CM 20598 – DILUTING FLUID A (as per USP)

INTENDED USE

For sterility testing of pharma products.

PRODUCT SUMMARY AND EXPLANATION

DilutingFluid A isrecommended asrinsing 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 withpositive control to determine presence of fungistasis or bacteriostasis activity in test specimen.

COMPOSITION

Ingredients	Gms / Ltr
Peptone	1.000

PRINCIPLE

Themediumconsists of Peptone which provide nitrogenous nutrients to support bacterial growth.

INSTRUCTION FOR USE

Dissolve 1.0grams in 1000 ml purified/distilled water.
Heat if necessary to dissolve the medium completely.
Dispense into tubes or flasks as desired and sterilize by autoclaving at 15 psi pressure (121°C) for 15 minutes.

QUALITY CONTROL SPECIFICATIONS

Appearance of Powder	: Cream to yellow homogeneous free flowing powder.
Appearance of prepared medium	: Light yellow coloured clear solution.
pH (at 25°C)	: 7.1 ± 0.2

INTERPRETATION

Culturalcharacteristics 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

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.

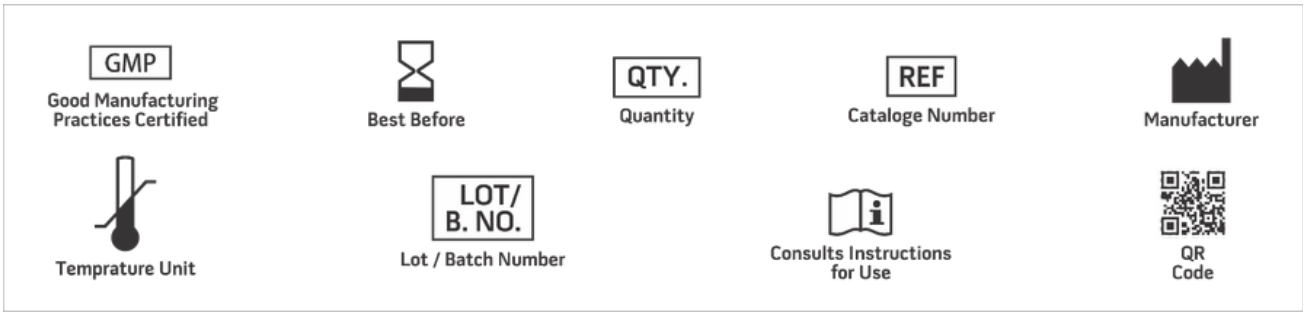
Product Deterioration: Do not use if they show evidence of microbial contamination, discoloration, drying or any other signs of deterioration.

DISPOSAL

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

REFERENCES

1Isenberg,H.D.Clinical Microbiology Procedures Handbook 2nd Edition
2. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L.,Richter, S.S and Warnock., D.W. (2015) Manual Clinical Microbiology, 11th Edition. Vol. 1.
3. The United States Pharmacopoeia / National Formulary, USP34 / NF29, 2011, Asian Edition, US Pharmacopeial convention Inc., Rockville, MD.



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

*For LabUse Only