



Sample Submission Instructions and Form

Submitting a Compounded Preparation for Testing

Please read before completing Sample Submission Form.

- Determine your minimum required sample size (see right).
 - Samples for sterility testing should be sent in the dispensing container.
 - Suspensions require separate samples for microbiological and chemical tests.
 - Please send two separate sample containers if requesting potency and microbiological testing on the same sample.
- Complete a Sample Submission Form for each sample.
 - You can download this form or submit your sample online at eagleanalytical.com. Or, call 800.745.8916 to request a faxed form.
 - Include a formula worksheet for all preparations requiring a chemical test. Absence of a formula worksheet for your compound will delay getting your results.
 - Be sure to indicate any special handling requirements for your preparation.
- Ship your preparation, suitably packaged, to Eagle Analytical.
 - We suggest that you use overnight shipping so that you can track your shipment.
 - For preparations that are temperature sensitive, send in a cool pack container.
 - Be sure to properly package to prevent leaking or breaking. Make sure all vials or syringes are capped securely.
 - Ship to: **Eagle Analytical Services**
Attn: Sample Submission
9940 W. Sam Houston Pkwy S., Ste. 310
Houston, TX 77099
 - International Customers should add the following:
 - Clearly mark on the shipping documents: "PHARMACEUTICAL SAMPLE FOR ANALYSIS ONLY – NOT FOR HUMAN USE"
 - Give the shipment a value of \$10.00
 - Send tracking number to info@eagleanalytical.com
- A laboratory report will be faxed to you immediately upon completion of each test that you have indicated. You can also view your results online if you complete the [Client Registration form](#).
- At the conclusion of all of your tests, Eagle will issue a final laboratory report and invoice.

NOTE: Any cancellation of an extended study must be requested by the customer. **There is a \$100 fee applied to each cancellation** to cover documentation of sample reconciliation and destruction.

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	Powder Aliquots: 1 Gm
Capsules: 5	Suppositories: 5
Creams/Lotions/Gels: 3 mL	Suspensions: 5 mL
Liquids: 2 mL	Tablets: 5
Lollipops: 2	Troches: 5
Pellets: 5	

Microbiological Testing

Bacterial Endotoxins: 2 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.