



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Precautions to be taken after major breakdown of Blow, Fill and Seal Machine

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	1 of 4

1.0 OBJECTIVE:

To lay down a Procedure for the Precautions to be taken after Major Breakdown of Blow Fill and Seal (BFS) Machine.

2.0 SCOPE:

This SOP is applicable for the Precautions to be taken after Major Breakdown of Blow, Fill and Seal (BFS) Machine due to Machine, Utilities Problems or Filtration Problem at Production Area.

3.0 RESPONSIBILITY:

Officer / Executive- Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

AHU	Air Handling Unit
BFS	Blow, Fill and Seal
CIP	Cleaning in Place
Ltd.	Limited
No.	Number
Pvt	Private
QA	Quality Assurance
QC	Quality Control
SIP	Sterilization In Place
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 FOR MACHINE BREAKDOWNS:

6.1.1 If during filling of a Batch, Machine Breakdown occurs for more than 6 hours, then drain the line solution (holding to BFS machine) through automated CIP line into filling area drain point.

6.1.2 Close the holding vessel bottom valve after that start the flushing of product line through WFI.

6.1.3 Before commencing Filling flush the Product Line and the Filtration System with hot Water for Injection and carry out SIP of the Product Line and the Filtration System.

6.2 FOR MACHINE BREAKDOWNS WHERE THE PRODUCT LINE OR FILTRATION SYSTEM IS EXPOSED:

6.2.1 During Filling, if the Cartridge Filter gets choked or does not perform well and needs to be replaced with a new Filter or if due to some or the other reasons the Product Contact Parts are exposed, then remove the Solution from the entire Product Line & discard it.



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6.2.2 Now Install new filter into BFS machine, after taking pre integrity of the filter, and start the manual CIP of the product line along with filter (new filter).

6.2.3 After CIP start the SIP of the product line along with BFS machine followed by filter drying.

6.2.4 As the SIP and filter drying of the product line completed, take line clearance for the filling process, and start the product transfer pump of the holding tank and start the filling activity.

6.2.5 As the filling resume, discard the initial 5 cycles (bottles), and after that send the sample to QC /micro for the sterility and assay of the product, after breakdown.

6.3 FOR INTERRUPTIONS DUE TO POWER FAILURE: (PRECAUTIONS DURING POWER FAILURE)

6.3.1 Power failure is also a non-routine intervention which occurs due to interrupted power / other power source failure. As the power failure occurs, immediately close the Sterile Area Openings through which the Filled/Sealed Containers are coming out from the Filling Machine, to avoid the cross contamination in the aseptic area (due to pressure differential) due to power cut.

6.3.2 Minimize the Movements inside the Sterile Area and do not carry out any operations till the Power Supply of the area resume and environment condition of the area is not within limit.

6.3.3 Do not open any doors of the Sterile Area.

6.3.4 If Power Interruption occurs for more than 10 Minutes then before commencing Filling Operation mop the Sterile Area with 70 % IPA Solution .

6.3.5 Give initial Filled/Sealed Shots Sample for Microbiological Testing.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Manual Recording of CIP & SIP of Product line	

ENCLOSURES: SOP Training Record.

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Production
- Master Copy Quality Assurance

9.0 REFERENCES:

Not Applicable



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10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for change	Effective Date	Updated By



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ANNEXURE – I MANUAL RECORDING OF CIP & SIP OF PRODUCT LINE

Equipment ID:

Location :

Section :

Month / Year :

Product :

Batch No. :

Date	Cleaning Details (CIP)		Done By	Checked By	SIP Hold time		Time After every 05 minute	Sensor Temp. °C	Done By	Checked By
	From	To			From	To				
							00 min.			
							05 min.			
							10 min.			
							15 min.			
							20 min.			
							25 min.			
							30 min.			