

CM 20692 - 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.

INSTRUCTIONFOR USE

- Sterile powder can be used directly for 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

Cultural characteristics observed after inoculation and incubation as mentioned.

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



