

## Soyabean Casein Digest Agar Plate (Lockable plate, $\gamma$ -irradiated, Triple pack)

MP290LGT

### Intended use

Recommended for cultivation of a wide variety of microorganisms from non-clinical samples and for sterility testing in pharmaceutical procedures.

### Composition\*\*

Ingredients	g / L
Tryptone #	15.000
Soya peptone	5.000
Sodium chloride	5.000
Agar	15.000
Final pH ( at 25°C)	7.3±0.2

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

# Equivalent to Pancreatic digest of casein

### Directions

Either streak, inoculate or surface spread the test inoculum (50-100 CFU) aseptically on the plate.

### Principle And Interpretation

Soyabean Casein Digest Agar is a widely used medium, which supports the growth of wide variety of organisms even that of fastidious ones such as *Neisseria*, *Listeria*, and *Brucella* etc. The medium with addition of blood provides perfectly defined haemolysis zones, while preventing the lysis of erythrocytes due to its sodium chloride content. It has been frequently used in the health industry to produce antigens, toxins etc. It's simple and inhibitor-free composition makes it suitable for the detection of antimicrobial agents in the food and other products. Tryptone Soya Agar is recommended by various pharmacopoeias as sterility testing medium (1,2).

Tryptone Soya Agar conforms as per USP (1) and is used in microbial limit test and antimicrobial preservative - effective test. The combination of tryptone and soya peptone makes this media nutritious by providing amino acids and long chain peptides for the growth of microorganisms. Sodium chloride maintains the osmotic balance.

Soyabean Casein Digest Agar does not contains X and V growth factors. It can be conveniently used in determining the requirements of these growth factors by isolates of *Haemophilus* by the addition of X-factor (DD020), V-factor (DD021), and X+V factor discs (DD022) factor to inoculated TSA plates (4).

### Type of specimen

Pharmaceutical samples

### Specimen Collection and Handling:

For Pharmaceutical samples follow appropriate techniques for sample collection, handling and processing as per pharmacopoeias (1,2). After use, contaminated materials must be sterilized by autoclaving before discarding.

### Warning and Precautions

Read the label before opening the pack. 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 strain of a microorganism may have unique growth requirements with respect to nutrients and physical conditions. Based on which the growth pattern of each varies on a medium and some even may display significant delay in development.
2. Environmental Monitoring Test : Exposure of media plates for 4 h as a settle plate or in air sampler or even under laminar air flow may lead reduction in some available moisture on the surface. This may cause development of tiny cracks in the agar or slight shrinkage. This however, does not impact the performance of the media.
3. It is recommended to store the plates at 24-30°C to avoid minimum condensation.

4. 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 Agar in 90 mm lockable disposable plates with smooth surface and absence of black particles/cracks/ bubbles ( $\gamma$ - Irradiated, Triple packed).

### Colour of medium

Light yellow coloured medium

### Quantity of medium

32 ml of medium in 90 mm disposable plates.

### pH

7.10-7.50

### Dose of irradiation (Kgy)

13.00- 20.00

### Sterility Check

Passes release criteria

### Cultural response

Cultural characteristics was observed after an incubation for Bacterial at 30-35°C for 18-24 hours and for Fungal at 20-25°C for  $\leq$ 5days.

### Recovery rate

Recovery rate is considered 100% for bacterial growth on Soyabean Casein Digest Agar and fungal 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  $\leq$ 100 cfu (at 30-35°C for  $\leq$ 18 hours). Growth is also observed at 20-25°C for  $\leq$ 5 days for fungus

Organism	Inoculum (CFU)	Growth	Observed Lot value (CFU)	Recovery	Incubation temperature	Incubation period
<b>Growth promoting</b>						
** <i>Bacillus spizizenii</i> ATCC 6633 (00003*)	50 -100	luxuriant	35 -100	$\geq$ 70 %	30 -35 °C	18 -24 hrs
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 25923 (00034*)	50 -100	luxuriant	35 -100	$\geq$ 70 %	30 -35 °C	18 -24 hrs
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 6538 (00032*)	50 -100	luxuriant	35 -100	$\geq$ 70 %	30 -35 °C	18 -24 hrs
<i>Escherichia coli</i> ATCC 25922 (00013*)	50 -100	luxuriant	35 -100	$\geq$ 70 %	30 -35 °C	18 -24 hrs
<i>Escherichia coli</i> ATCC 8739 (00012*)	50 -100	luxuriant	35 -100	$\geq$ 70 %	30 -35 °C	18 -24 hrs
<i>Pseudomonas aeruginosa</i> ATCC 27853 (00025*)	50 -100	luxuriant	35 -100	$\geq$ 70 %	30 -35 °C	18 -24 hrs
^ <i>Pseudomonas paraaeruginosa</i> ATCC 9027 (00026*)	50 -100	luxuriant	35 -100	$\geq$ 70 %	30 -35 °C	18 -24 hrs
<i>Salmonella</i> Abony NCTC 6017	50 -100	luxuriant	35 -100	$\geq$ 70 %	30 -35 °C	18 -24 hrs
\$ <i>Kokuria rhizophila</i> ATCC 9341	50 -100	luxuriant	35 -100	$\geq$ 70 %	30 -35 °C	18 -24 hrs
<i>Salmonella</i> Typhimurium ATCC 14028 (00031*)	50 -100	luxuriant	35 -100	$\geq$ 70 %	30 -35 °C	18 -24 hrs

<i>Candida albicans</i> ATCC 10231 (00054*)	50 -100	luxuriant	35 -100	>=70 %	30 -35 °C	<=5 d
<i>Candida albicans</i> ATCC 2091 (00055*)	50 -100	luxuriant	35 -100	>=70 %	30 -35 °C	<=5 d
# <i>Aspergillus brasiliensis</i> ATCC 16404 (00053*)	50 -100	luxuriant	35 -100	>=70 %	30 -35 °C	<=5 d
<i>Candida albicans</i> ATCC 10231 (00054*)	50 -100	luxuriant	35 -100	>=70 %	20 -25 °C	<=5 d
<i>Candida albicans</i> ATCC 2091 (00055*)	50 -100	luxuriant	35 -100	>=70 %	20 -25 °C	<=5 d
# <i>Aspergillus brasiliensis</i> ATCC 16404 (00053*)	50 -100	luxuriant	35 -100	>=70 %	20 -25 °C	<=5 d
<i>Clostridium sporogenes</i> ATCC 19404 (00008*)	50 -100	luxuriant	35 -100	>=70 %	30 -35 °C	<=48 hours

Key : (\*) Corresponding WDCM numbers.

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

(^) Formerly known as *Pseudomonas aeruginosa*

( \$ ) Formerly known as *Micrococcus luteus*

( # ) Formerly known as *Aspergillus niger*

## Storage and Shelf Life

On receipt store between 20-30°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 (5,6).

## Reference

- 1.The United States Pharmacopoeia-National Formulary (USP-NF), 2022.
- 2.Indian Pharmacopoeia, 2022, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare Government of India.
- 3.Gunn B. A., Ohashi D K., Gaydos C. A., Holt E. S., 1977, J. Clin. Microbiol., 5(6) : 650.
- 4.Forbes B. A., Sahm A. S. and Weissfeld D. F., 1998, Bailey and Scotts Diagnostic Microbiology, 10th Ed., Mosby Inc. St. Louis, Mo.
- 5.Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition.
- 6.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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