OOS Number: OOS-

Phase I

Section A – Test Details					
Initiator:		**Test Date:**		**Date Initiated:**	
Date of Incident:		**Test Name:**	Scan RDI Sterility Test	**Sample ID:**	
Name of Analyst who Performed the Test:		**Sample / Active Name**		**Lot #:**	
		Dosage Form	Injectable		
Description of Incident:		☑ Client Care notified of OOS ☑ Sterility and Endotoxin test related OOS; Client must be notified within 24 hours of OOS			
	SOP / Test Method # 2.600.023 (10) 2.700.004 (03)	Effective Date: 07Apr2025 02Jan2023	SOP / Test Method Rev: Rev: 10 Rev: 03	Limits/Specification: <1 event	
Manager notified	Manager/designee name: Kathan Parikh	Date:	Quality Assurance Department notified:	Yes ☑ No ☐	

Section B – Investigation and Root Cause Analysis			
Personnel Discrepancy		**Comments**	
Analyst interviewed?	☑Yes ☐ No ☐ N/A		
Correct samples analyzed?	☑Yes ☐ No ☐ N/A		
Correct SOP / Test Method used/followed?	☑Yes ☐ No ☐ N/A	Yes, as per SOP 2.600.023, 2.700.004	
Correct sample collection/technique?	☑Yes ☐ No ☐ N/A	Yes, as per SOP 2.600.023, 2.700.004	
Are the Test Result Records Attached & Calculations Verified and Correct?	☑Yes ☐ No ☐ N/A		
Is the analyst qualified to perform the test?	☑Yes ☐ No ☐ N/A		
Is formula worksheet provided and verified?	☐Yes ☐ No ☑ N/A	Not Applicable	
Does the processing method/method set conform to the required specification?	☐Yes ☐ No ☑ N/A	Not Applicable	
Was the sample stored appropriately?	☑Yes ☐ No ☐ N/A		
Material Discrepancy		**Lot Number**	**Expiry Date**
Is the integrity of the sample(s) questionable?	☐Yes ☑ No ☐N/A		
Was the sample transported appropriately?	☑Yes ☐ No ☐N/A		
Are the other test results from this run under investigation?	☐Yes ☑ No ☐N/A		

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Appropriate/correct glassware used?	☐Yes ☐ No ☑N/A		
Are reagents stored in proper condition and not expired?	☑Yes ☐ No ☐N/A	Scan Consumables: See the attached data packet Environmental Plates: TSA and Surface Plate: see attached environmental logs Monthly Cleaning: H2O2 strips and IPA: See attached monthly cleaning logs	Scan Consumables: See attached data packet Environmental Plates: TSA and Surface Plate: see attached environmental logs Monthly Cleaning: H2O2 strips and IPA: See attached monthly cleaning logs
Standard Used			
Solvent Used	Not Applicable	Not Applicable	Not Applicable
Is the standard the source of the root cause?	☐Yes ☐ No ☑N/A		
Has the analyst been instructed to keep the original test solution for possible retesting?	☐Yes ☐ No ☑N/A		
Equipment Discrepancy		**Equipment ID**	**Calibration Due Date**
Was the instrument set up correctly?	☑Yes ☐ No ☐ N/A		Oct26
Is the clean room facility certified?	☑Yes ☐ No ☐ N/A		Dec25
System Performance Check (if applicable)?	☑Yes ☐ No ☐ N/A		Oct26
System Suitability RSD < 2% (PDA)?	☐Yes ☐ No ☑ N/A	Not Applicable	Not Applicable
System Suitability RSD < 10% (QDA, CAD)?	☐Yes ☐ No ☑ N/A	Not Applicable	Not Applicable
Do the environmental monitoring results conform to required standards?	☑Yes ☐ No ☐ N/A	See Phase I Summary	See Phase I Summary
Do the controls (i.e., positive, negative, etc.) conform to the required standards?	☑Yes ☐ No ☐ N/A	See Phase I Summary	See Phase I Summary
Is equipment/instrument functional and calibrated/qualified/certified/PM?	☑Yes ☐ No ☐ N/A	Incubator E001034 (Sensor E001501) Incubator E001031 (Sensor E001505)	Aug26 Feb26 Aug26 Feb26

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Are chromatogram/spectra/raw data correct?	☐ Yes ☐ No ☑ N/A	Not Applicable	Not Applicable

Section C – Evaluation of Laboratory Testing/Hypothesis Testing (if applicable)

- ☑ N/A
- ☐ Re-injection of sample vial
- ☐ Re-injection of original standard vial
- ☐ Re-vialing of original working standard solution
- ☐ Re-vialing of original working sample solution
- ☐ Re-dilution of a working sample solution from the original stock
- ☐ Re-dilution of a working standard solution from the original stock standard
- ☐ Other: NA QYC

Section D – Phase I Summary

Phase I Summary:

Phase I Summary (continued):

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Phase I Summary (continued):

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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*)**:** Qiyue Chen	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: