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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	



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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)			



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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.



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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:

REPORT FOR PROCESS SIMULATION STUDY (MEDIA FILL) FOR THREE PIECE LINE

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Training Date: _____

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Турс	of Training:			Tuoinina ai
S. No.	Name of Trainee	Designation	Department Name	Training given on Protocol (Yes/No)
				1100001 (103/140)
Copy of T	raining Record to be attached.			
	By:			
Quality As				
Sign & Date				
S				
Inference:				
			•••••	•••••
				_
			Reviewed I	
			(Quality As	ssurance)



REPORT FOR PROCESS SIMULATION STUDY (MEDIA FILL) FOR THREE PIECE LINE (FOR SUSPENSION BATCH)

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6.0 MASTER DOCUMENT VERIFICATION:

S.No.	Desc	cription	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.		ml LDPE Sterilized Vial		
5.	Packaging Material Specifications	Sterilized Plug Eye Dropper		
6.		Sterilized Screw Cap		
Compiled (Quality (Sign & I	Assurance) Date)			
			Reviewed By: (Quality Assuran (Sign & Date)	nce)



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7.0 DETAIL OF MEDIA AND PRIMARY PACKAGING MATERIALS USED:

_	Category	/ Supplier Name	Required Quantity	Lot No. / A.R. No.	Date of Dispensing	Media Fill Batch No.
Soya Bean	Growth					
Casein Digest	Promotion					
Medium	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					
Compiled By: _ (Quality Assura (Sign & Date)		detail shall be fill i	iii Report as p	ger pack size	periorin during 1	vicula l'illi.
Inference:						
Inference:						

Reviewed By: ______(Quality Assurance)

(Sign & Date)



S.No.

REPORT FOR PROCESS SIMULATION STUDY (MEDIA FILL) FOR THREE PIECE LINE (FOR SUSPENSION BATCH)

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Done By

Media GPT

8.0 GROWTH PROMOTION TEST OF MEDIA (SCDM):

Media Lot

S.No.	Test	No.	Test	Report No.	(Microbiologist)	QA (Sign & Date)			
	Growth Promotion Test of Media (SCDM)*								
* Growt	* Growth Promotion Test Report of Media (SCDM) attached.								
Compiled By: (Quality Assurance) (Sign & Date)									
Inference	ce:								

Date of

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

Checked By



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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)		

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



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



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Sr. No.	Equipment / System ID Number	PQ Protocol / Report Number	Qualification Status	Checked By QA
1.		- 10		(Sign & Date)
2.				_
3.				_
4.				-
5.				_
6.				-
7.				-
8.				-
9.				
10.				
11				
12				
13				
14				
15				
(Qual	oiled By: lity Assurance) & Date) ence:	_		
			Reviewed By: _	
			(Quality Assura (Sign & Date)	nce)



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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)			

(Quality Assurance)	
(Sign & Date)	
Inference:	
	Davierna I Dru
	Reviewed By:(Quality Assurance)
	(Sign & Date)



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12.0 INSTRUMENT CALIBRATION VERIFICATION:

Equipment Name	Instrument Name	ID Number	Calibration Status (Calibrated / Not	Checked By QA
2quipment i tume		12 1 (4111501	Calibrated)	(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			
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			
HVAC	Magnehelic Gauge			
HVAC	Magnehelic Gauge			
HVAC	Magnehelic Gauge			
HVAC	Magnehelic Gauge			
HVAC	Magnehelic Gauge			
HVAC	Magnehelic Gauge			
Sign & Date) Inference:				
			Reviewed By: (Quality Assurance (Sign & Date))



Batch No. :__

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13.0 MACHINE PARTS AND ACCESSORIES STERILIZATION:

	arameter	Media Fill B. No.	Done By Operator	Checked By Production (Sign & Date)	Verified By QA (Sign & Date)
Date					
Autoclave	Start Time		1		
Cycle	End Time				
	Start Time		-		
Sterilization	End Time				
	Total Time				
Sterilization	Minimum		-		
Cemperature	Maximum		1		

Media Fill B. No.



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14.0 LACTOSE BULK SOLUTION STERILIZATION:

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

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



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15.0 THREE PIECE FILLING MACHINE:

Bat	tch 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)
	d By: Assurance) Date)					
Inference	e:					
				Rev	iewed By:	
					ality Assurance n & Date))



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16.0 ENVIRONMENTAL MONITORING OF THREE PIECE VIAL FILLING AND SEALING:

atch No.			

Date	Parameters	Environmental Monitoring Stage			Done By Production	Checked BY QA
		Initial	Middle	End	(Sign & Date)	(Sign & Date)
	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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17.0 CLARITY TEST:

Sr. No.	Sampling Time	Clarity Test Results (OK/NOT OK)	Done By (Production)	Checked By QA (Sign & Date)
nference:				
ıference:				
nference:			Reviewed By (Quality Assi	



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18.0 MICROBIOLOGICAL ANALYSIS RESULTS:

Batch No) .

Sr. No.	Microbiologic	cal Tests	Date of Test	Report No.	Done By (Microbiologist)	Checked By QA (Sign & Date)
1.	WFI used for Media Solution	MLT Test				
	Preparation	BET				
2.	Active Air Sar Aseptic Area Media Fill					
3.	Active Air Sar Aseptic Area Media Fill	During				
4.	Active Air Sar Aseptic Area Af Fill					
5.	Passive Air San Aseptic Area Media Fill	Before				
6.	Passive Air San Aseptic Area Media Fill					
7.	Passive Air San Aseptic Area Af Fill					
8.	Non – Viable Count of Asep Before Media Fi	ptic Area				
9.	Non – Viable Count of Asep During Media F	ptic Area				
10.	Non – Viable Count of Asep After Media Fill	e Particle ptic Area				
11.	Microbiological Aseptic Area V Floors After Me	Walls and				
12.	Microbiological Machine Surfa Media Fill.	ace After				
13.	Microbiological Aseptic Area After Media Fill	Garments				



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Sr. No.	Microbiologica	al Tests	Date of Test	Report No.	Done By (Microbiologist)	Checked By QA (Sign & Date)
14.	Personal Monitor RODAC Plate an Dab of Aseptic A Persons (Staff & Operators) After Fill	d Finger rea				
15.	Collect Filtered IPA after	Initial				
	filtration and check for its Sterility	Middle				
		End				
	ity Assurance) & Date) nce:					
					Reviewed By:	



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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.	Interve ntion No.	Name of Person Involved During Intervention	Checked By (Production Officer / Executive)
				Manipula	tion (Ro	outine Int	tervention	1)			
	1	Aseptic Assembly of the Equipment and Initial Product	From: To:	From: To:							
		Connection or Introduction									
		• N. 15:11:	From:	From:							
	2	Normal Filling	To:	To:							
	Initial Fill 3 Volume	From:	From:								
		Adjustment	To:	To:							
	_	4 Normal Filling	From:	From:							
	4 1		To:	То:							
	_	Periodic Fill Volume	From:	From:							
	5	Checking & Verification	To:	То:							
	_		From:	From:							
	6	Normal Filling	То:	To:							
	7	Maximum	From:	From:							
		Filling Speed	To:	To:							
	8	Normal Filling	From:	From:							
		S =S	To:	To:							
	9	Optimum	From:	From:							
	_	Filling Speed	To:	To:							



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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.	Interve ntion No.	Name of Person Involved During Intervention	Checked By (Production Officer / Executive)
	10	N 1 E'II'	From:	From:							
	10	Normal Filling	To:	To:							
		Minimum	From:	From:							
	11	Filling Speed	To:	To:							
			From:	From:							
	12	Normal Filling	To:	To:							
		Vial charging in Star belt	From:	From:							
	13		To:	To:							
		14 Normal Filling	From:	From:							
	14		To:	To:							
		Dropper (Fixer) charging in Hopper	From:	From:							
	15		To:	To:							
			From:	From:							
		Normal Filling	To:	To:							
		Screw Cap	From:	From:							
	17	charging in Hopper	To:	To:							
			From:	From:							
	18	Normal Filling	To:	To:							
		Handling of	From:	From:							
	19	Vial, Dropper & Screw Cap by	To:	To:							
		using forceps									
	20	Normal Filling	From:	From:							
		T (offiner 1 ming	To:	To:							
	21	Operator Breaks		From:							
	21	& Meals	To:	То:							
			From:	From:							
	22	Normal Filling	To:	To:							



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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.	Interve ntion No.	Name of Person Involved During Intervention	Checked By (Production Officer / Executive)
			From:	From:							
	23	Product Spillage	To:	To:							
		Normal Filling	From:	From:							
	24		То:	To:							
	25	Operator Shift	From:	From:							
	25	Changes	То:	To:							
			From:	From:							
	26	Normal Filling	To:	To:							
	27	Environmental Monitoring with	From:	From:							
	21	active air sampling	To:	То:							
			From:	From:							
		Normal Filling	То:	To:							
		Environmental Monitoring with		From:							
	29	Passive Air Sampling (Settle Plate)	To:	To:							
			From:	From:							
	30	Normal Filling	То:	То:							
			Aseptic M	anipulatio	on (Non	-Routine	Interven	tion)			
		Sensor	From:	From:							
	31	Adjustment or Replacement	To:	То:							
	22	Normal Ellins	From:	From:							
	32	Normal Filling	To:	To:							



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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.	Interve ntion No.	Name of Person Involved During Intervention	Checked By (Production Officer / Executive)
	22	AHU of Filling	From:	From:							
	33	Area OFF for 05 Minute	To:	To:							
			From:	From:							
	34	Normal Filling	To:	То:							
		Machine Break down activities for 15 Minutes (MINOR)	From:	From:							
	35 fo		То:	To:							
			From:	From:							
	36	Normal Filling	To:	To:							
	27	Machine Break down activities	From:	From:							
	37	for 60 Minutes (MAJOR)	То:	То:							
		Normal Filling	From:	From:							
	38		To:	То:							
	20	Power Failure for 10 Minutes	From:	From:							
	39		To:	To:							
			From:	From:							
	40	Normal Filling	To:	То:							
		Increase in No. of Persons for	From:	From:							
	41	15 Minutes (Not more than 7 persons)	То:	To:							
		Normal Filling	From:	From:							
	42		To:	To:							



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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.	Interve ntion No.	Name of Person Involved During Intervention	Checked B (Production Officer / Executive)
	40	Operator Fatigue	From:	From:							
	43		To:	To:							
		Normal Filling	From:	From:							
	44		To:	To:							
	4.5	End Normal Filling	From:	From:							
	45		То:	То:							
(Qua		By: Assurance) Date)									
(Qua (Sigr	lity A	Assurance) Pate)									
(Qua (Sigr	ility A	Assurance) Pate)									
(Qua (Sigr	ility A	Assurance) Pate)									
(Qua (Sigr	ility A	Assurance) Pate)									
(Qua (Sigr	ility A	Assurance) Pate)									



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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 incl	udes total no. of In	tegral Vials and to	tal rejection durin	ng Visual inspection.
Compiled (Quality A (Sign & I	Assurance)	_			
Inference	:				
				Reviewed By: _ (Quality Assura (Sign & Date)	



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${\bf 21.0~ENVIRONMENTAL~MONITORING~RECORD~OF~INCUBATION~ROOM~/~CHAMBER:}$

21.1 MEDIA FILL BATCH INCUBATION DETAILS:

Datah Na		Temperature: o 25 ºC	Incubation Temperature: 30°C to 35 °C	
Batch No.	Started on	Completed on	Started on	Completed on

21.2 INCUBATION TEMPERATURE: 20°C to 25 °C Frequency: Once in a day

Date	Time	Temperature Range	Recorded By	Checked By
Date	Time	(20°C to 25 °C)	(Microbiologist)	(QA Executive / Officer)



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



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21.3 INCUBATION TEMPERATURE: 30°C to 35 °C Frequency: Once in a day

D.	Temperature Range		Recorded By	Checked By
Date	Time	(30°C to 35 °C)	(Microbiologist)	(QA Executive / Officer)



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(Sign & Dat	te)		
Compiled B (Quality As: (Sign & Dat	sy:surance)		



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22.0	OBSERVATION OF	MEDIA DILI DO	TITATO ADDITION	TRICTID A THORI.
ZZ.U	UBSERVATION OF	WIRIDIA RILIARID	VIALS AFIRE	CINCLIBATION:
	ODDEL VILLOT OF		A TATALON TATALON	LILICODILLICIII

22.1 OBSERVATION AFTER INCUBATION OF 1st 7 DAYS AT 20°C to 25 °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°C to 35 °C						
S. No.	Media Fill Batch Number	Date of Incubation	No. of Vials Incubated	No. of good Vials after Incubation	No. of Contaminate d Vials after Incubation (If any)	Remarks
Compiled By: (Quality Assurance) (Sign & Date)						

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



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23	Λ	POST	CPT	UE DEV	CTIVATED	VIAIC

- 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)*					

				1	
owth Promotion 7	Test Report of Media	(SCDM) Solu	tion attached for re	eference.	
	1	,			
mpiled By:					
uality Assurance)	1				
gn & Date)					
ference:					
				eviewed By:	
				uality Assurance)	
			(Si	ign & Date)	



S.

No.

Date

REPORT FOR PROCESS SIMULATION STUDY (MEDIA FILL) FOR THREE PIECE LINE (FOR SUSPENSION BATCH)

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Done By

Verified By

(QA)

Checked By

(Sign & Date)

24.0 DESTRUCTION OF INCUBATED VIALS AFTER INSPECTION:

Media Fill Batch

Number

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

No. of Vials

Destroyed

1.						
			·			
Compi	led By:					
(Qualit	y Assuranc	ce)				
(Sign &	& Date)					
Inferer	ice:					
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				Revie (Qual	wed By: ity Assurance)	



PROTOCOL No.	PRO	TO	COL	No.:
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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	
Compiled (Quality A (Sign & D	By: Assurance) (ate)	
Inference	:	
		Reviewed By:(Quality Assurance) (Sign & Date)



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26.0 PERSONNEL QUALIFIED FOR ASEPTIC AREA IN MEDIA FILL:

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



PRC	TC	CO	T.	No.	•
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S. No.	Name of Personnel	Designation	Department Name	Checked by QA (Sign & Date)
Compil (Qualit (Sign &	led By: ty Assurance) & Date)			
Inferen	ace:			
			Reviewed By:	nce)
			(Sign & Date)	



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27.0	REF	EREN	ICES :
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- 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:
30.0	DEVIATION FROM PRE-DEFINED SPECIFICATION (IF ANY):



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31.0	CHANGE CONTROL, IF ANY:
32.0	REVIEW (INCLUSIVE OF FOLLOW UP ACTION):
33.0	CONCLUSION:
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



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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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