IFU

HARDY DIAGNOSTICS
A Culture of Service™

Instructions for Use

USP RINSING AND DILUTING FLUIDS

Cat. no. U17	Fluid A, USP, 8oz. Wide Mouth Jar, 90ml	12 jars/box
Cat. no. U19	Fluid A, USP, 125ml Polypropylene Bottle, 100ml	12 bottles/box
Cat. no. U109	Fluid A, USP, 100ml Serum Bottle, 100ml	20 bottles/box
Cat. no. U249	Fluid A, USP, 16oz. Glass Bottle with septum cap, 600ml	10 bottles/box
Cat. no. U208	Fluid A, USP, 1L Polycarbonate Bottle, 1000ml	10 bottles/box
Cat. no. U342	Fluid A, USP, 500ml Glass Bottle, 300ml	10 bottles/box
Cat. no. U349	Fluid A, USP, 500ml Polycarbonate Bottle, 300ml	10 bottles/box
Cat. no. U436	Fluid A, USP, 8oz. Glass Bottle, 200ml	12 bottles/box
Cat. no. U110	Fluid D, USP, 100ml Glass Bottle, 100ml	20 bottles/box
Cat. no. U115	Fluid D, USP, 1L Polycarbonate Bottle, 1000ml	10 bottles/box
Cat. no. U135	Fluid D, USP, 180ml Wide Mouth Jar, 100ml	12 jars/box
Cat. no. U210	Fluid D, USP, 500ml Polycarbonate Bottle with septum cap, 300ml	10 bottles/box
Cat. no. U215	Fluid D, USP, 500ml Polycarbonate Bottle with septum cap, 500ml	10 bottles/box
Cat. no. U346	Fluid D, USP, 500ml Glass Bottle with septum cap, 300ml	10 bottles/box
Cat. no. U437	Fluid D, USP, 4oz. Glass Bottle, 100ml	20 bottles/box
Cat. no. U206	Fluid K, USP, 1L Polypropylene Bottle, 1000ml	10 bottles/box
Cat. no. U348	Fluid K, USP, 500ml Glass Bottle with septum cap, 300ml	10 bottles/box

INTENDED USE

Hardy Diagnostics USP Fluids A, D, and K are used by the pharmaceutical and medical device industry in procedures used to ensure sterility of injectables, non-injectables, liquid products, oils and ointments, antibiotic powders, sterile pathway devices and aerosols.[1]

SUMMARY

Hardy Diagnostics USP Fluids A, D, and K are formulated by the USP guidelines for use by the pharmaceutical and medical device industry to ensure sterility of pharmaceuticals and medical devices. The three fluids have specific applications as defined by the U.S. Pharmacopeia (USP) for diluting, neutralizing, dissolving and rinsing of devices and membrane filters.[1]

Fluid A, USP is a 0.1% peptone solution and if appropriate to the test being performed, beta-lactamase may be added to

neutralize any residual antibiotic activity on membrane surfaces. Fluid A, USP has wide applications for use with many different types of test articles including use with bacteriostatic or fungistatic articles or articles that contain a preservative, as Fluid A is recommended in validation tests of bacteriostasis and fungistasis by the USP. Other uses of Fluid A, USP are as a diluting fluid for both miscible and immiscible liquids and the dissolving of antibiotic powders followed by membrane filter rinses.(1)

Fluid D, USP is a 0.1% peptone solution, same formulation as Fluid A, USP, plus Tween® 80. Fluid D, USP also has several applications. Fluid D, USP can be used in validation test for bacteriostasis and fungistasis in articles containing lecithin, oil or a preservative. Fluid D, USP is also used as a membrane filter wash solution when testing ointments and oils. For sterile aerosol products, Fluid D, USP is used as a diluting solution. For devices labeled as "sterile pathway", Fluid D, USP is used to pass through each device.(1)

Fluid K, USP is a 0.5% peptone solution plus beef extract and Tween® 80. For those substances that contain petrolatum, Fluid K, USP is used both for moistening filter membranes prior to filtration and washing filter membranes following filtration.(1)

FORMULA

Ingredients per liter of deionized water*

Fluid A, USP	
Meat Peptone	1.0gm

Final pH 7.1+/- 0.2 at 25ºC.

Fluid D, USP	
Meat Peptone	1.0gm
Tween® 80	1.0ml

Final pH 7.1 +/- 0.2 at 25ºC.

Fluid K, USP	
Meat Peptone	5.0gm
Beef Extract	3.0gm
Tween® 80	10.0ml

Final pH 6.9 +/- 0.2 at 25ºC

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

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-25ºC. away from direct light. Media should not be used if there are any signs of deterioration, discoloration, contamination, or if the expiration date has passed. Product is light and temperature sensitive; protect from light, excessive heat, moisture, and freezing.

The expiration date on the product label applies to the product in its intact packaging when stored as directed. The product may be used and tested up to the expiration date on the product label and incubated for the recommended incubation times as stated below.

Refer to the document "Storage" for more information.

PRECAUTIONS

This product may contain components of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not guarantee the absence of transmissible pathogenic agents. Therefore, it is recommended that these products be treated as potentially infectious, and handle observing the usual universal blood precautions. Do not ingest, inhale, or allow to come into contact with skin.

This product is for laboratory use only. It is to be used only by adequately trained and qualified laboratory personnel. Observe approved biohazard precautions and aseptic techniques. All laboratory specimens should be considered infectious and handled according to "standard precautions." Refer to the document "Guidelines for Isolation Precautions" from the Centers for Disease Control and Prevention.

For additional information regarding specific precautions for the prevention of the transmission of all infectious agents from laboratory instruments and materials, and for recommendations for the management of exposure to infectious disease, refer to CLSI document M29: *Protection of Laboratory Workers from Occupationally Acquired Infections.*

Sterilize all biohazard waste before disposal.

Refer to the document "Precautions When Using Media" for more information.

PROCEDURE

It is recommended that all procedures involving the use of USP Fluids A, D, and K follow the guidelines as outlined in the U.S. Pharmacopeia (USP) Standard.

INTERPRETATION OF RESULTS

Interpretation of results would be those as defined by the U.S. Pharmacopeia (USP) Standard.

LIMITATIONS

It is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on colonies from pure culture for complete identification of bacteria and/or fungi.

Refer to the document "Limitations of Procedures and Warranty" for more information.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as loops, other culture media, swabs, applicator sticks, incinerators, and incubators, etc., as well as serological and biochemical reagents, are not provided.

QUALITY CONTROL

Hardy Diagnostics tests each lot of commercially manufactured media using appropriate quality control microorganisms and quality specifications as outlined on the Certificate of Analysis (CofA) and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media*. The following microorganisms are routinely used for testing at Hardy Diagnostics:

Test Organisms	Inoculation Method*	Incubation			Results
		Time	Temperature	Atmosphere	
Staphylococcus aureus ATCC® 6538	J	24hr	30 - 35°C	Aerobic	Growth
Pseudomonas aeruginosa					

ATCC® 9027	J	24hr	30 - 35°C	Aerobic	Growth
Bacillus subtilis ATCC® 6633	J	24hr	30 - 35°C	Aerobic	Growth
Candida albicans ATCC® 10231	J	24hr	20 - 25°C	Aerobic	Growth
Escherichia coli ATCC® 8739	J	24hr	30 - 35°C	Aerobic	Growth
Salmonella enterica ATCC® 14028	J	24hr	30 - 35°C	Aerobic	Growth
Aspergillus brasiliensis ATCC® 16404	J	24hr	20 - 25°C	Aerobic	Growth

* Refer to the document "Inoculation Procedures for Media QC" for more information.

USER QUALITY CONTROL

End users of commercially prepared culture media should perform QC testing in accordance with applicable government regulatory agencies, and in compliance with accreditation requirements. Hardy Diagnostics recommends end users check for signs of contamination and deterioration and, if dictated by laboratory quality control procedures or regulation, perform quality control testing to demonstrate growth or a positive reaction and to demonstrate inhibition or a negative reaction, if applicable. Hardy Diagnostics quality control testing is documented on the certificate of analysis (CofA) available from Hardy Diagnostics Certificate of Analysis website. Also refer to the document "Finished Product Quality Control Procedures," and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media* for more information on the appropriate QC procedures. See the references below.

PHYSICAL APPEARANCE

USP Fluids A, D, and K should appear clear, and light to medium amber in color.

REFERENCES

1. The Official Compendia of Standards. *USP-NF*. United States Pharmacopeial Convention, Rockville, MD.

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Ordering Information

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California · Washington · Utah · Arizona · Texas · Ohio · New York · Florida · North Carolina

The Hardy Diagnostics manufacturing facility and quality

management system is certified to ISO 13485.

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