Aseptic Media Fill Investigation **Investigation # _____**

Part I. Product and QC Lab Test Data:

Media Fill for Product/Container Closure System: _____

Batch Code and Number: _____

Media Type/Lot #/Expiration Date: _____

Volume of Media/Bulk Tank: _____

Fill Volume: _____

Date Filled: _____

Date Incubated: _____

Temperature Incubated: _____

Incubated by: _____

Environmental Monitoring	**Location**	**Results- Count & ID**
Particulates		
Air Samples/Settling Plates		
Rodac Plates		
Personnel Monitoring		

Media Growth Promotion Test: Passed/ Failed

Reference Lab Notebook/Page: _____

Media Fill Results:

# of Containers	Date	Inspected By	# Positive

# of Containers	Date	Inspected By	# Positive

# of Containers	Date	Inspected By	# Positive

Media Fill: Passed/Failed/Invalidated

Notification of QA/Who/Date/Time: _____

Part 2: Risk Based Assessment:

Identify all positive containers to species level: _____

Determine if any positive containers have cracks or other integrity defects: _____

Dosage Form of the Product: Injectable_____Ophthalmic_____Topical_____

Sterility Test Results _____

Possible sources of specific organism recovered_____

Was the organism(s) found in any environmental test samples? _____

Other dates specific organism was recovered and location _____

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

Did this media fill cover all appropriate interventions? Any new ones? _____

Media Fill history for this product/container/closure system: _____

Date of Last Media Fill for same container/closure system: _____

If current Media Fill failed, list all batches filled on same line since the last passed media fill:

List may be attached.

_____

_____

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

List possible root causes:_____

_____

_____

What is the most probable root cause? _____

_____

Are experiments needed to confirm?_____

_____

List batches to be put on-hold: _____

_____

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

Attach Appendix A- Production Data:

Attached By/Date: _____

Reviewed By (QA)/Date: _____

Part 3. Final Quality Assurance Assessment:

Corrective Action: What should be an immediate action? Are more media fills needed, and if so how many? 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:_____

Appendix A. Production Data for Media Fill Investigation:

This section must be filled out by Production Staff:

Date/Time Media Prepared:_____

Media Prepared By: _____

Formulation Tank: _____

Filtration Date/Time: _____

Filter Pre & Post Integrity Test Results: _____

Holding Tank: _____

Holding Tank SIP Date: _____

Filling Room number: _____

Filling Machine #: _____

Filling Line Equipment Sterilized Date/Time: _____

Autoclave # _____

Adequate Cycle _Yes/No Explain_____

List All Cleaning/Disinfecting Staff: _____

List All Sterile Operators: _____

List All Microbiology Technicians: _____

List All Maintenance Technicians: _____

Start Time of Filling Media: _____

Line speed: _____

List of number of containers filled each shift:_____ Total: _____

List of number of rejects found each shift: _____ Total: _____

End Time of Filling Media: _____Total Time: _____

Interventions:

Type	Date	Time	Operator
Weight/Volume adjustments			
Filling needle change			
Addition of components			
Change in personnel			
Shift Change			
EM Sampling			
Other: List below			

Prepared By/Date: _____

Approved by (Manufacturing)/Date: _____