Environmental and Personnel Monitoring Investigation Form For Out-of-Specification (OOS) Result Investigation #_____

Part I. Product and Lab Test Data

Out-of-specification (Action Excursion) ___ Out of Limits (Alert Excursion) ___

Time of Discovery of OOS/OOL_____QA Notified When/Who?_____

Product Name_____ Batch Number_____ Viable/Non-viable _____

Original Test Results _____ Specification (Limit) _____

Most Probable Root Cause _____

Identification of Organism(s) _____

Location of OOS _____ Date/time of sample _____

Date: Test Performed: Test Method/Monograph #/Version #

_____ EM Air_____ _____

_____ EM surface_____ _____

_____ Personnel_____ _____

Were there any deviations during the test or in production? If yes, explain_____

Operator's Name (Personnel excursion)_____ Training Completed?_____Other excursions in last 3 months?_____

Media/Reagents	Lot number	Expiration Date	Comments

Equipment	Calibration Due Date	Comments

Negative Controls passed? Yes/No Growth Promotion tests passed? Yes/No

On the spot verification (e.g., use of portable Particulate counter) _____

Interview comments by Microbiology Technician or Production Operator?

_____

Written By/Date: _____Approved By/Date: _____

Part 2. **Risk Based Assessment:**

Explain if non-viable or viable count could potentially impact the sterility of the product.

_____

Dosage Form of the Product: Injectable_____Ophthalmic_____Topical_____

Sterility Test Results _____

Possible sources of specific organism recovered_____

Other dates specific organism was recovered and location _____

Is the product capable of sustaining growth of the organism?_____

Is there more sampling that needs to be done to find root causes?
Describe_____

Last HEPA Filter Certification: _____

Verify that disinfection was done of filling room/Date: _____

Deviations/Investigations during product being filled: _____

Impact on Facility_____ Impact on Equipment _____

Impact on Product on-line/in-house or in market _____

List batches_____

_____

List possible root causes._____

_____

What is the most probable root cause? _____

Are experiments needed to confirm?_____

_____

Written By (QA)/Date: _____ Approved By (QA)/Date: _____

Part 3. Final Quality Assurance Assessment:

Corrective Action: What should be an immediate action? How should batch disposition be impacted? _____

_____

Preventive Action: What needs to be done to prevent a recurrence of the event?

_____

_____

Follow-up to ensure effectiveness of actions _____

_____

Written By/Date: _____ Approved By/Date:_____

QA notes/Batch Disposition Decision: _____

QA approval/Date:_____