



USP Sterility Sample Requirements
(For liquids only)

Quantity per Container	Minimum Quantity to be Used for each Medium
< 1 mL	The whole contents of each container
1 - 40 mL	Half the contents of each container, but not less than 1 mL
> 40 to ≤ 100 mL	20 mL
> 100 mL	10% of the contents of the container, but not less than 20 mL

Number of Items in the Batch	Minimum Number of Items to be Tested for each Medium^a
≤ 100 containers	10% or 4 containers, whichever is greater
> 100 to ≤ 500 containers	10 containers
> 500 containers	2% or 20 containers, whichever is less
For large volume parenterals	2% or 10 containers, whichever is less

^a If the contents of each sample are of sufficient quantity, they may be divided so that equal appropriate portions are added to each of the specified media (two or more media must be employed). If each sample does not contain sufficient quantities for each medium, use twice the number of samples indicated.