Sample Submission Guidelines

1. Sample Submission

a. Shipping Samples

Please send your samples to us "overnight" via traceable means, such as FedEx, UPS or DHL. Please fill out our sample submission form and submit with your sample. Please send the sample to the attention of the Sample Administration Department. Samples will be received at ARL Monday through Friday (excluding holidays).

If potential degradation due to heat during shipping is possible, we ask that you please utilize igloos and freezer packs. 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 be packed appropriately to prevent breakage and forms be placed inside a plastic bag that is sealable in order to reduce condensation damage.

b. Sample Quantity

The following are the **minimum sample** sizes for each potency test for each analyte 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 Analyte)		
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 material for method suitability if required)	
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
	C. albicans	2 g or 2 mL
	C. sporogenes	4 g or 4 mL
	E. coli	2 g or 2 mL
	P. aeruginosa	2 g or 2 mL
	S. aureus	2 g or 2 mL
	S. enterica	12 g or 12 mL

Sterility testing USP <71> - In order to cite USP <71> as the test method, you must submit a copy of a formulation sheet and sufficient sample material to perform method suitability testing.

Sterility testing MBI-144 - This is an internal ARL method that will be cited in the event that you do not provide the proper number of articles per USP <71> or method suitability cannot be traced to your specific formulation. This method does not comply with USP <71>.

Endotoxin testing USP <85> - To calculate an Endotoxin limit, you must provide ARL with the maximum dosage per hour, average patient weight and route of administration. For veterinary use, the client must also include the largest dose in the smallest animal. ARL's sample submission form allows for the required information to be documented. This information is needed in order to establish the most accurate endotoxin limit for your product as is outlined in USP <85>.

Endotoxin testing MBI-145 - This is an internal ARL method that will be cited in the event that you do not provide maximum dosage per hour, average patient weight and route of administration. This method does not comply with USP <85>.

Antimicrobial effectiveness testing USP <51> - In order to cite USP <51> as the test method, you must submit a copy of a formulation sheet and sufficient sample material to perform method suitability testing.

Microbial Enumeration testing USP <61> - In order to cite USP <61> as the test method, you must submit a copy of a formulation sheet and sufficient sample material to perform method suitability testing.

Testing for specified organisms USP <62> - In order to cite USP <62> as the test method, you must submit a copy of a formulation sheet and sufficient sample material to perform method suitability testing.

USP Compendia Specific Tests	
Particulate Matter <788> or <789>	25mL minimum in a single article, OR 10 units if the unit is less than 25mL

c. Turnaround Time (in business days) –

Turnaround time is calculated from the day after receipt of the sample. For example, if a sample was received on Monday, day one would begin on Tuesday.

	# actives	**Standard**	***Rush**
Potency (Cream/Ointment)	1 – 3	4	2
Potency (Cream/Ointment)	4 – 8	10	5
Potency (Cream/Ointment)	9+	Call for TAT	NA
Potency	1 – 3	3	1
Potency	4 – 8	1 day/active	2-4***
Potency	9+	Call for TAT	NA
Sterility**		3	NA
Sterility Method Suitability		10	NA
Endotoxin		3	1
Fungal**		4	NA
USP <51>		30	NA
USP <61>		15	NA
USP <62>		15	NA

When containers must be shared between sterility/fungal and potency the potency test(s) turnaround time will be extended an additional 2 business days.

*For most rush testing, there is an additional $50 fee per analyte
**Preliminary reading. Final results are available in 14-18 days
***Depending on number of analytes

d. When submitting drugs for potency testing that are not on our current drug list we ask that you please call in advance to verify testing capability.

2. **Testing Time Points-** Samples sent in for time point testing are analyzed within a testing window of ± 3 days with results reported the next business day after the test is completed. Clients have the option to specify a shorter testing window of ± 1 days or ± 0 days for the pre-defined time point. Specified testing windows will have fees assigned according to the following table:

Testing Window (in business days)	Service Fee (per analyte, per time point)
± 3 days	$0
± 1 days	$50
± 0 days	$100

The initial test date will be defined as the date received unless otherwise specified. Applicable tests for the selection of testing windows are:

- HPLC, IC, Endotoxin, pH, Appearance, Fill Volume
- Sterility and Fungal tests will be started according to the selected testing window and results will be reported based upon the actual setup date

The following tests are excluded from selection of a tighter testing window and require discussion with our business development department:

- Titration, GC, Particulate Matter, Any outsourced test
- Samples with > 3 active components in one preparation

3. Formulation Sheet – when requesting USP microbiology testing, please supply a formulation number and sheet with your sample for method suitability determination. If your formulation changes, please notify ARL and provide a new formulation number and sheet.

4. Confidentiality – ARL Bio Pharma maintains strict confidentiality with its customers. Formal Confidentiality agreements may be initiated by the customer or by ARL Bio Pharma.

5. 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.

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

7. Financial Information:

a. Payment in advance is required for customers whose credit has not been established with ARL Bio Pharma.
b. Payment terms are "Net 15" from date of invoice unless otherwise stated in a quote. Client agrees to pay all costs, including, but not limited to attorney and accounting fees and other expenses of collection resulting from any default by client in any terms of this contract.
c. Purchase orders or valid credit card information are required.
d. Contracts for services without this information may cause delay in testing.
e. For third party billing a signed purchase order must be received from the party being billed for the service.
f. Published pricing in designed for single samples. Project or volume discounts may be available. Quotations will be provided upon request by the client.
g. Additional charges may be assessed (i.e. hazardous samples) with client approval.
h. Liability of ARL Bio Pharma is limited to an amount no greater than the amount invoiced.

8. 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 @ http://www.arlok.com/arl-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.