

Alternative Fluid Thioglycollate medium/ FTM without Resazurine

356-4224

DEFINITION

Medium used for sterility tests using the membrane filtration method or direct inoculation.

STANDARDS

USP 30/NF 25 US Pharmacopeia and National Formulary (2007): Sterility Tests (71)
- Microbiological Tests

PRESENTATION

Dehydrated

500 g

code 356-4224

STORAGE

- Dehydrated: +15-25°C, in carefully sealed bottles in a cool, dry place
- Expiration date and batch number are shown on the package.

TYPICAL FORMULA

Pancreatic casein hydrolysate	15 g
Yeast extract	5 g
Sodium thioglycollate	0.5 g
Sodium chloride	2.5 g
L-cystine	0.5 g
Glucose	5.5 g
Distilled water	1,000 ml
Final pH (25°C) = 7.1 ± 0.2	

NB: the formula has been adapted to attain the required performance criteria.

OTHER PRODUCTS REQUIRED (NOT SUPPLIED)

- Diluent(s)
- Distilled water

EQUIPMENT REQUIRED (NOT SUPPLIED) (non-exhaustive)

- Scales
- Sterile weighing bags
- Grinder
- Hotplate
- Mixer-homogenizer
- Test tubes (16 x 160 mm) with autoclave-proof stoppers
- 50 ml Pyrex bottles with autoclave-proof stoppers
- Sterile pipettes (0.1 ml, 1 ml, etc)
- Sterile Pasteur pipettes or inoculating loop
- Filtration apparatus

- Membrane filters ($\varnothing = 47$ mm and ≤ 0.45 mm)
- Tweezers for handling membranes
- Water-bath precise to $\pm 1^\circ\text{C}$
- Thermostatically-controlled incubator or incubation room, precise to $\pm 1^\circ\text{C}$
- Autoclave
- All usual laboratory equipment

PREPARATION OF DEHYDRATED MEDIUM

Always shake well before use.

Dissolve 29 g of powder in 1 liter of distilled water. Bring to boiling point until completely dissolved.

Pour into tubes or bottles and sterilize in autoclave at $121^\circ\text{C} \pm 1^\circ\text{C}$ for 15 minutes.

The medium should be used immediately after its preparation, otherwise it will require regeneration in a boiling water-bath before use, followed by rapid cooling.

Reconstitution ratio: 29 g/l

500 g of powder makes 17.2 liters of medium.

PROTOCOL

• Preparation of samples

According to the standards applicable to the product concerned.

• Inoculation and incubation

- Membrane filtration

Collect the recommended quantity of product to be examined (in solution if the product is solid). Filter, then under aseptic conditions introduce the membrane into the medium.

- Direct inoculation

Collect the recommended quantity of product to be analyzed and introduce it into the medium.

In both cases, incubate in anaerobiosis: 30-35°C for 7 days for the detection of bacteria.

PRECAUTIONS

- The time lapse between the end of preparation of the stock solution (or the 10^{-1} dilution in the case of a solid product) and the moment when the dilutions come into contact with the culture medium must not exceed 15 minutes.
- Comply with Good Laboratory Practice.

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QUALITY CONTROL

In view of the current harmonization of pharmacopoeias, we recommend that you refer to the certificates of analysis for procedures relating to the quality control (performance and selectivity) of media produced by Bio-Rad.

Every product manufactured and marketed by Bio-Rad is subject to a quality-assurance procedure at all stages, from the reception of raw materials to the marketing of the end-product. Each batch of finished product undergoes quality control and is marketed only if it satisfies the acceptability criteria.

Documentation relative to the production and control of each batch is kept on file.

KEY WORDS

Thioglycollate without Resazurine/Sterility tests/Filtration/Direct inoculation/Medium