Soybean CaseinDigest Medium (Casein Soyabean Digest Broth) MH011

Intended Use:

Recommended as a general-purpose medium used for cultivation of a wide variety of microorganisms and for sterility testing of moulds and lower bacteria in accordance with the harmonized method of USP/EP/BP/JP/IP.

Composition**

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

*pH can also be measured after sterilization at 25°C *pH after sterilization 7.3±0.2
**Formula adjusted, standardized to suit performance parameters
Pancreatic digest of casein ## Papaic digest of soybean (soyabean)

Directions

Suspend 29.77 grams (the equivalent weight of dehydrated medium per litre) in 1000 ml purified/ distilled water. Heat if necessary to dissolve the medium completely. Dispense in tubes or flasks as desired. Sterilize by autoclaving at 15lbs pressure (121°C) for 15 minutes or as per validated cycle.

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 as a sterility testing medium in accordance with the harmonized method of USP/EP/BP/JP/IP (1,2,3,4,5). 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.

The combination of tryptone and soya peptone makes this medium nutritious by providing nitrogenous, carbonaceous compounds, long chain amino acids, vitamins and other minerals for the growth of microorganisms. Natural sugars in soybean promote growth of fastidious organism. Glucose monohydrate is the fermentable source of carbon and dipotassium hydrogen 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 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.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.

2.Individual organisms differ in their growth requirement and may show variable growth patterns on the medium.
3.Biochemical characterization is necessary to be performed on colonies from pure cultures for further identification.

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

Reaction of 2.98% 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 <=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.

Sterility Testing + Validation

The medium is tested with suitable strains of microrganisms inoculating <=100cfu 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*)	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Pseudomonas aeruginosa ATCC 27853 (00025*)	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Bacillus subtilis subsp. *spizizenii* ATCC 6633 (00003*)	50 -100	luxuriant	18 -24 hrs	30 -35 °C
$ *Kocuria rhizophila* ATCC 9341	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Salmonella Typhimurium ATCC 14028 (00031*)	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Escherichia coli ATCC 8739 (00012*)	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Escherichia coli ATCC 25922 (00013*)	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Pseudomonas aeruginosa ATCC 9027 (00026*)	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Staphylococcus aureus subsp. *aureus* ATCC 6538 (00032*)	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Staphylococcus aureus subsp. *aureus* ATCC 25923 (00034*)	50 -100	luxuriant	18 -24 hrs	30 -35 °C
Sterility Testing- Growth promotion+Validation				
Candida albicans ATCC 2091 (00055*)	50 -100	luxuriant	<=5 d	20 -25 °C

Candida albicans ATCC 10231 (00054*)	50 -100	luxuriant	<=5 d	20 -25 °C
#*Aspergillus brasiliensis* ATCC 16404 (00053*)	50 -100	luxuriant	<=5 d	20 -25 °C
Salmonella Abony NCTC 6017 (00029*)	50 -100	luxuriant	<=3 d	20 -25 °C
Pseudomonas aeruginosa ATCC 27853 (00025*)	50 -100	luxuriant	<=3 d	20 -25 °C
$ *Kocuria rhizophila* ATCC 9341	50 -100	luxuriant	<=3 d	20 -25 °C
Salmonella Typhimurium ATCC 14028 (00031*)	50 -100	luxuriant	<=3 d	20 -25 °C
Staphylococcus aureus subsp. *aureus* ATCC 6538 (00032*)	50 -100	luxuriant	<=3 d	20 -25 °C
Escherichia coli ATCC 8739 (00012*)	50 -100	luxuriant	<=3 d	20 -25 °C
Escherichia coli ATCC 25922 (00013*)	50 -100	luxuriant	<=3 d	20 -25 °C
Pseudomonas aeruginosa ATCC 9027 (00026*)	50 -100	luxuriant	<=3 d	20 -25 °C
Bacillus subtilis subsp. *spizizenii* ATCC 6633 (00003*)	50 -100	luxuriant	<=3 d	20 -25 °C
Staphylococcus aureus subsp. *aureus* ATCC 25923 (00034*)	50 -100	luxuriant	<=3 d	20 -25 °C

Key : (#) Formerly known as *Aspergillus niger*, $- Formerly known as *Micrococcus luteus*
(*) 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. 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 United States Pharmacopoeia-National Formulatory (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, 2022, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare Government of India.
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.

Revision : 10 /2023