



STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning and Operation of Pinhole Detection System

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

1.0 OBJECTIVE:

To lay down a procedure for Cleaning and Operation of Pinhole Detection System (Jekson).

2.0 SCOPE:

This SOP is applicable to the Cleaning and Operation of Pinhole Detection System (Jekson) in production area.

3.0 RESPONSIBILITY:

Technical Associate : Cleaning and Operation

Production : Officer / Executive / Assistant Manager

Head Production: To ensure execution & compliance.

4.0 PROCEDURE:

4.1 Cleaning Procedure:

4.1.1 Cleaning procedure is applicable at the time of change over from one batch to next batch of same product and different Product or after maintenance.

4.1.2 Ensure that the main power supply is 'OFF' before cleaning.

4.1.3 Ensure that all the materials of previous batch are removed from the Blister Packing cubicle.

4.1.4 Clean the outer part of the Pinhole detector as well as lens, cables with dry lint free cloth.

4.2 OPERATION

4.2.1 Power 'ON' the Blister packing machine and select administration in HMI to set the parameter for pinhole detector.

4.2.3 Select machine setting, click on "ENABLE MACHINE SETTING" and put count from pin hole detector to punching station in terms of number of blisters. Then start the operation.



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- 4.2.4 Go for “MAIN MENU” and Following data will be displayed :
- A. ACCURACY: Set the hole size 10, 25, 50, 75, 100 micron whichever is required and then press enter.
 - B. COUNT: For No. of blisters to be rejected.
 - C. REJECTION QUE: Set 0 then press enter.
 - D. SYS SETTING: Enter – O/P timing (200 ms) and Set the offset count.
- 4.2.5 If pinhole exists on leading foil or base foil, alarm is generated and the defective blisters get rejected from the punching station.
- 4.3 Challenge test :**
- 4.3.1 Procedure:- Stop the tablet / capsule in channel and make pinhole by using needle on foil before pinhole detector and check whether the corresponding blister is rejected at punching station & record the details in Annexure-I.
- Frequency:** Carry out the challenge test at the start of the batch / shift, every four hours and towards end of the batch.
- 5.0 ANNEXURE (S):**
- Annexure I: Challenge Test Report of Pin Hole Detector.
- 6.0 REFERENCE (S):**
- SOP: Preparation, approval, distribution control, revision and destruction of Standard Operating Procedure (SOP).
- 7.0 ABBREVIATION (S) /DEFINITION (S):**
- SOP : Standard Operating Procedure
No. : Number
PLC : Programmable logic control



PHARMA DEVILS

PRODUCTION DEPARTMENT

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REVISION CARD

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