Technical Data

# Soyabean Casein Digest Medium

LQ027C3B

## Intended Use

Sterility test media prepared in accordance with harmonized methods of USP, EP, BP, JP & IP.

## Composition**

| Ingredients | g / L |
|---|---|
| Tryptone$ | 17.000 |
| Soya peptone^ | 3.000 |
| Sodium chloride | 5.000 |
| Glucose monohydrate | 2.500 |
| Dipotassium hydrogen phosphate | 2.500 |
| Final pH after sterilization ( at 25°C) | 7.3±0.2 |

**Formula adjusted, standardized to suit performance parameters

$ Equivalent to Pancreatic digest of casein

^ Equivalent Papaic digest of soyabean meal

## Directions

Label the ready to use LQ027C3B bottle. Inoculate the sample and Incubate at specified temperature and time.

## Principle And Interpretation

Soyabean Casein Digest Medium is recommended as a sterility testing medium in accordance with the harmonized method of USP/EP/BP/JP/IP (1-5). It is used for the sensitivity testing of antimicrobial agents by the tube dilution method (6). 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.

Tryptone and soya peptone makes this medium nutritious by providing nitrogeneous and carbonaceous compounds, long chain peptides, vitamins and other essential nutrients for the growth of microorganisms. Natural sugars in soybean promote growth of fastidious organism. Glucose monohydrate is the fermentable source of carbon and dibasic potassium 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 guidelines (1-5). 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.Individual organisms differ in their growth requirement and may show variable growth patterns on the medium.

3.Each lot of the medium has been tested for the organisms specified on the COA. It is recommended to users to validate the medium for any specific microorganism other than mentioned in the COA based on the user's unique requirement.

## 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 a glass bottle.
**Colour**
Light yellow coloured clear solution
**Quantity of Medium**
300 ml of medium in glass bottle.
**pH**
7.10- 7.50
**Growth Promotion Test**
In accordance with the harmonized method of USP/EP/BP/JP.
**Sterility Check**
Passes release criteria.
**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 ). Growth promotion is carried out as per USP/EP/BP/JP.
**Sterility Testing + Validation**
The medium is tested with suitable strains of microorganisms inoculating ≤ 100 cfu 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.

| Organism | Inoculum (CFU) | Growth[$] | Incubation period | Incubation temperature |
|---|---|---|---|---|
| **Growth promoting** | | | | |
| *Salmonella* Abony NCTC 6017 (00029*) | ≤ 100 | luxuriant | 18 -24 hrs | 30 -35 °C |
| *Salmonella* Typhimurium ATCC 14028 (00031*) | ≤ 100 | luxuriant | 18 -24 hrs | 30 -35 °C |
| ^ *Pseudomonas paraeruginosa* ATCC 9027 (00026*) | ≤ 100 | luxuriant | 18 -24 hrs | 30 -35 °C |
| *Escherichia coli* ATCC *8739 (00012*)* | ≤ 100 | luxuriant | 18 -24 hrs | 30 -35 °C |
| *$$ Bacillus spizizeni* ATCC 6633 (00003*) | ≤ 100 | luxuriant | 18 -24 hrs | 30 -35 °C |
| *## Kokuria rhizophila* ATCC 9341 | ≤ 100 | luxuriant | 18 -24 hrs | 30 -35 °C |
| *Staphylococcus aureus* subsp. *aureus* ATCC 6538 (00032*) | ≤ 100 | luxuriant | 18 -24 hrs | 30 -35 °C |
| **Sterility Testing- Growth promotion+Validation** | | | | |
| ^ *Pseudomonas paraeruginosa* ATCC 9027 (00026*) | ≤ 100 | luxuriant | <=3 d | 20 -25 °C |
| *$$Bacillus spizizenii* ATCC 6633 (00003*) | ≤ 100 | luxuriant | <=3 d | 20 -25 °C |
| *Staphylococcus aureus* subsp. *aureus* ATCC 6538 (00032*) | ≤ 100 | luxuriant | <=3 d | 20 -25 °C |
| *##Kokuria rhizophila* ATCC 9341 | ≤ 100 | luxuriant | <=3 d | 20 -25 °C |
| *Candida albicans* ATCC 10231 (00054*) | ≤ 100 | luxuriant | <=5 d | 20 -25 °C |
| *#Aspergillus brasiliensis* ATCC 16404 (00053*) | ≤ 100 | luxuriant | <=5 d | 20 -25 °C |

Key : (*) Corresponding WDCM numbers, $ - Luxuriant growth refers to turbid growth
# - Formerly known as *Aspergillus niger,* ## - Formerly known as *Micrococcus luteus*
^ Formerly known as *Pseudomonas aeruginosa* $$- Formerly known as *Bacillus subtilis* subsp. *spizizenii*

## Storage and Shelf Life

Store between 15-30°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 (7,8).

## Reference

1.The British Pharmacopoeia, 2022, Medicines and Healthcare products Regulatory Agency.
2.European Pharmacopoeia, 2022, 10 th volume, European Directorate for the quality of medicines & Healthcare.
3.The Japanese Pharmacopoeia, 17th edition, 2016, The Ministry of Health, Labour and welfare.
4.Indian Pharmacopoeia, Addendum 2024, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare Government of India.
5.The United States Pharmacopoeia-National Formulatory (USP-NF), 2022.
6. Wright and Welch, 1959-60, Antibiotics Ann., 61.
7.Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition.
8.Jorgensen,J.H., Pfaller , M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

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