



Tryptic Soy Agar + Lecithin

Culture medium for environmental and personnel hygiene monitoring with inactivation of disinfectants.

INTENDED PURPOSE

Non-selective solid medium used for the monitoring of microbial contamination. This medium is not intended for use in the diagnosis of disease or other conditions in humans.

DESCRIPTION

Tryptic Soy Agar (TSA) + Lecithin is used for Total Colony Count in surfaces testing, including equipment and personnel, as well as in air sampling.

The composition of the culture medium complies with the recommendations of the harmonized chapter of the United States (USP), European (EP) and Japanese (JP) Pharmacopoeia with the addition of lecithin.

TYPICAL FORMULA* (Per Litre of Purified Water)

Casein Peptone	15.0 g
Soy Peptone	5.0 g
Sodium Chloride	5.0 g
Lecithin	0.7 g
Agar	15.0 g
Final pH 7.3 ± 0.2 at 25°C	

*Adjusted and/or supplemented as required to meet performance specifications.

METHOD PRINCIPLE

Casein peptone and soy peptone provide amino acids, nitrogen, carbon, minerals, vitamins and other nutrients which support the growth of microorganisms. Sodium chloride maintains the osmotic balance of the medium. Lecithin is a neutralizer particularly effective against quaternary ammonium compounds. Agar is the solidifying agent.

PREPARATION

Suspend 40.7 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil shaking frequently until completely dissolved. Sterilize in autoclave at 121°C for 15 minutes. Cool to 45-50°C and pour in Petri dishes or contact plates.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as: Autoclave, water bath, sterile Petri plates and/or Contact plates, air sampler, test tubes, inoculating loops, swabs, incubator, quality control organisms.

TEST PROCEDURE

For active air monitoring, place the contact plate, lid up, in the air sampler, remove the lid of the plate and sample a specific volume of air according to laboratory procedure.

For passive air monitoring, take the lid off the settle plate and leave the medium exposed to the air for a period of time no longer than 4 hours. The plates can be placed according to the 1/1/1 scheme (for 1 h, about 1 above the floor, at least 1 m from the walls or any obstacle).

For surfaces and personnel hygiene monitoring, take a swab sample for irregular surfaces or use a 10x10 cm sampling template in order to sample a well defined area and inoculate a 90 mm plate by streaking the swab over the agar surface. Alternatively, press directly the agar medium against the test area, including clothing, face masks and gloves/hands (e.g. in a 5-finger-print), for about 10 seconds. Do not move laterally the plate. Residues of the medium should be subsequently removed from the area tested.

After sampling close the plate with the lid and transfer to an incubator. Incubation conditions may vary depending on the organisms under study. For detection of bacteria incubate the plates at 30-35°C for 18-72 hours. For detection of yeasts and moulds incubate at 20-25°C for 2-7 days. Other temperature and time

conditions may be chosen but should be validated under the specific protocol used for environmental monitoring testing.

INTERPRETING RESULTS

Observe for the formation of colonies and record the number of CFU per plate.

The user is responsible for interpretation. It is recommended to establish alarm levels and levels that require user intervention, in order to take the most appropriate corrective action.

STORAGE

The powder is very hygroscopic, store the powder at 10-30°C, in a dry environment, in its original container tightly closed. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

SHELF LIFE

4 years

QUALITY CONTROL

Appearance of Dehydrated Medium: Free-flowing, homogeneous, beige.

Appearance of Prepared Medium: Slightly opalescent, light amber.

Expected Cultural Response:

Control strain		Inoculum	Incubation	Criteria	Specification
<i>Bacillus subtilis</i>	WDCM 00003 (ATCC® 6633; NCTC 10400)	≤100 CFU	18-24 h / 32.5 ± 2.5°C	P _R ≥ 0.7	Good growth
<i>Escherichia coli</i>	WDCM 00012 (ATCC® 8739; NCTC 12923)				
<i>Staphylococcus aureus</i>	WDCM 00032 (ATCC® 6538; NCTC 10788)				
<i>Pseudomonas aeruginosa</i>	WDCM 00026 (ATCC® 9027; NCTC 12924)				
<i>Candida albicans</i>	WDCM 00054 (ATCC® 10231; NCPF 3179)		Up to 48 h / 32.5 ± 2.5°C		
<i>Aspergillus brasiliensis</i>	WDCM 00053 (ATCC® 16404; NCPF 2275)		Up to 72 d / 22.5 ± 2.5°C		

A productivity ratio (P_R) of 0.7 is equivalent to a recovery rate of 70%.

Please refer to the actual batch related Certificate of Analysis (CoA).

PERFORMANCE CHARACTERISTICS

Performance testing of TSA + Lecithin was carried out using the QC strains listed above. The results obtained met the established criteria.

LIMITATIONS

Invalid results can be caused by poor sample quality, improper sample collection, improper transportation, improper laboratory processing, or a limitation of the testing technology. The operator should understand the principles of the procedures, including its performance limitations, in advance of operation to avoid potential mistakes.

Due to nutritional variation, some strains may be encountered that grow poorly or fail to grow on this medium.

WARNING AND PRECAUTIONS

For professional use only. Operators must be trained and have certain experience. Please read the instructions carefully before using this product. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this document.

Consult the Safety Data Sheet (SDS) for information regarding hazards and safe handling practices.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to national and local regulations in force.

BIBLIOGRAPHY

See the references at the end of this document.

TABLE OF SYMBOLS

See the table of symbols at the end of this document..

ORDER INFORMATION

Product	Format	Packaging	Ref.
Tryptic Soy Agar + Lecithin	Dehydrated media	500 g	610403

Revision History

Revision	Release Date	Change Summary
0	2024-03-13	Document creation

This IFU document and the SDS are available from the online Support Center:

liofilchem.com/ifu-sds

REFERENCES

1. EN ISO 11133:2014+Amd1:2018. Microbiology of food, animal feed and water – Preparation, production, storage and performance testing of culture media.
2. United States Pharmacopeial Convention (2014) The United States Pharmacopeia 38/National Formulation 33, Supp. 2. Chapter <61> Microbiological examination of non-sterile products: Microbial enumeration tests and Chapter <62> Microbiological examination of non-sterile products: Test for specified products. Chapter <71> Sterility Tests. Rockville, Md., USA.
3. European Directorate for the Quality of Medicines and Healthcare (2014) The European Pharmacopoeia. 8th Ed. Chapter 2.6.12 Microbiological examination of non-sterile products: Microbial enumeration tests and Chapter 2.6.13 Microbiological examination of non-sterile products: Test for specified products. Strasbourg, France.
4. PDA Technical Report No. 13 (2014 Revised) Fundamentals of an Environmental Monitoring Program.
5. Japanese Ministry of Health, Labour and Welfare (2011) The Japanese Pharmacopoeia. 16th Ed. Chapter 4.05 Microbial Limit Test I. Microbiological examination of non-sterile products: Total viable aerobic count and II. Microbiological examination of non-sterile products: Test for specified products. Japanese Ministry of Health, Labour and Welfare. Tokyo, Japan.
6. Pharmaceutical Inspection Convention Co-operation Scheme (PIC/S). Recommendation on the Validation of Aseptic Processes (2011) Revision 6.
7. FDA (2004) Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice.
8. Swanson KJ, Busta FF, Peterson EH, and Johnson MG (1992). Colony Count Methods, p. 75-95.

TABLE OF SYMBOLS

	Batch code
	Catalogue number
	Manufacturer
	Use by
	Fragile, handle with care
	Temperature limitation
	Contains sufficient for <n> tests
	Consult instructions for use
	Do not reuse
	Keep away from sunlight



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