



INSTRUCTIONS FOR USE – READY-TO-USE BOTTLED MEDIA

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For Laboratory Use Only

BD™ Fluid A • BD Fluid A, Double Wrapped • BD Fluid D • BD Fluid D, Double Wrapped • BD Fluid A, ETO

INTENDED USE

Fluid A and Fluid D are diluting and rinsing fluids used for sterility tests of pharmaceutical products according to the membrane filtration method.

Note that this document is valid for all catalogue numbers of Fluid A and Fluid D ready-to use bottled media, intended for laboratory use, which are manufactured by the Becton Dickinson GmbH Heidelberg, Germany.

PRINCIPLES AND EXPLANATION OF THE PROCEDURE

Fluid A and Fluid D are diluting and rinsing fluids according to the United States and the European Pharmacopeias.^{1,2} They are used for dissolving the materials in test and for rinsing sterile devices or materials to release possible contaminating organisms from the device or material in test without affecting the viability of these contaminating micro-organisms. Fluid D is Fluid A supplemented with 0.1% Polysorbate 80 [= Polyoxyethylene (80) sorbitan monooleate]. Fluid D is used for dissolving oils or materials containing lecithin or for rinsing articles and devices with bacteriostatic or fungistatic activity. Polysorbate 80 may act as an inactivator of microbicides present in the articles or on the devices.¹

Proteose Peptone No. 3, a peptic digest of animal tissue, acts as a stabilizer for microorganisms, maintaining their viability. Polysorbate 80 acts as a neutralizer of certain disinfectants or preservatives and improves the solubility of oily materials.

REAGENTS

Formulas* Per Liter Purified Water

BD Fluid A

Peptic Digest of Animal Tissue	1.0 g
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pH 7.1 +/- 0.2

*Adjusted and/or supplemented as required to meet performance criteria.

BD Fluid D, in addition to the ingredients listed above, contains 1.0 ml/l of Polysorbate 80.

Packaging and Sterility Information

Containers of **BD Fluid A, Double Wrapped** and **BD Fluid D, Double Wrapped**, are packaged in two **Stericlin®** bags before autoclaving. These products provide sterile container surfaces. This allows their use in sterile production areas.

BD Fluid A, ETO: after autoclaving the medium in the containers, the whole package unit is sealed in a Stericlin bag and is sterilized by ethylene oxide (=ETO) treatment, providing a sterile outer surface of the containers and package.

The multiple bags in these products allow the introduction of the containers into clean rooms from a non-sterile to a sterile area without the risk of contamination.

The products mentioned in this document are sterilized by autoclaving in their final containers. For many of these products, a sterility claim is available on the Certificate of Analysis (<http://regdocs.bd.com> or <http://www.bd.com/europe/regulatory/>).

PRECAUTIONS

For laboratory use only

Do not use containers if they show evidence of microbial contamination, discoloration, drying, cracking or other signs of deterioration.

Consult **GENERAL INSTRUCTIONS FOR USE** document for aseptic handling procedures, biohazards, and disposal of used product.

STORAGE AND SHELF LIFE

On receipt, store containers in the dark according to the storage temperature instructions on the label until just prior to use. Avoid freezing and overheating. The containers may be used up to the expiration date.

USER QUALITY CONTROL

Inoculate samples of Fluid A and Fluid D with 100 to 1000 cfu/ml and mix well.. Determine the cfu of these samples directly after inoculation and mixing by plating suitable amounts (e.g., 50 or 100 µl) on **BD Trypticase™** Soy Agar plates. To simulate the time needed to complete handling when using the membrane filtration procedures, incubate the inoculated samples at room temperature for 30 min to 2 hours. Then, subculture again suitable amounts of the samples on **BD Trypticase™** Soy Agar plates. The cfu obtained after incubation must not be significantly lower than the cfu after inoculation and mixing. However, an increase in cfu after incubation may have taken place since the strains may have multiplied at room temperature.

Organism	Survival in Fluid A and Fluid D
<i>Candida albicans</i> ATCC 10231	Good
<i>Staphylococcus aureus</i> ATCC 6538	Good to excellent
<i>Bacillus subtilis</i> ATCC 6633	Good
<i>Aspergillus niger</i> ATCC 16404	Good
<i>Pseudomonas aeruginosa</i> ATCC 9027	Good to excellent

Toxicity Test: Inoculate duplicate tubes of Tryptic Soy Broth with the test organisms (10-100 CFU/ml) and add 1 ml of Fluid A or Fluid D to one tube of each set. Incubate tubes at 20-25° C for up to 5 days and compare to each other for growth. Growth intensity (turbidity) must be comparable in the tubes with Fluid A or D to those containing only TSB.

Organism	Recovery
<i>Candida albicans</i> ATCC 10231	Good
<i>Bacillus subtilis</i> ATCC 6633	Good
<i>Kocuria rhizophila</i> ATCC 9341	Good

PROCEDURE

Materials Provided

BD Fluid A; BD Fluid D, BD Fluid A, Double Wrapped BD Fluid D, Double Wrapped and BD Fluid A, ETO: prepared bottled media

Materials Not Provided

Ancillary culture media, reagents and laboratory equipment as required.

Test Procedure

Consult the respective reference for sample processing and subsequent treatment. ^{1,2}

Results

Consult the respective reference.^{1,2}

LIMITATIONS OF THE PROCEDURE

Although Fluid A and Fluid D possess a certain low nutritive capacity and may support the growth of microorganisms, it is not recommended to use them as growth media.

If the actual viable count on the materials in test is evaluated, an incubation and longer dwelling time at room temperature before filtration (which result in multiplication of the organisms originally present on the material in test) must be avoided.

Use of these products with clinical specimens has not been validated.

REFERENCES

1. U.S. Pharmacopeial Convention, Inc. The U.S. Pharmacopeia /The national formulary *Current edition*. U.S. Pharmacopeial Convention, Inc., Rockville, Md
2. Council of Europe. European Pharmacopoeia, *current edition*. European Pharmacopoeia Secretariat. Strasbourg/France.

PACKAGING/AVAILABILITY

BD Fluid A and **BD Fluid D** are available in several container types, fill volumes, and package sizes.

For details on the available products, contact your local BD representative.

FURTHER INFORMATION

For further information please contact your local BD representative.



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