OXFORD LAB FINE CHEM LLP
ISO 9001-2008 Certified Company

Regd Office: Unit no 12, 1st Floor,
Neminath Industrial Estate No.6,
Navghar, Vasai (East), Palghar - 410210.
Maharashtra, INDIA.

Tel: +91 250 2390032 / 2390989 / 2390990
Email: sales@oxfordlabchem.com /
info@oxfordlabchem.com
Web: www.oxfordlabchem.com

Oxford
Range of
Laboratory Chemicals

TECHNICAL DATA SHEET

Diluting Fluid D

Principle

As per USP (2011), 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. After filtering 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.

Use: For sterility testing of pharma products.

Contents*

Ingredients	Gram/Litre
Peptone	1.000
Polysorbate 80	1.000
pH at 25˚C	7.1 ±0.2

*** Formula adjusted for optimum performance and parameters**

Directions: Dissolve 2.00 grams in 1000 ml distilled water. Boil to dissolve the medium completely and distribute in desired. Sterilize by autoclaving at 15 lbs pressure (121 °C) for 15 min, cool it to 42-45 °C and inoculate test sample aseptically.

Specimens types analyzed

Pharmaceutical samples etc.

Precautions to be taken

These microbial media are intended for the in-vitro use only. All the handling, experiments, storage, and discarding should be performed with the help of skilled and knowledgeable technicians and as per the established guidelines. The material should be disposed only after proper sterilization by autoclaving. Please go through the MSDS of the media to avoid any accidents or in emergency.

OXFORD LAB FINE CHEM LLP
ISO 9001-2008 Certified Company

Regd Office: Unit no 12, 1st Floor,
Neminath Industrial Estate No.6,
Navghar, Vasai (East), Palghar - 410210.
Maharashtra, INDIA.

Tel: +91 250 2390032 / 2390989 / 2390990
Email: sales@oxfordlabchem.com /
info@oxfordlabchem.com
Web: www.oxfordlabchem.com

Oxford
Range of
Laboratory Chemicals

Performance and Evaluation

The expected performance of the medium is liable to use as per the direction on the label when stored at optimum conditions and within expiry date.

Quality Control

Appearance	**Light Beige colored free flowing, homogeneous powder**
Reaction of 0.2% solution	**7.1 ±0.2 at 25 ˚C**
pH	**6.90- 7.30**
Color and clarity of ready medium	**Light amber colored opalescent solution**
Growth Promotion properties	**Best at ≤ 100 CFU at 32-37 ºC for 18-72 h**
Indicative properties	**Optimum at ≤ 100 CFU at 32-37 ºC for 18-48 h**
Negative control	**Performed using sterile distilled water**

Different Microbial Response

Growth promotion is carried out in accordance with the harmonized method of USP/EP/JP/IP and growth is observed after incubation at 30°C-35°C for ≤ 3 days for bacteria and ≤ 5 days for fungi.

Organism	ATCC	Inoculum	Growth
Escherichia coli	**8739**	**50-100**	**Luxurious**
Staphylococcus aureus	**25923**	**50-100**	**Luxurious**
Staphylococcus pneumoniae	**6303**	**50-100**	**Luxurious**
Candida albicans	**10231**	**50-100**	**Luxurious**

Storage and Shelf Life: The product is highly hygroscopic; keep the container tightly closed at all times and store it properly as per the conditions mentioned on the label. The declared expiry is valid only when stored as per the conditions mentioned on the label. Note: Sterilize media immediately after reconstitution.

Regd Office: Unit no 12, 1st Floor,
Neminath Industrial Estate No.6,
Navghar, Vasai (East), Palghar - 410210.
Maharashtra, INDIA.

Tel: +91 250 2390032 / 2390989 / 2390990
Email: sales@oxfordlabchem.com /
info@oxfordlabchem.com
Web: www.oxfordlabchem.com

Disposal: To avoid the contamination or propagation of any hazardous microbes the used, unusable or modified preparation of this product must be disposed after autoclaving after completion of task.

Reference

1. **Atlas, R. M. (2005). *Handbook of media for environmental microbiology*. CRC press.**
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.**

Disclaimer:

****

The information contained herein in good faith but makes no representations as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose.

Oxford Lab Fine Chem LLP makes no representations or warranties, either express or implied, including without limitation any warranties of merchantability, fitness for a particular purpose with respect to the information set forth herein or the product to which the information refers. Accordingly, Oxford Lab Fine Chem LLP will not be responsible for damages resulting from use of or reliance upon this information.