

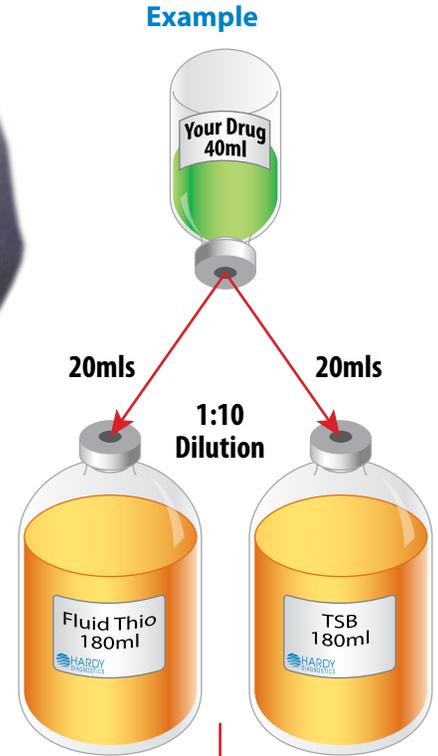
# USP <71> Simplified



## Sterility Testing Direct Inoculation Method for Compounding Pharmacies\*

### Step 1 - What is the sample size that I should use?

Determine how much drug needs to be tested from each container.



**Incubate**

Quantity per container	Minimum quantity to be used (unless otherwise justified & authorized)
<i>Liquids (other than antibiotics)</i>	
Less than 1ml	The whole contents of each container
1 - 40ml	Half the contents of each container, but not less than 1ml
Greater than 40ml and not greater than 100ml	20ml
Greater than 100ml	10% of the contents of each container, but not less than 20ml
<i>Antibiotic liquids</i>	1ml
<i>Other preparations soluble in water or in isopropyl myristate</i>	The whole contents of each container to provide not less than 200 mg
<i>Insoluble preparations, creams, and ointments to be suspended or emulsified</i>	Use the contents of each container to provide not less than 200mg
<i>Solids</i>	
Less than 50mg	The whole contents of each container
50mg or more, but less than 300mg	Half the contents of each container, but not less than 50mg
300mg - 5g	150mg
Greater than 5g	500mg
<i>Devices</i>	
Catgut and other surgical sutures for veterinary use	Three sections of strand (each 30cm long)
Surgical dressing/cotton/gauze (in packages)	100mg per package
Sutures and other individually packaged single-use material	The whole device
Other medical devices	The whole device, cut into pieces or disassembled

\* These guidelines are an interpretation of the USP <71> and should not be used as a substitute for the complete regulations to be found within.

## Step 2 – How much culture media broth do I need to use?

Determine the amount of the culture media required for your sample size. USP <71> recommends a minimum 1:10 dilution of your drug to the culture media broth (Tryptic Soy Broth and Fluid Thioglycollate Broth).

**Example:** If your sample size is 20mls, to make a 1:10 dilution by adding 20ml of sample to 180ml of Tryptic Soy Broth and 180ml of Fluid Thioglycollate Broth. See page 4 for a selection of culture media.

In this example, 180ml of culture media is used to make a 1:10 dilution of a 20ml sample. It is acceptable to use a larger (but not a smaller) dilution factor. The higher the dilution, the greater the likelihood of diluting out the preservative effects in your drug sample.

**If the drug is oily,** use Tryptic Soy Broth with Lecithin and Tween® 80 and Fluid Thioglycollate with Lecithin and Tween® 80. Lecithin and Tween® 80 are emulsifying agents.

**If the drug is a cream or ointment,** make a 1:10 dilution in Fluid A and then transfer to Tryptic Soy Broth and Fluid Thioglycollate Medium

**If the drug is a solid,** transfer the sample amount (from the table in Step 1) to 200ml of Tryptic Soy Broth and 200ml of Fluid Thioglycollate Broth, then incubate.

## Step 3 - How many samples do I need to test?

Determine the number of samples to be tested based on batch size.

Number of containers in the batch	Minimum number of containers to be tested for each medium (unless otherwise justified & authorized)
<i>Parenteral Preparation</i>	
Not more than 100 containers	10% or 4 containers, whichever is greater
More than 100 containers but not more than 500 containers	10 containers
More than 500 containers	2% or 20 containers, whichever is less
For large-volume parenterals	2% or 10 containers, whichever is less
<i>Antibiotic Solids</i>	
Pharmacy bulk packages (<5g)	20 containers
Pharmacy bulk packages (>5g)	6 containers
Bulks and blends	See Bulk Solid Products
<i>Ophthalmic and other non-injectable preparations</i>	
Not more than 200 containers	5% or 2 containers, whichever is greater
More than 200 containers	10 containers
If the product is presented as single-dose containers, apply the scheme shown above for preparations for parenteral use	
<i>Devices</i>	
Catgut and other surgical sutures for veterinary use	2% or 5 packages, whichever is greater, up to a maximum total of 20 packages
Not more than 100 articles	10% or 4 articles, whichever is greater
More than 100 articles but not more than 500 articles	10 articles
More than 500 articles	2% or 20 articles, whichever is less
<i>Bulk Solid Products</i>	
Up to 4 containers	Each container
More than 4 containers but not more than 50 containers	20% or 4 containers, whichever is greater
More than 50 containers	2% or 10 containers, whichever is greater

# Step 4 - How long do I incubate?

Incubation Time - 14 days

Incubation Temperatures

- 30-35 °C for Fluid Thioglycollate Broth
- 20-25 °C for Tryptic Soy Broth

Incubation Atmosphere - ambient air



# Step 5 – How do I QC the media?

Growth promotion testing of the culture media broth is recommended in USP <71> in order to ensure that the broth will support the growth of microorganisms.

Inoculate Tryptic Soy Broth and Fluid Thioglycollate Broth with an organism preparation that will deliver less than 100 CFU. Inoculate each broth separately with one of each of the EZ-Accu Shot Select organisms listed below, then incubate for three days for bacteria and five days for fungi. You must get turbidity of the broth for the culture medium to pass the growth promotion test. This must be done with each lot of media received.



**Licensed, traceable strains:**

- Aspergillus brasiliensis* ATCC® 16404™
- Bacillus subtilis* subsp. *spizizenii* ATCC® 6633™
- Candida albicans* ATCC® 10231™

- Clostridium sporogenes* ATCC® 19404™
- Kocuria rhizophila* ATCC® 9341™
- Pseudomonas aeruginosa* ATCC® 9027™
- Staphylococcus aureus* subsp. *aureus* ATCC® 6538™



Cat. no. 8172

# Septum Bottle Media for USP <71>

## Septum Bottle Size Comparison

- A** 20ml glass bottle with flip seal
- B** 100ml glass bottle with flip seal
- C** 125ml (4oz) polycarbonate bottle
- D** 200ml glass bottle with flip seal
- E** 500ml (16oz) glass bottle
- F** 500ml (16oz) polycarbonate bottle
- G** 16x125mm glass tube with hungate cap
- H** 1000ml glass bottle (*image not shown*)

### Fluid Thioglycollate Medium

- G** 16x125mm tube, 7ml fill, 20/pk.....K284
- G** 16x125mm tube, 10ml fill, 20/pk.....K282
- A** 20ml glass bottle, 10ml fill, 50/pk ..... U6610
- A** 20ml glass bottle, 12ml fill, 50/pk..... U6612
- A** 20ml glass bottle, 15ml fill, 50/pk..... U66
- A** 20ml glass bottle, 20ml fill 50/pk..... U68
- B** 100ml glass bottle, 50ml fill, 20/pk.....U269
- B** 100ml glass bottle, 100ml fill, 12/pk ..... U84
- C** 125ml polycarbonate bottle, 100ml fill, 16/pk.....U121
- D** 200ml glass bottle, 150ml fill, 12/pk .....U207
- E** 500ml glass bottle, 300ml fill, 10/pk.....U427
- E** 500ml glass bottle, 400ml fill, 12/pk.....U272
- E** 500ml glass bottle, 500ml fill, 10/pk.....U273
- H** 1000ml glass bottle, 900ml fill, 10/pk.....U428

### Tryptic Soy Broth

- G** 16x125mm, 7ml fill, 20/pk.....K283
- A** 20ml glass bottle, 10ml fill, 50/pk ..... U8210
- A** 20ml glass bottle, 15ml fill, 50/pk..... U82
- A** 20ml glass bottle, 20ml fill, 50/pk ..... U38
- B** 100ml glass bottle, 50ml fill, 20/pk.....U267
- B** 100ml glass bottle, 70ml fill, 20/pk..... U79
- B** 100ml glass bottle, 100ml fill, 20/pk..... U46
- B** 100ml glass bottle, unlabeled, 100ml fill, 20/pk ..... U56
- D** 200ml glass bottle, 150ml fill, 12/pk .....U420
- C** 125ml polycarbonate bottle, 100ml fill, 16/pk.....U141
- E** 500ml glass bottle, 300ml fill, 10/pk.....U421
- E** 500ml glass bottle, 400ml fill, 12/pk.....U271
- E** 500ml glass bottle, 500ml fill, 10/pk.....U274
- H** 1000ml glass bottle, 900ml fill, 10/pk.....U422



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# CUSTOM MEDIA

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The Hardy Team includes a custom product development specialist and an experienced staff of microbiologists and medical technologists to provide support often needed with microbiology products.

Call (800) 266-2222 ext. 5696 to begin a relationship with a company that will work with you every step of the way to achieve your ultimate satisfaction!

**Note:** Custom media fill volumes and formulas can be requested if needed. Needle-port septum containers are generally recommended.

