Soybean-Casein Digest Agar, Granulated® GMH290

(Casein Soyabean Digest Agar, Granulated®)

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	g / L
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

Suspend 40.00 grams in 1000 ml purified/ distilled water. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes or as per validated cycle. Cool to 45-50°C. Mix well and pour into sterile Petri plates.

Principle And Interpretation

Various pharmacopoeias recommend Soybean Casein Digest Agar 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 (1-5). This medium is used in microbial limit test and antimicrobial preservative- effective test. Gunn et al (6) 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 (1-5). 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. 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 coloured granular medium

Gelling

Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium

Light yellow coloured clear to slightly opalescent gel forms in Petri plates

pH

7.10-7.50

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 for bacteria and <=5 days in case of fungi. Recovery rate is considered 100% for bacteria growth on Soyabean Casein Digest 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 for bacteria and <=5 days for fungi). Growth of fungal cultures is also observed at 20-25°C for <=5 days.

Cultural Response

Organism	Inoculum (CFU)	Observed Lot value (CFU)	Recovery	Incubation period	Incubation temperature
****Bacillus spizizenii* ATCC 6633 (00003*)	50 -100	35 -100	>=70 %	18 -24 hrs	30 -35 °C
Staphylococcus aureus subsp. aureus ATCC 25923 (00034*)	50 -100	35 -100	>=70 %	18 -24 hrs	30 -35 °C
Staphylococcus aureus subsp. *aureus* ATCC 6538 (00032*)	50 -100	35 -100	>=70 %	18 -24 hrs	30 -35 °C
Escherichia coli ATCC 25922 (00013*)	50 -100	35 -100	>=70 %	18 -24 hrs	30 -35 °C
Escherichia coli ATCC 8739 (00012*)	50 -100	35 -100	>=70 %	18 -24 hrs	30 -35 °C
Pseudomonas aeruginosa ATCC 27853 (00025*)	50 -100	35 -100	>=70 %	18 -24 hrs	30 -35 °C
^*Pseudomonas paraeruginosa* ATCC 9027 (00026*)	50 -100	35 -100	>=70 %	18 -24 hrs	30 -35 °C
Salmonella Abony NCTC 6017 (00029*)	50 -100	35 -100	>=70 %	18 -24 hrs	30 -35 °C
$ *Kokuria rhizophila* ATCC 9341	50 -100	35 -100	>=70 %	18 -24 hrs	30 -35 °C
Salmonella Typhimurium ATCC 14028 (00031*)	50 -100	35 -100	>=70 %	18 -24 hrs	30 -35 °C
Candida albicans ATCC 10231 (00054*)	50 -100	35 -100	>=70 %	<=5 d	30 -35 °C
Candida albicans ATCC 2091 (00055*)	50 -100	35 -100	>=70 %	<=5 d	30 -35 °C
#*Aspergillus brasiliensis* ATCC 16404 (00053*)	50 -100	35-100	>=70 %	<=5 d	30 -35 °C
Candida albicans ATCC 10231 (00054*)	50 -100	35 -100	>=70 %	<=5 d	20 -25 °C
Candida albicans ATCC 2091 (00055*)	50 -100	35 -100	>=70 %	<=5 d	20 -25 °C
#*Aspergillus brasiliensis* ATCC 16404 (00053*)	50 -100	35-100	>=70 %	<=5 d	20 -25 °C
$$*Clostridium sporogenes ATCC 19404* (00008*)	50 -100	35 -100	>=70 %	<=48 hours	30 -35 °C

Key : (*) Corresponding WDCM numbers $$ Incubated anaerobically

^ Formerly known as *Pseudomonas aeruginosa* ** Formerly known as *Bacillus subtilis* subsp. *spizizenii*

$ Formerly known as *Micrococcus luteus* # Formerly known as *Aspergillus niger*

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 20-30°C. Use before expiry date on thelabel. 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. Gunn B. A., Ohashi D K., Gaydos C. A., Holt E. S., 1977, J. Clin. Microbiol., 5(6) : 650.
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.

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