



CHAIN OF CUSTODY USP<71> Sterility Testing

Page _____ of _____

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.

Please visit azzurlabs.com/contact-us for shipping address for the lab location of your choosing.

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: 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	



**CHAIN OF CUSTODY
USP<71> Sterility Testing**

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.

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