TECHNICAL DATA SHEET

THIOGLYCOLATE BROTH WITH RESAZURIN HALAL (FTM HALAL)

STERILITY TESTS

1 INTENDED USE

Thioglycolate Medium with Resazurin is used for sterility tests of biological products and for the culture of aerobic, anaerobic and microaerophilic bacteria. The typical composition corresponds to that defined in European (EP), United States (UP) and Japanese (JP) Pharmacopeias, and the AOAC for the bacteriological analysis of antibiotics and the determination of the sporicidal effect of disinfectants. The manufacturing protocol and the rigorous selection of solidification agents allow the special transparency of this media.

The medium is certified Halal by Halal Feed and Food Inspection Authority (HFFIA), The Hague, Netherlands.

2 HISTORY

Brewer demonstrated the value of this medium, containing a small quantity of agar and of a reducing substance, for the culture of anaerobic bacteria in the presence of sodium thioglycolate. Nungester, Hood and Warren then showed that sodium thioglycolate neutralized the inhibitory effect of mercuric compounds present in the samples analyzed. Malin and Flynn observed that in the presence of carbohydrates, thioglycolate was slightly inhibitory for several species.

3 PRINCIPLES

Enzymatic digest of casein (Halal certified), yeast extract, cystine and glucose assures the growth of a large variety of aerobic and anaerobic bacteria.

Sodium thioglycolate at the concentration of 0.05% decreases the redox potential without having a toxic effect. It also neutralizes the antibacterial power of mercuric derivatives used as preservatives in biological products.

Agar favors the development of anaerobic bacteria by stabilizing the medium against convection currents so anaerobiosis is maintained in the lower part of the recipients.

Resazurin, less toxic than methylene blue, is used as a redox indicator: it is colorless in a reducing medium and becomes pink in an oxidized medium.

4 TYPICAL COMPOSITION

The composition can be adjusted in order to obtain optimal performance.

For 1 liter of media:

- Enzymatic digest of Casein Halal ..... 15.00 g
- Yeast extract ..... 5.00 g
- Glucose monohydrate ..... 5.50 g
- Sodium chloride ..... 2.50 g
- Sodium thioglycolate ..... 0.50 g
- L-cystine ..... 0.50 g
- Resazurin ..... 1.0 mg
- Solidifying agents ..... 0.75 g

pH or the ready-to-use media at 25 °C: 7.1 ± 0.2.

5 PREPARATION

- Dissolve 29.7 g of dehydrated media (BK245) in 1 liter of distilled or demineralized water.
- Slowly bring to boiling, stirring with constant agitation until complete dissolution.
- Dispense into tubes of vials.
- Sterilize in an autoclave at 121°C for 15 minutes.
- Cool the media to room temperature.

✓ **Reconstitution:**
29.7 g/L

✓ **Sterilization:**
15 min at 121 °C

6 INSTRUCTIONS FOR USE

- Inoculate the sample to test, according to the protocols in use defined in the pharmacopeia, in tubes or vials prepared as above.
- Incubate for at least 14 days at 30-35 °C.

Incubation:
14 days at à 30-35 °C

Note:
If, before inoculation, the media demonstrates a slight pinkish tint, (sign of oxidation), greater that 1/3 of the height of the tube from the surface, the anaerobic conditions should be restored by heating to 95-100°C for 10 minutes. Do not repeat this operation more than once.

7 QUALITY CONTROL

Dehydrated media: cream-white powder, free-flowing and homogeneous.
Prepared media: semi-solid medium, slightly opalescent, light amber with a pink ring on the surface.

Typical culture response after 72 hours of incubation at 30-35 °C, inoculum ≤ 10^2 microorganisms (acc. EP, USP, JP):

Microorganisms		Growth
Staphylococcus aureus	WDCM 00032	Positive
Pseudomonas aeruginosa	WDCM 00026	Positive
Clostridium sporogenes	WDCM 00008	Positive

8 STORAGE / SHELF LIFE

Dehydrated media: 2-30 °C.
The expiration dates are indicated on the labels.

Prepared media in tubes or vials (*): 180 days at 2-8 °C.
(*) Benchmark value determined under standard preparation conditions, following manufacturer's instructions.

9 PACKAGING

Dehydrated media:
500 g bottle..... BK245HA
5 kg drum BK245GC

10 BIBLIOGRAPHY

Brewer, J.H. 1940. Clear Liquid medium for the "aerobe" cultivation of anaerobes. JAMA, 115: 598.

MacFaddin, J.F. 1985. Media for Isolation. Cultivation. Identification. Maintenance of Medical Bacteria. Vol 1. Williams and Wilkins. Baltimore, 755-762.

European Pharmacopeia. Chapitre 2.6.1. Sterility tests. Harmonized text.

The United States Pharmacopeia. Chapter <71> Sterility tests.

The Japanese Pharmacopoeia. Chapter 4.06 Sterility tests.

11 ADDITIONAL INFORMATION

The information provided on the labels take precedence over the formulations or instructions described in this document and are susceptible to modification at any time, without warning.

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