


**QUALITY SYSTEM**
FORM
**DOCUMENT #: 3.100.019.F01**
**LEVEL: 3**

Effective Date:

APPROVED

Revision #: 11

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**TITLE:**
**LABORATORY OOS INVESTIGATION FORM**

Page 1 of 6

**OOS Number: OOS-**
**Phase I**
**Section A – Test Details**

<b>Initiator:</b>		<b>Test Date:</b>		<b>Date Initiated:</b>	
<b>Date of Incident:</b>		<b>Test Name:</b>		<b>Sample ID:</b>	
<b>Name of Analyst who Performed the Test:</b>		<b>Sample / Active Name</b>		<b>Lot #:</b>	
		<b>Dosage Form</b>			
<b>Description of Incident:</b>			<input type="checkbox"/> Client Care notified of OOS <input type="checkbox"/> Sterility and Endotoxin test related OOS; Client must be notified within 24 hours of OOS		
	SOP / Test Method #	Effective Date:	SOP / Test Method Rev:	Limits/Specification:	
<b>Manager notified</b>	Manager/designee name:	Date:	Quality Assurance Department notified:	Yes <input type="checkbox"/>	No <input type="checkbox"/>

**Section B – Investigation and Root Cause Analysis**

<b>Personnel Discrepancy</b>			<b>Comments</b>	
Analyst interviewed?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
Correct samples analyzed?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
Correct SOP / Test Method used/followed?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
Correct sample collection/technique?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
Are the Test Result Records Attached & Calculations Verified and Correct?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
Is the analyst qualified to perform the test?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
Is formula worksheet provided and verified?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
Does the processing method/method set conform to the required specification?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
Was the sample stored appropriately?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
<b>Material Discrepancy</b>			<b>Lot Number</b>	<b>Expiry Date</b>
Is the integrity of the sample(s) questionable?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
Was the sample transported appropriately?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	
Are the other test results from this run under investigation?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	

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Revision #: 11

**TITLE:****LABORATORY OOS INVESTIGATION FORM**

Page 2 of 6

**OOS Number: OOS-**

Appropriate/correct glassware used?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A		
Are reagents stored in proper condition and not expired?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A		
Standard Used			
Solvent Used			
Is the standard the source of the root cause?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A		
Has the analyst been instructed to keep the original test solution for possible retesting?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A		
Equipment Discrepancy	Equipment ID	Calibration Due Date	
Was the instrument set up correctly?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A		
Is the clean room facility certified?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A		
System Performance Check (if applicable)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A		
System Suitability RSD < 2% (PDA)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A		
System Suitability RSD < 10% (QDA, CAD)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A		
Do the environmental monitoring results conform to required standards?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A		
Do the controls (i.e., positive, negative, etc.) conform to the required standards?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A		
Is equipment/instrument functional and calibrated/qualified/certified/PM?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A		

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Revision #: 11

**TITLE:****LABORATORY OOS INVESTIGATION FORM**

Page 3 of 6

**OOS Number: OOS-**

Are chromatogram/spectra/raw data correct?

 Yes    No    N/A**Section C – Evaluation of Laboratory Testing/Hypothesis Testing (if applicable)**

- |                                                                           |                                                                                                      |
|---------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> N/A                                              | <input type="checkbox"/> Re-vialing of original working sample solution                              |
| <input type="checkbox"/> Re-injection of sample vial                      | <input type="checkbox"/> Re-dilution of a working sample solution from the original stock            |
| <input type="checkbox"/> Re-injection of original standard vial           | <input type="checkbox"/> Re-dilution of a working standard solution from the original stock standard |
| <input type="checkbox"/> Re-vialing of original working standard solution | <input type="checkbox"/> Other: _____                                                                |

**Section D – Phase I Summary****Phase I Summary:**

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Revision #: 11

**TITLE:****LABORATORY OOS INVESTIGATION FORM**

Page 4 of 6

**OOS Number: OOS-****Phase I Summary (continued):**

**QUALITY SYSTEM****FORM****DOCUMENT #:** 3.100.019.F01**LEVEL: 3**

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Revision #: 11

**TITLE:****LABORATORY OOS INVESTIGATION FORM**

Page 5 of 6

**OOS Number: OOS-****Phase I Summary (continued):**

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Revision #: 11

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Page 6 of 6

**OOS Number:** OOS-**Has root cause been identified as a possible laboratory error?***Note: Root cause must be conclusive, verifiable, and well-documented.* Yes If retesting is **required**, complete Phase II of the OOS (initiate Form 3.100.019.F02). No, the OOS result is valid.**Reviewer comment(s):****Prepared by (Print):**

Signature/Date:

**Lab Manager/Designee (Print):**

Signature/Date:

**Section E – Quality Disposition****Can investigation be closed?** Yes Original result is valid. No, initiate Form 3.100.019.F02.**Approved by QA Representative (Print):**

Signature/Date: