CM 21999 - FILL TEST MEDIUM

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
Tryptone	17.000
Soya peptone	3.00
Sodium chloride	5.000
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 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 powdercan beused directlyfor the evaluation of sterility in manufacturing processes.
For, sterile liquid medium, aseptically add 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.

Note: If any fibres are observed in the solution it is recommended to filter the solution through 0.22 micron filter to eliminate any possibility of presence of fibres

QUALITY CONTROL SPECIFICATIONS

Appearance of Powder : Cream to yellow homogeneous free flowing powder.
Appearance of prepared medium : Yellow colour clear solution.
pH (at 25°C) : 7.30±0.2

INTERPRETATION

Culturalcharacteristics observed after inoculation and incubation as mentioned.

Microorganism	*ATCC*	*Inoculum (CFU/ml)*	*Growth*	*Appearance*	*Recovery*	*Incubation Te mpera ture*	*Incubation Period*
Escherichia coli	25922	50-100	luxuriant	Red to maroon colour	>=70%	30 -35°C	≤3 days
Escherichia coli	8739	50-100	luxuriant	Red to maroon colour	>=70%	30 -35°C	≤3 days
Staphylococcus aureus	25923	50-100	luxuriant	Red to maroon colour	>=70%	30 -35°C	≤3 days
Staphylococcus aureus	6538	50-100	luxuriant	Red to maroon colour	>=70%	30 -35°C	≤3 days
Pseudomonas aeruginosa	27853	50-100	luxuriant	Red to maroon colour	>=70%	30 -35°C	≤3 days
Pseudomonas aeruginosa	9027	50-100	luxuriant	Red to maroon colour	>=70%	30 -35°C	≤3 days
Bacillus subtilis	6633	50-100	luxuriant	Red to maroon colour	>=70%	30 -35°C	≤3 days
Salmonella typhimurium	14028	50-100	luxuriant	Red to maroon colour	>=70%	30 -35°C	≤3 days
Salmonella abony	6017	50-100	luxuriant	Red to maroon colour	>=70%	30 -35°C	≤3 days
Streptococcus pneumoniae	6305	50-100	luxuriant	Red to maroon colour	>=70%	30 -35°C	≤3 days
Micrococcus luteus	9341	50-100	luxuriant	Red to maroon colour	>=70%	30 -35°C	≤3 days
Clostridium perfringens	12924	50-100	luxuriant	Red to maroon colour	>=70%	30 -35°C	≤3 days

Candida albicans	10231	10-100	luxuriant	Red to maroon colour	>=70%	20 -25°C	≤5 Days
Aspergillus brasiliensis	16404	10-100	luxuriant	Red to maroon colour	>=70%	20 -25°C	≤5 Days

PACKAGING:

Inpacksizeof500 gm bottles.

STORAGE

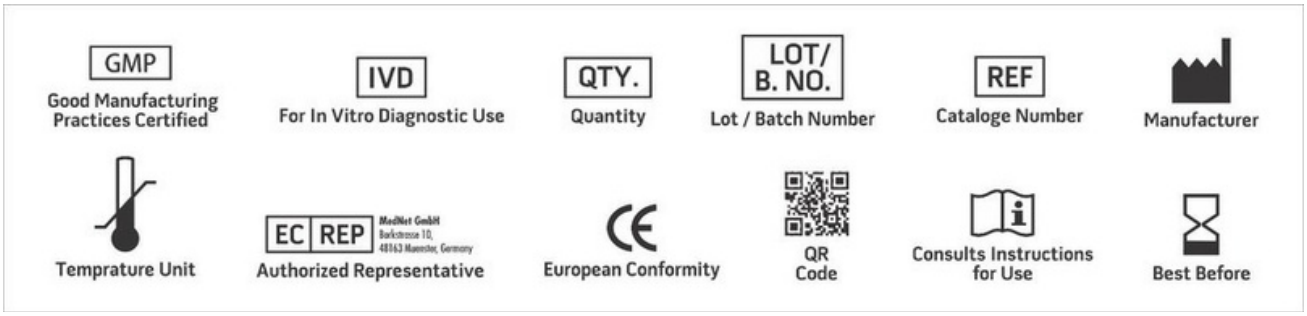
Dehydrated powder, hygroscopic in nature, store in a dry place, in tightly-sealed containers between 10-25°C and protect from direct sunlight. Under optimal conditions, the medium has a shelf life of 4 years. When the container is opened for the first time, note the time and date on the label space provided 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

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

REFERENCES

1.AtlasR. 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., Pfaller M. A., Jorgensen J. H. and Yolken R. H., (Ed.), 2003, Manual of Clinical Microbiology, 8th Ed., American Society for Microbiology, Washington, D.C.



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

*ForLabUseOnly