

## 1. Sample Submission

Please send samples to ARL via traceable means, such as FedEx, UPS, or DHL. Please complete our sample submission form and submit it with the sample. Please send the sample to the attention of the Sample Administration Department. Samples are received at ARL Monday through Friday (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 department to avoid testing delay. When containers must be shared between sterility/fungal and potency, the potency test(s) turnaround time will be extended an additional 2 business days. Failure to provide the minimum required quantities may result in testing delay.

Potency (Per Requested Active)		
Raw Powders	50 mg	
Triturate/ Blend Powders	1 g	
Capsules/ Solid Doses	5 Capsules/Doses	
Oral Suspensions	10 mL	
All Other Liquid Samples	2 mL	
Creams or Lotions	3 grams	
Suppositories	5 Suppositories	
Microbiology		
Sterility USP <71>	Refer to USP <71> for # of Articles (PLUS additional sample for method suitability if required)	
Rapid Sterility MBI-200	2 mL (Can also sample per USP <71>)	
Sterility MBI-144	2 mL	
Endotoxin USP <85>	1 mL	
Endotoxin MBI-145	1 mL	
Fungal	1 mL	
USP <51>	70 g or 70 mL	
USP <61>	12 g or 12 mL	
USP <62>	Bile-Tolerant Gram Neg	2 g or 2 mL
	<i>C. albicans</i>	2 g or 2 mL
	<i>C. sporogenes</i>	4 g or 4 mL
	<i>E. coli</i>	2 g or 2 mL
	<i>P. aeruginosa</i>	2 g or 2 mL
	<i>S. aureus</i>	2 g or 2 mL
	<i>S. enterica</i>	12 g or 12 mL

## 3. USP Test Method Requirements 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 identifier (number preferred) and 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. This method does not comply with USP <71>.

**Rapid Sterility Testing MBI-199** – This is a validated sterility test per USP <797>/<1223> with a 6-day turnaround time. To cite this method, a copy of a formulation sheet for the finished product that includes a formulation identifier (number preferred), maximum batch size, and formulation sheets for any sub-formulas must be submitted to determine if method suitability or method verification is required. This evaluation is subject to the library verification fee and will inform the client if method suitability or method verification is required and how much sample is needed. The library verification fee will be deducted if method suitability or method verification is later performed on the same formulation following the instructions provided with the library verification results.

**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 dosage per hour, average patient weight, and route of administration must be provided to ARL. For ARL to calculate the most conservative endotoxin limit, please provide the highest potential dose in the lowest weight potential 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. This method does not comply with USP <85>.

**Antimicrobial Effectiveness Testing USP <51>** – To cite USP <51> as the test method, a copy of a formulation sheet 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 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 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.

**Container Closure Integrity Testing by Dye Ingress or Vacuum Decay** Contact ARL for available options.

**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 a single test article (vial, bag, syringe) or 10 articles if each contains less than 25 mL.

## 4. Turnaround Time (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.

**Potency Testing** – See ARL’s Potency List at <https://www.arlok.com/Forms> 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** – If method suitability has been established, ARL begins 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.

**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. If method suitability samples are sent before sterility test samples, the turnaround time is 10 business days.

**Endotoxin** – The standard turnaround time is 3 business days. 1-day or same day rush analysis are available for an additional 50% or 100% upcharge, respectively.

**Particulate Matter** – The standard turnaround time is 5 business days. 3-day or 1-day rush analysis are available for an additional 50% or 100% upcharge, respectively.

If rush services are requested on multiple tests, all requested rush services must be met for rush fees to apply.

## 5. Time Point Testing – The initial test date will be defined as the date received unless otherwise specified. The default time point testing window is + 3 days but rush options are available by selecting “Rush” for $\pm 1$ day or + 0 days by requesting “same day” in the comments box.

- Potency rush fees are defined in ARL’s Potency List at <https://www.arlok.com/Forms>. Potency time point test results, except for time zero, are reported the following business day for all turnaround time service levels.
- Endotoxin rush fees are defined above.
- Sterility testing rush fees are 50% upcharge for + 1 day and 100% for + 0 days.
- Rush services may not be available for outsourced tests. Contact ARL for more information.

## 6. Actives 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. See potency list <https://www.arlok.com/Forms>.

## 7. Potency Out Of Specification (OOS) Samples – Samples that are initially deemed OOS require an additional 4 business days to complete an investigation and to report final test results. When rush service is 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.

## 8. 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.

## 9. 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 identifier (number preferred) and maximum batch size and formulation sheets for any sub-formulas.

## 10. Confidentiality – ARL Bio Pharma maintains strict confidentiality. Formal Confidentiality agreements may be initiated by request or by ARL.

## 11. 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.

## 12. Litigation Samples – For samples submitted of a suspect or forensic nature or for purposes of litigation, please contact ARL for a quote.

## 13. Terms and Conditions – By submitting samples to ARL you certify that (1) all information provided is true and correct; (2) you have reviewed the Terms and Conditions located on ARL’s website @ <https://www.arlok.com/Forms>; (3) you agree to be bound by the Terms and Conditions; and (4) 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 and request a quotation and quality agreement.