STANDARD OPERATING PROCEDURE

Title: Clean and Sterilization in Place of Form, Fill and Seal Machine

SOP No.:		**Department:**	Production
		Effective Date:	
Revision No.:	00	**Revision Date:**	
Supersede Revision No.:	Nil	**Page No.:**	1 of 5

1.0 OBJECTIVE:

To lay down a Procedure for Clean and sterilization In Place of Form, Fill and Seal Machine.

2.0 SCOPE:

This SOP is applicable for Clean and sterilization In Place of Form, Fill and Seal Machine (Make: **Micro tools**) in FFS section.

3.0 RESPONSIBILITY:

Officer / Executive - Production

4.0 ACCOUNTABILITY:

Head – Production

5.0 ABBREVIATIONS:

°C	Degree Celsius
CIP	Clean in place
FFS	Form, Fill & Seal
LHS	Left Hand Side
PLC	Programmable Logic Controller
QA	Quality Assurance
QC	Quality Control
RHS	Right Hand Side
SS	Steam Sterilization
SOP	Standard Operating Procedure
SIP	Sterilization in place
WFI	Water For Injection

6.0 PROCEDURE:

6.1 PRECAUTIONS:

6.1.1 **For CIP**-Check and ensure that the WFI Line is connected/supply properly to the FFS Machine.

6.1.2 **For SIP**- Ensure that the FFS Machine CIP done prior to SIP.

6.1.3 Check & ensure that the Pure Steam Line is connected properly.

6.2 PHILOSOPHY:

6.2.1 **For CIP**- Clean in Place is carried out to perform Product Line cleaning as well as Mold cleaning prior to Steam Sterilization to completely remove all the traces of previous product from the machine mould, pipe lines and all contact parts.

6.2.2 The CIP of the FFS Machine shall be performed for minimum 30 minutes.

6.2.3 The CIP shall be performed during Batch Changeover/Before SIP or whenever its required.

6.2.4 **For SIP**- The Sterilization in Place is carried out at a temperature above than 121°C for 30 minutes to remove microbiological contamination and reduce the bioload using by Moist Steam.

6.2.5 The Blow Down program (Filter Drying) requires 10-30 minutes for successful completion of the Filter Drying program.

6.2.6 The SIP shall be performed during Batch Changeover/machine break down more than 6 Hrs/or whenever its required.

6.3 PROCEDURE:

6.3.1 **CIP and SIP** - of Form Fill and Seal Machine shall involves: Product Line Cleaning [Includes Cleaning of SS 316L Pipeline of product contact parts, Cleaning along with SS Housings, Air Filters installed over the FFS M/C, Filling Mandrels etc.]

6.3.2 **CIP**- Vacuum Line Cleaning & Mould Cleaning.

6.4 PRODUCT LINE CLEANING IN PLACE (CIP):

6.4.1 Ensure that the WFI Line attached to the FFS Machine (Product Line).

6.4.2 Move the Mould carriage to Parison position.

6.4.3 Operate the filling head and to down position.

6.4.4 Attach the Hoods from its resting position and fix it on to the filling head.

6.4.5 Select the Cleaning Program PLC and interlock the Program.

6.4.6 Open Supply of Water For Injection (WFI).

6.4.7 Let WFI flows and clean all those parts which come in to it's contact from Holding area line to M/C ,entire product line and drain it out.

6.4.8 Intimate the QA Officer / Executive to collect the Sample of Rinse Water at drain point after Product Line cleaning and send for QC for Analysis.

6.4.9 The Product line cleaning will be continued till the Rinse Water result complies.

6.4.10 SIP of FFS Machine shall be carried out only after receiving CIP Pass Report from QA. Record the CIP Operation Details in respective record, and respective Batch Production and Control Record.

6.5 PRODUCT LINE STERILIZATION IN PLACE (SIP) :

6.5.1 Insure the availability of the Pure Steam supply to FFS m/c and product line both.

6.5.2 Attach the Filling Mandrel Hoods before starting the SIP procedure.

6.5.3 Open the Pure Steam Valve gradually, now pure steam is available to the Machine, set the Steam Pressure not exceeding 2.5 bars by manual valve.

6.5.4 Switch "ON" the Machine for the Sterilization cycle.

6.5.5 Lock the Program to Steam Sterilization and Interlock.

6.5.6 As soon as Steam is opened and flows through all Product Lines and also from Filling Nozzle, Blow Down Filter (Air Vent Filter) etc.

6.5.7 When the Stem temperature reaches at the set point of 121°C (sensed by all temperature Probes installed at 8 different locations in FFS m/c) the Sterilization Time starts for 30 min.

PROBE No's	PROBE LOCATIONS
1	STEAM IN
2	PR FILTER IN
3	PR FILTER OUT
4	LHS FILLING IN
5	RHS FILLING IN
6	LHS FILLING RETURNE
7	RHS FILLING RETURNE
8	FFS MACHINE DRAIN POINT

6.5.8 When the pre-set time reaches Sterilization elapsed message is displayed.

6.5.9 Close the Steam Inlet Valve and intimate for stop the pure steam supply.

6.5.10 After completion of Sterilization, select the Blow Down program from the Machine PLC for Blow Down (Filter Drying).

6.5.11 After completion of 'Blow Down' select the program if heating.

6.5.12 LFR blower will automatically start after completion of Blow Down Cycle to maintain Class-100.

6.5.13 Remove the Filling Mandrel Hoods and keep at designated place.

6.5.14 Record the SIP Operation Details in respective log book and attaché the print out in respective Batch Production and Control Record with following details:
Product Name:
Batch No.:
S.S time:
Checked by:
Date:
Verified by:
Date:

6.6 VACUUM LINE CLEANING & MOLD CLEANING:

6.6.1 This is carried out in case of Vacuum System contaminated with Product OR whenever required.

6.6.2 The Vacuum Line Cleaning & Mold Cleaning shall be performed using Manual Operation Mode only.

6.6.3 Remove the Vacuum Line and Connect the WFI Line. Ensure that the TC Clamp is connected properly and tight.

6.6.4 Open the WFI Valve.

6.6.5 Clean the Mold (Head Mold / Seal Mold, Main Mold and Holding Jaw) using WFI.

6.6.6 Stop the Supply of Water For Injection.

6.6.7 Empty the Vacuum Lines for 05 minutes by switching on the Vacuum Pump.

6.6.8 Record the Vacuum Line Cleaning & Mold Cleaning operation details in respective m/c break down record.

7.0 ANNEXURES:

Not Applicable
ENCLOSURES: SOP Training Record.

8.0 DISTRIBUTION:

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

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9.0 REFERENCES:

WHO & GMP

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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