DILUTING AND RINSING FLUIDS

PRODUCTS:

Bottled Media:

Fluid A	B8103, B8140, B8160, B8171, B8174, B8206, B8210, B8212, B8213, B8214, B8215, B8216, B8220, B8222 B8140 (MonoTek®), B8155 (DuoTek®) WrapSure®: B8169, B8159, B8176, B8189, B8197, B8309
Fluid D	B8172, B8173, B8215, B8218, B8225, B8227, B8306, B8310, B8313, B8319 B8325 (DuoTek) WrapSure: B8191, B8195, B8420
Fluid K	B8328

PURPOSE:

Fluid A, Fluid D, and Fluid K are used as diluting or rinsing fluids when performing Sterility Testing. These formulations meet the U.S. Pharmacopeia (USP) standards in performing Sterility Testing.

PRINCIPLE:

Fluid A is a 0.1% peptone solution used as a diluting and rinsing fluid. Peptones from casein provide a source of organic nitrogen necessary for bacterial growth. Beta-lactamase may be added to the fluid in order to inactivate residual penicillin or cephalosporin activity on the membranes.[7]

Fluid D incorporates polysorbate 80 for neutralizing residual germicides or disinfectants. Fluid D is used for specimens containing lecithin, oils, or preservatives and can be used in devices labeled as “sterile pathway”.[7]

Fluid K is a 0.5% peptone solution used for diluting viscous samples such as those containing petrolatum.

Irradiation of the double packaged media allows this product to be used in critical environments where introduction of contaminants and particulates are not desired. Double wrapped packaging with sterile inner packaging allows transfer of product into a classified clean room environment without the tedious process of disinfection.

WrapSure products are sterilized inside of two autoclavable bags, allowing use of the product in a critical environment. WrapSure products are validated sterile at a Sterility Assurance Level (SAL) of 10^{-6}.

The MonoTek and DuoTek products are validated sterile to a SAL of 10^{-6}. The bottle material is a resin PETG®. The optically clear bottle is lightweight and suitable for environmentally friendly disposal and cost effective shipping. The MonoTek has a wide-mouth screw cap opening (46mm) for direct transfer of larger articles. The DuoTek septum/screw cap combination allows both an injectable septum for liquid specimens as well as a wide-mouth screw cap opening.

FORMULAS:

Approximate, per liter of deionized filtered water.

(1) Fluid A:

Peptic Digest of animal tissue ..... 1.00 g

Final pH 7.1 ± 0.2 at 25°C

(2) Fluid D:

Same as **(1)** above with the addition 1.0 ml of Polysorbate 80

(3) Fluid K:

Peptic Digest of animal tissue ..... 5.0 g
Beef extract 3.0
Polysorbate 80 ..... 10.0 ml

Final pH 6.9 ± 0.2 at 25°C

PRECAUTIONS:*

For laboratory use only. Observe approved biohazard precautions.

Storage: Upon receipt store at 2-25°C away from light. Media should not be used if there are signs of contamination, deterioration (i.e. leaking, cracking, or discoloration), violation of package seal, or if the expiration date has passed. Do not open outer wrapping until ready to use. Media can be inoculated up to the expiration date and incubated for the appropriate incubation period up to 14 days.

Limitations: See appropriate references. A complete contamination control program should emphasize traffic control, special dress code procedures in critical areas, suitable ventilation, as well as good cleaning and disinfecting practices.

PROCEDURE:*

Method of Use: For use as rinsing or diluting fluid in membrane filtration for the purpose of sterility testing. See appropriate reference or regulatory guidelines for individual requirements.

If sterility of the inner packaging is required, appropriate procedures should be used to minimize or eliminate risks.
Inner package must not be opened until ready to use. The DuoTek bottle may be inoculated through the septum, or the bottle may be used by removing the cap.

Interpretation: Not applicable. Growth is evident by the appearance of turbidity in the fluid and must be subcultured to appropriate media for the determination of organism viability and identification.

Materials Required but Not Provided: Standard microbiological supplies and equipment such as those commonly found in a microbiological laboratory are not provided.

QUALITY CONTROL:

Microorganisms Used (ATCC#):	Expected Results:
*Not Applicable	Not Applicable

User Quality Control: Check for contamination and deterioration. Fluid A, D, and K should appear clear and light yellow in color.

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* For more detailed information, consult appropriate references.

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