

## Diluting Fluid D w/1% Tween 80

LQ560C

### Intended Use:

Recommended as diluent in testing of pharmaceuticals in accordance with USP and for determining efficiency of sanitization of containers, equipment surfaces, water miscible cosmetics etc.

### Composition\*\*

Ingredients	g / L
Peptone	1.000
Polysorbate 80 (Tween 80)	10.00
Final pH ( at 25°C)	7.1±0.2

\*\*Formula adjusted, standardized to suit performance parameters

### Directions

Label the ready to use LQ560C bottle. In sterile environment, unscrew the bottle. Inoculate or add the sample to be tested. mix the sample well. Incubate at specified temperature for 24-48 hours.

### Principle And Interpretation

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 (1). 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 (1).

### Type of specimen

Pharmaceutical sample

### Specimen Collection and Handling

For pharmaceutical sample samples follow appropriate techniques for handling specimens as per established guidelines (1). After use, contaminated materials must be sterilized by autoclaving before discarding.

### Warning and Precautions

For professional use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

### Limitations

1. Further serological or biochemical testing is required for complete identification.
2. Use of this method is appropriate only when test samples are clear.

### Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

### Quality Control

#### Appearance

Sterile Diluting Fluid D w/1% Tween 80 in a glass bottle.

#### Colour of medium

Light yellow coloured clear medium

**Quantity of Medium**

100 ml of medium in glass bottle.

**pH**

6.90-7.30

**Sterility Check**

Passes release criteria

**Cultural Response**

Cultural characteristics observed after an incubation at 35-37°C for 24-48 hours.

<b>Organism</b>	<b>Inoculum (CFU)</b>	<b>Growth</b>
<i>Candida albicans</i> ATCC 10231 (00054*)	50-100	good
<i>Escherichia coli</i> ATCC 25922 (00013*)	50-100	good
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 25923 (00034*)	50-100	good
<i>Escherichia coli</i> ATCC 8739 (00012*)	50-100	good
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 6538 (00032*)	50-100	good

Key : (\*) Corresponding WDCM numbers.

**Storage and Shelf Life**

Store between 15-30°C. Use before expiry date on the label. Product performance is best if used within stated expiry period.

**Disposal**

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with sample must be decontaminated and disposed of in accordance with current laboratory techniques (2,3).

**Reference**

1. The United States Pharmacopoeia / National Formulary, 2019, The US Pharmacopeial convention Inc., Rockville, MD.
2. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition
3. 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.

Revision : 00/2024

**Disclaimer :**

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