



# 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

Creams/Lotions/Gels: 3 mL

Pellets: 5

Suspensions: 5 mL

Bacterial Endotoxins: 2 mL (only)

Liquids: 2 mL

Powder Aliquots: 1 Gm

Tablets: 5

Capsules: 5

Lollipops: 2

Suppositories: 5

Troches: 5

## Contact Information

Name: \_\_\_\_\_

PCCA Member #/Customer #: \_\_\_\_\_

Company: \_\_\_\_\_

PO #: \_\_\_\_\_

Address: \_\_\_\_\_

Type of Facility (check one):  503A  503B

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

Email: \_\_\_\_\_

## 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.*



# 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](http://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](mailto: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.