Soybean Casein Digest Medium (Casein Soybean Digest Broth)  

**Intended Use:**
Recommended as a general-purpose medium used for cultivation of a wide variety of microorganisms and for sterility testing of moulds and lower bacteria in accordance with the harmonized method of USP/EP/BP/JP/IP. It can also be used for clinical samples.

**Composition**

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Gms / Litre</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tryptone #</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 hydrogen phosphate</td>
<td>2,500</td>
</tr>
<tr>
<td>Glucose monohydrate</td>
<td>2,500</td>
</tr>
<tr>
<td>Final pH (at 25°C)</td>
<td>7.3±0.2</td>
</tr>
</tbody>
</table>

**Directions**

Suspend 29.77 grams (the equivalent weight of dehydrated medium per litre) in 1000 ml purified/distilled water. Heat if necessary to dissolve the medium completely. Dispense in tubes or flasks as desired. Sterilize by autoclaving at 15lbs pressure (121°C) for 15 minutes or as per validated cycle.

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

**Principle And Interpretation**

Soybean Casein Digest Medium is recommended as a sterility testing medium in accordance with the harmonized method of USP/EP/BP/JP/IP (7,2,1,5,3). It is used for the sensitivity testing of antimicrobial agents by the tube dilution method (8). It is also employed in diagnostic research in microbiology. This medium is used as a diluent and suspending medium for preparation of samples or test strains. It is also employed in sample preparation for testing of products, wherein incubation is carried out, only to serve sufficient resuscitation of the cell, while avoiding multiplication of the organism. The combination of tryptone and soya peptone makes this medium nutritious by providing nitrogenous, carbonaceous compounds, long chain amino acids, vitamins and other minerals for the growth of microorganisms. Natural sugars in soybean promote growth of fastidious organism. Glucose monohydrate is the fermentable source of carbon and dipotassium hydrogen phosphate serves as the buffer in the medium. Sodium chloride maintains the osmotic balance of the medium.

This medium is recommended for sterility checking and for studying total aerobic microbial count in verification of microbiological testing procedures employed for sterility checking.

**Type of specimen**

Pharmaceutical samples; Clinical samples- urine, blood

**Specimen Collection and Handling**

For pharmaceutical samples, follow appropriate techniques for sample collection, processing as per pharmaceutical guidelines (7,2,1,5,3). For clinical samples, follow appropriate techniques for sample collection and processing as per guidelines (4,8). After use, contaminated materials must be sterilized by autoclaving before discarding.

**Warning and Precautions**

In Vitro diagnostic use. 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 clinical 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 homogeneous free flowing powder

**Colour and Clarity of prepared medium**
Light yellow coloured clear solution without any precipitate.

**Reaction**
- pH of 2.98% w/v aqueous solution at 25°C (after sterilization). pH : 7.3±0.2
- pH: 7.10-7.50

**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 <=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.

**Sterility Testing + Validation**
The medium is tested with suitable strains of microorganisms inoculating <=100cfu and incubating at 20-25°C for not more than 3 days in case of bacteria and not more than 5 days in case of fungi.

<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 Abony NCTC 6017 (00029</em>)</td>
<td>50 -100</td>
<td>luxuriant</td>
<td>18 -24 hrs</td>
<td>30 -35 °C</td>
</tr>
<tr>
<td>*Streptococcus pneumoniae ATCC 6305</td>
<td>50 -100</td>
<td>luxuriant</td>
<td>18 -24 hrs</td>
<td>30 -35 °C</td>
</tr>
<tr>
<td><em>Escherichia coli NCTC 9002</em></td>
<td>50 -100</td>
<td>luxuriant</td>
<td>18 -24 hrs</td>
<td>30 -35 °C</td>
</tr>
<tr>
<td><em>Pseudomonas aeruginosa ATCC 27853 (00025</em>)*</td>
<td>50 -100</td>
<td>luxuriant</td>
<td>18 -24 hrs</td>
<td>30 -35 °C</td>
</tr>
<tr>
<td><em>Bacillus subtilis subsp. spizizenii ATCC 6633 (00003</em>)*</td>
<td>50 -100</td>
<td>luxuriant</td>
<td>18 -24 hrs</td>
<td>30 -35 °C</td>
</tr>
<tr>
<td><em>Micrococcus luteus ATCC 9341</em></td>
<td>50 -100</td>
<td>luxuriant</td>
<td>18 -24 hrs</td>
<td>30 -35 °C</td>
</tr>
<tr>
<td><em>Salmonella Typhimurium ATCC 14028 (00031</em>)*</td>
<td>50 -100</td>
<td>luxuriant</td>
<td>18 -24 hrs</td>
<td>30 -35 °C</td>
</tr>
<tr>
<td><em>Escherichia coli ATCC 8739 (00012</em>)*</td>
<td>50 -100</td>
<td>luxuriant</td>
<td>18 -24 hrs</td>
<td>30 -35 °C</td>
</tr>
<tr>
<td><em>Escherichia coli ATCC 25922 (00013</em>)*</td>
<td>50 -100</td>
<td>luxuriant</td>
<td>18 -24 hrs</td>
<td>30 -35 °C</td>
</tr>
<tr>
<td><em>Pseudomonas aeruginosa ATCC 9027 (00026</em>)*</td>
<td>50 -100</td>
<td>luxuriant</td>
<td>18 -24 hrs</td>
<td>30 -35 °C</td>
</tr>
<tr>
<td><em>Staphylococcus aureus subsp. aureus ATCC 6538 (00032</em>)*</td>
<td>50 -100</td>
<td>luxuriant</td>
<td>18 -24 hrs</td>
<td>30 -35 °C</td>
</tr>
</tbody>
</table>
### 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 (4,6).
Reference

3. Indian Pharmacopoeia, 2018, Govt. of India, the controller of Publication, Delhi, India.

In vitro diagnostic medical device

CE Marking

Storage temperature

Do not use if package is damaged

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