

CM 20599 – DILUTING FLUID D (as per USP)

INTENDED USE

For sterility testing of pharma products.

PRODUCT SUMMARY AND EXPLANATION

Diluting Fluid D is recommended as rinsing fluid for membrane filter method used in validation tests for bacteriostasis and fungistasis activity of pharmaceutical articles before carrying out sterility test procedures as per USP. After filtering the specified quantity of the test specimen, the membrane is rinsed with measured portions of rinsing or diluting fluid. This rinse is inoculated with known number of test bacteria and fungi as specified in pharmacopoeia. The resultant growth is compared with positive control to determine presence of fungistasis or bacteriostasis activity in test specimen. This medium is recommended for articles containing lecithin or oil or for devices labeled as sterile pathway.

COMPOSITION

Ingredients	Gms / Ltr
Peptic digest of animal tissue	1.000
Polysorbate 80	1.000

PRINCIPLE

The medium consists of peptic digest of animal tissue which provide nitrogenous nutrients to support bacterial growth. Polysorbate 80 in the medium act as an emulsifier.

INSTRUCTION FOR USE

- Dissolve 2.0 grams in 1000 ml purified/distilled water.
- Heat if necessary to dissolve the medium completely.
- Sterilize by autoclaving at 15 psi pressure (121°C) for 15 minutes.

QUALITY CONTROL SPECIFICATIONS

- Appearance of Powder : Cream to yellow coloured homogeneous free flowing powder.
- Appearance of prepared medium : Light amber coloured clear solution without any precipitate.
- pH (at 25°C) : 7.1 ± 0.2

INTERPRETATION

Cultural characteristics observed after incubation.

Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Incubation Temperature	Incubation Period
Candida albicans	10231	10-100	Good	35-37°C	24-48 Hours



Escherichia coli	25922	50-100	Good	35-37°C	24-48 Hours
Escherichia coli	8739	50-100	Good	35-37°C	24-48 Hours
Staphylococcus aureus subsp. aureus	25923	50-100	Good	35-37°C	24-48 Hours
Staphylococcus aureus subsp. aureus	6538	50-100	Good	35-37°C	24-48 Hours

PACKAGING:

Inpacksizeof500 gm bottles.

STORAGE

Dehydrated powder, hygroscopic in nature, store in a dry place, in tightly-sealed containers between 25-30°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.TheUnitedStates Pharmacopoeia / National Formulary, USP34 / NF29, 2011, The US Pharmacopeial convention Inc., Rockville, MD.

 GMP Good Manufacturing Practices Certified	 Best Before	 QTY. Quantity	 REF Cataloge Number	 Manufacturer
 Temperature Unit	 LOT/ B. NO. Lot / Batch Number	 Consults Instructions for Use	 QR Code	

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

*For LabUse Only