Sample Submission Form

Please read instructions before completing this form.

9940 W. Sam Houston Pkwy S., Suite 310, Houston, TX 77099
Email: info@eagleanalytical.com | **Call:** 800.745.8916 | **Fax:** 713.570.2350

OFFICE USE ONLY
Date Received: _____
Sample ID #: _____

Minimum Required Sample Sizes

Individual samples are required per test, per time point.

Animal Treats: 5
Bacterial Endotoxins: 2 mL (only)
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

Contact Information

Name: _____
Company: _____
Address: _____
City: _____ State: _____ Zip: _____
Phone: _____ Fax: _____
Email: _____

PCCA Member #/Customer #: _____
PO #: _____
Type of Facility (check one): ☐ 503A ☐ 503B

Sample Information

Enter all information as labeled on container.

Lot Number: _____
Sample Name: _____
Storage Conditions: ☐ Room Temperature ☐ Refrigerated ☐ Frozen
Number of Articles (containers): _____

Chemistry Tests

Indicate free base, salt or hydrated form. Active will be reported as indicated below. List additional actives in the Comments section.

☐ Potency — Active _____ Concentration _____
☐ pH — Active _____ Concentration _____
☐ Raw Material Assay — Active _____ Concentration _____
☐ Raw Material ID — Active _____ Concentration _____
☐ Specific Gravity

Account for any overfill in bags, or include overfill test.

Rush Service: ☐ Yes ☐ No

Comments: _____

Note: Absence of a formula worksheet with submission may cause a delay in analysis.

Microbiological Tests

Refer to Sample Submission Instructions to determine your minimum required sample size.

☐ ScanRDI® Sterility Test
Method Suitability Test required on file.
Rush Service: ☐ Yes ☐ No
Batch Size (e.g., 5x10 mL vials) _____

☐ Scan RDI Method Suitability Test
Batch Size (e.g., 5x10 mL vials) _____

☐ USP <51> Anti-Microbial Effectiveness (AME) Test

☐ USP <61> Microbial Enumeration Test

☐ USP <61>/<62> Method Suitability Test

☐ USP <62> Objectionable Organisms

☐ USP <71> Sterility Test
Method Suitability Test required on file.
Batch Size (e.g., 5x10 mL vials) _____

☐ USP <71> Method Suitability Test
Batch Size (e.g., 5x10 mL vials) _____

☐ USP <85> Bacterial Endotoxin Test
Provide sample concentration details in the Additional Information section.
Maximum Dose (per kg per hour) _____
Average Weight of Patient (kg) _____
Route of Administration _____
Rush Service: ☐ Yes ☐ No

☐ USP <788> Particulate Count Test
Rush Service: ☐ Yes ☐ No

☐ USP <1207> Container Closure Integrity Test
Rush Service: ☐ Yes ☐ No

☐ Media Fill

☐ Microbial ID

Additional Information: _____

Note: Early cancellation of sterility tests may result in cancellation fees.

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Sample Submission Instructions and Form

Submitting a Compounded Preparation for Testing

Please read before completing Sample Submission Form.

1. 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.

2. 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.

3. 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

4. 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.

5. 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.

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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: 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 5 FTM 10 total articles	10 TSB 10 FTM 20 total articles	12 TSB 12 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.