Technical Specification Sheet



Tryptic Soy Agar (Soybean-Casein Digest Agar) (NCM0002)

Intended Use

Tryptic Soy Agar is used for the preparation and maintenance of test strains used in growth promotion tests, suitability of the counting methods and as negative controls as described in the Harmonized USP/EP/JP. It is also a support plating medium for various protocols described in the microbial enumeration test section of the Harmonized USP/EP/JP. Tryptic Soy Agar is not intended for use in the diagnosis of disease or other conditions in humans.

Enzymatic digests of casein and soybean act as a source of nitrogen and amino acid and sodium chloride maintains the osmotic balance.

Typical Formulation

Enzymatic Digest of Casein 15.0 g/L
Enzymatic Digest of Soybean 5.0 g/L
Sodium Chloride 5.0 g/L
Agar 15.0 g/L

Final pH: 7.3 ± 0.2 at 25°C

Formula may be adjusted and/or supplemented as required to meet performance specifications.

Precaution

Refer to SDS

Preparation

- 1. Suspend 40 grams of the medium in one liter of purified water.
- 2. Heat with frequent agitation and boil for one minute to completely dissolve the medium.
- 3. Autoclave at 121°C for 15 minutes.
- 4. Cool to 45-50°C.

Test Procedure

Refer to appropriate references for specific procedures using Tryptic Soy Agar.

Quality Control Specifications

Dehydrated Appearance: Powder is homogeneous, free flowing and light beige.

Prepared Appearance: Prepared medium without enrichment is trace to slightly hazy and yellow beige in color. Prepared medium with 5% sheep blood is red and opaque.



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Expected Cultural: Cultural response on Tryptic Soy Agar tested at Harmonized USP/EP/JP specified temperatures and incubation times.

| Microorganism | Approx. Inoculum (CFU) | Recovery |
|--|---------------------------|----------|
| Aspergillus brasiliensis ATCC® 16404 | 10-100 | 70-200% |
| Bacillus subtilis ATCC® 6633 | 10-100 | 70-200% |
| Candida albicans ATCC® 10231 | 10-100 | 70-200% |
| Escherichia coli ATCC® 8739 | 10-100 | 70-200% |
| Pseudomonas aeruginosa ATCC® 9027 | 10-100 | 70-200% |
| Salmonella typhimurium ATCC® 14028 | 10-100 | 70-200% |
| Staphylococcus aureus ATCC® 6538 | 10-100 | 70-200% |
| Staphylococcus epidermidis ATCC® 12228 | 10-100 | 70-200% |

Tryptic Soy Agar was prepared according to label directions with 5% sheep blood and inoculated. Cultures were incubated at 30 - 35°C under the appropriate atmosphere and examined for growth at 18 – 24 hours.

| Microorganism | Approx. Inoculum (CFU) | Expected Results | |
|-------------------------------------|---------------------------|------------------|-----------------|
| | | Recovery | Hemolysis |
| Escherichia coli ATCC® 25922 | 10 - 100 | 70-200% | Beta hemolysis |
| Staphylococcus aureus ATCC® 25923 | 10 - 100 | 70-200% | Beta hemolysis |
| Streptococcus pneumoniae ATCC® 6305 | 10 - 100 | 70-200% | Alpha hemolysis |
| Streptococcus pyogenes ATCC® 19615 | 10 - 100 | 70-200% | Beta hemolysis |

The organisms listed are the minimum that should be used for quality control testing.

Results

Refer to appropriate references for test results.

Expiration

Refer to expiration date stamped on the container. The dehydrated medium should be discarded if it is not free flowing, or if medium has changed from the original color. Expiry applies to medium in its intact container when stored as directed.

Limitations of the Procedures

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

Storage

Store dehydrated culture media at $2-30^{\circ}$ C away from direct sunlight. Once opened and recapped, place the container in a low humidity environment at the same storage temperature. Protect from moisture and light by keeping container tightly closed.

References

- 1. European Pharmacopoeia 10th Edition (2020)
- 2. United States Pharmacopeia National Formulary 2018: USP 41 NF 36
- 3. Japanese Pharmacopeia 17th Edition (2017)
- 4. Orth, D. S. 1993. Handbook of cosmetic microbiology. Marcel Dekker, Inc., New York, NY.



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- 5. Greenberg, A. E., L. S. Clesceri, and A. D. Eaton (eds.). 2017. Standard methods for the examination of water and wastewater, 23rd ed. American Public Health Association, Washington, D.C.
- 6. <u>www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalytical manualBAM/default.htm.</u>
- 7. Curry, A. S., G. G. Joyce, and G. N. McEwen, Jr. 1993. CTFA Microbiology guidelines. The Cosmetic, Toiletry, and Fragrance Association, Inc. Washington, D.C.