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? ______________________

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<th>Media/Reagents</th>
<th>Lot number</th>
<th>Expiration Date</th>
<th>Comments</th>
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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: ________________________