

Microbiology Out of Specification (OOS) Investigation and Report Form

(Ref. MICLAB 110)

Phase 1

Out of Specification Result
(Action Level Excursions) ☐

Out of Limits Result
(Alert Limit Excursions) ☐

PART A – Product or Sample Details

Form Initiated by:		Unique Identifier	
Product Description		DR Number	
Batch Production Number (BPN)		Product Code	
Original Test Result		Limits/ Specification	
Micro Manager Notified	Yes <input type="checkbox"/> No <input type="checkbox"/>	By who?	Initial and Date

PART B – Evaluation of Laboratory Testing

Test Type	(tick)	SOP Reference	Control Method reference (if applicable)
Non-Sterile Testing	<input type="checkbox"/>	MICLAB 075	
Water	<input type="checkbox"/>	MICLAB 055	
Sterility Testing	<input type="checkbox"/>	MICLAB 060	
Endotoxin	KCA <input type="checkbox"/>	MICLAB 085	
	GEL <input type="checkbox"/>	MICLAB 080	
Other	<input type="checkbox"/>		
Name of Technician who performed the test		Training records complete	Yes <input type="checkbox"/> No <input type="checkbox"/>
Date Sampled		Date Test performed	
Was test conducted in accordance with SOP & Control method	Yes <input type="checkbox"/> No <input type="checkbox"/>	If No, comment:	
Media/Reagents Used	Lot Number	Expiry Date	Passed QC Checks
			Yes <input type="checkbox"/> No <input type="checkbox"/>
			Yes <input type="checkbox"/> No <input type="checkbox"/>
			Yes <input type="checkbox"/> No <input type="checkbox"/>
			Yes <input type="checkbox"/> No <input type="checkbox"/>
			Yes <input type="checkbox"/> No <input type="checkbox"/>
			Yes <input type="checkbox"/> No <input type="checkbox"/>