REPORT

FOR

PROCESS SIMULATION STUDY

(MEDIA FILL)

FOR LIQUID VIAL LINE

REFERENCE PROTOCOL No.	
DATE OF VALIDATION	
VALIDATION BATCH NUMBER	
VALIDATION BATCH SIZE	

PROTOCOL CONTENTS

1.0 REPORT PRE-APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
EXECUTIVE/MANAGER (QUALITY ASSURANCE)			
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			
HEAD (QUALITY CONTROL)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- Process Simulation Study (Media Fill) is carried out to simulate the whole Aseptic Process in order to evaluate the Sterility Confidence of the Process. Process Simulation studies include Formulation (Compounding), Filtration and Filling with suitable media.
- Prospective as well as Re-Validation of Aseptic Process provides the necessary level of assurance for aseptically produced products.
- Simulations are made to ensure that the regular process for commercial batches repeatedly and reliably produces the finished product of required quality.
- To establish documented evidence that the whole process is capable of performing as per specified acceptance criteria and is adequate to provide the aseptic assurance for which the process is intended.

3.0 SCOPE:

- The Scope of this Report is to lay down the process which includes exposing the Microbiological Growth Support Medium (MGSM) to Product Contact Surfaces of Equipment, Container Closure System, Critical Environments, and Process Manipulations to closely simulate the same exposure that the product itself will undergo.
- This Report is applicable for performing Process Simulation Study (Media Fill) Liquid Vial Line.

4.0 RESPONSIBILITY:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, Compilation and Approval of Process Simulation Study (Media Fill) Report. • To Evaluate Report Completeness and Technical Accuracy. • To Co – Ordinate and schedule with other departments for carrying out Media fill as per protocol. • To monitor all Process Simulation Study Activities and ensure Media fill as per Protocol. • To review and compile the Media Fill data.
Production	• To Review the Compiled Report. • To schedule the Process Simulation Study Activity. • To assist in the preparation and execution of the process.
Quality Control	• To Review the Compiled Report. • To provide all applicable Analytical Procedures and Documentation. • To carry out Microbiological Test / Sampling as per Sampling Plan mentioned in Media Fill Protocol. • To incubate and monitor the Media Filled Vials. • To analyze the sample collected and provide all analysis data during Media Fill.
Engineering	• To Review the Compiled Report. • To Co-Ordinate and support the Process Simulation Study Activity. • To provide engineering support during Process Simulation Study (Media Fill).

5.0 TRAINING ATTANDANCE RECORD:

Name of Trainer: _____ **Training Date: _____**

Type of Training: _____

S. No.	Name of Trainee	Designation	Department Name	Training given on Protocol (Yes/No)

***** Copy of Training Record to be attached.

Compiled By: _____
(Quality Assurance)
Sign & Date
Inference:

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Reviewed By:
(Quality Assurance)
Sign & Date ……....

6.0 MASTER DOCUMENT VERIFICATION:

S.No.	Description		Document No.	Verified by (QAO/QAE)
1.	SOP for Media Fill			
2.	SOP for Destruction of Media			
3.	SOP for Post Media Fill Cleaning			
4.	Packaging Material Specifications	Glass Vial ____ ml		
5.		Rubber Stopper Bromo Butyl _____mm		
6.		Aluminum Seal F/O _____mm		

* Primary packaging material detail shall be fill in Report as per pack size perform during Media Fill.

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(Sign & Date)

Inference:

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Reviewed By: _____
(Quality Assurance)
(Sign & Date)

7.0 DETAIL OF MEDIA AND PRIMARY PACKAGING MATERIALS USED:

Material Description	Category	Manufacturer / Supplier Name	Required Quantity	Lot No. / A.R. No.	Date of Dispensing	Media Fill Batch No.
Soya Bean Casein Digest Medium	Growth Promotion Medium					
Glass Moulded Clear _____ml	Primary Packaging Material					
Rubber Stoppers Bromobutyl _____mm	Primary Packaging Material					
Aluminum Seals F/O _____ mm	Primary Packaging Material					

* Primary packaging material detail shall be fill in Report as per pack size perform during Media Fil

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(Sign & Date)

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(Quality Assurance)
(Sign & Date)

8.0 GROWTH PROMOTION TEST OF MEDIA (SCDM):

Sr. No.	Test	Media Lot No.	Date of Test	Media GPT Report No.	Done By (Microbiologist)	Checked By QA (Sign & Date)
	Growth Promotion Test of Media (SCDM)*					

* Growth Promotion Test Report of Media (SCDM) attached.

Compiled By: _____
(Quality Assurance)
(Sign & Date)

Inference:

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Reviewed By: _____
(Quality Assurance)
(Sign & Date)

9.0 EQUIPMENTS DETAILS:

S. No.	Equipment Description	Equipment ID Number	PQ Protocol Number	Qualification Status
1.	Manufacturing Vessel			
2.	Holding vessel			
3.	Pure Steam Generation System			
4.	Water System (PW & WFI)			
5.	Multi Column Distillation Plant			
6.	Autoclave Cum Bung Processor			
7.	Rotary Vial Washing Machine			
8.	Depyrogenating Tunnel			
9.	Dynamic Garment Storage Cabinet			
10.	Liquid vial Filling with Rubber Stoppering Machine			
11.	Liquid vial Sealing Machine			
12.	Dynamic Pass Box			
13.	Vertical Hanging Laminar Air Flow Unit (filling & Stoppering)			
14.	Vertical Hanging Laminar Air Flow Unit (Sealing Room)			
15.	Vertical Hanging Laminar Air Flow Unit (Cooling zone)			

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(Quality Assurance)
(Sign & Date)

10.0 AIR HANDLING UNIT (AHU) QUALIFICATION VERIFICATION:

Sr. No.	Equipment / System ID Number	PQ Protocol / Report Number	Qualification Status	Checked By QA (Sign & Date)
1.				
2.				
3.				
4.				
5.				
6.				
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8.				
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Compiled By: _____
(Quality Assurance)
(Sign & Date)

Inference:

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Reviewed By: _____
(Quality Assurance)
(Sign & Date)

11.0 UTILITY QUALIFICATION VERIFICATION

Sr. No.	Equipment / System Description	Equipment / System ID Number	PQ Protocol / Report Number	Qualification Status	Checked By QA (Sign & Date)
1.	Pure Steam Generation System				
2.	Water System (Purified Water)				
3.	Water System (WFI)				

Compiled By: _____
(Quality Assurance)
(Sign & Date)

Inference:

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Reviewed By: _____
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(Sign & Date)

12.0 INSTRUMENT CALIBRATION VERIFICATION:

Equipment Name	Instrument Name	ID Number	Calibration Status (Calibrated / Not Calibrated)	Checked By QA (Sign & Date)
HVAC	Magnehelic Gauge			
HVAC	Magnehelic Gauge			
HVAC	Magnehelic Gauge			
HVAC	Magnehelic Gauge			
HVAC	Magnehelic Gauge			
HVAC	Magnehelic Gauge			
HVAC	Magnehelic Gauge			
HVAC	Magnehelic Gauge			
HVAC	Magnehelic Gauge			
HVAC	Magnehelic Gauge			
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HVAC	Magnehelic Gauge			

Equipment Name	Instrument Name	ID Number	Calibration Status (Calibrated / Not Calibrated)	Checked By QA (Sign & Date)
HVAC	Magnehelic Gauge			
HVAC	Magnehelic Gauge			
HVAC	Magnehelic Gauge			
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HVAC	Magnehelic Gauge			
HVAC	Magnehelic Gauge			

Compiled By: _____
(Quality Assurance)
(Sign & Date)

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(Quality Assurance)
(Sign & Date)

13.0 RUBBER BUNG PROCESSING DETAILS:

Equipment Name	Process Parameter		Media Fill Batch No.	Done By (Production)	Checked By (QAO/ QAE)
Bung Processor cum Autoclave	Date				
	Cycle	Start time			
		End time			
	Wash-I Total Time (1st Wash with Purified Water & Cleaning with SLS)				
	Wash-IInd Total Time Rinsing with Purified water				
	Wash-IIIrd Total time Rinsing with WFI				
	Sterilization	Start Time			
		End Time			
		Total Time			
	Sterilization Temperature	Minimum			
		Maximum			
S. No.	**Rubber Bung Critical Parameters Observations**				
1	Sterility Test (Should Comply Test for Sterility)				
2	Endotoxin Test (NMT 0.25 EU/Bung)				

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(Quality Assurance)
(Sign & Date)

Inference:_____

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Reviewed By: _____
(Quality Assurance)
(Sign & Date)

14.0 (A) GARMENTS STERILIZATION:

Equipment Name	Process Parameter		Media Fill B. No.	Done By Operator	Checked By Production (Sign & Date)	Verified By QA (Sign & Date)
Autoclave cum Bung Processor	Date					
	Autoclave Cycle	Start Time				
		End Time				
	Sterilization	Start Time				
		End Time				
		Total Time				
	Sterilization Temperature	Minimum				
		Maximum				

(B) MACHINE PARTS AND ACCESSORIES STERILIZATION:

Equipment Name	Process Parameter		Media Fill B. No.	Done By Operator	Checked By Production (Sign & Date)	Verified By QA (Sign & Date)
Autoclave cum Bung Processor	Date					
	Autoclave Cycle	Start Time				
		End Time				
	Sterilization	Start Time				
		End Time				
		Total Time				
	Sterilization Temperature	Minimum				
		Maximum				

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(Sign & Date)

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(Sign & Date)

15.0 VIAL WASHING AND DEPYROGENATION:

Equipment Name	Process Parameter	Media Fill Batch No.	Done By (Production)	Checked By (QAO/QAE)
Vial washing Machine	Speed (_____Vials Per Minute)			
	Compressed Air Pressure (0.20 –0.66 Mpa)			
	Pressure of Recycle WFI-I 0.20-0.60 Mpa)			
	Pressure of Recycle WFI-II (0.12-0.60 Mpa)			
	Pressure of Water for Injection (0.07-0.30 Mpa)			
Depyrogenat -ion Tunnel	Conveyor Speed _____mm/min			
	Drying Zone 5-10 Pa			
	Hot Zone 6-12 Pa			
	Cool Zone 5-10 Pa			
Vial Washing and Depyrogenation Critical Parameters Observation				
1.	Clarity Test (Should be free from Particles)			
2.	Sterility Test (Should Comply Sterility Test)			
3.	Endotoxin (NMT 0.25 EU/Vial)			

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(Sign & Date)

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(Quality Assurance)
(Sign & Date)

16.0 GROWTH PROMOTION TEST OF MEDIA SOLUTION AFTER STERILIZATION:

S. No.	Test	Media Lot No.	Media Fill Batch No.	Date of Test	Media GPT Report No.	Done By (Microbiologist)	Checked By (QAO / QAE)
	Growth Promotion Test of Media Solution*						

Compiled By: _____
(Quality Assurance)
(Sign & Date)

Inference:_____

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Reviewed By: _____
(Quality Assurance)
(Sign & Date)

17.0 VIAL FILLING & RUBBER STOPPERING MACHINE:

Sterilized Empty Vials were filled with Sterilized Media using Liquid vial filling with Rubber Stoppering Machine.

S. No.	Date of Media Fill	Media Fill Batch Number	Machine Speed			Vial Filling machine Operated By (Name of Machine Operators)	Checked By (Sign & Date) (Production)
			Minimum Speed	Optimum Speed	Maximum Speed		
1.							

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(Sign & Date)

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(Sign & Date)

18.0 ENVIRONMENTAL MONITORING OF LIQUID VIAL FILLING AND SEALING:

(A) Batch No. _____

Date	Parameters	Environmental Monitoring Stage			Done By Production (Sign & Date)	Checked BY QA (Sign & Date)
		Initial	Middle	End		
	Temp NMT 25°C					
	RH NMT 55%					
	Differential Pressure Change Room -1 Aseptic Area (15-30 Pascal)					
	Differential Pressure Change Room -2 Aseptic Area (15-30 Pascal)					
	Differential Pressure Change Room -3 Aseptic Area (15-30 Pascal)					
	Differential Pressure Aseptic Corridor (05-15 Pascal)					
	Differential Pressure Filling Room (05-15 Pascal)					
	Differential Pressure Filtration Room (05-15 Pascal)					
	Differential Pressure Exit Room -1 Aseptic Area (05-15 Pascal)					
	Differential Pressure Exit Room-2 Aseptic Area (15-30 Pascal)					

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(Sign & Date)

19.0 CONTAINER CLOSER INTEGRITY (LEAK TEST) TEST:

(A) Batch No. _____

S.No.	Sampling Time	Leak Test Results (OK/NOT OK)	Done By (Production)	Checked By QA (Sign & Date)

Compiled By: _____
(Quality Assurance)
(Sign & Date)

Inference:

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Reviewed By: _____
(Quality Assurance)
(Sign & Date)

20.0 MICROBIOLOGICAL ANALYSIS RESULTS:

(A) Batch No. _____

Sr. No.	Microbiological Tests		Date of Test	Report No.	Done By (Microbiologist)	Checked By QA (Sign & Date)
1.	WFI used for Media Solution Preparation	MLT Test				
		BET				
2.	Active Air Sampling of Aseptic Area Before Media Fill					
3.	Active Air Sampling of Aseptic Area During Media Fill					
4.	Active Air Sampling of Aseptic Area After Media Fill					
5.	Passive Air Sampling of Aseptic Area Before Media Fill					
6.	Passive Air Sampling of Aseptic Area During Media Fill					
7.	Passive Air Sampling of Aseptic Area After Media Fill					
8.	Non – Viable Particle Count of Aseptic Area Before Media Fill					
9.	Non – Viable Particle Count of Aseptic Area During Media Fill					
10.	Non – Viable Particle Count of Aseptic Area After Media Fill					
11.	Microbiological Swab of Aseptic Area Walls and Floors After Media Fill					
12.	Microbiological Swab of Machine Surface After Media Fill.					
13.	Microbiological Swab of Aseptic Area Garments After Media Fill					

Sr. No.	Microbiological Tests		Date of Test	Report No.	Done By (Microbiologist)	Checked By QA (Sign & Date)
14.	Personal Monitoring by RODAC Plate and Finger Dab of Aseptic Area Persons (Staff & Operators) After Media Fill					
15.	Collect Filtered IPA after filtration and check for its Sterility	Initial				
		Middle				
		End				

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(Quality Assurance)
(Sign & Date)

Inference:

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Reviewed By: _____
(Quality Assurance)
(Sign & Date)

21.0 INTERVENTIONS DURING FILLING & SEALING (WORST CASE CONDITION):

Record the Interventions and reconciliation of Incubated vials as per Media Fill Protocol in the table below.

(A) Batch No. _____

Date	Sr. No.	Intervention / Worst Case Condition	Intervention Time	Operation Time	Filled Vials (Nos.)	Filling & Capping Rejection (Nos.)	Qty. sent to Visual Inspection	Tray No. / Crate No.	Intervention No.	Name of Person Involved During Intervention	Checked By (Production Officer / Executive)
Aseptic Manipulation (Routine Intervention)											
	1	Aseptic Assembly of the Equipment and Initial Product Connection or Introduction	From: To:	From: To:							
	2	Normal Filling	From: To:	From: To:							
	3	Initial Fill Volume Adjustment	From: To:	From: To:							
	4	Normal Filling	From: To:	From: To:							
	5	Periodic Fill Volume Checking & Verification	From: To:	From: To:							
	6	Normal Filling	From: To:	From: To:							
	7	Maximum Filling Speed (_____)	From: To:	From: To:							
	8	Normal Filling	From: To:	From: To:							
	9	Optimum Filling Speed (_____)	From: To:	From: To:							
	10	Normal Filling	From:	From:							

Date	Sr. No.	Intervention / Worst Case Condition	Intervention Time	Operation Time	Filled Vials (Nos.)	Filling & Capping Rejection (Nos.)	Qty. sent to Visual Inspection	Tray No. / Crate No.	Intervention No.	Name of Person Involved During Intervention	Checked By (Production Officer / Executive)
			To:	To:							
	11	Minimum Filling Speed (_____)	From: To:	From: To:							
	12	Normal Filling	From: To:	From: To:							
	13	Rubber bung charging in hopper	From: To:	From: To:							
	14	Normal Filling	From: To:	From: To:							
	15	Rubber stoppering M/C adjustment for 2 min.	From: To:	From: To:							
	16	Normal Filling	From: To:	From: To:							
	17	Handling of Vials by using forceps	From: To:	From: To:							
	18	Normal Filling	From: To:	From: To:							
	19	Operator Breaks & Meals	From: To:	From: To:							
	20	Normal Filling	From: To:	From: To:							
	21	Defective seals on container	From: To:	From: To:							
	22	Normal Filling	From: To:	From: To:							

Date	Sr. No.	Intervention / Worst Case Condition	Intervention Time	Operation Time	Filled Vials (Nos.)	Filling & Capping Rejection (Nos.)	Qty. sent to Visual Inspection	Tray No. / Crate No.	Intervention No.	Name of Person Involved During Intervention	Checked By (Production Officer / Executive)
	23	Operator Shift Changes	From: To:	From: To:							
	24	Normal Filling	From: To:	From: To:							
	25	Environmental Monitoring with active air sampling	From: To:	From: To:							
	26	Normal Filling	From: To:	From: To:							
	27	Environmental Monitoring with Passive Air Sampling (Settle Plate)	From: To:	From: To:							
	28	Normal Filling	From: To:	From: To:							
Aseptic Manipulation (Non-Routine Intervention)											
	29	Sensor Adjustment or Replacement	From: To:	From: To:							
	30	Normal Filling	From: To:	From: To:							
	31	AHU of Filling Area OFF for 05 Minute	From: To:	From: To:							
	32	Normal Filling	From: To:	From: To:							

Date	Sr. No.	Intervention / Worst Case Condition	Intervention Time	Operation Time	Filled Vials (Nos.)	Filling & Capping Rejection (Nos.)	Qty. sent to Visual Inspection	Tray No. / Crate No.	Intervention No.	Name of Person Involved During Intervention	Checked By (Production Officer / Executive)
	33	Machine Break down activities for 15 Minutes (MINOR)	From: To:	From: To:							
	34	Normal Filling	From: To:	From: To:							
	35	Machine Break down activities for 60 Minutes (MAJOR)	From: To:	From: To:							
	36	Normal Filling	From: To:	From: To:							
	37	Power Failure for 10 Minutes	From: To:	From: To:							
	38	Normal Filling	From: To:	From: To:							
	39	Increase in No. of Persons for 15 Minutes (Not more than 7 persons)	From: To:	From: To:							
	40	Normal Filling	From: To:	From: To:							
	41	Filling Room door open	From: To:	From: To:							
	42	Normal Filling	From: To:	From: To:							

Date	Sr. No.	Intervention / Worst Case Condition	Intervention Time	Operation Time	Filled Vials (Nos.)	Filling & Capping Rejection (Nos.)	Qty. sent to Visual Inspection	Tray No. / Crate No.	Intervention No.	Name of Person Involved During Intervention	Checked By (Production Officer / Executive)
	43	Operator Fatigue	From:	From:							
			To:	To:							
	44	Normal Filling	From:	From:							
			To:	To:							
	45	End of Filling	From:	From:							
			To:	To:							

(B) Batch No. _____

Aseptic Manipulation (Routine intervention):- Rubber Bung Charging

Date	S.No	Intervention detail	No. of intervention observed during commercial batches	Intervention Time		Operation Time		Done By	Checked By
				From	To	From	To		
		Rubber Bung Charging in Hopper							

Compiled By: _____
(Quality Assurance)
(Sign & Date)

Inference:

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Reviewed By: _____
(Quality Assurance)
(Sign & Date)

22.0 INSPECTION OF FILLED VIALS:

Date	Media Fill Batch Number	*Total No. of Filled vials transferred for visual inspection	Total No. of Integrated vials	Total No. of Rejected vials	Total No. of vials Transferred for Incubation

*** Total No. of Filled Vials includes total no. of Integral Vials and total rejection during Visual inspection.**

Compiled By: _____
(Quality Assurance)
(Sign & Date)

Inference:

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Reviewed By: _____
(Quality Assurance)
(Sign & Date)

23.0 ENVIRONMENTAL MONITORING RECORD OF INCUBATION ROOM / CHAMBER:

23.1 MEDIA FILL BATCH INCUBATION DETAILS:

Batch No.	Incubation Temperature: 20^{0}C to 25 ^{0}C		Incubation Temperature: 30 ^{0}C to 35 ^{0}C	
	Started on	Completed on	Started on	Completed on

23.2 INCUBATION TEMPERATURE: 20^{0}C to 25 ^{0}C **Frequency: Once in a day**

Date	Time	Temperature Range (20^{0}C to 25 ^{0}C)	Recorded By (Microbiologist)	Checked By (QA Executive / Officer)

Compiled By: _____
(Quality Assurance)
(Sign & Date)

Inference:

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Reviewed By: _____
(Quality Assurance)
(Sign & Date)

23.3 INCUBATION TEMPERATURE: 30 ^{0}C to 35 ^{0}C Frequency: Once in a day

Date	Time	Temperature Range (30 ^{0}C to 35 ^{0}C)	Recorded By (Microbiologist)	Checked By (QA Executive / Officer)

Compiled By: _____
(Quality Assurance)
(Sign & Date)

Inference:

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Reviewed By: _____
(Quality Assurance)
(Sign & Date)

24.0 OBSERVATION OF MEDIA FILLED VIALS AFTER INCUBATION:

24.1 OBSERVATION AFTER INCUBATION OF 1st 7 DAYS AT 20 ^{0}C to 25 ^{0}C

S. No.	Media Fill Batch Number	Date of Incubation	No. of Vials Incubated	No. of good Vials after Incubation	No. of Contaminated Vials after Incubation (If any)	Remarks

24.2 OBSERVATION AFTER INCUBATION OF NEXT 7 DAYS AT 30 ^{0}C to 35 ^{0}C

S. No.	Media Fill Batch Number	Date of Incubation	No. of Vials Incubated	No. of good Vials after Incubation	No. of Contaminated Vials after Incubation (If any)	Remarks

Compiled By: _____
(Quality Assurance)
(Sign & Date)

Inference:

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Reviewed By: _____

(Quality Assurance)
(Sign & Date)

25.0 POST GPT OF DEACTIVATED VIALS:

- The Post GPT of Deactivated and Sterilized Vials was performed as per Protocol prior to Destruction of Vials.
- The Post GPT Report for Individual Batch is attached with the respective Media Fill Record.

S. No.	Test	Media Lot No.	Date of Test	Media GPT Report No.	Done By (Microbiologist)	Checked By QA (Sign & Date)
1.	Growth Promotion Test of Media (SCDM)*					

* Growth Promotion Test Report of Media (SCDM) Solution attached for reference.

Compiled By: _____
(Quality Assurance)
(Sign & Date)

Inference:

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Reviewed By: _____
(Quality Assurance)
(Sign & Date)

26.0 DESTRUCTION OF INCUBATED VIALS AFTER INSPECTION:

- The Deactivated and Sterilized Vials were destroyed after Post GPT Results as per Media Fill Protocol.

S. No.	Date	Media Fill Batch Number	No. of Vials Destroyed	Done By	Checked By	Verified By
1.						

Compiled By: _____
(Quality Assurance)
(Sign & Date)

Inference:

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Reviewed By: _____
(Quality Assurance)
(Sign & Date)

27.0 BATCH YIELD:

S. No.	Stage	Media Fill Batch Number
1.	Theoretical Batch Size	
2.	No. of Good Vials Incubated	
3.	No. of Filled Vials	
4.	Total Rejection	
5.	No. of In process Sample	
6.	% of Rejection	
7.	% Batch Yield	

Compiled By: _____
(Quality Assurance)
(Sign & Date)

Inference:

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Reviewed By: _____
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(Sign & Date)

28.0 PERSONNEL QUALIFIED FOR ASEPTIC AREA IN MEDIA FILL:

S. No.	Name of Personnel	Designation	Department Name	Checked by QA (Sign & Date)

S. No.	Name of Personnel	Designation	Department Name	Checked by QA (Sign & Date)

Compiled By: _____
(Quality Assurance)
(Sign & Date)

Inference:

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Reviewed By: _____
(Quality Assurance)
(Sign & Date)

29.0 REFERENCES:

- Pharmaceutical Inspection Convention (Pharmaceutical Inspection Co-Operation Schemes) (PIC/S) PI 007-6, "Recommendation on the Validation of Aseptic Processes".
- USFDA Guidelines for Sterile Drug Products Produced by Aseptic Processing Current Good Manufacturing Practices.
- WHO Technical Report Series - 961
- United States Pharmacopoeia – 37
- Validation Master Plan.
- SOP Entitled "Process Simulation Study (Media Fill)" Sop.

30.0 DOCUMENTS TO BE ATTACHED:

- Executed Raw Data.
- Calibration Certificate of test Instruments.
- Any Other Relevant Documents.

31.0 NON COMPLIANCE:

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32.0 DEVIATION FROM PRE-DEFINED SPECIFICATION (IF ANY):

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33.0 CHANGE CONTROL, IF ANY:

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34.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION):

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35.0 CONCLUSION:

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36.0 RECOMMENDATION:

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37.0 ABBREVIATIONS:

SOP	:	Standard Operating Procedure
Ster.	:	Sterilization
Temp.	:	Temperature
NLT	:	Not Less than
NMT	:	Not More Than
LAF	:	Laminar Air Flow
No.	:	Number
Min.	:	Minimum
Max.	:	Maximum
QA	:	Quality Assurance
QC	:	Quality Control
EU	:	Endotoxin Unit
WFI	:	Water for Injection
SS	:	Stainless Steel
A.R. No.	:	Analytical Report Number
MLT	:	Microbial Limit Test
Kg	:	Kilogram
Mg	:	Milligram
Qty.	:	Quantity
VMP	:	Validation Master Plan
GPT	:	Growth Promotion Test
PIC/S	:	Pharmaceutical Inspection Convention OR Pharmaceutical Inspection Co-Operation Scheme
GMP	:	Good Manufacturing Practice
SCDM	:	Soya bean Casein Digest Medium
PDA	:	Parentral Drug Association, INC.
USP	:	United States Pharmacopoeia
HVAC	:	Heating, Ventilation and Air Conditioning
QAO	:	Quality Assurance Officer
QAE	:	Quality Assurance Executive

38.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By

39.0 REPORT POST APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
EXECUTIVE/MANAGER (QUALITY ASSURANCE)			
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			
HEAD (QUALITY CONTROL)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			