Sample Submission Guidelines

1. Sample Submission

After completing the sample submission process via the Client Portal, please send samples to ARL via traceable means, such as FedEx, UPS, or DHL to:

ARL Bio Pharma
Attn: Sample Administration Department
840 Research Parkway, Suite 546
Oklahoma City, OK 73104

Please include a copy of the sample submission confirmation page from the portal to prevent testing delays.

Samples are received at ARL Monday through Saturday (excluding holidays).

If potential degradation due to heat during shipping is possible, we recommend using insulated packaging, freezer packs, and overnight shipping. Please note the freezer packs will collect moisture on the surface due to condensation. This moisture can cause problems with paperwork and sample labels. It is therefore recommended that the samples are packed appropriately to prevent breakage and forms placed inside a plastic bag that is sealable to reduce condensation damage.

2. Sample Quantity

The following are the **minimum sample** sizes for potency testing of each active selected. If requesting both microbiology and potency testing, please provide separate containers for each test to avoid delays. When containers must be shared between sterility/fungal and potency, the potency test(s) turnaround time will be extended by 2 business days. Failure to provide the minimum required quantities may result in delays.

Potency (Per Requested Active)	
Raw Powders	50 mg
Triturates/Blend Powders	1 g
Capsules/Solid Doses	5 capsules/doses
Suspensions	10 mL*
All Other Liquid Samples	2 mL
Creams/Lotions	3 g

*The sample container's maximum volume should be no more than 2X the amount of sample provided. For example, 10 mL's should be provided in no larger than a 20 mL bottle.

Sample quantity requirements for all other tests are listed in the Price Book.

3. USP Test Method Citations and Alternative Methods

Sterility Testing USP <71> – To cite USP <71> as the test method, a copy of a formulation sheet for the finished product that includes a formulation identification number, maximum batch size, and formulation sheets for any sub-formulas must be submitted for method suitability library verification. If ARL has a library match, the result will be sent, and library verification fees apply. If ARL does not have a method suitability on file for the submitted formula, the result will be sent, library verification fee will apply, and the amount of sample required for method suitability will be requested. If method suitability is later performed on the same formulation following the instructions provided with the library verification result, the library verification fee will be deducted from the method suitability fee.

Sterility Testing MBI-144 – This is an internal ARL method that will be cited in the event the number of articles required per USP <71>

are not submitted for testing or method suitability cannot be traced to the specific formulation.

Rapid Sterility Testing – ARL offers multiple technologies for sterility tests that provide test results faster than USP <71> or MBI-144. All rapid sterility test methods are validated per USP <797>/<1223> and require formulation specific method suitability. ARL offers multiple avenues to obtain a method suitability. To determine what is required for method suitability, please submit a copy of a formulation sheet for the finished product that includes a formulation identification number, maximum batch size, and formulation sheets for any sub-formulas. The initial assessment is subject to a fee, which may be reimbursed to you if method suitability is performed. After the assessment is completed, ARL will inform you of the next steps including any sample requirements and fees.

Endotoxin Testing USP <85> – To cite USP <85>, an endotoxin limit must be provided or the information to calculate the limit. To calculate an endotoxin limit, the maximum dose per hour, average patient weight, and route of administration must be provided to ARL. For ARL tocalculate the most conservative endotoxin limit, please provide the highest potential dose in the lowest potential weight patient during sample submission.

Endotoxin Testing MBI-145 – This is an internal ARL method that will be cited if the endotoxin limit or the information required to calculate the limit is not provided.

Antimicrobial Effectiveness Testing USP <51> – To cite USP <51> as the test method, a copy of a formulation sheet that includes a formulation identification number and sufficient sample must be provided to perform method suitability.

Microbial Enumeration Testing USP <61> – To cite USP <61> as the test method, a copy of a formulation sheet that includes a formulation identification number and sufficient sample must be provided to perform method suitability.

Testing For Specified Organisms USP <62> – To cite USP <62> as the test method, a copy of a formulation sheet that includes a formulation identification number and sufficient sample must be provided to perform method suitability.

Container Closure Integrity Testing USP <1207> – To cite this method, method validation or method verification is required. To determine if validation or verification is required, provide ARL with formulation and container closure information.

Particulate Matter USP <788> and <789> – To cite USP <788> or <789> as the test method, there must be a minimum of 25 mL in asingle test article (vial, bag, syringe) or 10 articles if each contains less than 25 mL.

4. Turnaround Times (In Business Days) and Rush Options

The turnaround time for all tests except for sterility is calculated from the day after receipt of the sample. For example, if a sample were received on Monday, day one would begin on Tuesday.
If rush services are requested on multiple tests, all results must be delivered by the due date for rush fees to apply.

Rush service turnaround times may be extended +1 business day if

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samples are received past 12:00pm CST.

When requesting rush services on sample requiring multiple tests, please contact ARL for instructions on appropriate sample requirements. We recommend sending separate containers for each rush test. Failure to do so may result in testing delays.

Potency Testing – See ARL's Potency List for rush turnaround time options. If rush services are requested on more than one active, rush turnaround times will be based on the active with the longest turnaround time. Rush services must be met on all requested actives for rush fees to apply.

Sterility Method Suitability – If method suitability sample arrives at the same time as sterility test sample, ARL will attempt to complete method suitability by the time the sterility test is completed.

Sterility – If method suitability has been established, ARL attempts to begin the sterility test on the day of sample arrival. In most cases, if method suitability has not been established, ARL will begin sterility test one day after sample arrival. Preliminary test results will be sent after approximately 3 days of incubation. Final test results are sent after 14 – 18 days of incubation.

Time Point Testing – The initial test date and all future test dates will be determined from the date received unless otherwise specified by the client. The default time point testing window is ± 3 days but rush options are available by selecting "Rush" for + 1 day or + 0 days by requesting "Super Rush".

A. Potency rush fees are defined in ARL's Potency List. Potency time point test results, except for time zero, are reported the following business day for all turnaround time service levels.
B. Rush services may not be available for outsourced tests. Contact ARL for more information.

5. Analytes Not On The Potency List

When submitting actives for potency testing that are not on our current potency list, please contact ARL in advance to verify testing capability.

6. Potency Out Of Specification (OOS) Samples

The turnaround time for OOS investigations is 4 business days. Additional days may be required if more than one analyte must be investigated. When rush potency services are requested and preliminary results are sent via e-mail within the requested testing window, the rush fee will apply if the cause of the OOS investigation is not due to lab error. Final Test results will be sent when the OOS investigation has been completed.

7. Special Handling/Shipping Fees

A minimum fee of $50 can be assigned at ARL's discretion when special handling instructions such as mixing, crushing, combining, special storage conditions or other special requests are requested. Also, a shipping & handling fee will be charged to return samples or to ship samples elsewhere. Please contact ARL for more information about fees associated with shipping samples.

8. Formulation Changes

If a formulation changes after method suitability has been established, please provide a copy of a formulation sheet for the finished product that includes a formulation identification number, maximum batch size, and formulation sheets for any sub-formulas.

9. Sample Retention and Disposal

Samples are retained for 30 days after analysis. Prior arrangements must be made to retain samples under other condition or to return samples. Unless alternate arrangements have been made, raw data will be retained for 5 years plus the current year after report date. Documents that have surpassed their retention time and/or documents that have been scanned and saved electronically will be shredded by a third party.

10. Litigation Samples

For samples submitted of a suspect or forensic nature or for purposes of litigation, please contact ARL for a quote

11. Terms and Conditions

By submitting samples to ARL, you certify that

A. All information provided is true and correct.
B. You have reviewed the Terms and Conditions located on ARL's website at www.arlok.com/Forms.
C. You agree to be bound by the Terms and Conditions and
D. If you are submitting samples on behalf of a company or other entity, you have the authority to bind that company or entity to the Terms and Conditions. For cGMP services, please contact ARL to request a quotation and quality agreement.