



## Instructions for Use

### USP RINSING AND DILUTING FLUIDS

<a href="#">Cat. no. K205</a>	Fluid A, USP, 20x125mm Tube, 18ml	20 tubes/box
<a href="#">Cat. no. U13</a>	Fluid A, USP, 4oz. Glass Bottle, 100ml	20 bottles/box
<a href="#">Cat. no. U17</a>	Fluid A, USP, 8oz. Wide Mouth Jar, 90ml	12 jars/box
<a href="#">Cat. no. U19</a>	Fluid A, USP, 125ml Polypropylene Bottle, 100ml	12 bottles/box
<a href="#">Cat. no. U109</a>	Fluid A, USP, 100ml Serum Bottle, 100ml	20 bottles/box
<a href="#">Cat. no. U249</a>	Fluid A, USP, 16oz. Glass Bottle with septum cap, 600ml	10 bottles/box
<a href="#">Cat. no. U208</a>	Fluid A, USP, 1L Polycarbonate Bottle, 1000ml	10 bottles/box
<a href="#">Cat. no. U209</a>	Fluid A, USP, 200ml Serum Bottle, 200ml	10 bottles/box
<a href="#">Cat. no. U342</a>	Fluid A, USP, 500ml Glass Bottle, 300ml	10 bottles/box
<a href="#">Cat. no. U349</a>	Fluid A, USP, 500ml Polycarbonate Bottle, 300ml	10 bottles/box
<a href="#">Cat. no. U436</a>	Fluid A, USP, 8oz. Glass Bottle, 200ml	12 bottles/box
<a href="#">Cat. no. U110</a>	Fluid D, USP, 100ml Glass Bottle, 100ml	20 bottles/box
<a href="#">Cat. no. U115</a>	Fluid D, USP, 1L Polycarbonate Bottle, 1000ml	10 bottles/box
<a href="#">Cat. no. U135</a>	Fluid D, USP, 180ml Wide Mouth Jar, 100ml	12 jars/box
<a href="#">Cat. no. U210</a>	Fluid D, USP, 500ml Polycarbonate Bottle with septum cap, 300ml	10 bottles/box
<a href="#">Cat. no. U215</a>	Fluid D, USP, 500ml Polycarbonate Bottle with septum cap, 500ml	10 bottles/box
<a href="#">Cat. no. U346</a>	Fluid D, USP, 500ml Glass Bottle with septum cap, 300ml	10 bottles/box
<a href="#">Cat. no. U437</a>	Fluid D, USP, 4oz. Glass Bottle, 100ml	20 bottles/box
<a href="#">Cat. no. U206</a>	Fluid K, USP, 1L Polypropylene Bottle, 1000ml	10 bottles/box
<a href="#">Cat. no. U348</a>	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.<sup>(1)</sup>

### 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.<sup>(1)</sup>

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.<sup>(1)</sup>

Fluid D, USP is a 0.1% peptone solution, same formulation as Fluid A, USP, plus Tween<sup>®</sup> 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.<sup>(1)</sup>

Fluid K, USP is a 0.5% peptone solution plus beef extract and Tween<sup>®</sup> 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.<sup>(1)</sup>

## FORMULA

Ingredients per liter of deionized water\*

Fluid A, USP	
Meat Peptone	1.0gm

Final pH 7.1+/- 0.2 at 25°C.

Fluid D, USP	
Meat Peptone	1.0gm
Tween <sup>®</sup> 80	1.0ml

Final pH 7.1 +/- 0.2 at 25°C.

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

Final pH 6.9 +/- 0.2 at 25°C

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

## STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-25°C. 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 dating 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 quality control incubation times.

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." The "Guidelines for Isolation Precautions" is available from the Centers for Disease Control and Prevention at [www.cdc.gov/ncidod/dhqp/gl\\_isolation.html](http://www.cdc.gov/ncidod/dhqp/gl_isolation.html).

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 M-29: *Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline*.

Sterilize all biohazard waste before disposal.

Refer to the document "[Precautions When Using Media](#)" for more information.

Refer to the document [SDS Search](#) instructions on the Hardy Diagnostics' website 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.

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 Certificates of Analysis (CofA). The following

organisms are routinely used for testing at Hardy Diagnostics:

Test Organisms	Inoculation Method*	Incubation			Results
		Time	Temperature	Atmosphere	
<i>Staphylococcus aureus</i> ATCC® 6538	J	24hr	30 - 35°C	Aerobic	Growth
<i>Pseudomonas aeruginosa</i> ATCC® 9027	J	24hr	30 - 35°C	Aerobic	Growth
<i>Bacillus subtilis</i> ATCC® 6633	J	24hr	30 - 35°C	Aerobic	Growth
<i>Candida albicans</i> ATCC® 10231	J	24hr	20 - 25°C	Aerobic	Growth
<i>Escherichia coli</i> ATCC® 8739	J	24hr	30 - 35°C	Aerobic	Growth
<i>Salmonella enterica</i> ATCC® 14028	J	24hr	30 - 35°C	Aerobic	Growth
<i>Aspergillus brasiliensis</i> 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 certificates of analysis (CofA) available from Hardy Diagnostics [Certificates of Analysis](#) website. In addition, refer to the following document "[Finished Product Quality Control Procedures](#)," for more information on QC or see reference(s) for more specific information.

## 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](#)

Distribution Centers:

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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