



STANDARD OPERATING PROCEDURE

Department: Quality Assurance	SOP No.:
Title: Operation and Cleaning of Blister Packing Machine	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down a Procedure for the Operation and Cleaning of Blister Packing Machine.

2.0 SCOPE:

This SOP is applicable for Operation and Cleaning of Blister Packing Machine (Make: IMA -PG) in Production area at

3.0 RESPONSIBILITY:

Officer/Executive – Production

4.0 ACCOUNTABILITY:

Head – Production

5.0 DEFINITIONS:

Not Applicable

6.0 PROCEDURE:

6.1 PRECAUTIONS AND CHECK POINT:

6.1.1 Ensure the Power Supply, Chilled Water Supply, Compressed Air Supply and Vacuum Supply to the machine are proper.

6.1.2 Ensure all the emergency switches are working properly.

6.1.3 Check the text matter of preprinted foil and ensure that it is correct.

6.1.4 Check that the width and thickness of PVC & foil (Aluminium Foil or Paper Foil) and it is same as per our requirement.

6.2 OPERATION:

6.2.1 Adjust the forming plug on the forming die & adjust sealing die at the respective places.

6.2.2 Adjust the sealing plate at the respective place.

6.2.3 Adjust the punching die according to the requirement.

6.2.4 Adjust the guide track accordingly.

6.2.5 Adjust the forming heater and sealing heater accordingly.



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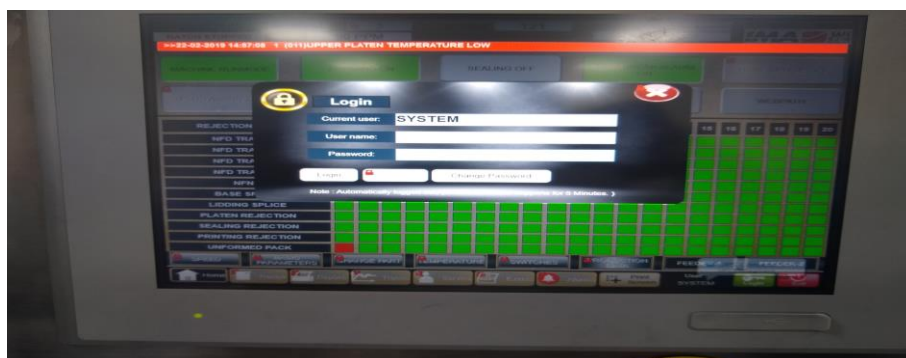
6.2.6 Adjust the product Infeed Feeder according to the appropriate size.

6.2.7 Switch “ON” the chilled water, compressed air and vacuum pump.

6.2.8 Switch ON the Main Switch of the Machine.



6.2.9 Login the machine by using user name and password.



6.2.10 Switch “ON” the sealing heater and wait for attaining temperature at $165^{\circ}\text{C} \pm 10^{\circ}\text{C}$.

6.2.11 Switch “ON” the forming heater and wait for attaining temperature at $145^{\circ}\text{C} \pm 10^{\circ}\text{C}$.

6.2.12 Adjust the PVC or PVDC roll with guide track at the forming, sealing and punching die accordingly.

6.2.13 Adjust the preprinting foil and printing roller Stereos etc.

6.2.14 Perform Challenge test of sensors before start of operation and after any break-down of machine.

6.2.15 Record the details of sensors challenge test in **Annexure-I**

6.2.16 After adjustment of all part run the machine without feeding the material (Ampoule or Vials) and ensure that the quality of forming, sealing, printing, punching etc are as per our standard.



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6.2.17 After observation & compliance of the Quality of Forming, Sealing, Printing, Punching etc. are ok, feed the ampoule or vials and run the machine till completion of blister sealing of desired Vials / Ampoules.

6.2.18 Exit out from the machine after completion of operation.



6.2.19 Record the operation details as per “**Equipment Log**” in Format of SOP.

6.3 CLEANING:

6.3.1 Switch “**OFF**” the main electrical supply to the machine.

6.3.2 Remove left over previous product Material.

6.3.3 Clean the machine from outside with 70% IPA and remove any ink spots by Thinner.

6.3.4 Clean the die with Compressed Air.

6.3.5 Record the cleaning details as per “**Equipment Log**” in SOP and affix “**Cleaned**” label on it.



PHARMA DEVILS

PRODUCTION DEPARTMENT

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7.0 ABBREVIATIONS:

SOP	Standard Operation Procedure
WFI	Water for Injection
Ltd.	Limited
No.	Number
IPA	Isopropyl Alcohol
ID No.	Identification Number
PVDC	Polyvinyl Dichloride
PVC	Polyvinyl Chloride
QA	Quality Assurance

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Sensor Challenge Test Record	

9.0 DISTRIBUTION:

- Master Copy Quality Assurance Department
- Controlled Copy No.1 Production Department

10.0 REFERENCES:

SOP Titled "Equipment Log".

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		



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ANNEXURE-I

	PRODUCTION
	SENSOR CHALLENGE TEST RECORD

Frequency: Before Start of Operation and After Machine Break-Down

Date	Product Name	Batch No.	Sensor Details	Status (Ok / Not Ok)	Done By Sign & Date	Checked By Sign & Date	Verified By Sign & Date	Remarks
			No Form No Fill Sensor					
			Product out of Pocket Sensor					
			PRC Eye mark Sensor					
			Bad Blister Rejection Sensor					
			Door Interlocking Sensor					