

Minimum Required Sample Size

Please note: Separate samples are required for microbiological and potency tests. Individual samples are required per test, per time point.

Potency Testing (minimum per active per analysis)

Animal Treats: 5

Capsules: 5

Creams/Lotions/Gels: 3 mL

Liquids: 2 mL

Lollipops: 2

Pellets: 5

Powder Aliquots: 1 Gm

Suppositories: 5

Suspensions: 5 mL

Tablets: 5

Troches: 5

Microbiological Testing

Bacterial Endotoxins: 1 mL (only)



Sterility Testing

Proper quality control procedures dictate the minimal amount of sample and number of samples necessary to perform an analysis, not necessarily to conduct a statistically valid sterility test. In general, the more product furnished for analysis, the higher the probability of detecting a non-sterile item. If possible, a sample size sufficiently large enough to represent the compounded preparation, packaged in the final delivery container, allows for the best chance in obtaining a valid sterility test.

Method Suitability: The sample size necessary to complete a USP <71> method suitability analysis is 6 times the sample size necessary to complete a single sterility test. Please consult USP <71> Tables 2 and 3 in order to determine this size, or consult an Eagle Client Care Specialist.

Example: The batch size is 50 of 5 mL articles. The sample size necessary to complete a single sterility test is 5 articles (see USP <71>, Table 3) multiplied by the minimum quantity to complete the analysis, or 2.5 mL/article/medium, or 25 mL total (see USP <71>, Table 2). Thus, the sample size necessary to complete a method suitability analysis is 6 times 25 mL, or 30 each of 5 mL articles.

USP <71> Table 2 and 3

Batch Size & Article Submission Examples

	50 containers	500 containers	600 containers
1 mL Use entire content in each media	5 TSB <u>5</u> FTM 10 total articles	10 TSB <u>10</u> FTM 20 total articles	12 TSB <u>12</u> FTM 24 total articles
5 mL Split contents in each media	5	10	12
50 mL Split contents in each media	5	10	12
100 mL Split contents in each media	5	10	12
150 mL Split contents in each media	5	10	12

*Need additional 1 sample to be used for endotoxin and potency testing.

**For solid dosage form use 1 mL example.