Tryptone Soya Agar with Lecithin and Polysorbate 80 (Soyabean Casein Digest Agar with Lecithin and Polysorbate 80)

Intended Use
Tryptone Soya Agar with Lecithin and Polysorbate 80 is recommended for validation of cleanliness on surfaces of containers, equipment surfaces and water miscible cosmetics.

Summary
Tryptone Soya Agar with Lecithin and Polysorbate 80 is recommended for validation of cleanliness on surface of containers, equipment surfaces and water miscible cosmetics. For the microbiological examination of surfaces, RODAC (Replicate Organism Detection and Counting) and surface plates are used. Microbiological examination of surfaces before and after treatment with disinfectants provides data about cleanliness, which is used for validation of cleaning procedures in environmental sanitation.

Principle
Casein enzymic hydrolysate and papaic digest of soyabean meal serves as a source of nitrogen. Sodium chloride provides sodium ions for the membrane transport and maintains osmotic equilibrium of the medium. Lecithin and Polysorbate 80 inactivates disinfectant. Lecithin neutralizes quaternary ammonium compounds and tween 80 neutralizes substituted phenolic disinfectant. Agar is the solidifying agent.

Formula*

Ingredients	**g/L**
Casein Enzymic Hydrolysate	15.0
Papaic Digest of Soyabean Meal	5.0
Sodium Chloride	5.0
Polysorbate 80 (Tween 80)	5.0
Lecithin	0.7
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 sample

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 45.70 g of the powder in 1000 mL purified / distilled water.
2. Mix thoroughly.
3. Boil with frequent agitation to dissolve the powder completely.
4. Sterilize by autoclaving at 121°C (15 psi) for 15 minutes as per validated cycle.
5. Cool the medium to approximately 45°C-50°C pour into sterile petridishes.

Quality Control

Dehydrated Appearance: Light yellow to yellow coloured, homogenous, free flowing powder.
Prepared Appearance: Light yellow to amber coloured, clear to slightly opalescent gel forms in petridishes.
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 ≤ 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	Incubation hours
Escherichia coli (8739)	Good	30°C-35°C	18 hours
Staphylococcus aureus subsp. *aureus* (6538)	Good	30°C-35°C	18 hours
Pseudomonas aeruginosa (9027)	Good	30°C-35°C	18 hours
Bacillus spizizenii (6633)	Good	30°C-35°C	18 hours
Salmonella enterica subsp. *enterica* serovar *Abony* (NCTC 6017)	Good	30°C-35°C	18 hours
Salmonella enterica subsp. *enterica* serovar *Typhimurium* (14028)	Good	30°C-35°C	18 hours
Candida albicans 3147 (10231)	Good	30°C-35°C	24 hours
Candida albicans 3147 (10231)	Good	20°C-25°C	48 hours
Aspergillus brasiliensis WLRI 034(120) (16404)	Good	30°C-35°C	48 hours
Aspergillus brasiliensis WLRI 034(120) (16404)	Good	20°C-25°C	72 hours

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.

Interpretation of Results

1. Count all developing colonies.
2. Interpretation of Results are relative, each laboratory should establish its own values for cleanness and compare the counts 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

Precautions/Limitations

1. Neutralization of disinfectant depends on its concentration and type.

Warranty

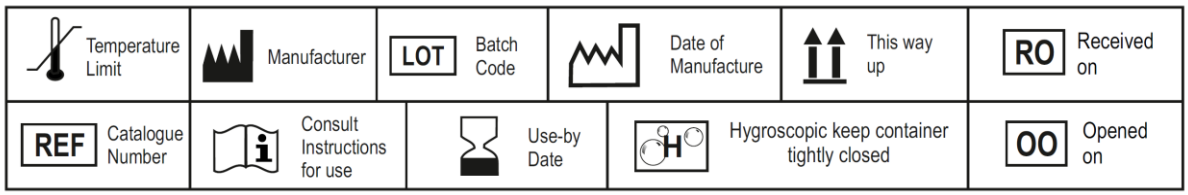
This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

References

1. Vesley D., Keenan K. M., AND Halbert M. M.1966.Appl. Environ. Microbiol.14: 203- 205.
2. Brumer B,1976 Appl. Environ. Microbiol.32:80.
3. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:

Cat No.	Product description	Pack Size
201200780100	Dehydrated Culture Media	100 g
201200780500	Dehydrated Culture Media	500 g



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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.