



# Fluid Thioglycollate Media

Ordering number: 1669030012-CN

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 125 ml-bottles are filled with 100ml of media and closed with a screw cap and septum and packed 12/box.

The formulation of the basic medium is prepared according to the recommendations of the current European, Japanese and United States Pharmacopoeia.

## 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	15.0 g/l
Yeast Extract	5.0 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	1.0 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.

## Application and Interpretation

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

The surface of the containers 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.
- 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 or the media transfer into membrane filtration units 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 as 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 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. To provide enough oxygen for the growth of aerobic microorganisms in bottles sterile ventilation device may be necessary. But 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.

If a sterile aeration device is not available, ventilation of the bottle must be performed in a sterile environment (isolator, cleanroom class A).

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.

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 Strain	ATCC #	Inoculum CFU	Incubation	Expected Result
<i>Clostridium sporogenes</i>	19404	10-100	less than 72h at 30-35 °C	good growth; pronounced turbidity
<i>Staphylococcus aureus</i>	6538	10-100	less than 72h at 30-35 °C	good growth; pronounced turbidity
<i>Pseudomonas aeruginosa</i>	9027	10-100	less than 72h at 30-35 °C	good growth; pronounced turbidity

Please refer to the actual batch related Certificate of Analysis.

## Literature

European Pharmacopoeia: 2.6.1. Sterility

Japanese Pharmacopoeia: 4.06. Sterility Test

United States Pharmacopoeia: <71> Sterility Tests

## Ordering Information

Product	Cat. No.	Pack size
Fluid Thioglycollate Medium 100ml 12/PK	1669030012-CN	12 x 100 ml bottles

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