Technical Data Sheet

Tryptic Soy Broth + 1 % Tween® 80

Ordering number: 1.46669.0006

Tryptic Soy Broth with 1 % Tween® 80 is a universal complex medium for the isolation and cultivation of fastidious aerobic bacteria, yeasts and molds.

The medium is designed for the testing of sterile and non-sterile substances, preparations and products according to the European Pharmacopoeia (EP) and the United States Pharmacopoeia (USP).

The formulation of the basic medium (Soybean-Casein Digest Broth) is prepared according to the recommendations of the current European, Japanese and United States Pharmacopoeia (EP, 2.6.1.; JP, 4.06 and USP, 71).

Tryptic Soy Broth is available in various concentration of Tween® 80, filling volumes and with various locking mechanisms:

- Tryptic Soy Broth + 0.1 % Tween® 80 (article number 146623): 17 ml-tube, filling volume 9 ml
- Tryptic Soy Broth + 0.1 % Tween® 80 (article number 146630): 250 ml-bottle with **screw cap**, filling volume 90 ml
- Tryptic Soy Broth + 0.1 % Tween® 80 (article number 146376): 1000 ml-bottle with **screw cap**, filling volume 1000 ml
- Tryptic Soy Broth + 0.5 % Tween® 80 (article number 146714): 125 ml-bottle with **flip cap**, filling volume 100 ml
- Tryptic Soy Broth + 1 % Tween® 80 (article number 146669): 500 ml-bottle with combined **septum** and **screw cap**, filling volume 500 ml

Mode of Action

Tryptic Soy Broth is a highly nutritious media and hence supports the growth of a wide variety of aerobic and facultative anaerobic microorganisms including fungi. The addition of polysorbate 80 (Tween® 80) serves as neutralizing agent for disinfectants such as quaternary ammonium compounds, iodines and parabens.

Typical Composition

Additive	TSB + 0.1% Polysorbate (Tween®) 80	TSB + 0.5% Polysorbate (Tween®) 80	TSB + 1% Polysorbate (Tween®) 80
Casein Peptone	17 g/l	17 g/l	17 g/l
Soy Peptone	3 g/l	3 g/l	3 g/l
Glucose	2.5 g/l	2.5 g/l	2.5 g/l
K_2HPO_4	2.5 g/l	2.5 g/l	2.5 g/l
NaCl	5 g/l	5 g/l	5 g/l
Polysorbate (Tween®) 80	1 ml/l	5 ml/l	10 ml/l

The appearance of the medium is clear and yellowish. The pH value is in the range of 7.1-7.5. The medium can be adjusted and/or supplemented according to the performance criteria required.

Application and Interpretation

Tryptic Soy Broth with Polysorbate 80 is provided in tube and bottle and can be used for the detection of aerobic and anaerobic microorganisms in sterile and non-sterile products.

Sterility testing:

According to EP sterility tests may be carried out using the technique of membrane filtration or by direct inoculation.

For membrane filtration, diluents e.g. Fluid A (article number 146470) or Fluid D (article number 146397) may be used. The filter or its half is transferred into Tryptic Soy Broth or vice versa and incubated at 20-25 °C for not less than 14 days.

For direct inoculation the volume of the sample which has to be tested should not extend 10 % of the volume of the Tryptic Soy Broth and incubated at 20-25 °C for not less than 14 days.

If the material to be tested renders the medium turbid and a visual examination is not possible after 14 days of incubation, portions not less than 1 ml of the inoculated Tryptic Soy Broth are transferred into fresh Tryptic Soy Broth. The original inoculated broth as well as the freshly inoculated broth are incubated at 20-25 °C for not less than 4 days and examined again.

In case of growth it is recommended to identify the colonies using microbiological methods (e.g. selective media, biochemical methods) in order to identify and remove the source of contamination.

Non sterile testing:

For total aerobic microbial count (TAMC), the product to be tested should be prepared as described in EP (2.6.12). 1g or 1ml of the prepared sample is used to inoculate Tryptic Soy Broth with Polysorbate 80, which is then incubated at 30-35°C for up to 3 days. Subculture can be performed on Tryptic Soy Agar (Article No: 146004) and incubated at 30-35°C for 24-48 h.

Storage and Shelf Life

The product can be used for tests until the expiry date if protected from light and properly sealed at +2 °C to +25 °C.

The testing procedures as described on the CoA can be started up to the expiry date printed on the label.

Disposal

Please mind the respective regulations for the disposal of used culture medium (e.g. autoclave for 20 min at 121 °C, disinfect, incinerate etc.).

Quality Control

Control Strains	ATCC #	Inoculum CFU	Incubation	Expected Results
Staphylococcus aureus	6538	10-100	20-24 h at 30-35 °C	good growth; pronounced turbidity
Pseudomonas aeruginosa	9027	10-100	20-24 h at 30-35 °C	good growth; pronounced turbidity
Bacillus subtilis	6633	10-100	20-24 h at 30-35 °C	good growth; pronounced turbidity
			3 d at 20-25 °C	good growth; pronounced turbidity
Candida albicans	10231	10-100	max. 5 d at 20-25 °C	good growth; pronounced turbidity
Aspergillus brasiliensis	16404	10-100	max. 5 d at 20-25 °C	good growth; pronounced flocculation

Please refer to the actual batch related Certificate of Analysis.

Literature

European Pharmacopoeia 8.0 (2014): 2.6.1. Sterility; 2.6.12. Microbial examination of non-sterile products (total viable aerobic count).

Japanese Pharmacopoeia 16th edition (2011): 4.05 Microbial Limit Test; 4.06 Sterility Test.

United States Pharmacopoeia 38 NF 33 (2015): <71> Sterility Tests; <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests.

Ordering Information

Product	Cat. No.	Pack size
Tryptic Soy Broth + 1 % Tween® 80	1.46669.0006	6 x 500 ml bottle
Tryptic Soy Broth + 0.1 % Tween® 80	1.46623.0020	20 x 9 ml tube
Tryptic Soy Broth + 0.1 % Tween® 80	1.46630.0006	6 x 90 ml bottle
Tryptic Soy Broth + 0.1 % Tween® 80	1.46376.0006	6 x 1000 ml bottle
Tryptic Soy Broth + 0.5 % Tween® 80	1.46714.0010	10 x 100 ml bottle
Fluid A	1.46470.0010	10 x 100 ml bottle
Fluid D	1.46397.0010	10 x 100 ml bottle
Tryptic Soy Agar - LI	1.46004.0020	20 x 90 mm plate
Tryptic Soy Agar - LI	1.46004.0120	120 x 90 mm plate

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