

Reference: DSHB3056

Product:

Specification

Highly nutritious general purpose medium for the isolation and cultivation of fastidious and non-fastidious microorganisms according to Pharmacopeial Harmonized Methods.

Formula * in q/L

| <u> </u> | |
|-----------------|-------|
| Casein peptone | 10.00 |
| Meat peptone | 5.00 |
| Heart peptone | |
| Yeast extract | 5.00 |
| Maize starch | 1.00 |
| Sodium chloride | 5.00 |
| Agar | 15.00 |
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Final pH 7.3 ±0.2 at 25 °C

Suspend 44 g of powder in 1 l of distilled water. Heat to boiling with constant stirring. Distribute into suitable containers and sterilize by autoclaving at 121 °C for 15 minutes. If necessary, cool to 45-50 °C and add the supplements or inhibitors as per use. Homogenize and pour into plates.

In 1966, Ellner et al. of Columbia University described a new culture medium for medical bacteriology that could be used with or without the addition of blood to obtain abundant growth and characteristic colonies. Since then a lot of modifications of this medium have been made to serve several purposes.

The present formulation complies with the description as per the Harmonized Method of the European Pharmacopoeia 6th ed. for the microbiological examination of non-sterile products. In the test for Clostridia, Columbia Agar is used to verify the identity of the colonies sub-cultured from Reinforced Clostridial Medium in anaerobic conditions. The European Pharmacopoeia Methodology recommends the sterile addition of gentamicin sulphate equivalent to 20 mg/l of gentamicin base whereever necessary, before pouring the plates.

Quality control

Incubation temperature: 35°C ±2.0 Incubation time: 24 h ±2

Inoculum: Practical range 50-100 CFU (productivity), according to ISO 11133:2014/Amd 1:2018 and Ph. Eur. Spiral Plate Method

| Microorganism | Growth | Remarks |
|------------------------------------|---------------------|---------|
| Staphylococcus aureus ATCC® 6538 | Productivity > 0.70 | - |
| Escherichia coli ATCC® 8739 | Productivity > 0.70 | - |
| Clostridium sporogenes ATCC® 19404 | Productivity > 0.70 | - |
| Bacillus subtilis ATCC® 6633 | Productivity > 0.70 | - |
| Salmonella typhimurium ATCC® 14028 | Productivity > 0.70 | - |

References

- · ELLNER, P.D., C.J. STOESSEL, E. DRAKENFORD & F. VASSI (1966) A new culture medium for medical bacteriology. Am. J. Clin. Pathol. 45:502-504.
- · EUROPEAN PHARMACOPOEIA 8.0 (2014) 8th ed. § 2.6.13. Microbiological examination of non-sterile products: Test for specified microorganisms. Harmonised Method. EDQM. Council of Europe. Strasbourg.
- MacFADDIN, J. F. (1985) Media for Isolation-Cultivation-Identification- Maintenance of Medical Bacteria. Vol I. William & Wilkins, Baltimore, USA.
- · USP 33 NF 28 (2011) <62> Microbiological examination of non-sterile products: Test for specified microorganisms. Harmonised Method. USP Corp. Inc. Rockville. MD. USA.
- · ISO 10272-1 Standard (2017) Microbiology of the food chain Horizontal Method for detection and enumeration of Campylobacter spp. - Part 1: Detection method.
- ISO 10272-2 Standard (2017) Microbiology of the food chain Horizontal Method for detection and enumeration of Campylobacter spp. - Part 2:Colony count-tecnique.

Keep tightly closed, away from light, in a dry place (4-30 °C).

^{*} Adjusted and /or supplemented as required to meet performance criteria