



CHAIN OF CUSTODY USP<71> Sterility Testing

4125 Independence Drive, Suite5
Schnecksville, PA, 18078
484.550.7709

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Sample Submission – Please ship samples with Priority Overnight or Standard Overnight Shipping. For Saturday delivery, make prior arrangements with Azzur Labs and choose the Saturday Delivery/ First Priority overnight or Early AM options. Ship samples according to storage requirements. If the samples require refrigeration, ship them in an insulated container with ice packs. Do not allow ice packs to come in contact with samples. Include a return shipping label if you would like your ice packs and box returned.

Normal Business Hours Ship to: **Azzur Labs Sample Receipt Department 4125 Independence Drive Suite 5 Schnecksville, PA 18078**

Saturday Delivery Ship to: **Azzur Labs Sample Receipt Department 4125 Independence Drive Suite 5 Schnecksville, PA 18078 Saturday Delivery/ First Priority overnight or Early AM**

| | | | |
|--|--|-----------------|-----------------|
| Submitted By (Signature) | | Date | |
| Company Name | | PO# | Submission Date |
| Contact Name and Name of Person Sampling or Shipping | | Contact Email | |
| Report To Name | | Report To Email | |

| For AL Use Only Extension Number | Drug Name / Sample ID | Controlled Substance? | Sample Date | Lot Number | Test Requested Check all that apply | Product type e.g. parenteral, ophthalmic, etc | Total amount submitted for testing | Requested amount to test | Batch Size (Total number produced in batch) | Volume of unit | Antibiotic and/or preservative added? | Suitability Testing Completed within the last year? | Storage |
|--|--------------------------|--------------------------|-------------|------------|--|---|--|--------------------------------|---|-------------------|--|---|---------|
| | | O Yes O No | | | O Sterility Test (ST03) O Suitability Test (ST05) | | | | | | O Yes O No | O Yes O No | |
| | | O Yes O No | | | O Sterility Test (ST03) O Suitability Test (ST05) | | | | | | O Yes O No | O Yes O No | |
| | | O Yes O No | | | O Sterility Test (ST03) O Suitability Test (ST05) | | | | | | O Yes O No | O Yes O No | |
| | | O Yes O No | | | O Sterility Test (ST03) O Suitability Test (ST05) | | | | | | O Yes O No | O Yes O No | |
| | | O Yes O No | | | O Sterility Test (ST03) O Suitability Test (ST05) | | | | | | O Yes O No | O Yes O No | |

****If anything has changed during the manufacture/processing of any product, please contact Azzur Labs so that it can be determined if the suitability needs to be repeated.**** Stat reporting - Azzur Labs, LLC will issue a final report within 24 hours or 5 days of completed testing. Next day- Samples will be set up next business day. Weekend or Holiday- Azzur Labs, LLC will set up the testing on the weekend or holiday if given 72 hours notice and if it is received by the agreed upon time. All of these expedited services will incur an additional charge. By submitting samples to Azzur Labs, LLC you agree with the terms and conditions found at: <http://www.azzurlabs.com/terms-and-conditions/> Please contact Azzur Labs, LLC if you would like more information.

| | | | |
|--------------------------------------|--|--------------------|--|
| To be completed by Azzur Labs | | Report ID | |
| Received By / Date | | Reviewed By / Date | |



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Tables 2 and 3 are from USP <71>. Use these for reference in determining the appropriate amount of /number of containers to test. If this information is not provided, a Pass / Fail status cannot be assigned to the sample.

Table 3

| # of Items in Batch Size | Minimum # of Items to be Tested for each Medium |
|-------------------------------------|---|
| Parenteral | |
| NMT 100 containers | 10% or 4 containers, whichever is greater |
| > 100 but NMT 500 containers | 10 containers |
| > 500 containers | 2% or 20 containers, whichever is less |
| Ophthalmic and other Non-injectable | |
| NMT 200 containers | 5% or two containers, whichever is greater |
| >200 containers | 10 containers |

Table 2

| Quantity per Container | Minimum Quantity to be Used for each Medium |
|--|---|
| Liquids | |
| <1mL | The whole contents of each container |
| 1 to 40mL | Half the contents of each container, but not less than 1mL |
| > 40mL, and not greater than 100mL | 20 mL |
| > 100mL | 10% of the contents of the container, but not less than 20mL |
| Antibiotic Liquids | |
| Any amount | 1mL |
| Insoluble Preparations, Creams and Ointments to be suspended or emulsified | |
| Any amount | The contents of each container to provide not less than 200mg |

If it not possible to submit enough product to meet the requirements for submission, please indicate why.

| | | | |
|--------------------------------------|--|--------------------|--|
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