

TM 719 – DILUTING FLUID K (as per USP)

INTENDED USE

For sterility testing of pharma products.

PRODUCT SUMMARY AND EXPLANATION

Diluting Fluid K 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.

COMPOSITION

| Ingredients | Gms / Ltr |
|---------------------------|-----------|
| Peptone | 5.000 |
| Beef extract | 3.000 |
| Polysorbate 80 (Tween 80) | 10.000 |

PRINCIPLE

The medium consists of Peptone and beef extract which provide nitrogenous nutrients to support bacterial growth. Polysorbate 80 in the medium act as an emulsifier.

INSTRUCTION FOR USE

- Dissolve 18.0 grams 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) | : 6.9 ± 0.2 |

INTERPRETATION

Cultural characteristics observed after incubation.

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



| | | | | | |
|--|-------|--------|------|---------|-------------|
| <i>Escherichia coli</i> | 25922 | 50-100 | Good | 35-37°C | 24-48 Hours |
| <i>Escherichia coli</i> | 8739 | 50-100 | Good | 35-37°C | 24-48 Hours |
| <i>Staphylococcus aureus subsp. aureus</i> | 6538 | 50-100 | Good | 35-37°C | 24-48 Hours |

PACKAGING:

In pack size of 500 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

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

REFERENCES

- 1 Isenberg, 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.

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|--|---|---|--|---|
|  GMP Good Manufacturing Practices Certified |  Best Before |  QTY. Quantity |  REF Catalogue 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 Lab Use Only**
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