



STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning of Blister packing machine (EPI3010)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

1.0 OBJECTIVE :

To lay down a procedure for Cleaning of Blister packing machine (EPI 3010).

2.0 SCOPE :

This procedure is applicable for Cleaning of Blister packing machine (EPI 3010).

3.0 RESPONSIBILITY:

Technical Associate : Cleaning and Operation

Production: Officer /Executive/Assistant Manager

Head Production: To ensure execution & compliance

4.0 PROCEDURE:

4.1 TYPE "A" CLEANING

Change over from one batch to next batch of the same product, same potency and of similar product with ascending potency provided the color is same.

4.1.1 Ensure that all the materials of previous batch are removed from the blister-packing cubicle.

4.1.2 Ensure that the power supply and compressed air supply are put off.

4.1.3 Replace the 'UNDER PROCESS' status label by 'TO BE CLEANED' status label then 'UNDER CLEANING' Label while starting the cleaning procedure.

4.1.4 Clean the machine with dry lint free cloth.

4.1.5 Clean the forming upper & lower platen, hopper, linear vibrator feeder part, Upper & lower sealing platen, embossing tool, perforation tool, punching tools, acrylic cover and guards with a dry lint free cloth.



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4.1.6 Affix the “CLEANED” label on the machine with date and sign of the production officer as per SOP.

4.1.7 Record the Start time and end time of cleaning in equipment usage log book and Clean the area as per SOP.

4.1.8 Maintain The Type ‘A’ Cleaning Checklist As Per Annexure I.

4.2 TYPE B CLEANING

During changeover of product with different actives / color / descending potency or after maintenance of contact parts.

4.2.1 Replace the ‘UNDER PROCESS‘ status label by ‘TO BE CLEANED’ status label then ‘UNDER CLEANING ‘ while starting the cleaning procedure.

4.2.2 Ensure that the power supply and compressed air supply are put off.

4.2.3 Product contact parts like upper forming platen to be clean with nylon brush when cool, to remove any accumulated deposit on the surface of the platens. Use 70% IPA for the removal of adhered dried PVC.

4.2.4 Clean The hopper/linear vibrating parts with lint free cloth dipped in purified water and then followed by dry lint free cloth.

4.2.5 Feeder parts: Remove entire change part assembly from the basic feeder unit. Wash the assembly with purified water and dry with lint free cloth and then reassemble it.

4.2.6 Clean the sealing plate with Copper wire brush if the knurling has been clogged.

4.2.8 Ensure cleaning of Embossing tool, perforation tool, punching tool shall be clean by dry lint free cloth before and after every batch.



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- 4.2.9 Acrylic covers and guards shall clean with Teepol followed by purified water and dry with lint free cloth.
- 4.2.10 Dry the cleaned parts with a dry lint free cloth.
- 4.2.11 Wipe the dismantled parts with 70% v/v IPA solution.
- 4.2.12 Clean the inner and outer surface of the machine, control panel and utility lines with a dry lint free cloth.
- 4.2.13 Wipe the machine with 70% v/v IPA solution.
- 4.2.14 Reassemble the cleaned hopper, channel and hopper lid.
- 4.2.15 Affix the 'CLEANED' status label with date and sign of the production officer.
- 4.2.16 Record the Start time and end time of cleaning in equipment usage log book and Clean the area as per SOP No.

Maintain The Type 'B' Cleaning As Per Annexure II.

5.0 ANNEXURE (S) :

Annexure I: Blister packing machine (EPI -3010) Type 'A' cleaning checklist.

Annexure II: Blister packing machine (EPI -3010) Type 'B' cleaning checklist.

6.0 REFERENCE (S):

SOP: Preparation, approval, distribution control, revision and

Destruction of Standard Operating Procedure (SOP).

SOP: Status labeling in production dept.

SOP: Procedure for area line clearance.



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7.0 ABBREVIATION (S) / DEFINITION (S):

PVC : Poly vinyl chloride

v/v : Volume/ Volume

IPA :Isopropyl alcohol

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S)FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	----	---	New SOP	----