

Tryptone Soy Broth – DM226

Introduction

MAST® Tryptone Soy Broth is a general purpose medium that can be used for the culture of non-fastidious organisms. MAST® culture media is supplied in a dehydrated powder form, allowing the end-user to prepare a suitable medium for bacterial & fungal culture. It is suitable to be prepared in a variety of receptacles and at volumes that conform to the end-users desired purpose. The culture of bacterial and fungal species are essential for routine laboratory purposes.

FOR IN VITRO USE ONLY
NOT FOR USE IN DIAGNOSIS OF HUMAN DISEASE

Intended Purpose

Tryptone Soy Broth dehydrated culture medium powder is intended for use to produce a general purpose, fluid enrichment medium. When prepared in accordance with the instructions for use it produces a liquid medium for the non-selective enrichment of non-fastidious organisms, including aerobic and some facultatively anaerobic organisms. Tryptone Soy Broth is also suitable as a recovery medium for sterility testing in non-clinical applications such as Media Fill Tests carried out in the pharmaceutical industry.

Tryptone Soy Broth is intended to be used in conjunction with other *in vitro* tests, such as for the preparation of the inoculum by the broth culture method for Kirby-Bauer (CLSI) disc diffusion susceptibility testing. It is intended to be used by professional, trained, clinical laboratory users for *in vitro* use and is not intended for use in the diagnosis of disease or other conditions in humans or as the basis of treatment or case management decisions.

Principle of the test

Culture media remains the gold standard for the growth and isolation of viable bacterial and fungal cells. The liquid culture medium is inoculated by sampling 3-5 independent colonies using a sterile loop and suspending in the prepared broth (broth suspension). Broth suspensions should be incubated under the appropriate atmospheric conditions and temperature for the target organism(s), after which time the medium will become turbid as an indication of growth

These methods should be used in conjunction with other *in vitro* devices in the aid of diagnosis.

Once prepared a single aliquot of culture media broth is only for single use and cannot be re-used.

Components

MAST® culture media is supplied in a dehydrated form for reconstitution by the end-user. The formulation of the product is described in Table 1.

Table 1. Formulation of DM226*

| Material | Concentration in medium |
|------------------------------|-------------------------|
| Casein hydrolysate – enzymic | 17.0g/L |
| Soy peptone | 3.0g/L |
| D-Glucose/Dextrose | 2.5g/L |
| Sodium chloride | 5.0g/L |

*Formulation may change to meet performance criteria.

The formulation is illustrative of the DM226 product range. The product is manufactured within an ISO:9001 and ISO:13485 environment. Inter-batch variation is expected to be minimal with no direct impact on the product.

Stability and storage

The expiry date applies to unopened containers of MAST® dehydrated culture media when stored in the primary container and in accordance with the manufacturer's instructions. The expiry date and batch number are indicated on each pack label.

- Store packs in a dry environment.
- Store packs at room temperature (10°C to 25°C).
- Avoid sources of moisture such as autoclaves, CO₂ incubators and water-baths.
- Limit the time a pack remains open whilst in use.
- This product is hygroscopic, avoid prolonged exposure to ambient moisture.
- For opened packs of dehydrated culture media ensure lid is firmly closed after every use.
- Before use ensure the appearance of the media conforms to the expected colour and texture i.e. free flowing, no excessive lumps. Media that is discoloured or lumpy should be further examined for performance against the recommended QC organism panel.

Warnings and precautions

1. Tryptone Soy Broth is for *in vitro* use only, and must be used by trained professional laboratory staff.
2. All microbiological cultures and equipment used to transfer and manipulate them should be treated as infectious. Autoclave sterilise all biohazard waste before disposal in accordance with local regulations.
3. On receipt, store MAST® dehydrated culture media at the recommended storage temperature and conditions stated on the pack.
4. Do not store near sources of moisture or within high humidity environments.

5. Do not use if media powder is discoloured and/or lumpy, examine against recommended QC organism panel before continuing use. Discolouration could be a sign of degradation and must be examined further.
6. When handling the device ensure that local and regulatory health and safety advice is followed.
7. When handling the sterilised solution, beware of the temperature, use thermal resistant gloves where appropriate.
8. When preparing culture media after sterilisation, ensure that this is performed in an aseptic manner.

MAST[®] dehydrated culture media are supplied in a sealed primary container, which helps to prevent moisture ingress from the environment. The nature and frequency of use of the device is conducive to an end-user re-entering the container. When the product is not in use, the primary container should remain sealed.

Materials Provided

Mast[®] dehydrated culture media is supplied in a powder form contained within a re-usable primary container for end-user reconstitution.

Materials required but not provided

Standard microbiological supplies and equipment such as petri dishes, bottles, tubes, laminar flow cabinet, water bath, autoclave, balance, weigh boats, spatulas, thermometer, timer, additives such as defibrinated blood, deionised water, or suitable control strains of microorganisms.

Procedure

1. Refer to pack label for quantities and volumes required. Prepare MAST[®] Tryptone Soy Broth by suspending the powder in distilled or deionised water.
2. Sterilise the solution in an autoclave at 121°C (15 p.s.i) for 15 minutes.
3. The media should then be distributed into containers appropriate for the testing required.
4. To accommodate fastidious organisms, cool the broth to 49 ± 1°C and aseptically add 5 to 7% defibrinated horse or sheep blood.

Refer to local Health and Safety handling procedures for infectious waste disposal guidelines.

Technical Guidance

Observe the powder before use. If the powder is discoloured or lumpy, this could be a sign of degradation and must be further examined.

Interpretation of results

Following incubation, the inoculated broth will become turbid as an indication of growth. The broth can then be plated onto the appropriate medium to confirm growth of target organisms.

Limitations of use

MAST[®] media are not intended to be used as the sole, and primary isolation medium in instances where a failure to detect a pathogenic infection would result in death, serious illness or possible transmission of infectious disease.

Quality Control

Check for signs of deterioration. Quality control must be performed with at least one organism to demonstrate expected performance. Do not use the product if the result with the control organism is incorrect. The list below illustrates a range of performance control strains which the end user can easily obtain.

Table 2. Suggested organisms for QC

| Test Organism | Result |
|---|--------|
| <i>Escherichia coli</i> ATCC [®] 25922 | Growth |
| <i>Staphylococcus aureus</i> ATCC [®] 25923 | Growth |

References

Bibliography is available on request.