Technical Data

Tryptone Soya Agar Plate (γ-irradiated) (Triple pack)

MPH290GT

Intended use

Recommended as a general purpose medium used for cultivation of a wide variety of microorganisms from pharmaceutical products in accordance with harmonized method of USP/EP/BP/JP/IP (Medium 2).

Composition**

Ingredients	Gms / Litre
Tryptone #	15.000
Soya peptone ##	5.000
Sodium chloride	5.000
Agar	15.000
pH after sterilization (at 25°C)	7.3±0.2

**Formula adjusted, standardized to suit performance parameters

Pancreatic digest of casein

Papaic digest of soyabean (soybean)

Directions

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

Principle And Interpretation

Various pharmacopoeias recommend Tryptone Soya Agar Plate (γ-irradiated) (Triple pack) as sterility testing medium. It is also used in validation of sterility checking procedure in accordance with the microbial limit testing harmonized methodology of USP/EP/BP/JP/IP (1,2,3,4,5). This medium is used in microbial limit test and antimicrobial preservative-effective test. Gunn et al (5) used this medium for the growth of fastidious organisms and study of haemolytic reaction after addition of 5% v/v blood. The combination of tryptone and soya peptone makes these media nutritious by providing amino acids and long chain peptides for the growth of microorganisms. Natural sugars of soy enhance growth of microorganism. Sodium chloride maintains the osmotic balance in the medium. Agar is the solidifying agent.

The total aerobic count is considered to be equal to the number of colony forming units found on this medium, if colonies of fungi are detected on this medium they are counted along with total aerobic count.

Type of specimen

Pharmaceutical samples

Specimen Collection and Handling

For pharmaceutical samples, follow appropriate techniques for sample collection, processing as per pharmaceutical guidelines (1,2,3,4,5).

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. 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.
4. It is recommended to store the plates at 24-30°C to avoid minimum condensation.

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 Agar in 90 mm disposable plates.

Colour of medium
Light yellow coloured coloured medium

Quantity of medium
25 ml of medium in 90 mm disposable plates.

pH
7.10-7.50

Dose of irradiation (Kgy)
13.00- 20.00

Sterility Test
Passes release criteria

Growth Promotion Test
Growth Promotion was carried out in accordance with the harmonized method of USP/EP/BP/JP, and growth was observed after an incubation at 30-35°C for 18-24 hours. Recovery rate is considered 100% for bacteria growth on Blood Agar and fungus 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 <=100 cfu (at 30-35°C for 18 hours).

Cultural Response

Organism	Inoculum (CFU)	Observed Lot value (CFU)	Recovery	Incubation period
Bacillus subtilis subsp. spizizenii ATCC 6633 (00003*)	50 -100	35 -100	>=70 %	18 -24 hrs
Staphylococcus aureus subsp. aureus ATCC 25923 (00034*)	50 -100	35 -100	>=70 %	18 -24 hrs
Staphylococcus aureus subap. aureus ATCC 6538 (00032*)	50 -100	35 -100	>=70 %	18 -24 hrs
Escherichia coli ATCC 25922 (00013*)	50 -100	35 -100	>=70 %	18 -24 hrs
Escherichia coli ATCC 8739 (00012*)	50 -100	35 -100	>=70 %	18 -24 hrs
Escherichia coli NCTC 9002	50 -100	35 -100	>=70 %	18 -24 hrs
Pseudomonas aeruginosa ATCC 27853 (00025*)	50 -100	35 -100	>=70 %	18 -24 hrs
Pseudomonas aeruginosa ATCC 9027 (00026*)	50 -100	35 -100	>=70 %	18 -24 hrs
Salmonella Abony *NCTC* 6017 (00029*)	50 -100	35 -100	>=70 %	18 -24 hrs

Micrococcus luteus ATCC 9341	50 -100	35 -100	>=70 %	18 -24 hrs
Streptococcus pneumoniae ATCC 6305	50 -100	35 -100	>=70 %	18 -24 hrs
Salmonella Typhimurium *ATCC 14028* (00031*)	50 -100	35 -100	>=70 %	18 -24 hrs
Candida albicans ATCC 10231 (00054*)	50 -100	35 -100	>=70 %	<=5 d
Candida albicans ATCC 2091 (00055*)	50 -100	35 -100	>=70 %	<=5 d
#Aspergillus brasiliensis ATCC 16404 (00053*)	50 -100	25 -70	50-70 %	<=5 d

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

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 (6,7).

Reference

1. British Pharmacopoeia, 2019, The Stationery office British Pharmacopoeia
2. European Pharmacopoeia, 2019, European Dept. for the quality of Medicines.
3. Indian Pharmacopoeia, 2018, Govt. of India, the controller of Publication, Delhi, India.
4. The United States Pharmacopoeia, 2019, The United States Pharmacopoeial Convention. Rockville, MD.
5. Japanese Pharmacopoeia, 2016.
6. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition.
7. 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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