# USP Chapter <71> FAQs

**What is a USP <71> test ?**

Typically performed by a microbiologist at a third party laboratory, USP <71> is the test that is performed on compounds, which according to USP, are required to be sterile. The preferred method is membrane filtration, direct inoculation is sometimes used depending on the formulation and the method validation.

**What media are used?**

*Fluid Thioglycollate Medium* is used for the culture of anaerobic bacteria, but can also detect aerobic bacteria. *Soybean–Casein Digest Medium* is suitable for the culture of both fungi and aerobic bacteria.

**What are Growth Promotion and Method Suitability Tests?**

Growth promotion tests use specific (six) strains of bacteria and fungi to ensure recovery and that there is no inhibition of growth by the formulation, which would result in a false negative result. See USP <71> table 1 for the specific species of microorganisms used.

Method suitability verifies that the method used for sterility testing for a specific formulation is capable of detecting contamination, and accounts for any necessary steps that must be performed, such as dilution, ensuring an accurate result. Standard protocol requires three separate tests of the formulation to validate the method.

**How many units and what volumes are needed for the USP <71> Test?**

See USP <71>, and the tables below, which outline the minimum number of units and the minimum volumes that need to be tested, based on batch size and the volume per CSP container. Keep in mind that testing is performed using two media. Also keep in mind that if the volume per container is less than 1 mL, the entire contents of the container will be used.

The table below specifies number of units to be tested according to the number of units prepared in the batch.

| # Units Prepared in Batch | # Units Tested per Batch |
|---|---|
| **≤ 100** | 10% or 4 (whichever is greater) |
| **> 100 but ≤ 500** | 10 units |
| **> 500** | 2% or 20 units (whichever is less) |

The table below specifies the minimum quantity (or volume) to be used for each medium according to the CSP unit volume.

| Volume Quantity (mL) of CSP | Minimum Quantity to be Used per Sterility Test Unit |
|---|---|
| **< 1mL** | Entire contents of CSP |
| **1 mL to 40 mL** | Half the contents of the unit but not < 1 mL |
| **> 40mL but ≤ 100 mL** | 20 mL |
| **> 100 mL** | 10% of the contents of the unit but not < 20 mL |

*Source: USP Chapter <71> Current with USP 38-NF 33*