Soyabean Casein Digest Medium (Tryptone Soya Broth) (Harmonized)

Intended Use
Soyabean Casein Digest Medium is used for isolation and cultivation of a wide variety of microorganisms from pharmaceutical products with microbial limit testing by harmonized methodology of USP/EP/BP/JP/IP.

Summary
Soyabean Casein Digest Medium (SCDM) is widely used for the cultivation of microorganisms from environmental sources, supporting the growth of a wide variety of microorganisms including common aerobic, facultative and anaerobic bacteria and fungi. It is also used for preparing dilutions of organisms for colony counts and preparation of standard inocula for disc diffusion and dilution antimicrobial susceptibility testing as standardized by the National Committee for Clinical Laboratory Standards (NCCLS). This medium is used in sterility testing for the detection of contamination with low incidence fungi and aerobic bacteria and in the performance of microbial limit test. It is used in the coliphage detection procedure, a Methodology in Standard Methods for the Examination of Water and Wastewater. Soyabean Casein Digest Agar and Medium are included in the Bacteriological Analytical Manual for food and cosmetics testing, in the Compendia of Methods for the examination of milk, water and wastewater and foods.

Principle
The combination of pancreatic digest of casein and papaic digest of soyabean makes the medium highly nutritious by supplying organic nitrogen, particularly amino acids and long chain peptides. Sodium chloride maintains the osmotic balance. Dibasic hydrogen phosphate acts as a buffer to control pH. Soyabean Casein Digest Medium may be supplemented with blood to provide a more nutritious medium for fastidious organisms, or with antimicrobials to provide a selective medium for specific organisms out of a mixed flora sample.

Formula*

Ingredients	**g/L**
Pancreatic Digest of Casein	17.0
Papaic Digest of Soyabean	3.0
Sodium Chloride	5.0
Glucose Monohydrate	2.5
Dibasic Hydrogen Phosphate	2.5
Final pH (at 25°C)	7.3 ± 0.2

*Adjusted to suit performance parameters.

Storage and Stability
Store between 10-30°C in a tightly closed container and the prepared medium at 15-25°C. Avoid freezing and overheating. Use before expiry date on the label. Once opened keep powdered medium closed to avoid hydration.

Type of Specimen
Pharmaceutical samples

Specimen Collection and Handling
Ensure that all samples are properly labelled. Follow appropriate techniques for handling samples as per established guidelines. Some samples may require special handling, such as immediate refrigeration or protection from light, follow the standard procedure. The samples must be stored and tested within the permissible time duration. After use, contaminated materials must be sterilized by autoclaving before discarding.

Directions
1. Suspend 29.77 g of (equivalent weight of dehydrated medium per litre) the powder in 1000 mL purified water.
2. Mix thoroughly. Boil with frequent agitation to dissolve the powder completely.
3. Sterilize by autoclaving at 121°C (15 psi) for 15 minutes as per validated cycle.

Quality Control

Dehydrated Appearance: Cream to yellow coloured, homogeneous, free flowing powder.
Prepared Appearance: Amber to dark coloured, clear solution without any precipitate.
Growth Promotion Test: Growth promotion is carried out in accordance with the harmonized method of USP/EP/JP/IP/BP and growth is observed after an incubation at 30°C-35°C for ≤ 3 days for bacteria and ≤ 5 days for fungi.
Growth Promoting Properties: The test results observed are within the specified temperature and shortest period of time, inoculating ≤ 100 cfu (at 30°C-35°C for ≤ 3 days for bacteria and ≤ 5 days for fungi).

Growth Promoting

Organism (ATCC)	**Growth**
Staphylococcus aureus subsp. *aureus* (6538)	Good
Pseudomonas aeruginosa (9027)	Good
Bacillus spizizenii (6633)	Good
Aspergillus brasiliensis WLRI 034(120) (16404)	Good
Candida albicans 3147 (10231)	Good

Validation and Growth Promotion:
Growth promotion is carried out at an incubation of 20°C-25°C for ≤ 3 days for bacteria and ≤ 5 days for fungi as per USP/EP/JP/IP.

Organism (ATCC)	**Growth**
Candida albicans 3147 (10231)	Good
Bacillus spizizenii (6633)	Good
Aspergillus brasiliensis WLRI 034(120) (16404)	Good

Note: Inoculum cfu for good growth is 10 – 100.

Performance and Evaluation

Performance of the product is dependent on following parameters as per product label claim:
1. Directions
2. Storage
3. Expiry

Warranty

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

Reference

1. The United States Pharmacopoeia, 2023, The United States Pharmacopoeial Convention Inc., Rockville, MD.
2. British Pharmacopoeia, 2023, The Stationery Office British Pharmacopoeia
3. European Pharmacopoeia, 2011, European Dept. for the quality of Medicines.
4. Japanese Pharmacopoeia, 2008.
5. Gunn. B. A. *et al.,* 1977, J. Clin. Microbiol., 5(6): 650
6. The Indian Pharmacopoeia 2010, Govt of India, Ministry of Health and Family Welfare, New Delhi.
7. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:

Cat No.	Product description	Pack Size
201190240500	Dehydrated Culture Media	500 g
201190242500	Dehydrated Culture Media	2.5 k
201190245000	Dehydrated Culture Media	5k
203190610100	Bottle Media	100 mL