



CHAIN OF CUSTODY USP<71> Sterility Testing

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Sample Submission – Please ship samples with Priority Overnight or Standard Overnight Shipping. **For Saturday delivery, make prior arrangements with Gillson Testing 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.

Ship to: Gillson Testing Receiving Department 4125 Independence Dr Suite 1 Schnecksville, PA 18078 Phone: 484.550.7709

Company Name		Date	
Submitted By (Signature)		PO#	
Contact Name, Name and email of Person Sampling and/or Shipping		Report to Name/Email	
Is STAT Testing/Setup required?*	<input type="checkbox"/> No <input type="checkbox"/> Yes - Detail Timeline:	Is STAT Reporting Required?*	<input type="checkbox"/> Not Required <input type="checkbox"/> Same Day STAT Report <input type="checkbox"/> 24-hour STAT Report <input type="checkbox"/> 5-day STAT Report
Additional Testing/Reporting Directives:			

*Subject to additional fees.

For GT 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
		<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Sterility Test (ST03) <input type="checkbox"/> Suitability Test (ST05)						<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes, Study #: _____ <input type="checkbox"/> No	
		<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Sterility Test (ST03) <input type="checkbox"/> Suitability Test (ST05)						<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes, Study #: _____ <input type="checkbox"/> No	
		<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Sterility Test (ST03) <input type="checkbox"/> Suitability Test (ST05)						<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes, Study #: _____ <input type="checkbox"/> No	
		<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Sterility Test (ST03) <input type="checkbox"/> Suitability Test (ST05)						<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes, Study #: _____ <input type="checkbox"/> No	
		<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Sterility Test (ST03) <input type="checkbox"/> Suitability Test (ST05)						<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes, Study #: _____ <input type="checkbox"/> No	

If anything has changed during the manufacture/processing of any product, please contact Gillson Testing so that it can be determined if the suitability needs to be repeated. Stat reporting – Gillson Testing, LLC will issue a final report within the above STAT time from the testing completion date. Stat Testing, Weekend or Holiday- Gillson Testing 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 Gillson Testing you agree with our terms and conditions. For a copy of the Terms and Conditions, please email Gillson Testing. Please contact Gillson Testing if you would like more information.

To be completed by Gillson Testing				
Report ID:		Received By/Date:		Reviewed By / Date



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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 Gillson Testing				
Report ID:		Received By/Date:		Reviewed By / Date