REPORT

FOR

PROCESS SIMULATION STUDY

(MEDIA FILL)

FOR DRY POWDER 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) Dry powder 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 ATTENDANCE 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.

Compiled By: _____
(Quality Assurance)
(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					
Sterilized Lactose	Process Simulation Diluent					
Glass Moulded Clear _____ml	Primary Packaging Material					
Rubber Stoppers Bromobutyl _____mm	Primary Packaging Material					
Aluminum Seals F/O _____ mm	Primary Packaging Material					

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

Inference:

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

8.0 GROWTH PROMOTION TEST OF MEDIA (SCDM):

S.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 LACTOSE STERILIZATION DETAILS & STERILITY TEST OF LACTOSE:

LACTOSE STERILIZATION DETAILS	**Date of Testing**	
	Lot No.	
	Mfg. Date	
	Expiry Date	
	Report No.	
	Done by	
	Checked By	

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

Inference:

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

10.0 GPT AND STERILITY TEST OF COMBINATION OF STERILIZED LACTOSE AND, MEDIA (SCDM) SOLUTION:

S.No.	Test	Media Concentration	Date of Test	GPT Report No.	Sterility Test Report No.	Done By (Microbiologist)	Checked By (QAO / QAE)
1.	Growth Promotion Test of Combination of Sterilized Lactose and Media Solution.						
2.	Sterility Test of Combination of Sterilized Lactose and Media Solution.						

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(Quality Assurance)
(Sign & Date)

Inference:

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

11.0 EQUIPMENTS DETAILS:

Following Qualified Equipment were used during Process Simulation Study.

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

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(Quality Assurance)
(Sign & Date)

12.0 AIR HANDLING UNIT (AHU) QUALIFICATION VERIFICATION:

S. No.	Equipment / System ID Number	PQ Protocol / Report Number	Qualification Status	Checked By QA (Sign & Date)

1.				
2.				
3.				
4.				
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7.				
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Compiled By: _____
(Quality Assurance)
(Sign & Date)

Inference:

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

13.0 UTILITY QUALIFICATION VERIFICATION:

S. 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: _____
(Quality Assurance)
(Sign & Date)

14.0 INSTRUMENT CALIBRATION VERIFICATION:

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

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			
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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			
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HVAC	Magnehelic Gauge			
HVAC	Magnehelic Gauge			
HVAC	Magnehelic Gauge			
HVAC	Magnehelic Gauge			

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(Sign & Date)

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(Quality Assurance)
(Sign & Date)

15.0 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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(Quality Assurance)
(Sign & Date)

16.0 MACHINE PARTS AND ACCESSORIES STERILIZATION:

Equipment Name	**Process Parameter**		**Media Fill Batch. No.**	**Done By (Sign & Date) (Production)**	**Checked By (Sign & Date) (QAO/QAE)**
Bung Processor cum Autoclave	Date				
	Autoclave Cycle	Start Time			
		End Time			
	Sterilization	Start Time			
		End Time			
		Total Time			
	Sterilization Temperature	Minimum			
		Maximum			

Compiled By: _____
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(Sign & Date)

Inference:_____

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(Sign & Date)

17.0 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 _____ bar				
	Pressure of Recycle WFI-I 1.5 to 2.5 bar				
	Pressure of Recycle WFI-II 1.5 to 2.5 bar				
	Pressure of Water for Injection 1.5 to 2.5 bar				
Depyrogenat -ion Tunnel	Conveyor Speed _____ mm/min				
	Temp. Sterile Entry Zone	Min.			
		Max.			
	Temp. Sterile Exit Zone	Min.			
		Max.			
	Drying Zone 70 to 120 Pa				
	Hot Zone 150 to 250 Pa				
	Cool Zone 70 to 120 Pa				
	Stabilizing zone 70 to 120 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)

18.0 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)

19.0 VIAL FILLING & RUBBER STOPPERING MACHINE:

Sterilized Empty Vials were filled with Sterilized Lactose and Sterilized Media using Dry Powder Filling with Rubber Stoppering Machine.

S.No.	Date of Media Fill	Media Fill Batch Number	Machine Speed	Vial Filling, Rubber Stoppering Machine Operated By (Name of Machine Operators)	Checked By (Sign & Date) (Production)	Verified By (Sign & Date) (QAO/QAE)
1.						

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

Inference:_____

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

20.0 ENVIRONMENTAL MONITORING OF VIAL FILLING ROOM & SEALING ROOM :

A) Batch No. _____

Date	Parameters	Environmental Monitoring Stage			Done By (Sign & Date) (Production)	Checked By (Sign & Date) (QAO/QAE)
		Initial	Middle	End		
	Temp NMT 20°C					
	RH NMT 20%					
	Differential Pressure Air Lock I (15-30 Pascal)					
	Differential Pressure Air Lock II (15-30 Pascal)					
	Differential Pressure Air Lock III (05-15 Pascal)					
	Differential Pressure of Sterile Corridor (05-15 Pascal)					
	Differential Pressure of Vial Filling and bunging Room (05-15 Pascal)					
	Differential Pressure of Vial Sealing Room (15-30 Pascal)					

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(Quality Assurance)
(Sign & Date)

Inference:_____

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

21.0 CONTAINER CLOSER INTEGRITY:

21.1 LEAK TEST:

S. No.	Batch No.	Sampling Time	Leak Test Results (OK/NOT OK)	Done By (Production)	Checked By (QAO/QAE)

21.2 CLARITY TEST:

S. No.	Batch No.	Sampling Time	Clarity Test Results (OK/NOT OK)	Done By (Production)	Checked By (QAO/QAE)

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

Inference:_____

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

22.0 MICROBIOLOGICAL ANALYSIS RESULTS:

S.No.	Microbiological Tests		Date of Test	Report No.	Done By (Microbiologist)	Checked By QA (Sign & Date)
Batch No. :-						
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.	Microbiological Swab of Aseptic Area Walls and Floors Before Media Fill					
9.	Microbiological Swab of Aseptic Area Walls, Floors and Machine Surface During Media Fill.					
10.	Microbiological Swab of Aseptic Area Garments During Media Fill.					
11.	Microbiological Swab of Aseptic Area Garments After Media Fill					

12.	Personal Monitoring by RODAC Plate and Finger Dab of Aseptic Area Persons (Staff & Operators) Before Media Fill				
13.	Personal Monitoring by RODAC Plate and Finger Dab of Aseptic Area Persons (Staff & Operators) During Media Fill				
14.	Personal Monitoring by RODAC Plate and Finger Dab of Aseptic Area Persons (Staff & Operators) After Media Fill				

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

Inference:_____

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(Quality Assurance)
(Sign & Date)

23.0 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. _____

S. No.	Date	Interventions	Time of interventions		Line Speed /min.	No. of Vial Collected	Interventions by (Name)	Operated By (Name)	Checked By
			From	To					
1.		**Normal conditions** **(After assembly)**							
2.		Initial Fill weight adjustment during filling **(Routine Intervention)** **Multiple**							
3.		During Filling Fill weight adjustment **(Routine Intervention)**							
4.		**Normal Breaks** (Routine Intervention)							
5.		**Picking of fallen vial from the filling line track** (Routine Intervention)							
6.		**Movement of Mobile LAF** (Routine Intervention)							
7.		**Running the machine at Minimum speed** **(**Non-Routine Intervention)							
8.		Running the machine at higher speed than actual production run. (Non-Routine Intervention)							

9.		**Operator change** (Routine Intervention)							
10.		**Glove Replacement** (Routine Intervention)							
11.		**Aseptic operator movement from filling machine rare side during filling and transfer of sterilized stopper bags** (Routine Intervention)							
12.		**Person enter through Swing conveyor** (Routine Intervention)							
13.		**Power failure** (Non-Routine Intervention)							
14.		**AHU off 5 min** (Non-Routine Intervention)							
15.		**Environmental monitoring Settle plate exposure** (Routine Intervention)							
16.		**Environmental monitoring microbial air sampling.** (Routine Intervention)							
17.		**Operator fatigue NLT 5 Hrs. Presence in Aseptic Area** (Non-Routine Intervention)							
18.		Maximum persons. **7-person intervention** (Worst case Intervention)							

19.		Simulation of minor maintenance Job. **(Non-Routine Intervention)**							
20.		**Minimum 4 hours filling machine idle intervention (**Non-Routine Intervention)							
21.		**Extended Shift Hours (More than one shift in Duty hours)** (Non-Routine Intervention)							
22.		**Acrylic door open** (Non-Routine Intervention)							
23.		**Room door Open** (Non-Routine Intervention)							
24.		**Any other** (Non-Routine Intervention)- If Applicable							
25.		**Balance filling**							

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(Sign & Date)

Inference:

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(Quality Assurance)
(Sign & Date)

(B) Batch No. _____

Aseptic Manipulation (Routine intervention):- Rubber Bung Charging

S.No	Date	Intervention detail	No. of intervention observed during commercial batches	Intervention Time		Done By	Checked By
				From	To		
		Charging of rubber stopper to the hopper					

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(Quality Assurance)
(Sign & Date)

Inference:

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

24.0 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)

25.0 ENVIRONMENTAL MONITORING RECORD OF INCUBATION ROOM / CHAMBER:

25.1 MEDIA FILL BATCH INCUBATION DETAILS:

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

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

Date	Time	Temperature Range (20^0C 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)

25.3 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)

26.0 OBSERVATION OF MEDIA FILLED VIALS AFTER INCUBATION:

26.1 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

26.2 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)

27.0 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)

28.0 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)

29.0 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: _____
(Quality Assurance)
(Sign & Date)

30.0 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)

31.0 REFERENCES:

- Pharmaceutical Inspection Convention (Pharmaceutical Inspection Co-Operation Schemes) (PIC/S) PI 007-6, "Recommendation on the Validation of Aseptic Processes".
- WHO Technical Report Series - 961
- United States Pharmacopoeia – 37
- Validation Master Plan.
- SOP Entitled "Process Simulation Study (Media Fill)" Sop.

32.0 DOCUMENTS TO BE ATTACHED:

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

33.0 NON COMPLIANCE:

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

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35.0 CHANGE CONTROL, IF ANY:

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36.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION):

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37.0 CONCLUSION:

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38.0 RECOMMENDATION:

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39.0 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

40.0 REVISION HISTORY:

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

41.0 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)			