Fluid Casein Digest Soya Lecithin Polysorbate 20 Medium (Twin Pack) USP

Intended Use
Fluid Casein Digest Soya Lecithin Polysorbate 20 Medium (Twin Pack) is a medium used for detection of microbes on sanitized surfaces in compliance with USP.

Summary
Fluid Casein Digest Soya Lecithin Medium is recommended for sanitary examination of surfaces in compliance with IP and USP. NASA also recommends this medium for the microbiological sampling of environmental surfaces sanitized with quaternary ammonium compounds.

Principle
Pancreatic digest of casein provides the essential nutrients for the growth of bacteria. Soya lecithin neutralizes the quaternary ammonium compounds whereas polysorbate 20 neutralizes phenolic disinfectants, hexachlorophene and formalin.

Formula*

Ingredients	**g/L**
Part A	
Pancreatic Digest of Casein	20.0
Soya Lecithin	5.0
Part B	
Polysorbate 20	40.0 mL
Final pH (at 25°C)	7.3 ± 0.2

*Adjusted to suit performance parameters.

Storage and Stability
Store dehydrated medium below 30°C in tightly closed container and the prepared medium at 2°C-8°C. Avoid freezing and overheating. Use before expiry date on the label. Once opened keep powdered medium closed to avoid hydration.

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. Dissolve 25.00 g of Part A powder in 960 mL purified / distilled water.
2. Heat gently to dissolve the powder completely. Do not boil.
3. Add 40 mL of Part B.
4. Mix and dispense as desired.
5. Sterilize by autoclaving at 121°C (15 psi) for 15 minutes as per validated cycle.

Quality Control

Dehydrated Appearance: Part A: Cream to Yellow coloured, homogenous, free flowing powder.
Part B: Yellow coloured, clear, viscous liquid.
Prepared Appearance: Light yellow to yellow coloured, clear to slightly opalescent solution.
Growth Promotion Test: Growth promotion is carried out in accordance with the harmonized method of USP/EP/JP/IP and growth is observed after an incubation at 30°C-35°C for ≤ 18-24 hours for bacteria and ≤ 24-48 hours 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 18 hours for bacterial and 24 hours for fungal).

Growth Promoting Organism (ATCC)	**Growth**
Staphylococcus aureus subsp. *aureus* (6538)	Good
Bacillus spizizenii (6633)	Good
Candida albicans 3147 (10231)	Good
Escherichia coli (8739)	Good
Staphylococcus aureus subsp. *aureus* (25923)	Good
Escherichia coli (25922)	Good

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

Growth Promotion Test in presence of Quartenary Ammonium Compound :

Organisms (ATCC)	**Test I**	**Test II**
Staphylococcus aureus subsp. *aureus* (6538)	Good	Inhibited
Bacillus spizizenii (6633)	Good	Inhibited
Candida albicans 3147 (10231)	Good	Inhibited
Escherichia coli (8739)	Good	Inhibited
Staphylococcus aureus subsp. *aureus* (25923)	Good	Inhibited
Escherichia coli (25922)	Good	Inhibited

Test I : Fluid Casein Digest Soya Lecithin Polysorbate 20 Medium (Twin Pack) USP + Quaternary Ammonium Compound
Test II : Soyabean Casein Digest Medium + Quaternary Ammonium Compound

Interpretation of Results

Refer to appropriate references and procedures for results.

Performance and Evaluation

Performance of the product is dependent on following parameters as per product label claim:

1. Directions
2. Storage
3. Expiry

Warranty

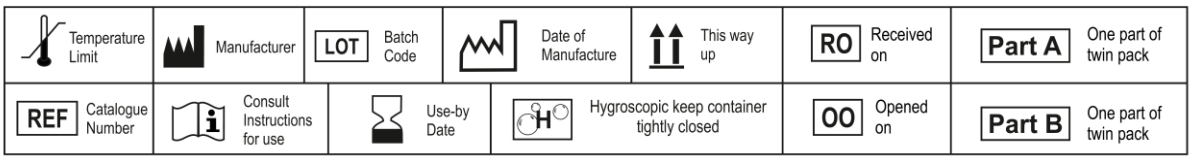
This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

Reference

1. Indian Pharmacopoeia, 2007. Govt. of India, Ministry of Health and Family Welfare. Vol II, Controller of Publications, New Delhi.
2. United States Pharmacopeial National Formulatory 2008. USP 31 NF 26
3. National Aeronautics and Space Administration, 1966. Standard Procedures for the Microbiological Examination of Space Hardware.
4. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:

Cat No.	Product description	Pack Size
201060010100	Dehydrated Culture Media	100 g
201060010500	Dehydrated Culture Media	500 g



Revision: 0825/VER-03

Disclaimer

Information provided is based on our inhouse technical data on file, it is recommended that user should validate at his end for suitable use of the product.