

TMKH 011 – DILUTING FLUID D (USP)

INTENDED USE

Used as diluent 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 presence of pancreatic digest of animal tissue makes this medium nutritious by providing nitrogenous, carbonaceous compounds, long chain amino acids, vitamins and other minerals for the growth of microorganisms.

INSTRUCTION FOR USE

- Diluting fluid is used as the diluting or rinsing solution for membrane filter techniques in pharmaceutical products.
- Measured portions of Diluting fluid D should be used to rinse the membrane after filtration.
- Inoculate this rinse with 50-100 cfu of test organisms.
- Simultaneously run a positive control of the same medium.
- Incubate both the set of medium at the specified time and temperature.
- Compare the growth obtained for the rinse with that obtained in the positive control after incubation.

QUALITY CONTROL SPECIFICATIONS

Appearance of Prepared media	: Light amber coloured medium.
Sterility test	: Passes the release criteria.
pH (at 25°C)	: 7.1±0.2

INTERPRETATION

Cultural characteristics observed after incubation.

Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Incubation Temperature	Incubation Period
<i>Escherichia coli</i>	8739	50 – 100	Good	35-37°C	24-48 Hours



<i>Escherichia coli</i>	25922	50 – 100	Good	35-37°C	24-48 Hours
<i>Staphylococcus aureus</i>	6538	50 – 100	Good	35-37°C	24-48 Hours
<i>Staphylococcus aureus</i>	25923	50 - 100	Good	35-37°C	24-48 Hours
<i>Candida albicans</i>	10231	50 – 100	Good	35-37°C	24-48 Hours

PACKAGING:

In pack size of 100 ml X 25 bottles.

STORAGE










On receipt, store bottles in the dark at 10–25 °C. Avoid freezing and overheating. Do not open until ready to use. Minimize exposure to light. Bottled media stored as labeled until just prior to use may be inoculated up to the expiration date and incubated for the recommended incubation times. Allow the medium to warm to room temperature before inoculation

DISPOSAL

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

REFERENCES

1. The United States Pharmacopoeia / National Formulary, USP34 / NF29, 2011, The US Pharmacopeial convention Inc., Rockville, MD.

 Good Manufacturing Practices Certified	 Best Before	 Quantity	 Catalogue Number	 Manufacturer
 Temperature Unit	 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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