Millipore®
Preparation, Separation,
Filtration & Monitoring Products

Data Sheet

Fluid Thioglycollate Medium

Ordering number: 1.46220.0100

Fluid Thioglycollate Medium is a universal complex medium for the isolation and cultivation of fastidious anaerobic as well as for aerobic microorganisms. Fluid Thioglycollate Medium is used for sterility control of pharmaceutical products.

The formulation of the basic medium is prepared according to the recommendations of the current European and United States Pharmacopoeia (EP, 2.6.1. and USP, 71).

The Fluid Thioglycollate Medium is available in different filling volumes and various locking mechanism:

- Fluid Thioglycollate Medium (article number 146220): **tube,** filling volume 9 mL
- Fluid Thioglycollate Medium (article number 146139): **tube,** filling volume 10 mL
- Fluid Thioglycollate Medium (article number 146385): 125 mL-bottle with **screw cap,** filling volume 100 mL

Mode of Action

Thioglycollate and L-Cystine in the medium reduce the redox potential of the culture medium in order to create an anaerobic atmosphere. In addition, mercury and other heavy metal compounds are inactivated by these agents. The content of agar further reduces a rapid diffusion of oxygen through the medium, but may lead to a slight turbidity in larger volumes (filled bottles). Resazurin indicates the reduction potential of the medium. An increased concentration of oxygen is indicated by a color change to pink.

Typical Composition

Casein Peptone	**15 g/L**
Yeast extract	**5 g/L**
Glucose Monohydrate	**5.5 g/L**
NaCl	**2.5 g/L**
L-Cystine	**0.5 g/L**
Sodium Thioglycollate	**0.5 g/L**
Resazurin	**1 mg/L**
Agar	**0.75 g/L**

The appearance of the medium is clear to slightly turbid and yellowish. The pH value is in the range of 6.9-7.3. The medium can be adjusted and/or supplemented according to the performance criteria required.

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Application and Interpretation

The broth medium should be equilibrated to room temperature before use.

The surface of the containers, including the septum below the protective cap, is not sterile. Therefore, please be aware about a risk of secondary contamination due to handling. In order to reduce the risk of secondary contamination by defect glass containers or handling the following recommendations may be helpful:

- Please control each single container for visible defects or turbidity. Do not use such containers.
- Please avoid the contamination of culture media by contact with skin or body fluids. Such contaminated media cannot be used anymore.
- In the case of negative pressure due to prior heat-sterilization, the containers should be ventilated by sterile filter-units before usage to avoid aspiration of potential contaminated air.
- The risk of transfer of microorganisms from the surface of the containers into the sterile culture medium can be minimized by disinfection of these surfaces followed by handling in sterile environments, e.g. isolators. The inoculation of the containers by sterile cannulas is safer than procedures which require opening of media bottles or tubes.

Media which contain ingredients of animal or human origin such meat extract must be considered potentially infectious. After contact of such media a disinfection of the affected skin area is recommended.

Strictly anaerobic microorganisms such as *Clostridium sporogenes* are growing in the lower, yellowish part of the broth medium. The growth of facultative anaerobic microorganisms such as *Staphylococcus aureus* is distributed in the complete broth medium. Aerobic microorganisms such as *Pseudomonas aeruginosa* are able to grow in the upper, oxidized part of Fluid Thioglycollate Medium indicated by a slight pink color. Usually the incubation is performed under aerobic conditions. Not more than the upper half of the medium should have undergone a color change to pink indicative of oxygen uptake at the end of the incubation period.

Fluid Thioglycollate Medium is recommended for sterility testing of pharmaceutical products according to the European and US Pharmacopoeia. According to the Pharmacopoeia a membrane filtration method should be performed wherever possible, but also direct inoculation methods are possible.

Fluid Thioglycollate Medium (Ordering information table - page 3) - due to their closure system and filling volumes - are solely designed and tested for direct inoculation method.

If a completely clear Fluid Thioglycollate Medium is required for direct inoculation, we offer Fluid Thioglycollate Medium Clear (Ordering information table - page 3). Fluid Thioglycollate Medium Clear contains a reduced Agar content, whereby the other part of agar is replaced by a clear gelling agent. This does not influence the growth promoting properties of the medium.

Note: For membrane filtration application, we recommend the use of our 100 mL Fluid Thioglycollate Medium or our 100 mL clear Fluid Thioglycollate Medium (Ordering information table - page 3).

For direct inoculation the amount of the inoculated sample material should not exceed 10% of the volume of Fluid Thioglycollate Medium. Fluid Thioglycollate Medium is incubated for 14 days at 30 to 35 °C and visually inspected for growth.

The sterility test is passed, if no growth is visible at the end of incubation.

It is recommended to identify grown microorganisms in order to find out the origin of contamination and to implement corrective actions.

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
Clostridium sporogenes	**19404**	10-100	20-24 h at 33-35 °C	good growth; pronounced turbidity
Clostridium sporogenes	**11437**	10-100	20-24 h at 33-35 °C	good growth; pronounced turbidity
Staphylococcus aureus	**6538**	10-100	20-24 h at 33-35 °C	good growth; pronounced turbidity
Pseudomonas aeruginosa	**9027**	10-100	20-24 h at 33-35 °C	good growth; pronounced turbidity

Please refer to the actual batch related Certificate of Analysis.

Literature

European Pharmacopoeia 9.0 (2016): 2.6.1. Sterility.

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

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

United States Pharmacopoeia 41 (2018): <71> Sterility Tests.

Ordering Information

Product	Cat. No.	Pack size
Fluid Thioglycollate Medium	**1.46220.0100**	100 x 9 mL tubes
Fluid Thioglycollate Medium	**1.46139.0100**	100 x 10 mL tubes
Fluid Thioglycollate Medium	**1.46385.0010**	10 x 100 mL bottles
Fluid Thioglycollate Medium	**1.46386.0010**	10 x 100 mL bottles
Fluid Thioglycollate Medium	**1.46406.0010**	10 x 100 mL bottles
Fluid Thioglycollate Medium Clear	**1.46333.0010**	10 x 100 mL bottles
Fluid Thioglycollate Medium Clear	**1.46456.0010**	10 x 100 mL bottles
Fluid Thioglycollate Medium Clear	**1.46387.0006**	6 x 750 mL bottles
Fluid Thioglycollate Medium Clear	**1.46590.0006**	6 x 900 mL bottles

To place an order or receive technical assistance

Order/Customer Service:
SigmaAldrich.com/order

Technical Service:
SigmaAldrich.com/techservice

SigmaAldrich.com/sterilitytesting

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