Microbiology Out of Specification (OOS)
Investigation and Report Form

Phase 1

SECTION A – Product or Sample Details

Microbiology OOS Number:	
Form Initiated by:	
Sample Name:	
Laboratory Ref Number:	
Microbiology Ref Number:	
Batch Number (BN):	
Original Test Result:	
Limits/ Specification:	
Analyst Name & Signature:	
Date:	

SECTION B – Evaluation of Laboratory Testing

Test Type		**(tick)**	**SOP Reference No.**	**Control Method reference (if applicable)**
Microbial Limit Testing		□		
Sterility Testing		□		
Microbial Assay		□		
Bacterial Endotoxin	**KCA**	□		
	GEL	□		
Other ……..		□		

Name of Technician who performed the test		**Training records complete**	Yes □ No □
Date Test Performed		**Date Test completed**	
Was test conducted in accordance with SOP or Control method	Yes □ No □	If No, comment:	

Media/Reagents Used	**Lot Number**	**Expiry Date**	**Passed QC Checks**
			Yes □ No □
			Yes □ No □
			Yes □ No □
			Yes □ No □
			Yes □ No □
			Yes □ No □

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PART B – Evaluation of Laboratory Testing (continued)

Equipment Used	Calibration due date	Temperature trends in range
		Yes □ No □ N/A □
		Yes □ No □ N/A □
		Yes □ No □ N/A □
		Yes □ No □ N/A □
		Yes □ No □ N/A □
		Yes □ No □ N/A □

Test result records attached?	Yes □ No □	Comment:	
Are calculations verified and correct?	Yes □ No □	Comment:	
Negative controls passed?	Yes □ No □	Comment:	
Were correct diluents, reagents, media, filters, analytical conditions etc used in the analytical procedure & documented	Yes □ No □	Comment:	
Are other tests from same test session within limits?	Yes □ No □	Comment:	
Any Other assignable sources of error? From Technicians observations during testing	Yes □ No □	Comment:	
Brief Description of the investigation findings to date			
Is the initial test result valid?	Yes □ No □	**If NO, is re-testing required?**	Yes □ No □ N/A □
		If YES, is confirmatory or investigational testing required?	Yes □ No □ N/A □

	Name	Signature	Date
Analyst:			
Approved By: Supervisor			

NOTE: Refer to relevant SOP for appropriate Retest Procedures.

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Part C - Retesting

Authorization for Retesting: (Signature/Date)	
Analyst Assigned (Name):	

Part D – Repeat Results	
Result(s) Obtained:	
Were Result(s) (√ one):	☐ In-specification ☐ OOS
Analyst: (Date/Signature):	

Part E – Supervisor's Conclusion for Retest		
Were Result(s) comparable to initial results (√ one):	☐ **Yes**	☐ **No**
If no was Assignable Cause(s) for the difference found?	☐ **Yes**	☐ **No**
If yes, identify the root cause:		
Supervisor (Date/Signature):		

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Part F – Investigation Retest Results	
Conclusion:	
Release results (Tick as appropriate):	☐ **Initial Results** ☐ **Retest Results** ☐ **Initial Results + Retest Results** ☐ **Unable to use**
Deputy Director Technical Services: (Date/Signature)	
Part G – QA Approval	
QA Manager (Date/Signature):	