

Technical Data Sheet

Tryptic Soy Broth (TSB) – Media Fill 10l

Ordering number: 146316



Tryptic Soy Broth is a universal complex medium for the isolation and cultivation of microorganisms, especially for the microbiological validation of aseptic filling processes (Media Fill Test).

The broth is suitable for media fill tests according to the recommendations of the "FDA Aseptic Guide" in aseptic production lines.

The formulation of the basic medium (Soybean-Casein Digest Broth) is prepared according to the recommendations of the current European and United States Pharmacopoeia (EP, 2.6.12.; JP, 4.05 and USP, 61).

Mode of Action

Tryptic Soy Broth is suitable for use in media fill tests. The included peptones and glucose allow the cultivation and isolation of a broad range of fastidious aerobic bacteria, yeasts and molds.

Typical Composition

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Casein Peptone	17 g/l
Soy Peptone	3.0 g/l
NaCl	5.0 g/l
K ₂ HPO ₄	2.5 g/l
Glucose Monohydrate	2.5 g/l

Preparation

The 10l bags are ready-to-use.

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.

Description

The medium is very suitable for the simulation of aseptic filling processes. The fluid medium is autoclaved and filled into the previously gamma-sterilized, multilayer bags via a sterile filter (pore size 0.2 µm). After filling the bags are triple bagged and gamma-irradiated at a dose of 9-20 kGy.

The self-collapsing bag contains an 80 cm long tube with an MPC connector (male insert 3/8 ") for removal of the medium. The short tube is used for filling of the bag and should not be used for media fill tests. In addition, a third short tube with septum is available, which allows the supplementation of the broth medium, e.g. with neutralizers, antibiotic inactivators or growth supplements.



Application

Media Fill tests are simulations of aseptic production processes. Following the "FDA Aseptic Guide" the complete process should be simulated by using culture media instead of regularly processed products. Detailed information about study design is given in the "FDA Aseptic Guide". After completion of the filling process each device is checked for sterility. An incubation time of 14 days at 20 to 35 °C is recommended. The incubation temperature should be maintained within ± 2.5 °C of the target temperature. If different incubation temperatures are chosen for the incubation of filled media fill units, the units should be incubated for at least 7 days at lower temperature followed by 7 days at higher temperature.

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 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 #	Incubation	Expected Results
<i>Staphylococcus aureus</i>	6538	1 - 3 days; 30°C - 35°C	Visible growth
<i>Pseudomonas aeruginosa</i>	9027	1 - 3 days; 30°C - 35°C	Visible growth
<i>Bacillus subtilis</i>	6633	1 - 3 days; 30°C - 35°C	Visible growth
<i>Bacillus subtilis</i>	6633	2 - 3 days; 20°C - 25°C	Visible growth
<i>Geobacillus stearothermophilus</i>	7953	1 - 3 days; 55°C - 60°C	Visible growth
<i>Candida Albicans</i>	10234	2 - 5 days; 20°C - 25°C	Visible growth
<i>Aspergillus brasiliensis</i>	16404	2 - 5 days; 20°C - 25°C	Visible growth

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).

Guidance for Industry (2004): Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice.

Hedderich, A., Klees, A., Eiermann, K., Greulich, Y. and Müller, R. (2009): Growth promoting properties of a vegetable peptone broth (VPB) in comparison to tryptic soy broth (TSB). Poster presentation at PDA's Annual Global Conference on Pharmaceutical Microbiology.

Japanese Pharmacopoeia 17th edition (2016): 4.05 Microbial Limit Test.

PDA Technical Report No. 13 (2014 Revised): Fundamentals of an Environmental Monitoring Program.

United States Pharmacopoeia 38 NF 33 (2015): <61> Microbial Limit Tests; <71> Sterility Tests.

Ordering information

Product	Cat. No.	Pack size
Tryptic Soy Broth - Media Fill 10l	1463160001	1 x 10l

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