C

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

**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. 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 (4,5).

**Reference**

2. Indian Pharmacopeia, 2018, Govt. of India, Ministry of Health and Family Welfare, New Delhi, India.