Soyabean Casein Digest Agar (Harmonized)

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

Summary
Soyabean Casein Digest Agar (SCDA) is used for total aerobic microbial count and antimicrobial preservative effective test. It is also used for testing bacterial contaminants in cosmetics and for a multitude of purpose including maintenance of stock cultures, plate counts and as a base for media containing blood. Gunn *et al.,* used this medium for the study of haemolytic reactions after addition of 5% v/v blood. 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.

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. Soyabean casein digest agar 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. Since Soyabean Casein Digest Agar contains no added carbohydrate, it may be used with added blood to determine haemolysis. When Soyabean Casein Digest Agar is supplemented with 0.7 g lecithin and 5 g polysorbate (Tween 80) per liter of medium, it can be used as microbial content test agar for testing quaternary ammonium compounds (collection of samples from identical areas before and after treatment with disinfectant yields data useful in evaluating cleaning procedures in environmental sanitation).

Formula*

Ingredients	**g/L**
Pancreatic Digest of Casein	15.0
Papaic Digest of Soyabean	5.0
Sodium Chloride	5.0
Agar	15.0
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 20-30°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 40.00 g of the powder in 1000 mL purified water & mix thoroughly.
2. 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.
4. Mix well and pour.

Quality Control

Dehydrated Appearance: Light yellow coloured, homogenous, free flowing powder.
Prepared Appearance: Light yellow coloured, very slightly opalescent gel forms in petridishes.
Growth Promotion Test: Growth promotion is carried out in accordance with the harmonized method of USP/EP/BP/JP/IP and growth is observed after an incubation at 30°C-35°C for ≤ 3 days for bacteria and at 30°C-35°C and 20°C-25°C for ≤ 5 days for fungi.
Growth Promoting Properties: The test results observed are within the specified temperature and shortest period of time specified in the test, inoculating ≤ 100 cfu of appropriate microorganism.

Organism (ATCC)	Growth	Incubation Temperature
Escherichia coli (8739)	Good	30°C-35°C
Staphylococcus aureus subsp. *aureus* (6538)	Good	30°C-35°C
Pseudomonas aeruginosa (9027)	Good	30°C-35°C
Bacillus spizizenii (6633)	Good	30°C-35°C
Salmonella enterica subsp. *enterica* serovar *Abony* (NCTC 6017)	Good	30°C-35°C
Salmonella enterica subsp. *enterica* serovar *Typhimurium* (14028)	Good	30°C-35°C
Candida albicans 3147 (10231)	Good	30°C-35°C
Candida albicans 3147 (10231)	Good	20°C-25°C
Aspergillus brasiliensis WLRI 034(120) (16404)	Good	30°C-35°C
Aspergillus brasiliensis WLRI 034(120) (16404)	Good	20°C-25°C

Note: For good growth - Growth obtained on test media should not differ by a factor greater than 2 from calculated value for a standardized inoculum.

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 Pharmacopeial Convention. 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
201190200500	Dehydrated Culture Media	500 g
201190202500	Dehydrated Culture Media	2.5 k
201190205000	Dehydrated Culture Media	5 k
203190560100	Bottle Media	100 mL
203190560250	Bottle Media	6 x 250 mL
203190560500	Bottle Media	500 mL
203190570012	Ready Prepared Slant	12 Slants