**Technical Data**

**Soybean-Casein Digest Agar**

**SMH290D**

**Intended use**

Recommended as a general purpose medium used for cultivation of a wide variety of microorganisms from pharmaceutical products in accordance with harmonized method of USP/EP/BP/JP/IP.

**Composition**

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Gms / Litre</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tryptone #</td>
<td>15,000</td>
</tr>
<tr>
<td>Soya peptone ##</td>
<td>5,000</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>5,000</td>
</tr>
<tr>
<td>Agar</td>
<td>15,000</td>
</tr>
<tr>
<td>pH after sterilization ( at 25°C)</td>
<td>7.3±0.2</td>
</tr>
</tbody>
</table>

**Directions**

This is a ready to use solid media in glass bottle. The medium is pre-sterilized, hence it does not need sterilization. Medium in the bottle can be melted either by using a pre-heated water bath or any other method. Slightly loosen the cap before melting. When complete melting of medium is observed dispense the medium in tubes as butts /slants or in plates as desired and allow to solidify. If on plate, either streak, inoculate or surface spread the test inoculum (50-100 CFU) aseptically.

**Principle And Interpretation**

Various pharmacopoeias recommend Soybean Casein Digest Agar as sterility testing medium. It is also used in validation of sterility checking procedure in accordance with the microbial limit testing harmonized methodology of USP/EP/BP/JP/IP (7,2,1,5,3). This medium is used in microbial limit test and antimicrobial preservative- effective test. Gunn et al (5) used this medium for the growth of fastidious organisms and study of haemolytic reaction after addition of 5% v/v blood. The combination of tryptone and soya peptone makes these media nutritious by providing amino acids and long chain peptides for the growth of microorganisms. Natural sugars of soy enhance growth of microorganism. Sodium chloride maintains the osmotic balance in the medium. Agar is the solidifying agent.

The total aerobic count is considered to be equal to the number of colony forming units found on this medium, if colonies of fungi are detected on this medium they are counted along with total aerobic count.

**Type of specimen**

Pharmaceutical samples; Clinical samples- blood and other body fluids, faeces

**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 handling specimens as per established guidelines (4,6). 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**

Please refer disclaimer Overleaf.
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**

Sterile Soybean-Casein Digest Agar in glass bottle.

**Colour of medium**

Light yellow coloured coloured medium

**Quantity of medium**

500ml of medium in glass bottle.

**Reaction**

7.10-7.50

**Sterility Test**

Passes release criteria

**Growth Promotion Test**

Growth Promotion was carried out in accordance with the harmonized method of USP/EP/BP/JP, and growth was observed after an incubation at 30-35°C for 18-24 hours. Recovery rate is considered 100% for bacteria growth on Blood Agar and fungus growth on Sabouraud Dextrose Agar.

**Growth promoting properties**

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 hours).

**Cultural Response**

<table>
<thead>
<tr>
<th>Organism</th>
<th>Inoculum (CFU)</th>
<th>Observed Lot value (CFU)</th>
<th>Recovery</th>
<th>Incubation period</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Bacillus subtilis subsp. spizizenii</em> ATCC 6633 (00003*)</td>
<td>50-100</td>
<td>35-100</td>
<td>&gt;=70 %</td>
<td>18-24 hrs</td>
</tr>
<tr>
<td><em>Staphylococcus aureus subsp. aureus</em> ATCC 25923 (00034*)</td>
<td>50-100</td>
<td>35-100</td>
<td>&gt;=70 %</td>
<td>18-24 hrs</td>
</tr>
<tr>
<td><em>Staphylococcus aureus</em> subsp. aureus ATCC 6538 (00032*)</td>
<td>50-100</td>
<td>35-100</td>
<td>&gt;=70 %</td>
<td>18-24 hrs</td>
</tr>
<tr>
<td><em>Escherichia coli</em> ATCC 25922 (00013*)</td>
<td>50-100</td>
<td>35-100</td>
<td>&gt;=70 %</td>
<td>18-24 hrs</td>
</tr>
<tr>
<td><em>Escherichia coli</em> ATCC 8739 (00012*)</td>
<td>50-100</td>
<td>35-100</td>
<td>&gt;=70 %</td>
<td>18-24 hrs</td>
</tr>
<tr>
<td><em>Escherichia coli</em> NCTC 9002</td>
<td>50-100</td>
<td>35-100</td>
<td>&gt;=70 %</td>
<td>18-24 hrs</td>
</tr>
<tr>
<td><em>Pseudomonas aeruginosa</em> ATCC 27853 (00025*)</td>
<td>50-100</td>
<td>35-100</td>
<td>&gt;=70 %</td>
<td>18-24 hrs</td>
</tr>
<tr>
<td><em>Pseudomonas aeruginosa</em> ATCC 9027 (00026*)</td>
<td>50-100</td>
<td>35-100</td>
<td>&gt;=70 %</td>
<td>18-24 hrs</td>
</tr>
<tr>
<td><em>Salmonella</em> Typhimurium ATCC 14028 (00031*)</td>
<td>50-100</td>
<td>35-100</td>
<td>&gt;=70 %</td>
<td>18-24 hrs</td>
</tr>
</tbody>
</table>

Please refer disclaimer Overleaf.
Candida albicans ATCC 10231 (00054*)
50 -100   35 -100   >=70 %   <=5 d

Candida albicans ATCC 2091 (00055*)
50 -100   35 -100   >=70 %   <=5 d

#Aspergillus brasiliensis ATCC 16404 (00055*)
50 -100   25 -70    50-70 %   <=5 d

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

Storage and Shelf Life
On receipt store between 15-25°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 (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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