

Soyabean Casein Digest Medium (Tryptone Soya Broth) Granulated, Sterile

GMH011G

Soyabean Casein Digest Medium, granulated, sterile is gamma irradiated medium recommended for evaluation of sterility in manufacturing process.

Composition**

Ingredients	Gms / Litre
Pancreatic digest of casein	17.000
Papaic digest of soybean (soyabean)	3.000
Sodium chloride	5.000
Dipotassium hydrogen phosphate	2.500
Glucose monohydrate	2.500
pH after sterilization (at 25°C)	7.3±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Sterile medium can be used directly for the evaluation of sterility in manufacturing process. For sterile liquid medium aseptically add 29.77 grams in 1000 ml sterile distilled water. Heat if necessary to dissolve the medium completely. DO NOT AUTOCLAVE OR OVERHEAT. Excessive heating is detrimental. Dispense aseptically in sterile flasks or tubes as desired.

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. It is also employed in sample preparation for testing of products, wherein incubation is carried out, only to serve sufficient resuscitation of the cell, while avoiding multiplication of the organism.

The combination of pancreatic digest of casein and papaic digest of soybean meal makes this medium nutritious by providing amino acids and long chain peptides for the growth of microorganisms. Natural sugars in soybean promote growth of fastidious organism. Glucose is the fermentable source of carbon and dibasic potassium 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.

Quality Control

Appearance

Cream to yellow coloured granular medium

Colour and Clarity of prepared medium

Light yellow coloured clear solution without any precipitate.

Reaction

pH of 2.98% w/v aqueous solution at 25°C (after sterilization). pH : 7.3±0.2

pH

7.10-7.50

Sterility Testing

No growth is observed after 14 days for Bacteria at 30-35°C and for fungi at 20-25°C.

Test for Mycoplasma (PCR)

None detected.

Stability test

Light yellow coloured clear solution without any precipitation or sedimentation at room temperature for 7 days.

Growth Promotion Test

In accordance with the harmonized method of USP/EP/BP/IP.

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).

Sterility Testing + Validation

The medium is tested with suitable strains of microorganisms inoculating ≤ 100 cfu 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.

Cultural Response

Organism	Growth	Incubation period	Inoculum (CFU)	Incubation temperature
Growth promoting				
<i>Salmonella</i> Abony NCTC 6017	luxuriant	18 -24 hrs	50 -100	30 -35 °C
<i>Staphylococcus aureus</i> ATCC 6538	luxuriant	18 -24 hrs	50 -100	30 -35 °C
<i>Escherichia coli</i> ATCC 8739	luxuriant	18 -24 hrs	50 -100	30 -35 °C
<i>Escherichia coli</i> ATCC 25922	luxuriant	18 -24 hrs	50 -100	30 -35 °C
<i>Escherichia coli</i> NCTC 9002	luxuriant	18 -24 hrs	50 -100	30 -35 °C
<i>Pseudomonas aeruginosa</i> ATCC 9027	luxuriant	18 -24 hrs	50 -100	30 -35 °C
<i>Pseudomonas aeruginosa</i> ATCC 27853	luxuriant	18 -24 hrs	50 -100	30 -35 °C
<i>Bacillus subtilis</i> ATCC 6633	luxuriant	18 -24 hrs	50 -100	30 -35 °C
<i>Micrococcus luteus</i> ATCC 9341	luxuriant	18 -24 hrs	50 -100	30 -35 °C
<i>Salmonella</i> Typhimurium ATCC 14028	luxuriant	18 -24 hrs	50 -100	30 -35 °C
<i>Streptococcus pneumoniae</i> ATCC 6305	luxuriant	18 -24 hrs	50 -100	30 -35 °C
<i>Staphylococcus aureus</i> ATCC 25923	luxuriant	18 -24 hrs	50 -100	30 -35 °C
Sterility Testing- Growth promotion+ Validation				
<i>Streptococcus pneumoniae</i> ATCC 6305	luxuriant	≤ 3 d	50 -100	20 -25 °C
<i>Staphylococcus aureus</i> ATCC 6538	luxuriant	≤ 3 d	50 -100	20 -25 °C
<i>Staphylococcus aureus</i> ATCC 25923	luxuriant	≤ 3 d	50 -100	20 -25 °C
<i>Escherichia coli</i> ATCC 8739	luxuriant	≤ 3 d	50 -100	20 -25 °C
<i>Escherichia coli</i> ATCC 25922	luxuriant	≤ 3 d	50 -100	20 -25 °C
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<i>Bacillus subtilis</i> ATCC 6633	luxuriant	≤ 3 d	50 -100	20 -25 °C
<i>Micrococcus luteus</i> ATCC 9341	luxuriant	≤ 3 d	50 -100	20 -25 °C
<i>Salmonella</i> Typhimurium ATCC 14028	luxuriant	≤ 3 d	50 -100	20 -25 °C
<i>Salmonella</i> Abony NCTC 6017	luxuriant	≤ 3 d	50 -100	20 -25 °C

* <i>Aspergillus brasiliensis</i> ATCC 16404	luxuriant	<=5 d	50 -100	20 -25 °C
<i>Candida albicans</i> ATCC 10231	luxuriant	<=5 d	50 -100	20 -25 °C
<i>Candida albicans</i> ATCC 2091	luxuriant	<=5 d	50 -100	20 -25 °C

Key : * - Formerly known as *Aspergillus niger*

Storage and Shelf Life

Store below 30°C in tightly closed container and the prepared medium at 2-8°C. Use before expiry date on the label.

Reference

- 1.The United States Pharmacopoeia, 2014, The United States Pharmacopoeial Convention, Rockville, MD.
2. British Pharmacopoeia, 2014, The Stationery Office British Pharmacopoeia.
- 3.European Pharmacopoeia, 2014, European Department for the Quality of Medicines of Council of Europe.
- 4.Japanese Pharmacopoeia, 2008, Published by Society of Japanese Pharmacopoeia, Tokyo, Japan.
- 5.Indian Pharmacopoeia, 2014 Ministry of Health and Family Welfare, Govt. of India.
- 6.Wright and Welch, 1959-60, Antibiotics Ann., 61.

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