Submitting Samples for Sterility Testing

The following information is to be used as a guideline for submitting sterility samples and is not intended to replace requirements of USP <71>, USP <797>, FDA, or State Boards of Pharmacy.

1. **Method Suitability**

Method suitability is a validation of the sterility test method. It is required to ensure the sterility test method is appropriate for the product being tested. ARL provides 2 options for clients to obtain method suitability data. Those options are as follows:

a. Method Suitability – a process in which 6 microorganisms are inoculated into to the test sample to ensure they can be detected.
b. Method Suitability Library Verification – a process by which your formulation is compared to others that already have method suitability on file. If there is a match, ARL completes paperwork linking the original method suitability and your formulation.

To determine if library verification is possible, please provide the following information:

a. a copy of the formulation sheet and formulation sheets for any sub-formulas or package inserts for any commercial products
b. the theoretical maximum batch size and fill volume
c. a formulation identification number

If a formulation sheet cannot be provided, method suitability library verification is not possible.

ARL does not perform library referencing for rapid sterility. Rapid sterility either requires method suitability or method verification. To determine which is required, please submit the information requested above.

2. **Method Suitability Sample Requirements**

Method suitability for USP <71> and MBI-144 require 3X the largest sample volume that will be tested. For example, if 100 mL is the maximum test volume (i.e., 10 vials with 10 mL each) then 300 mL is required for method suitability. Method suitability for rapid sterility requires 4X the largest sample volume that will be tested. Method verification for rapid sterility requires 1X the largest sample volume that will be tested.

Samples for method suitability can be submitted at the same time as samples for sterility testing.

If method suitability does not pass on the first attempt, additional sample by required for method suitability and any sample testing using the original method.

No sample is required for USP <71> method suitability library verification.

3. **Method Suitability Turnaround Times**

Please allow 10 business days to complete method suitability and 3 business days for the method

suitability library verification. Rapid sterility method verification requires 5 business days.

4. Method Suitability Results Reporting

Method suitability results will be released via a certificate of analysis. Method suitability results are reported as a pass or a fail. If method suitability fails, you may not receive a certificate of analysis. Instead, you may receive an email requesting additional sample and time to repeat method suitability. If this occurs, please include a copy of that email when sending the additional samples. Method suitability library referencing is reported as either available or not available. When library referencing is not available, you will receive a certificate of analysis and an email that specifies how much sample is required for method suitability. Please include a copy of that email when sending the samples for method suitability.

5. Formulation Changes and Method Suitability

Anytime the components of a drug product change, ARL recommends changing the formulation identification number and repeating the method suitability process.

6. Increasing Lot sizes or Increasing Fill Volumes and Method Suitability

Method suitability is test volume specific. Increasing the batch size or increasing the fill volume may require repeating sterility method suitability. Please be sure to consider maximum test volume when submitting method suitability information. ARL recommends changing formulation identification numbers when the fill volume changes.

7. Method Suitability for Product Families

To reduce the number of similar formulations requiring method suitability, ARL recommends sending the required information on all products.

8. MBI-144 Method Suitability

If sufficient formulation information can be provided, ARL may be able to perform sterility testing using MBI-144 without completing method suitability.

9. USP <71> Test Sampling

To list USP <71> as the test method, the correct number of articles must be submitted in accordance with Table 3 in <71>. Please note that the number of containers required per Table 3 must be doubled if the fill volume is < 2 mL. It is recommended that samples for sterility testing be collected from throughout the batch.

10. MBI-144 Test Sampling

If sampling per USP <71> and/or USP <797> is not followed, the test method will be MBI-144. A minimum of 2 mL's is required for MBI-144 testing.

11. Sample submission

Please submit samples on the portal at www.portal.arlok.com. Be sure to include a copy of the submission confirmation page with your samples. If applicable, please identify which samples are for method suitability and which are for sterility testing.

12. Sterility Test Results Reporting

ARL will send a preliminary report after 3 calendar days of incubation. If the 3rd calendar day falls on a weekend or holiday, the results will be reported the following business day. The final report will be released after 14 or 18 days of incubation, whichever is appropriate for your sample. We strive to provide sterility test results as soon as possible. However, please keep in mind that the incubation process cannot be rushed. Depending on the time of day that your sterility test begins incubation, your result may not be ready until the evening of the sterility read date.

Please call at 800-393-1595 if you have any questions.

Thank you,
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