

TSMV 2129 – FILL TEST MEDIUM (VEG.)

INTENDED USE

recommended for the evaluation of sterility in manufacturing process for easy detection of contamination by Media Fill Test.

PRODUCT SUMMARY AND EXPLANATION

Gamma-Irradiated TSB is particularly suitable for sterility testing and for the validation of aseptic filling procedures. In the Media Fill Test (MFT), a validation method used to assess the performance of aseptic processing in the pharmaceutical industry, pharmaceutical products are substituted by sterile powder, such as Gamma-Irradiated TSB. The medium is subjected to exactly the same conditions as the product, including filling and closing, to ensure that there is no microbial contamination occurring during the process.

COMPOSITION

| Ingredients | Gms / Ltr |
|--------------------------------|-----------|
| Veg hydrolysate | 17.000 |
| Sodium chloride | 5.000 |
| Papaic digest of soybean | 3.000 |
| Dipotassium hydrogen phosphate | 2.500 |
| Dextrose (Glucose) | 2.500 |
| MFT Indicator | 0.100 |

PRINCIPLE

Soyabean casein digest medium is recommended by various pharmacopoeia as sterility testing medium. Tryptone and Soya peptone in the medium provides nitrogenous and carbonaceous compounds, long chain amino acids, vitamins and other essential nutrients. Sodium chloride maintains the osmotic balance. Phosphate buffers the medium. Dextrose serves as energy source. In this line the Fill test medium (Veg.) with addition of MFT indicator, helps to verify the microbiological growth in aseptic production process. MFT indicator is the medium is utilized by all microorganisms and the microbial contamination is indicated by colour change from light yellow to maroon-red. It is an easier method for detection of contamination with no time consumption.

INSTRUCTION FOR USE

- Sterile powder can be used directly for the evaluation of sterility in manufacturing processes.
- For, sterile liquid medium, aseptically ass 30.10 grams in 1000 ml sterile distilled water.
- Do not autoclave or overheat the medium.
- Dispense aseptically in sterile tubes or flasks as desired.

QUALITY CONTROL SPECIFICATIONS

Appearance of Powder : Cream to yellow colour homogeneous free flowing powder.
Appearance of prepared medium : Yellow colour clear solution
pH (at 25°C) : 7.3±0.2

INTERPRETATION

Cultural characteristics observed after inoculation and incubation as mentioned.



| Microorganism | ATCC | Inoculum (CFU/ml) | Growth | Recovery | Incubation Temperature | Incubation Period |
|---------------------------------|-------|-------------------|-----------|----------|------------------------|-------------------|
| <i>Escherichia coli</i> | 25922 | 50-100 | luxuriant | >=70% | 30 -35°C | ≤3 days |
| <i>Escherichia coli</i> | 8739 | 50-100 | luxuriant | >=70% | 30 -35°C | ≤3 days |
| <i>Staphylococcus aureus</i> | 25923 | 50-100 | luxuriant | >=70% | 30 -35°C | ≤3 days |
| <i>Staphylococcus aureus</i> | 6538 | 50-100 | luxuriant | >=70% | 30 -35°C | ≤3 days |
| <i>Pseudomonas aeruginosa</i> | 27853 | 50-100 | luxuriant | >=70% | 30 -35°C | ≤3 days |
| <i>Pseudomonas aeruginosa</i> | 9027 | 50-100 | luxuriant | >=70% | 30 -35°C | ≤3 days |
| <i>Bacillus subtilis</i> | 6633 | 50-100 | luxuriant | >=70% | 30 -35°C | ≤3 days |
| <i>Salmonella typhimurium</i> | 14028 | 50-100 | luxuriant | >=70% | 30 -35°C | ≤3 days |
| <i>Streptococcus pneumoniae</i> | 6305 | 50-100 | luxuriant | >=70% | 30 -35°C | ≤3 days |
| <i>Micrococcus luteus</i> | 9341 | 50-100 | luxuriant | >=70% | 30 -35°C | ≤3 days |
| <i>Candida albicans</i> | 10231 | 10-100 | luxuriant | >=70% | 20 -25°C | 3-5 Days |
| <i>Aspergillus brasiliensis</i> | 16404 | 10-100 | luxuriant | >=70% | 20 -25°C | 3-5 Days |

PACKAGING:

In pack size of 500 gm bottles.

STORAGE

Dehydrated powder, hygroscopic in nature, store in a dry place, in tightly-sealed containers between 10-25°C and protect from direct sunlight. Under optimal conditions, the medium has a shelf life of 4 years. When the container is



opened for the first time, note the time and date on the label space provided on the container. After the desired amount of medium has been taken out replace the cap tightly to protect from hydration.













Product Deterioration: Do not use if they show evidence of microbial contamination, discoloration, drying or any other signs of deterioration.

DISPOSAL

After use, prepared plates, specimen/sample containers and other contaminated materials must be sterilized before discarding.

REFERENCES

1. Atlas R. M., 1993, Handbook of Microbiological Media, Parks L.C. (Ed.), CRC press, Boca Raton.
2. Forbes B. A. et al, 2002, Bailey and Scotts Diagnostic Microbiology, 11th Ed., Mosby Company, St. Louis, MO.
3. Murray P. R., Baron J. H., Tenover F. C., Tenover P. C., (Ed.), 2003, Manual of Clinical Microbiology, 8th Ed., American Society for Microbiology, Washington, D.C.

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|  GMP Good Manufacturing Practices Certified |  IVD For In Vitro Diagnostic Use |  QTY. Quantity |  LOT/ B. NO. Lot / Batch Number |  REF Catalogue Number |  Manufacturer |
|  Temperature Unit |  EC REP Authorized Representative <small>MedNet GmbH Borkstrasse 10, 48163 Moenster, Germany</small> |  European Conformity |  QR Code |  Consults Instructions for Use |  Best Before |

NOTE: Please consult the Material Safety Data Sheet for information regarding hazards and safe handling Practices.

***For Lab Use Only**
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