Soyabean Casein Digest Medium, Sterile powder

MH011G

Soyabean Casein Digest Medium, Sterile powder is gamma irradiated sterile powder 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
Dibasic potassium phosphate	2.500
Glucose monohydrate	2.500
Final pH (at 25°C)	7.3±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Sterile powder 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 OVERHAET. Excessive heating is detrimental. Dispense aseptically in sterile flasks or tubes as desired. (Sterilized by gamma irradiation).

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 homogeneous free flowing powder

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
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 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.

Cultural Response

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

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

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 Dept. for the quality of Medicines.
4.Japanese Pharmacopoeia, 2008.
5. Indian Pharmacopoeia, 2014, Govt. of India, the controller of Publication, Delhi, India.
6.Wright and Welch, 1959-60, Antibiotics Ann., 61.

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