Soyabean Casein Digest Medium

**Intended use**

Recommended as a sterility testing medium in accordance with the harmonized method of USP/EP/BP/JP/IP (Medium 1).

**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>Glucose monohydrate</td>
<td>2.500</td>
</tr>
<tr>
<td>Dipotassium hydrogen phosphate</td>
<td>2.500</td>
</tr>
<tr>
<td>Final pH (at 25°C)</td>
<td>7.3±0.2</td>
</tr>
</tbody>
</table>

**Directions**

Label the ready to use LQ027X bottle. Inoculate 50-100 cfu sample and Incubate at specified temperature and time.

**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

**Specimen Collection and Handling**

For pharmaceutical samples, follow appropriate techniques for sample collection, processing as per pharmaceutical guidelines (7,2,1,5,3). 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. 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 Soyabean Casein Digest Medium in glass bottle.

**Colour**
Light yellow coloured clear solution

**Quantity of Medium**
10 ml of medium in glass bottle.

**pH**
7.10- 7.50

**Sterility Test**
Passes release criteria.

**Growth Promotion Test**
In accordance with the harmonized method of USP/EP/BP/JP/IP.

**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 bacteria and 5 days for fungal). Growth promotion is carried out as per USP/EP/BP/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><strong>Growth promoting</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Salmonella Abony</em> NCTC 6017</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>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>Pseudomonas aeruginosa</em> ATCC 27853</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.</em> spizizenii ATCC 6633</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>Salmonella Typhimurium</em> ATCC 14028</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</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>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>Staphylococcus aureus subsp.</em> 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>Staphylococcus aureus subsp.</em> aureus ATCC 25923 (00034*)</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;=3 d</td>
<td>30 - 35°C</td>
</tr>
</tbody>
</table>

**Sterility Testing- Growth promotion+Validation**

Please refer disclaimer Overleaf.
### Technical Data

**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 (4,6).

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**Storage and Shelf Life**

Store between 15-25°C. Use before expiry date on the label. Product performance is best if used within stated expiry period.

- **Candida albicans ATCC 2091 (00055*)**
  - Growth: luxuriant
  - Temp: ≤5 d, 20 - 25 °C
- **Salmonella Abony NCTC 6017 (00029*)**
  - Growth: luxuriant
  - Temp: ≤3 d, 20 - 25 °C
- **Candida albicans ATCC 10231 (00054*)**
  - Growth: luxuriant
  - Temp: ≤5 d, 20 - 25 °C
- **#Aspergillus brasiliensis ATCC 16404 (00053*)**
  - Growth: luxuriant
  - Temp: ≤5 d, 20 - 25 °C
- **Streptococcus pneumoniae ATCC 6305**
  - Growth: luxuriant
  - Temp: ≤3 d, 20 - 25 °C
- **Escherichia coli NCTC 9002**
  - Growth: luxuriant
  - Temp: ≤3 d, 20 - 25 °C
- **Pseudomonas aeruginosa ATCC 27853 (00025*)**
  - Growth: luxuriant
  - Temp: ≤3 d, 20 - 25 °C
- **Micrococcus luteus ATCC 9341**
  - Growth: luxuriant
  - Temp: ≤3 d, 20 - 25 °C
- **Salmonella Typhimurium ATCC 14028 (00031*)**
  - Growth: luxuriant
  - Temp: ≤3 d, 20 - 25 °C
- **Staphylococcus aureus subsp. aureus ATCC 6538 (00032*)**
  - Growth: luxuriant
  - Temp: ≤3 d, 20 - 25 °C
- **Escherichia coli ATCC 8739 (00012*)**
  - Growth: luxuriant
  - Temp: ≤3 d, 20 - 25 °C
- **Escherichia coli ATCC 25922 (00013*)**
  - Growth: luxuriant
  - Temp: ≤3 d, 20 - 25 °C
- **Pseudomonas aeruginosa ATCC 9027 (00026*)**
  - Growth: luxuriant
  - Temp: ≤3 d, 20 - 25 °C
- **Bacillus subtilis subsp. spizizenii ATCC 6633 (00003*)**
  - Growth: luxuriant
  - Temp: ≤3 d, 20 - 25 °C
- **Staphylococcus aureus subsp. aureus ATCC 25923 (00034*)**
  - Growth: luxuriant
  - Temp: ≤3 d, 20 - 25 °C

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

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