



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Operation 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 the Operation of Form, Fill and Seal Machine.

2.0 SCOPE:

This SOP is applicable for the Operation 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:

FFS	Form, Fill & Seal
Ltd.	Limited
LDPE	Low Density Poly Ethylene
No.	Number
QA	Quality Assurance
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 PRESTART UP CHECKS:

6.1.1 Turn on the Chiller (if the same is not running) and open chilled water inlet and outlet valves.

6.1.2 Open Cooling Water Valve for Vacuum Pump.

6.1.3 Turn on Compressor and open Inlet Air.

6.1.4 Remove all scrap & accumulated plastic from the Carriage and below the Mold Area.

6.1.5 Remove the accumulated plastic around Parison Head Nozzles.

6.1.6 Clean out all residues from mold alignment pins and bushings (Main Mold and Seal Molds) and apply film of Petrogel to guide pins / keys.

6.1.7 Check and rectify the level of the Hydraulic Oils, level of the Mokon unit & level of Vacuum Pump reservoir.



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6.2 START OPERATION:

- 6.2.1 Turn on the Main Power of the Machine.
- 6.2.2 Turn on the Resin (LDPE Granule) Transfer Pump.
- 6.2.3 Turn the Master Control ON from the Operator Panel.
- 6.2.4 Turn on the Bottle Fill Off from the operator panel.
- 6.2.5 Turn on the Heaters from the Operator Panel & wait till Extruder heat up to Stand by Temperature.
- 6.2.6 Turn on the Blower for Positive Air Pressure of LFR (Laminar flow Region) in filling area of the machine.
- 6.2.7 Turn on the Hydraulic Pump from the Operator Panel.
- 6.2.8 Turn on the Vacuum Pump from Operator's Push Button Panel.
- 6.2.9 Energize the Seal Mold by touching the Seal Mold Open Button on the Operator Screen.
- 6.2.10 Energize the Extruder Lift Down by touching the Extruder Lift Down Button on the operator screen.
- 6.2.11 Switch the keys to Auto Mode.
- 6.2.12 Open the Valve to Transfer Solution from Holding Tank to FFS machine.
- 6.2.13 Turn the Extruder ON Button & Knife ON button from the Operator Panel.
- 6.2.14 After the Parison get straight and equal in length and check AUTO READY LED is glowing then start the machine by pressing the Cycle Start Buttons from the Operator Control.
- 6.2.15 Check & Adjust Empty Weight of Respoules (2.1 gm to 2.3 gm each Respoules OR 10.5 gm to 11.5 gm each Cassette, one cassette having 5 Nos. respoules).
- 6.2.16 Visually check and rectify the extra plastic at Respoules.
- 6.2.17 Start the filling and set the fill volume as required (5.1 to 5.3 ml each Respoules).

6.3 STOP OPERATION (FOR STOPPING PRODUCTION CYCLE):

- 6.3.1 Press the cycle stops button from the push button panel or machine automatically gets stop.



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6.3.2 Once the cycle gets completed and the machine stops, Turn the hydraulic off from the push button panel.

6.3.3 Turn the Extruder off from the Push Button Panel.

6.3.4 Turn off the Bottle Fill on from the operator panel.

6.3.5 Turn Off the Vacuum pump from the Push Button Panel.

6.3.6 Turn off the Heaters from the Push Button Panel.

6.3.7 Turn the Knife off from Push Button Panel.

6.3.8 Clear the respoules from the Mould Area.

6.3.9 Turn off all the utilities.

6.3.10 Turn the Main Power off.

6.4 Operation detail shall be filled as per Annexure – I.

6.5 SET OR RUNNING PARAMETERS (PRODUCTION CYCLE):

6.5.1 Hydraulic oil pressure 60-85 bar, temperature 40-50°C and level 70-80 % of its full Capacity.

6.5.2 Chilled water pressure 3-4 bar, temperature 10-14°C.

6.5.3 Compressed air pressure 6.5-7.5 bar.

6.5.4 Extruder temperature 160-190°C.

6.5.5 All detail shall be set filled as **Annexure – I**.

7.0 ANNEXURES:

ANNEXURE NO.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	FFS M/C Running Parameters Observation Record	

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No.01 Quality Assurance



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- Controlled Copy No.02 Production
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9.0 REFERENCES: NA

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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FFS M/C RUNNING PARAMETERS OBSERVATION RECORD

DATE:

SHIFT:

Product Name.	Batch No.	Time	Hydraulic Oil			Chilled Water		Comp. Air	Extruder temperature								
			Temp.	Pressure	% Level	Temp.	Pressure	Pressure	1	2	3	4	5	6	7	8	

Frequency: After every 2 hrs (When m/c under running).

Checked by Production
(Sign/Date)

Verified by QA
(Sign/Date)