REPORT

FOR

PROCESS SIMULATION STUDY

(MEDIA FILL)

FOR THREE PIECE LINE

(FOR SUSPENSION BATCH)

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) Three Piece 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	_____ml LDPE Sterilized Vial		
5.		Sterilized Plug Eye Dropper		
6.		Sterilized Screw Cap		

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

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

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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					
Lactose	Process Simulation Diluent					
____ml LDPE Sterilized Vial	Primary Packaging Material					
Sterilized Plug Eye Dropper	Primary Packaging Material					
Sterilized Screw Cap	Primary Packaging Material					

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

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(Sign & Date)

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(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 EQUIPMENTS DETAILS:

S.No.	Equipment Description	Equipment ID Number	PQ Protocol Number
1.	Manufacturing Vessel		
2.	Mobile mixing Vessel		
3.	Holding Vessel		
4.	Autoclave cum bung processer		
5.	Three Piece Filling Machine		
6.	Sterile Garment Cabinet (Change Room II)		
7.	Mobile trolley (Cool Zone)		
8.	Dynamic pass Box (Material Staging to Debagging)		
9.	Dynamic pass Box (Debagging to filling)		
10.	Dynamic Pass Box (Waste Out Equipment)		
11.	Dynamic Pass Box (DRM to Solution Preparation)		
12.	Dynamic pass box (Solution Preparation to filtration)		
13.	Laminar Air Flow (three piece Filling Machine)		
14.	Laminar Air Flow (Cool Zone)		
15.	Laminar Air Flow (Sampling)		
16.	Laminar Air Flow (Filtration room)		

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(Sign & Date)

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

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

11.0 UTILITY QUALIFICATION VERIFICATION

S. No.	Equipment / System Description	Equipment / System ID Number	PQ Protocol / Report Number	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)

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

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

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

13.0 MACHINE PARTS AND ACCESSORIES STERILIZATION:

Batch No. :_____

Equipment Name	**Process Parameter**		**Media Fill B. No.**	**Done By Operator**	**Checked By Production (Sign & Date)**	**Verified By QA (Sign & Date)**
Steam Sterilizer Autoclave	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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Reviewed By: _____
(Quality Assurance)
(Sign & Date)

14.0 LACTOSE BULK SOLUTION STERILIZATION:

Batch No. :_____

Equipment Name	Process Parameter		Media Fill B. No.	Done By Operator	Checked By Production (Sign & Date)	Verified By QA (Sign & Date)
Mobile mixing Vessel (MMV)	Date					
	MMV	Cycle Start Time				
		Cycle End Time				
	Sterilization	Start Time				
		End Time				
		Total Time				
	Magnetic Stirring speed	500-1440 RPM				

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(Quality Assurance)
(Sign & Date)

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(Quality Assurance)
(Sign & Date)

15.0 THREE PIECE FILLING MACHINE:

Batch No. _____

Sr. No.	Date of Media Fill	Media Fill Batch Number	Machine Speed	Three Piece Filling Machine Operated By (Name of Machine Operators)	Checked By Production (Sign & Date)	Verified By QA (Sign & Date)

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

Inference:

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

16.0 ENVIRONMENTAL MONITORING OF THREE PIECE VIAL FILLING AND SEALING:

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%					
	Ear and eye drop Filling w.r.t Aseptic Corridor (5-15 Pascal)					
	Aseptic Corridor W.R.T Filling Room Entry Airlock III (5-15 Pascal)					
	Cool Zone W.R.T. Aseptic Corridor (5-15 Pascal)					
	Waste out W.R.T. Aseptic Corridor (5-15 Pascal)					
	Filling Exit Airlock I W.R.T. Aseptic Corridor (5-15 Pascal)					
	Filtration Room W.R.T Aseptic Corridor (5-15 Pascal)					
	Filling Room Entry Airlock III W.R.T Filling Room Entry Airlock II (05-15 Pascal)					
	Filling Room Entry Airlock II W.R.T Entry Airlock I (15-30 Pascal)					
	Filling Room Entry Airlock I W.R.T Change Room (15-30 Pascal)					
	Filling Exit Airlock I W.R.T. Aseptic Corridor (5-15 Pascal)					
	Filling Exit Airlock II W.R.T. Filling Exit Airlock I (15-30 Pascal)					

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(Quality Assurance)
(Sign & Date)

Inference:_____

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

17.0 CLARITY TEST:

Batch No. _____

Sr. No.	Sampling Time	Clarity 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)

18.0 MICROBIOLOGICAL ANALYSIS RESULTS:

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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(Sign & Date)

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

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

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:							

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)
	10	Normal Filling	From: To:	From: To:							
	11	Minimum Filling Speed	From: To:	From: To:							
	12	Normal Filling	From: To:	From: To:							
	13	Vial charging in Star belt	From: To:	From: To:							
	14	Normal Filling	From: To:	From: To:							
	15	Dropper (Fixer) charging in Hopper	From: To:	From: To:							
	16	Normal Filling	From: To:	From: To:							
	17	Screw Cap charging in Hopper	From: To:	From: To:							
	18	Normal Filling	From: To:	From: To:							
	19	Handling of Vial, Dropper & Screw Cap by using forceps	From: To:	From: To:							
	20	Normal Filling	From: To:	From: To:							
	21	Operator Breaks & Meals	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	Product Spillage	From: To:	From: To:							
	24	Normal Filling	From: To:	From: To:							
	25	Operator Shift Changes	From: To:	From: To:							
	26	Normal Filling	From: To:	From: To:							
	27	Environmental Monitoring with active air sampling	From: To:	From: To:							
	28	Normal Filling	From: To:	From: To:							
	29	Environmental Monitoring with Passive Air Sampling (Settle Plate)	From: To:	From: To:							
	30	Normal Filling	From: To:	From: To:							
Aseptic Manipulation (Non-Routine Intervention)											
	31	Sensor Adjustment or Replacement	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	AHU of Filling Area OFF for 05 Minute	From: To:	From: To:							
	34	Normal Filling	From: To:	From: To:							
	35	Machine Break down activities for 15 Minutes (MINOR)	From: To:	From: To:							
	36	Normal Filling	From: To:	From: To:							
	37	Machine Break down activities for 60 Minutes (MAJOR)	From: To:	From: To:							
	38	Normal Filling	From: To:	From: To:							
	39	Power Failure for 10 Minutes	From: To:	From: To:							
	40	Normal Filling	From: To:	From: To:							
	41	Increase in No. of Persons for 15 Minutes (Not more than 7 persons)	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: To:	From: To:							
	44	Normal Filling	From: To:	From: To:							
	45	End Normal Filling	From: To:	From: To:							

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

Inference:

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

20.0 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.**

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(Quality Assurance)
(Sign & Date)

Inference:

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

21.0 ENVIRONMENTAL MONITORING RECORD OF INCUBATION ROOM / CHAMBER:

21.1 MEDIA FILL BATCH INCUBATION DETAILS:

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

21.2 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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(Quality Assurance)
(Sign & Date)

21.3 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)

22.0 OBSERVATION OF MEDIA FILLED VIALS AFTER INCUBATION:

22.1 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

22.2 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

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23.0 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)

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

24.0 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 (QA)
1.						

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

Inference:

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

25.0 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	

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(Sign & Date)

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Reviewed By: _____
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(Sign & Date)

26.0 PERSONNEL QUALIFIED FOR ASEPTIC AREA IN MEDIA FILL:

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

	**REPORT FOR PROCESS SIMULATION STUDY (MEDIA FILL) FOR THREE PIECE LINE (FOR SUSPENSION BATCH)**	**PROTOCOL No.:**	
		REVISION No: 00	
		REPORT No.:	
		REVISION No: 00	
		PAGE No.: 40 of 44	

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)

27.0 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.

28.0 DOCUMENTS TO BE ATTACHED:

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

29.0 NON COMPLIANCE:

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

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31.0 CHANGE CONTROL, IF ANY:

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32.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION):

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33.0 CONCLUSION:

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34.0 RECOMMENDATION:

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35.0 ABBREVIATIONS:

SOP	:	Standard Operating Procedure
NLT	:	Not Less than
NMT	:	Not More Than
LAF	:	Laminar Air Flow
No.	:	Number
Min.	:	Minimum
Max.	:	Maximum
QA	:	Quality Assurance
QC	:	Quality Control
WFI	:	Water for Injection
A.R. No.	:	Analytical Report Number
MLT	:	Microbial Limit Test
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

36.0 REVISION HISTORY:

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

37.0 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)			

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