REPORT

FOR

PROCESS SIMULATION STUDY

(MEDIA FILL)

FOR DRY POWDER INJECTION

VIAL SIZE: 7.5 ML TO 20 ML

SUPERSEDES REPORT No.	
DATE OF VALIDATION	
VALIDATION BATCH NUMBER	
VALIDATION BATCH SIZE	

PHARMA DEVILS	PROCESS SIMULATION STUDY / MEDIA FILL REPORT FOR VIAL SIZE – 7.5 ML TO 20 ML	PROTOCOL No.:

CONTENTS

PHARMA DEVILS	PROCESS SIMULATION STUDY / MEDIA FILL REPORT FOR VIAL SIZE – 7.5 ML TO 20 ML	PROTOCOL No.:

1.0 PRE- APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
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.
- 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:

- This report is applicable for performing Process Simulation Study (Media Fill) at Dry Powder Injection facility.
- This document provides information regarding the Process Simulation Study (Media Fill) activity and exhibits provided in the document shall be used for recording the data during execution of activity and to compile the data of analysis of various samples received from QC.

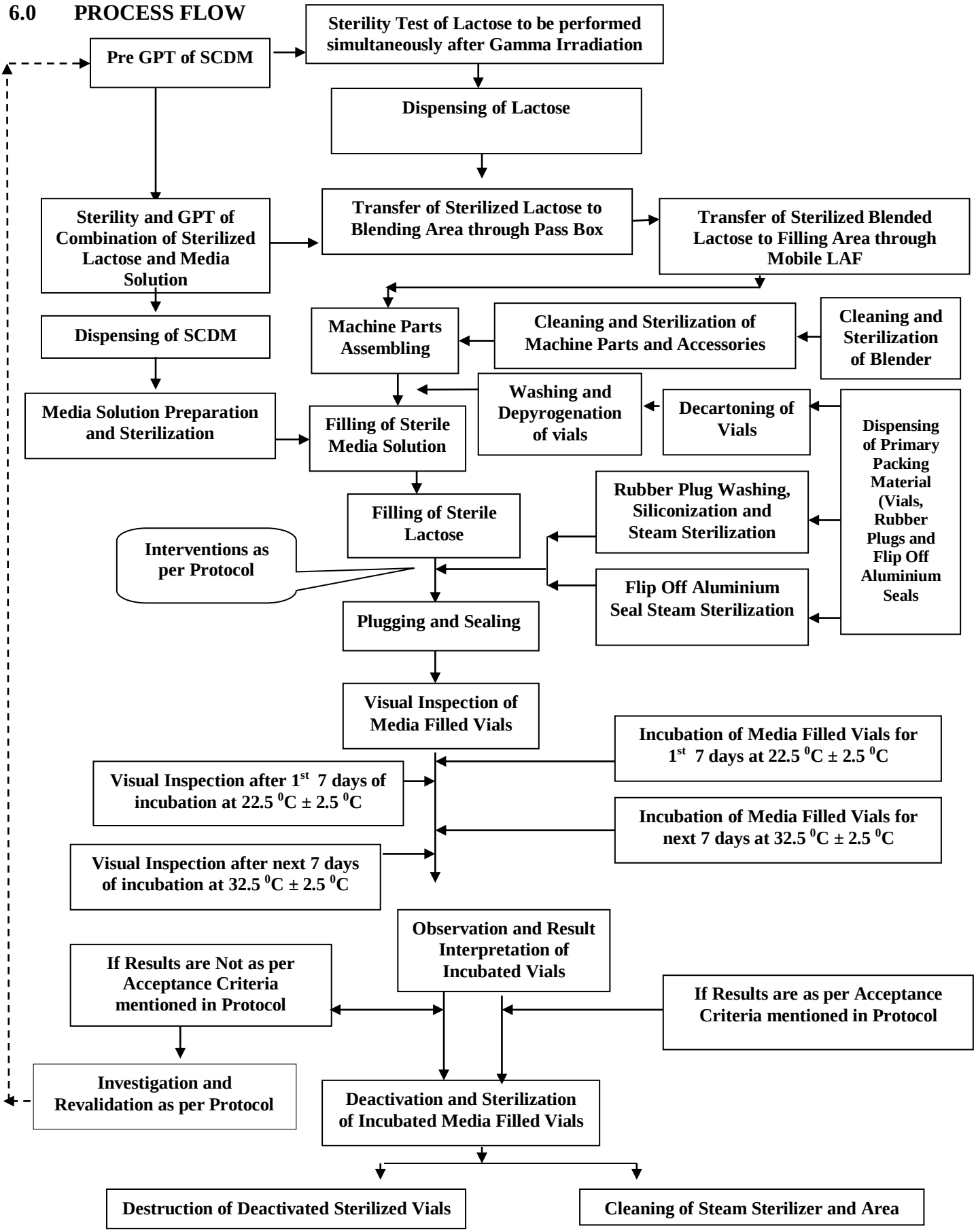
4.0 RESPONSIBILITY:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review and Approval of Process Simulation Study (Media Fill) Protocol & Report. • To Evaluate Protocol Completeness and Technical Accuracy. • Protocol Training • 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 Protocol and Report. • To schedule the Process Simulation Study Activity. • To assist in the preparation and execution of the process.
Quality Control	• To Review the Protocol and 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 Protocol and Report. • To co-ordinate and support the Process Simulation Study Activity. • To provide engineering support during Process Simulation Study (Media Fill).

5.0 DESCRIPTION OF PROCESS SIMULATION STUDY METHODOLOGY:

- Only after the Pre Approval, the Protocol shall be executed.
- Process Simulation Study includes Formulation and Filling with Suitable Media.
- During the course of Process Simulation Study (Media Fill) the Documentation System,
- Manufacturing Procedure, Laboratory Controls, In Process Checks and Media Filled Vials shall be evaluated.
- The type of validation to be carried out is Prospective validation (First Validation).
- The Process Simulation Study shall be carried out for three runs for each pack size to assess the process consistency.
- The Process Simulation Study (Media Fill) methodology consists of following basic parts -
  a) Process Parameters Monitoring,
- Incubation of Filled Vials at Specific Temperatures for 14 days.
- Visual Inspection of the vials after 1st 7 days of Incubation at 22.5ºC ± 2.5ºC for observing Fungal Growth or Turbidity (If any).
- Visual Inspection of the vials after Next 7 days of Incubation at 32.5ºC ± 2.5ºC for observing Bacterial Growth or Turbidity (If any).
- QC shall analyze all samples and the data will be recorded / attached with the report. Where applicable the graph and data print outs of critical process parameters shall be obtained and attached.
- All Parameters and Process Details shall be recorded in relevant records (e.g. Exhibits, Formats, and Media Fill Record etc.)
- A Summary Report shall be finally prepared summarizing the data obtained from the Process Simulation Study for three runs of minimum & maximum pack size, Conclusions Drawn and Recommendations, if any.

6.0 PROCESS FLOW



7.0 CRITICAL PROCESS PARAMETERS:

S.No.	PROCESS STEPS	MONITORING PARAMETERS
1.	**Blending of Material**	Blending start time Blending stop time Blending RPM
2.	**Rubber Bung Washing**	Washing start time
		Washing end time
		Rinsing with Purified water Start Time Stop Time
		Rinsing with WFI Start Time Stop Time
		Siliconization Start Time Stop Time
3.	**Sterilization of Rubber Bungs, Aluminum seals and Accessories**	Sterilization Time
		Sterilization Temperature (Min. & Max.)
		Vacuum Drying Time
4.	**Vial Washing**	Differential Pressure of Area
		Speed of Vial Washing Machine
		Recycled Water Pressure (Min. & Max.)
		Water For Injection Pressure (Min. & Max.)
		Compressed Air Pressure (Min. & Max.)
5.	**Vial Depyrogenation**	Tunnel Conveyor Belt Speed
		Temperature of Sterile Zone Entry
		Temperature of Sterile Zone exit
		Drying Zone Manometer reading
		Sterilization Zone Manometer reading
		Cool Zone Manometer reading
6.	**Vial Filling & Sealing**	Differential Pressure in Sterile Area
		Temperature
		Area Humidity
		Filling machine speed
		Sealing Inspection
		Clarity
		Leak test

8.0 EXHIBIT:

8.1 TRAINING RECORD:

Name of Trainer: _____ Training Date: _____

Type of Training: _____

S.No.	Name of Trainee	Designation	Department Name	Training on Protocol is given (Yes/No)	Checked by (QAO/QAE)

*** Controlled Copy of Training Record attached.**

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

Inference:

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Reviewed By:
(Manager QA)…….
Sign / Date

8.2 MASTER DOCUMENT VERIFICATION:

The Master Documents were verified and the details are compiled below:

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.	Media Fill Record			
5.	Packaging Material Specifications	USP-Type-III Glass Vial 7.5 ml / 30ml		
		Rubber Stopper Bromo Butyl 20mm		
		Aluminium Seal F/O 20 mm		

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(Quality Assurance)
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8.3 DETAIL OF MEDIA AND PRIMARY PACKAGING MATERIALS USED:

The Media and Primary Packaging Materials used for Media Fill Batches were procured from approved vendors. Detail of all materials and Primary Packaging Materials used is as below:

First Media Fill Batch No.:
Date of Dispensing:

Material Description	Category	Manufacturer / Supplier Name	Required Quantity	Lot No. / A.R. No.
Soya Bean Casein Digest Medium	Growth Promotion Medium			
Sterilized Lactose	Process Simulation Diluent			
Glass Moulded Clear USP Type-III 7.5 ml / 30ml	Primary Packaging Material			
Rubber Stoppers Bromobutyl 20 mm	Primary Packaging Material			
Aluminum Seals F/O 20 mm	Primary Packaging Material			

Second Media Fill Batch No.:
Date of Dispensing:

Material Description	Category	Manufacturer / Supplier Name	Required Quantity	Lot No. / A.R. No.
Soya Bean Casein Digest Medium	Growth Promotion Medium			
Sterilized Lactose	Process Simulation Diluent			
Glass Moulded Clear USP Type-III 7.5 ml / 30ml	Primary Packaging Material			
Rubber Stoppers Bromobutyl 20 mm	Primary Packaging Material			
Aluminum Seals F/O 20 mm	Primary Packaging Material			

PHARMA DEVILS	PROCESS SIMULATION STUDY / MEDIA FILL REPORT FOR VIAL SIZE – 7.5 ML TO 20 ML	PROTOCOL No.:

Third Media Fill Batch No.:
Date of Dispensing:

Material Description	Category	Manufacturer / Supplier Name	Required Quantity	Lot No. / A.R. No.
Soya Bean Casein Digest Medium	Growth Promotion Medium			
Sterilized Lactose	Process Simulation Diluent			
Glass Moulded Clear USP Type-III 7.5 ml / 30ml	Primary Packaging Material			
Rubber Stoppers Bromobutyl 20 mm	Primary Packaging Material			
Aluminum Seals F/O 20 mm	Primary Packaging Material			

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(Quality Assurance)
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Inference:

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(Manager QA)…….
Sign / Date

8.4 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)
1.	Growth Promotion Test of Media (SCDM)*					

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

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

Inference:

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(Manager QA)…….
Sign / Date

8.5 SOLUBILITY STUDY OF LACTOSE IN PREDEFINED CONCENTRATION AND VOLUME OF MICROBIOLOGICAL GROWTH SUPPORT MEDIUM (MGSM):

S. No.	DATE	TIME	QTY. OF LACTOSE	CONCENTRATION OF MEDIA SOLUTION	VOLUME OF MEDIA SOLUTION	VIAL SIZE (ml)	SOLUBILITY STATUS

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

Inference:

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Reviewed By:
(Manager QA)…….
Sign / Date

8.6 LACTOSE STERILIZATION (FROM OUTSIDE LABORATORY) DETAILS & STERILITY TEST OF LACTOSE:

LACTOSE	**Lot No.**	
	A.R. No.	
	Expiry Date	
Total Qty. of Lactose Packed and Sealed		
Total No. of Packs Prepared of 500 gm each		
Total No. of Packs sent for Sterilization to Outside Agency		
Returnable Gate Pass No.		
Date of Sending the Packed & Sealed Lactose Packs for Sterilization		
Date of Receiving of the Sterilized Lactose		
Outside Agency Gamma Irradiation Report No.		
Date of Sterility Test		
In –House Sterility Report No. (For Lactose)		

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

Inference:

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(Manager QA)…….
Sign / Date

8.7 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.						

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

Inference:

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Reviewed By:
(Manager QA)…….
Sign / Date

8.8 EQUIPMENTS DETAILS:

Following Qualified Equipments were used during Process Simulation Study.

S. No.	Equipment Description	Equipment ID Number	PQ Protocol Number
1.	Double Cone Blender		
2.	Pure Steam Generation System		
3.	HVAC 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.	Dry Powder Filling with Rubber Stoppering Machine		
11.	Dynamic Pass Box		
12.	Vertical Hanging Laminar Air Flow Unit (filling & Stoppering)		
13.	Vertical Hanging Laminar Air Flow Unit (Sealing Room)		

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(Sign/Date)

Inference:

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Sign / Date

8.9 AIR HANDLING UNIT (AHU) QUALIFICATION VERIFICATION:

S. No.	Equipment / System Description	Equipment / System ID Number	PQ Protocol / Report Number	Checked by (QAO/QAE)

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

Inference:

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Reviewed By:
(Manager QA)…….
Sign / Date

8.10 UTILITY QUALIFICATION VERIFICATION:

S. No.	Equipment / System Description	Equipment / System ID Number	PQ Protocol / Report Number	Checked by (QAO/QAE)

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

Inference:

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Reviewed By:
(Manager QA)…….
Sign / Date

8.11 INSTRUMENT CALIBRATION VERIFICATION:

Equipment Name	Instrument Name	ID Number	Calibration Status (Calibrated / Not Calibrated)	Checked by (QAO/QAE)
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			
HVAC	Magnehelic Gauge			
HVAC	Magnehelic Gauge			
HVAC	Magnehelic Gauge			
HVAC	Magnehelic Gauge			
HVAC	Magnehelic Gauge			
Depyrogenation Tunnel	Magnehelic Gauge			
Depyrogenation Tunnel	Magnehelic Gauge			
Depyrogenation Tunnel	Magnehelic Gauge			
Blending LAF	Magnehelic Gauge			
Cooling LAF	Magnehelic Gauge			
Filling LAF	Magnehelic Gauge			
Sealing LAF	Magnehelic Gauge			
Filling Machine	Pressure Gauge			
Filling Machine	Pressure Gauge			
Bung Processor	Pressure Gauge			
Bung Processor	Pressure Gauge			
Bung Processor	Pressure Gauge			

PHARMA DEVILS	PROCESS SIMULATION STUDY / MEDIA FILL REPORT FOR VIAL SIZE – 7.5 ML TO 20 ML	PROTOCOL No.:

Equipment Name	Critical Instrument	ID Number	Calibration Status (calibrated / not calibrated)	Checked by (QAO/QAE)
Bung Processor	Pressure Gauge			
Bung Processor	Pressure Gauge			
Bung Processor	Compound Gauge			
Bung Processor	Compound Gauge			
Bung Processor	Compound Gauge			
Bung Processor	Compound Gauge			
Bung Processor	Compound Gauge			
Bung Processor	Compound Gauge			

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

Inference:

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Reviewed By:
(Manager QA)…….
Sign / Date

8.12 BLENDER PROCESSING DETAILS:

Equipment Name	Process Parameter		Media Fill Batch No.			Done By (Production)	Checked By QAO/QAE)
			1st	2nd	3rd		
Blender Cleaning & Sterilization	Run No.						
	Date						
	Cleaning of Blender	Start time					
		End time					
	Cycle	Start time					
		End time					
	Sterilization	Start Time					
		End Time					
		Total Time					
	Sterilization Temperature	Minimum					
		Maximum					

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

Inference:

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Reviewed By:
(Manager QA)…….
Sign / Date

PHARMA DEVILS	PROCESS SIMULATION STUDY / MEDIA FILL REPORT FOR VIAL SIZE – 7.5 ML TO 20 ML	PROTOCOL No.:

8.13 RUBBER BUNG PROCESSING DETAILS:

Equipment Name	Process Parameter		Media Fill Batch No. 1st	2nd	3rd	Done By (Production)	Checked By (QAO/QAE)
Bung Processor cum Autoclave	Run No.						
	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						
	Total Siliconization Time						
	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)						

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

Inference:

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Reviewed By:
(Manager QA)…….
Sign / Date

8.14 FLIP OFF ALUMINIUM SEAL PROCESSING DETAILS:

Equipment Name	Process Parameter		Media Fill Batch No.			Done By (Sign and Date) (Production)	Checked By (Sign and Date) (QAO/QAE)
			1st	2nd	3rd		
Bung Processor cum Autoclave	Run No.						
	Date						
	Cycle	Start time					
		End time					
	Sterilization	Start Time					
		End Time					
		Total Time					
	Sterilization Temperature	Minimum					
		Maximum					
S. No.	**Aluminium Seal Critical Parameters Observations**						
	Sterility Test (Should Comply Sterility Test)						

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

Inference:

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Reviewed By:
(Manager QA)…….
Sign / Date

8.15 MACHINE PARTS AND ACCESSORIES STERILIZATION:

Equipment Name	Process Parameter		Media Fill Batch. No.			Done By (Sign & Date) (Production)	Checked By (Sign & Date) (QAO/QAE)
			1st	2nd	3rd		
Bung Processor cum Autoclave	Run No.						
	Date						
	Autoclave Cycle	Start Time					
		End Time					
	Sterilization	Start Time					
		End Time					
		Total Time					
	Sterilization Temperature	Minimum					
		Maximum					

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

Inference:

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Reviewed By:
(Manager QA)…….
Sign / Date

PHARMA DEVILS	PROCESS SIMULATION STUDY / MEDIA FILL REPORT FOR VIAL SIZE – 7.5 ML TO 20 ML	PROTOCOL No.:

8.16 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 1.5 – 4.0 Kg/cm²						
	Pressure of Recycle Water NLT 2.0 Kg/cm²						
	Pressure of Water for Injection NLT 1.0 Kg/cm²						
Depyrogenation Tunnel	Conveyor Speed NMT 192 mm/min						
	Temp. Sterile Entry Zone	Min.					
		Max.					
	Temp. Sterile Exit Zone	Min.					
		Max.					
	Drying Zone Manometer 13 to 20 mm						
	Hot Zone Manometer 23 to 30 mm						
	Stabilizing Zone Manometer 13 to 20 mm						
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)						

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

Inference:

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Reviewed By:
(Manager QA)…….
Sign / Date

8.17 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.
1.	Growth Promotion Test of Media Solution*				

Done By ……
(Microbiologist)

Checked By……..
(QAO / QAE)

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

Inference:

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Reviewed By:
(Manager QA)…….
Sign / Date

8.18 VIAL FILLING & RUBBER STOPPERING:

- 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.						
2.						
3.						

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

Inference:

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Reviewed By:
(Manager QA)…….
Sign / Date

8.19 ENVIRONMENTAL MONITORING OF VIAL FILLING AND SEALING:

FIRST BATCH Date: Batch No.:

Parameters	Environmental Monitoring Stage			Done By (Sign & Date) (Production)	Checked By (Sign & Date) (QAO/QAE)
	Initial	Middle	End		
Temp 23°C ± 2°C					
RH 28% ± 5%					
Differential Pressure Air Lock I (0.8-1.6)					
Differential Pressure Air Lock II (2.6-3.2)					
Differential Pressure Air Lock III (3.6-4.2).					
Differential Pressure of Sterile Corridor (4.6-5.0)					
Differential Pressure of Vial Filling and bunging Room (7.8-8.2)					
Differential Pressure of Vial Sealing Room (6.6-7.2)					

SECOND BATCH Date: Batch No.:

Parameters	Environmental Monitoring Stage			Done By (Sign & Date) (Production)	Checked By (Sign & Date) (QAO/QAE)
	Initial	Middle	End		
Temp 23°C ± 2°C					
RH 28% ± 5%					
Differential Pressure Air Lock I (0.8-1.6)					
Differential Pressure Air Lock II (2.6-3.2)					
Differential Pressure Air Lock III (3.6-4.2).					
Differential Pressure of Sterile Corridor (4.6-5.0)					
Differential Pressure of Vial					

Filling and bunging Room (7.8-8.2)					
Differential Pressure of Vial Sealing Room (6.6-7.2)					

THIRD BATCH **Date:** **Batch No.:**

Parameters	Environmental Monitoring Stage			Done By (Sign & Date) (Production)	Checked By (Sign & Date) (QAO/QAE)
	Initial	Middle	End		
Temp 23°C ± 2°C					
RH 28% ± 5%					
Differential Pressure Air Lock I (0.8-1.6)					
Differential Pressure Air Lock II (2.6-3.2)					
Differential Pressure Air Lock III (3.6-4.2).					
Differential Pressure of Sterile Corridor (4.6-5.0)					
Differential Pressure of Vial Filling and bunging Room (7.8-8.2)					
Differential Pressure of Vial Sealing Room (6.6-7.2)					

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

Inference:

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Reviewed By:
(Manager QA)…….
Sign / Date

8.20 CONTAINER CLOSER INTEGRITY:

8.20.1 LEAK TEST:

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

8.20.2 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:
(Manager QA)…….
Sign / Date

8.21 MICROBIOLOGICAL ANALYSIS RESULTS:

FIRST BATCH **Batch No.:**

S. 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.	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					

PHARMA DEVILS	PROCESS SIMULATION STUDY / MEDIA FILL REPORT FOR VIAL SIZE – 7.5 ML TO 20 ML	PROTOCOL No.:

SECOND BATCH **Batch No.:**

S. 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.	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					

PHARMA DEVILS	PROCESS SIMULATION STUDY / MEDIA FILL REPORT FOR VIAL SIZE – 7.5 ML TO 20 ML	PROTOCOL No.:

THIRD BATCH **Batch No.:**

S. 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.	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					

PHARMA DEVILS	PROCESS SIMULATION STUDY / MEDIA FILL REPORT FOR VIAL SIZE – 7.5 ML TO 20 ML	PROTOCOL No.:

S. No.	Microbiological Tests	Date of Test	Report No.	Done By (Microbiologist)	Checked By QA (Sign & Date)
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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Reviewed By:
(Manager QA)…….
Sign / Date

8.22 INTERVENTIONS DURING FILLING AND SEALING (Worst Case Condition):

FIRST BATCH:

S. No.	Date	Intervention / Worst Case Condition	Sample No.	Time	Tray No.	Qty.	Done By (Production Operator)	Checked By (Production)	Verified By (QA)
1.0		Aseptic transfer of sterile material from Blender to Hopper of Filling Machine	1.						
			2.						
			3.						
			4.						
2.0		Volume & Weight Adjustment (Fill Volume and Fill Weight setting)		From:					
				To:					
3.0		Aseptic Assembling of Machine Parts and Manipulations		From:					
				To:					
4.0		AHU of Filling Area OFF		From:					
				To:					
5.0		Machine Break down activities for 15 minutes (MINOR)		From:					
				To:					
				To:					
				To:					
6.0		Increase in No. of Persons for 15 min (Not more than 7 persons)		From:					
				To:					

PHARMA DEVILS	PROCESS SIMULATION STUDY / MEDIA FILL REPORT FOR VIAL SIZE – 7.5 ML TO 20 ML	PROTOCOL No.:

=SECOND BATCH:

S. No.	Date	Intervention / Worst Case Condition	Sample No.	Time	Tray No.	Qty.	Done By (Production Operator)	Checked By (Production)	Verified By (QA)
1.0		Aseptic transfer of sterile material from Blender to Hopper of Filling Machine	1.						
			2.						
			3.						
			4.						
2.0		Volume & Weight Adjustment (Fill Volume and Fill Weight setting)		From:					
				To:					
3.0		Aseptic Assembling of Machine Parts and Manipulations		From:					
				To:					
4.0		AHU of Filling Area OFF		From:					
				To:					
5.0		Machine Break down activities for 15 minutes (MINOR)		From:					
				To:					
				To:					
				To:					
6.0		Increase in No. of Persons for 15 min (Not more than 7 persons)		From:					
				To:					

PHARMA DEVILS	PROCESS SIMULATION STUDY / MEDIA FILL REPORT FOR VIAL SIZE – 7.5 ML TO 20 ML	PROTOCOL No.:

THIRD BATCH:

S. No.	Date	Intervention / Worst Case Condition	Sample No.	Time	Tray No.	Qty.	Done By (Production Operator)	Checked By (Production)	Verified By (QA)
1.0		Aseptic transfer of sterile material from Blender to Hopper of Filling Machine	1.						
			2.						
			3.						
			4.						
2.0		Volume & Weight Adjustment (Fill Volume and Fill Weight setting)		From:					
				To:					
3.0		Aseptic Assembling of Machine Parts and Manipulations		From:					
				To:					
4.0		AHU of Filling Area OFF		From:					
				To:					
5.0		Machine Break down activities for 15 minutes (MINOR)		From:					
				To:					
				To:					
				To:					

6.0		**Increase in No. of Persons for 15 min (Not more than 7 persons)**	**From:**					
			To:					

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

Inference:

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Reviewed By:
(Manager QA)…….
Sign / Date

8.23 INSPECTION OF FILLED AND SEALED VIALS:

Date	Media Fill Batch Number	Total No. of Vials Filled	Total No. of Good vials	Total No. of Rejected vials	Total No. of Vials Transferred for Incubation

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

Inference:

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Reviewed By:
(Manager QA)…….
Sign / Date

8.24 ENVIRONMENTAL MONITORING RECORD OF INCUBATION ROOM / CHAMBER:

8.24.1 Media Fill Batch Incubation Details:

Batch No.	Incubation Temperature: 22.5 ^{0}C ± 2.5 ^{0}C		Incubation Temperature: 32.5 ^{0}C ± 2.5 ^{0}C	
	Started on	Completed on	Started on	Completed on

8.24.2 INCUBATION TEMPERATURE: 22.5 ^{0}C ± 2.5 ^{0}C Frequency: Once in a shift

Date	Time	Temperature Range (22.5 ^{0}C ± 2.5 ^{0}C)	Recorded By (Microbiologist)	Checked By (QA Executive / Officer)

PHARMA DEVILS	PROCESS SIMULATION STUDY / MEDIA FILL REPORT FOR VIAL SIZE – 7.5 ML TO 20 ML	PROTOCOL No.:

Date	Time	Temperature Range ($22.5\ ^0C \pm 2.5\ ^0C$)	Recorded By (Microbiologist)	Checked By (QA Executive / Officer)

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

Inference:

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Reviewed By:
(Manager QA)…….
Sign / Date

8.24.3 INCUBATION TEMPERATURE: 32.5 ^{0}C ± 2.5 ^{0}C   Frequency: Once in a shift

Date	Time	Temperature Range (32.5 ^{0}C ± 2.5 ^{0}C)	Recorded By (Microbiologist)	Checked By (QA Executive / Officer)

PHARMA DEVILS	PROCESS SIMULATION STUDY / MEDIA FILL REPORT FOR VIAL SIZE – 7.5 ML TO 20 ML	PROTOCOL No.:

Date	Time	Temperature Range ($32.5\ ^0C \pm 2.5\ ^0C$)	Recorded By (Microbiologist)	Checked By (QA Executive / Officer)

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

Inference:

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Reviewed By:
(Manager QA)…….
Sign / Date

8.25 OBSERVATION OF MEDIA FILLED VIALS AFTER INCUBATION:

8.25.1 OBSERVATION AFTER INCUBATION OF 1st 7 DAYS AT 22.5°C±2.5°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

8.25.2 OBSERVATION AFTER INCUBATION OF NEXT 7 DAYS AT 32.5°C±2.5°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:
(Manager QA)…….
Sign / Date

8.26 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)*					
2.						
3.						

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

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

Inference:

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Reviewed By:
(Manager QA)…….
Sign / Date

8.27 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 (Operator)	Checked By (Production)	Verified By (QA)

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

Inference:

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Reviewed By:
(Manager QA)…….
Sign / Date

8.28 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:
(Manager QA)…….
Sign / Date

8.29 PERSONNEL QUALIFIED FOR ASEPTIC AREA IN MEDIA FILL:

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:
(Manager QA)…….
Sign / Date

9.0 DEVIATION (IF ANY):

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10.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION):

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11.0 CONCLUSION:

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12.0 RECOMMENDATION:

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13.0 REFERENCES:

- Media Fill Protocol for Process Simulation Study (MFP/PPQ/IB/001-00).
- Media Fill Record.
- PIC/S Validation of Aseptic processes, PI 007-6 January 2011.
- PDA Technical Report No.06.
- USFDA Guidelines for Sterile Drug Products Produced by Aseptic Processing.
- Schedule-M
- WHO Technical Report Series - 961
- United States Pharmacopoeia - 37

14.0 ABBREVIATIONS:

SOP	:	Standard Operating Procedure
Temp.	:	Temperature
NLT	:	Not Less than
NMT	:	Not More Than
LAF	:	Laminar Air Flow
No.	:	Number
min.	:	Minimum
max.	:	Maximum
EU	:	Endotoxin Unit
WFI	:	Water for Injection
A.R. No.	:	Analytical Report Number
PIC/S	:	Pharmaceutical Inspection Convention OR Pharmaceutical Inspection Co-Operation Scheme
PDA	:	Parenteral Drug Association
USP	:	United States Pharmacopeia
USFDA	:	United States Food and Drug Administration
QAO/QAE	:	Quality Assurance Officer / Quality Assurance Executive

15.0 POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			
HEAD (QUALITY CONTROL)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			