



# Technical Data

## Soyabean Casein Digest Medium (Tryptone Soya Broth)

M011

### Intended Use:

Recommended as a general purpose medium used for cultivation of a wide variety of microorganisms and recommended for sterility testing of moulds and lower bacteria.

### Composition\*\*

Ingredients	Gms / Litre
Tryptone	17.000
Soya peptone	3.000
Sodium chloride	5.000
Dextrose (Glucose)	2.500
Dipotassium hydrogen phosphate	2.500
Final pH ( at 25°C)	7.3±0.2

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

### Directions

Suspend 30.0 grams in 1000 ml purified/ distilled water. Heat if necessary to dissolve the medium completely. Mix well and dispense in tubes or flasks as desired. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes.

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

Soyabean Casein Digest Medium is recommended by various pharmacopeias as a sterility testing and as a microbial limit testing medium (2,5,6 ). This medium is a highly nutritious medium used for cultivation of a wide variety of organisms (1).

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. Dextrose/glucose serve as the carbohydrate source and dibasic potassium phosphate buffer the medium. Sodium chloride maintains the osmotic balance of the medium.

### Type of specimen

Pharmaceutical samples, Clinical samples - Blood samples.

### Specimen Collection and Handling

For clinical samples, follow appropriate techniques for handling specimens as per established guidelines (3,4).

For pharmaceutical samples, follow appropriate techniques for sample collection, processing as per pharmaceutical guidelines (5).

After use, contaminated materials must be sterilized by autoclaving before discarding.

### Warning and Precautions

In Vitro diagnostic Use only. 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 3.0% 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 not more than 100 cfu (at 30-35°C for 18-24 hours for bacteria and 5days for fungal) Growth promotion is carried out as per USP/EP/BP/JP/IP.

Organism	Inoculum (CFU)	Growth	Incubation temperature	Incubation period
<i>Salmonella</i> Typhimurium ATCC 14028 (00031*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Salmonella</i> Abony NCTC 6017 (00029*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Pseudomonas aeruginosa</i> ATCC 9027 (00026*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Streptococcus pneumoniae</i> ATCC 6305	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 6538 (00032*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Escherichia coli</i> ATCC 25922 (00013*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Escherichia coli</i> NCTC 9002	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Escherichia coli</i> ATCC 8739 (00012*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Bacillus subtilis</i> subsp. <i>spizizenii</i> ATCC 6633 (00003*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Micrococcus luteus</i> ATCC 9341	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Pseudomonas aeruginosa</i> ATCC 27853 (00025*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<i>Candida albicans</i> ATCC 10231 (00054*)	50 -100	luxuriant	20 -25 °C	<=5 d
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 25923 (00034*)	50 -100	luxuriant	30 -35 °C	18 -24 hrs
<b>Sterility Testing- Growth promotion+Validation</b>				
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 6538 (00032*)	50 -100	luxuriant	20 -25 °C	<=3 d

Please refer disclaimer Overleaf.

# <i>Aspergillus brasiliensis</i> ATCC 16404 (00053*)	50 -100	luxuriant	20 -25 °C	<=5 d
<i>Candida albicans</i> ATCC 2091 (00055*)	50 -100	luxuriant	30 -35 °C	<=5 d
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 25923 (00034*)	50 -100	luxuriant	20 -25 °C	<=3 d
<i>Escherichia coli</i> ATCC 25922 (00013*)	50 -100	luxuriant	20 -25 °C	<=3 d
<i>Pseudomonas aeruginosa</i> ATCC 9027 (00026*)	50 -100	luxuriant	20 -25 °C	<=3 d
<i>Bacillus subtilis</i> subsp. <i>spizizenii</i> ATCC 6633 (00003*)	50 -100	luxuriant	20 -25 °C	<=3 d
<i>Salmonella</i> Typhimurium ATCC 14028 (00031*)	50 -100	luxuriant	20 -25 °C	<=3 d
<i>Salmonella</i> Abony NCTC 6017 (00029*)	50 -100	luxuriant	20 -25 °C	<=3 d
<i>Streptococcus pneumoniae</i> ATCC 6305	50 -100	luxuriant	20 -25 °C	<=3 d
<i>Escherichia coli</i> ATCC 8739 (00012*)	50 -100	luxuriant	20 -25 °C	<=3 d
<i>Escherichia coli</i> NCTC 9002	50 -100	luxuriant	20 -25 °C	<=3 d
<i>Pseudomonas aeruginosa</i> ATCC 27853 (00025*)	50 -100	luxuriant	20 -25 °C	<=3 d
<i>Micrococcus luteus</i> ATCC 9341	50 -100	luxuriant	20 -25 °C	<=3 d

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

## 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 clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (3,4).

## Reference

1. Forbes B. A., Sahm D. F. and Weissfeld A. S., 1998, Bailey & Scotts Diagnostic Microbiology, 10th Ed., Mosby, Inc. St. Louis, Mo.
2. Indian Pharmacopeia, 2018, Govt. of India, Ministry of Health and Family Welfare, New Delhi, India.
3. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2<sup>nd</sup> Edition.
4. 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.
5. MacFaddin J. F., 1985, Media for Isolation-Cultivation-Identification-Maintenance of Medical Bacteria, Vol. 1, Williams & Wilkins, Baltimore, M.d.
6. The United States Pharmacopeia, 2019, The United States Pharmacopeial Convention, Rockville, MD.

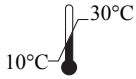
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In vitro diagnostic medical device



CE Marking



Storage temperature



Do not use if package is damaged



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