



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Leaflet Outsarter	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Vernacular SOP: No

1.0 OBJECTIVE:

1.1 To lay down a procedure for cleaning and Operation of Leaflet Outsarter.

2.0 SCOPE:

2.1 This procedure is applicable for the cleaning and Operation of Leaflet Outsarter in production area.

3.0 RESPONSIBILITY:

3.1 Technical Associate : Cleaning and Operation

3.2 Officer/ Executive Production : Supervision

3.3 Head Production : SOP Compliance

3.4 IPQA : Line Clearance

4.0 DEFINITION(S):

4.1 NA

5.0 PROCEDURE:

5.1 CLEANING

5.1.1 Ensure that all the material of previous product are removed from packing cubicle.

5.1.2 Remove the "UNDER PROCESS" label and affix "TO BE CLEAN" label on machine with date and sign of production officer.

5.1.3 Switch "OFF" all the utility supply before cleaning.

5.1.4 Clean the control panel with dry lint free cloth.

5.1.5 Clean the top and outer SS surface of machine by 70% v/v IPA solution using lint free cloth.

5.1.6 Open guard and clean inside surface of the machine, hopper and its assembly 70% v/v IPA solution by using lint free cloth.

5.1.7 Clean the product deposit area on top of machine and its parts by dry lint free cloth.

5.1.8 Replace the "TO BE CLEANED" status label by "CLEANED" status label on the machine with date and sign of production officer.

5.1.9 Record the cleaning activity in equipment usage log as per SOP.

5.1.10 Clean the surrounding area as per SOP.

5.2 OPERATING PROCEDURE:



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Leaflet Outsarter	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.2.1 Switch 'ON' the power supply, the following screen will be displayed:

5.2.2 Three different user with their different rights assignment as mentioned below:

S.No.	Type Of Functions	User Rights Assignment(Y/N)		
		Operator	Supervisor	Administrator (Production Head)
1.	RUN/STOP machine	Y	Y	Y
2.	Parameters Setting	N	Y	Y
3.	Change Password	N	N	Y

5.2.3 Click the first interface, input the password, then comes to main operation interface, as Displayed:

5.2.4 **Main operation interface:**

5.2.4.1 START/STOP: To start/stop the machine.

5.2.4.2 To display current running speed and current output.

5.2.4.3 To switch to function button interface of machine function and alarm interface.

5.2.4.4 To display current angle of encoder.

5.2.4.5 It is JOG button. Under un-automatic condition, press this button to make a main axis of motor runs at a certain speed, which is convenient for commissioning.

5.2.4.6 Automatic stop delay: Stop the main axis after all bottle pass the bottle spacing wheel.

5.2.4.7 To display current date and time and current stopper[□] big bottle stopper/small bottle stopper.

5.2.5 Machine function interface

5.2.6 Parameter Interface: Before entering into Parameter Setting Interface, enter the right password.

5.2.7 Speed Parameters as displayed below:

5.2.8 Main axis motor speed: 0-100 HZ.

5.2.9 Leaflet sticking angle M: To set the sticking angle on the container.

5.2.10 After setting the M angle, the main axis will place leaflets on the top of bottle, which locate at $90+M, 180+M, 270+M$ (IN THE CIRCLE AROUND THE MAIN AXIS).

5.2.11 Leaflet pick position N: To set the vacuum valve pick up leaflets and after setting N angle, main axis will pick up leaflet at $90+M, 180+M, 270+M$ (IN THE CIRCLE AROUND THE MAIN AXIS)



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Leaflet Outsarter	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 5.2.12 Glue dispenser K: To set the glue dispensing angle of glue dispenser. After setting K angle, the main axis will conduct glue dispensing at $90+K, 180+K, 270+K$ (IN THE CIRCLE AROUND THE MAIN AXIS)
- 5.2.13 Bar code variation L: The bar code sensor send triggering signal, after setting of L angle, the main axis conduct the trigger camera system for system checking at $90+L, 180+L, 270+L$ (IN THE CIRCLE AROUND THE MAIN AXIS).
- 5.2.14 Block bottle position H: When bottle jam downstream or leaflet deficiency happen, bottle stopping cylinder will shoot out at h, $90+H, 180+H, 270+H$; but not at other direction, which is to avoid knock at bottle when it shoot out.
- 5.2.15 Rejection delay time: Rejection delay time when rejection is required.
- 5.2.16 Rejection action time: Electrifying time for electromagnetic valve.
- 5.2.17 Vacuum forming time: The time for forming vacuum after vacuum pump starts up and the main axis can only run and bottle spacing wheel can only stars bottle infeeding after the set time reached.
- 5.2.18 Back conveyor bottle jam time: When the jam sensor defect back jam for a certain time i.e. back conveyor bottle jam time, the front bottle spacing wheel stops bottle infeeding.
- 5.2.19 Glue dispenser action time: The operator can set this value according to the amount of dispensed glue.
- 5.2.20 Blowing action time: The action time for blowing valve when sticking leaflets. Through this interface the operator can set.
- 5.2.21 The interlock between machine and conveyor: It is "OFF", the machine can without conveyor running.
- 5.2.22 Glue dispenser "ON"/"OFF": If it is "OFF" the glue dispenser stops. This button used during commissioning when glue dispensing is not required, which is also for safety
- 5.2.23 Origin revised interface:
- 5.2.23.1 Password required before switching to this interface:
- 5.2.23.2 "Origin revised" can only be conducted after the material position is adjusted and the current coder angle is not in the original position. After pressing this button the CPU system will automatically set the adjusted original position as the mechanical origin position. So please not press this button when its not necessary.
- 5.2.23.3 This interface can also display the current coder angle and revised angle.
- 5.2.24 Parameter interface:



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Leaflet Outsarter	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.2.25 Manual interface:

5.2.26 On this interface, the operator can manually operator can manually operate motor and electromagnetic valve when the machine un-automatically runs, which offer convenient for maintenance and commissioning.

5.2.27 Alarm interface:

5.2.27.1 Alarm information includes:

1. Emergency.
2. Power supply cut “OFF”.
3. Leaflet is deficient, please supply labels.
4. Conveyor stop.
5. Back conveyor jam.
6. Frequency invertor error.
7. Safety door is open.
8. Glue dispenser is not ready.
9. Glue level in glue dispenser is low.
10. The machine cannot run automatically when it is manually commissioned.
11. Machine stop for leaflets deficiencies.
12. Fallen bottle.
13. Upper limit for lifting motor.
14. Lower limit of lifting motor
15. Press deficient.
16. Vacuum pressure deficient.
17. Vacuum pump overload.
18. Glue dispenser is not startup.
19. Bottle stopper position is set incorrectly.
20. Current small bottle stopper selection.
21. Current big bottle stopper selection.

6.0 ABBREVIATION (S):

6.1 SOP: Standard Operating Procedure

6.2 MMI: Man Machine Interface



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Leaflet Outsarter	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

7.0 REFERENCES (S):

- 7.1 SOP: Making entries in equipment usage and cleaning log sheet
- 7.2 SOP: cleaning of production area.

8.0 ANNEXURE(S)

Annexure no.	Title of Annexure	Format no.	Mode of Execution
Annexure I	Cleaning Checklist of Leaflet Outsarter		Log Book

9.0 DISTRIBUTION:

- 9.1 **Master Copy** : Quality Assurance
- 9.2 **Controlled copy (S)** : Production department (02), Quality Assurance (01)
- 9.3 **Reference copy (S)** : Production department (07)

10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason (s) for Revision	Details of revision	Effective Date
01	00	NA	New SOP	NA	



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Leaflet Outsserter	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

ANNEXURE I

CLEANING CHECKLIST OF LEAFLET OUTSERTER

Name of the Equipment		LEAFLET OUTSERTER
Equipment I.D. No.		Date
Previous Product:		
Batch No.		
S.No.	Activity	Activity Performed
1.	Ensure that all the material of previous product are removed from packing cubicle.	
2.	Remove the "UNDER PROCESS" label and affix "TO BE CLEANED" label on the machine with sign and date of production officer.	
3.	Switch "OFF" all utility supply before cleaning.	
4.	Clean the control panel with dry lint free cloth.	
5.	Clean the top surface of machine and its parts by 70% v/v IPA solution using lint free cloth.	
6.	Open guard and clean inside surface of machine, hopper and its area with 70% w/w IPA solution using lint free cloth.	
7.	Wipe all the S.S. parts of machine with 70% v/v IPA solution followed by mopping with dry lint free cloth.	
8.	Wipe the inner and outer surface of conveyor belt and rejection box with 70% v/v	
9.	Wipe the machine guards with dry lint free cloth.	
10.	Remove the "TO BE CLEANED" status label with "CLEANED" status label on the machine with sign and date of production officer.	

Checked By (Prod.)
Sign/Date

Verified By (QA)
Sign/Date

Note: Put '√' mark if activity performed and put "X" if activity not performed.