



# Technical Data

## Tryptone Soya Broth w/ 0.1 % Polysorbate 80

LQ198XCD

### Intended Use:

Recommended as a sterility test medium also used for cultivation of wide variety of microorganisms and for determining efficiency of sanitization of containers, equipment surfaces, water miscible cosmetics etc.

### Composition\*\*

Ingredients	g/ L
Tryptone #	17.000
Soya peptone ##	3.000
Sodium chloride	5.000
Dipotassium hydrogen phosphate	2.500
Glucose monohydrate	2.500
Polysorbate 80 (Tween 80)	1.000
Final pH ( at 25°C)	7.3±0.2

\*\*Formula adjusted, standardized to suit performance parameters

# Pancreatic digest of casein ## Papaic digest of soybean (soyabean)

### Directions

Label the ready to use LQ198XCD bottle. Unscrew the cap and inoculate sample. Incubate at specified temperature and time.

### Principle And Interpretation

Tryptone Soya Broth is recommended by various pharmacopoeias as a sterility testing and as a microbial limit testing medium (1-5). This medium is a highly nutritious medium used for cultivation of a wide variety of organisms (6). The combination of Tryptone and soya peptone makes the medium nutritious by providing nitrogenous, carbonaceous substances, amino acids and long chain peptides for the growth of microorganisms. Sodium chloride maintains the osmotic balance of the medium. Polysorbate 80 (Tween 80) acts as a neutralizer to inactivate residual disinfectants from where the sample is collected (7). Collection of samples from areas before and after the treatment with disinfectant evaluates cleaning procedures in environmental sanitation. The presence and number of microorganisms is determined by the appearance of colonies on the agar surface. After counting the colonies, carry out biochemical testing for identification.

### Type of specimen

Pharmaceutical samples

### Specimen Collection and Handling

For pharmaceutical samples, follow appropriate techniques for sample collection, processing as per pharmaceutical 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. Individual organisms differ in their growth requirement and may show variable growth patterns on the medium.
2. 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.
3. Further isolation and biochemical tests must be carried out for confirmation.

## 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 Tryptone Soya Broth w/ 0.1% Polysorbate 80 in glass bottle.

### Colour

Light yellow coloured clear solution.

### Quantity of Medium

390 ml of medium in glass bottle.

### Sterility Check

Passes release criteria

### pH

7.10-7.50

### 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  $\leq 100$  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.

Organism	Inoculum (CFU)	Growth	Incubation temperature	Incubation period
<b>Growth promoting</b>				
<i>Staphylococcus aureus</i> subsp <i>aureus</i> ATCC 6538 (00032*)	50 -100	luxuriant	35°C	18Hours
<i>Staphylococcus aureus</i> subsp <i>aureus</i> ATCC 25923 (00034*)	50 -100	luxuriant	35°C	18Hours
<i>Escherichia coli</i> ATCC 8739 (00012*)	50 -100	luxuriant	35°C	18Hours
<i>Escherichia coli</i> ATCC 25922 (00013*)	50 -100	luxuriant	35°C	18Hours
^ <i>Pseudomonas paraaeruginosa</i> ATCC 9027 (00026*)	50 -100	luxuriant	35°C	18Hours
<i>Pseudomonas aeruginosa</i> ATCC 27853 (00025*)	50 -100	luxuriant	35°C	18Hours
** <i>Bacillus spizizenii</i> ATCC 6633 (00003*)	50 -100	luxuriant	35°C	18Hours
\$ <i>Kocuria rhizophila</i> ATCC 9341	50 -100	luxuriant	35°C	18Hours
<i>Salmonella</i> Typhimurium ATCC 14028 (00031*)	50 -100	luxuriant	35°C	18Hours
<i>Salmonella</i> Abony NCTC 6017 (00029*)	50 -100	luxuriant	35°C	18Hours
<i>Candida albicans</i> ATCC 10231 (00054*)	50 -100	luxuriant	25°C	2 Days
<i>Candida albicans</i> ATCC 2091 (00055*)	50 -100	luxuriant	25°C	2 Days
# <i>Aspergillus brasiliensis</i> ATCC 16404 (00053*)	50 -100	luxuriant	25°C	3 Days

Key : (\*) Corresponding WDCM numbers,

\*\*Formerly known as *Bacillus subtilis* subsp. *spizizenii*

\$ Formerly known as *Micrococcus luteus*

# Formerly known as *Aspergillus niger*

^ Formerly known as *Pseudomonas aeruginosa*

## Storage and Shelf Life

On receipt 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 (8,9).

## Reference

1. The United States Pharmacopoeia-National Formulary (USP-NF), 2022
2. European Pharmacopoeia, 2022, 10 th volume, European Directorate for the quality of medicines & Healthcare.
3. The British Pharmacopoeia, 2022, Medicines and Healthcare products Regulatory Agency.
4. The Japanese Pharmacopoeia, 17th edition, 2016, The Ministry of Health, Labour and welfare.
5. Indian Pharmacopoeia, 2018, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare Government of India.
6. Forbes B. A., Sahm D. F. and Weissfeld A. S., 1998, Bailey & Scotts Diagnostic Microbiology, 10th Ed., Mosby, Inc. St. Louis, Mo.
7. Brummer, 1976, Appl. Environ. Microbiol., 32:80.
8. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
9. 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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### Disclaimer :

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