Tryptone Soy Agar (Harmonized) RDM-H-TSA-02

Principle
Tryptone Soy Agar (Harmonized) is used for cultivation of a wide variety of organisms. It is also recommended by USP, IP and EP for sterility testing and as medium for microbial limit testing of pharmaceutical products and raw material used in pharmaceutical industries. The medium is a highly nutritious and prepared in accordance with the harmonized principles of USP/EP/IP. Medium is consisting of pancreatic digest of casein, papain digest of soybean, sodium chloride and agar. The pancreatic digest of casein, papain digest of soybean provides ample amount of the carbon and nitrogen source and trace. Sodium chloride maintains the osmotic balance and agar is used as solidifying agent.

Use: Recommended for the cultivation of a wide variety of microorganisms from pharmaceutical products in accordance with harmonized method of USP/EP/BP/JP/IP.

Contents*

Ingredients	Gram/Liter
Casein peptone	15.00
Soy peptone	5.00
Sodium chloride	5.00
Agar	15.00
pH at 25˚C	7.3 ±0.2

* Formula adjusted for optimum performance and parameters

Directions: Dissolve 40.00 grams in 1000 ml distilled. Boil to dissolve the medium completely. Sterilize by autoclaving at 15 lbs pressure (121 °C) for 15 min, cool it to 42-45 °C and distribute aseptically in petri plates and allow to solidify. Ensure complete solidification and inoculate test sample aseptically.

Specimens types analyzed
Pharmaceutical samples, clinical and non-clinical sample.

Precautions to be taken
All the handling, experiments, storage, and discarding should be performed with the help of skilled and knowledgeable technicians and as per the established guidelines. The material should be disposed only after proper sterilization by autoclaving. Please go through the MSDS of the media to avoid any accidents or in emergency.

Performance and Evaluation
The expected performance of the medium is liable to use as per the direction on the label when stored at optimum conditions and within expiry date.

Quality Control

Appearance	Light beige colored, free-flowing, homogeneous
Reaction of 4.0% solution	7.30 ±0.2 at 25 ˚C
pH	7.10- 7.50
Gelling	Firm comparable with 1.5% agar gel
Color and clarity of ready medium	Light amber, clear to slightly opalescent gel
Growth Promotion properties	Best at ≤ 100 CFU at 30-35ºC for 18-24 hours for bacteria and

	20°C-25°C 3-5 days for fungi.
Indicative properties	Optimum at ≤ 100 CFU at 30-35ºC for 18-24 hours for bacteria and 20°C-25°C 3-5 days for fungi.
Negative control	Performed using sterile distilled water

Different Microbial Response

Prepare media as per the label directions.

Growth Promotion Test: Growth promotion is carried out in accordance with the harmonized method of USP/EP/JP/IP and growth is observed after incubation at 30-35°C for 18-24 hours for bacteria and 20°C-25°C 3-5 days for fungi.

Organism	ATCC	Inoculum (CFU)	Growth	Recovery
Staphylococcus aureus	6538	50-100	Luxuriant	≥ 70 %
Staphylococcus aureus	25923	50-100	Luxuriant	≥ 70 %
Bacillus spizizenii	6633	50-100	Luxuriant	≥ 70 %
Pseudomonas aeruginosa	9027	50-100	Luxuriant	≥ 70 %
Pseudomonas aeruginosa	27853	50-100	Luxuriant	≥ 70 %
Salmonella typhimurium	14028	50-100	Luxuriant	≥ 70 %
Escherichia coli	8739	50-100	Luxuriant	≥ 70 %
Candida albicans	10231	50-100	Luxuriant	≥ 70 %
Aspergillus brasiliensis	16404	50-100	Luxuriant	≥ 60 %

Storage and Shelf Life: The product is highly hygroscopic; keep the container tightly closed at all times and store it properly as per the conditions mentioned on the label. The declared expiry is valid only when stored as per the conditions mentioned on the label.

Note: Sterilize media immediately after reconstitution.

Disposal: To avoid the contamination or propagation of any hazardous microbes the used, unusable or modified preparation of this product must be disposed after autoclaving after completion of task.

Reference

1. Atlas, R. M. (2005). Handbook of media for environmental microbiology. CRC press.
2. British Pharmacopoeia, (2011), The Stationery office British Pharmacopoeia
3. Difco Manual (1998). 11th Edition. Difco Laboratories., Division of Becton Dickinson and Company, Sparks, Maryland, USA.
4. European Pharmacopoeia, (2011), European Dept. for the quality of Medicines.
5. Indian Pharmacopoeia, (2018), Govt. of India, the Controller of Publication, New Delhi.
6. Rand, M. C., Arnold E. Greenberg, and Michael J. Taras, (1976), Standard methods for the examination of water and wastewater. Prepared and published jointly by American Public Health Association, American Water Works Association, and Water Pollution Control Federation.
7. The Japanese Pharmacopoeia, 17th Ed. (2016), The Ministry of Health, Labour and Welfare
8. The United States Pharmacopoeia, (2014), The United States Pharmacopeial Convention. 12601 Twinbrook Parkway, Rockvukke, MD 20852.