



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Camera on Blister /Alu-Alu Machine	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Vernacular SOP No.: NA

1.0 OBJECTIVE:

1.1 To lay down a procedure for Cleaning and Operation of Camera on Blister and Alu-Alu Machine.

2.0 SCOPE:

2.1 This procedure is applicable to the Cleaning and Operation of Camera on Blister Pack/Alu-Alu pack machine in the production area.

3.0 RESPONSIBILITY:

3.1 Technical Associate - for Execution

3.2 Officer/ Executive Production Department- for verification and implementation of SOP

3.3 Head Production Department- shall ensure compliance of the SOP.

4.0 DEFINITION(S):

4.1 NA

5.0 PROCEDURE:

5.1 CLEANING:

5.1.1 Change over from one batch to next batch of same product and different Product or after maintenance of contact part.

5.1.2 Ensure that the main power supply is 'OFF'.

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

5.1.4 Dry clean the outer part of the machine as well as utility cables with dry lint free cloth.

5.2 OPERATION:

5.2.1 SETTING:

5.2.1.1 Switch 'ON' the mains of Camera mounted on blister packing machine.

5.2.1.2 Wait for some time for stabilization of the camera.

5.2.1.3 Press red button present on the right side of PLC of camera on front display.



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- 5.2.1.4 Wait for few minutes for stabilization of the camera, PLC screen will initiate to open and will ask for login Administrator / Operator level.
- 5.2.1.5 Select “Administrator” for new recipe.
- 5.2.1.6 Camera will start functioning ‘Login screen will appear’
- 5.2.1.7 Enter the appropriate user name and password and then press OK.
- 5.2.1.8 Start the blister machine so that the filled web of tablets will be projected just below the camera for setting of ROI.
- 5.2.1.9 Stop the blister machine as one complete filled web of tablets reach below the camera.
- 5.2.1.10 Adjust blister pack in ‘ROI’ on screen. Once desired image is achieved with all good tablets/ capsules, click on ‘OK’ button.
- 5.2.1.11 After saving image set ROI/Setting /TOL. For getting complete adjustment of the ROI, set the image with the help of arrows provided for up ↑ and down ↓ movement of the ROI.
- 5.2.1.12 The display will show the complete field view then press ok (√).
- 5.2.1.13 On the left hand side the ‘Setting’ tab. Set the following parameters Appropriately:
- Select Tablet type: According to colour of tablets/ capsules select the choice given.
 - Dark/Bright: Select the Contrast for Blister.
 - Spot: Keep on for checking black spot on tablet.
 - Fill Hole: Keep on if Characters are printed on tablet.
 - Total Blisters: Enter the total no. of blisters as per seen in image.
 - Tablets per Blisters: Enter the no. of tablets per blister pack.
 - Ejection count: Enter the no. of blister between camera and ejection station.
- 5.2.1.14 Press close button in case to run capsules for colour variation on capsules if any.
- 5.2.1.15 For bi colour tablets/ capsules after selection of colour go to setting and option for bicolour to be selected.



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5.2.1.16 For inspection setting go to setting at the bottom of the PLC, and mark (✓) to inspect follows

- Broken tablets
- Extra tablets/ capsules
- Position error
- Shape match
- Colour match
- Without body / cap capsule

5.2.1.17 Save product and PLC will ask to specify the name of the product by entering the product name with the help of key board as appeared on PLC.

5.3 Tolerance:

5.3.1 Adjust following parameters as per specified product with the help of ↑↓ cursor:

- Tablets/ capsules area (area of pocket)
- Area P (tablets/ capsules area)
- Shape
- Color

5.3.2 The above adjustment is done thru slider by setting the slider for no. of tablets/ capsules in the ROI, by selecting the minimum and maximum slider value obtained as per no. of tablets/ capsules on the screen.

Example: If 30 tablets/ capsules are present in ROI, then if minimum value of slider is 120 and maximum is 170, therefore the average setting to be done is 145.

5.3.3 Select ejection Parameter which is product specific to eject the rejection of Blisters. (i.e no. of blisters formed between camera and punch tool + no. of packs adjusted into format).

5.4 RUN MODE:

5.4.1 Click on Start button after matching the criteria.

5.4.2 Start running the machine. Inspection will start accordingly.

5.4.3 Total, Good, Bad Indicators can be seen on screen to indicate the status of total number of images.

5.4.4 Shape, Area and colour Tolerance values can be changed by clicking on 'Tolerance' button.

5.5 Procedure for product Loading:

5.5.1 Press 'Log in' the display will show "User Name and Password"

5.5.2 Put the password then press "OK".

5.5.3 If Pass ward is not OK then the display show Error.



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- 5.5.4 Press the 'Setup' for loading the required product.
- 5.5.5 The display will go to Setup menu. Then press 'Product Format'
- 5.5.6 The display will show the list of products.
- 5.5.7 Select the required product by pressing on screen.
- 5.5.8 Press 'Load' then display will go to the selected product menu.
- 5.5.9 Then start the machine.
- 5.5.10 To set rejection count 'zero' then press 'Production'. Then press 'Statistics'.
- 5.5.11 The display will show the details of Rejection. Press "Reset" to zero the blister rejection.

5.6 Challenge test:

- 5.6.1 For performing checking Challenge test Pass one blister each without tablets/ capsules, broken tablet in blister or Empty blister and mark it with marker to identify the blister at rejection.
- 5.6.2 Ensure that machine rejects the blister.
- 5.6.3 Carry out the challenge test of the camera at the start of batch or any major stoppage and every 4 hrs.
- 5.6.4 Record the details in the BPR or format as apply.

5.7 Precaution:

- 5.7.1 For setting of new product on camera the machine has to stabilize for 30 minutes before setting.

6.0 ABBREVIATION (S):

- 6.1 SOP : Standard Operation Procedure
- 6.2 No. : Number
- 6.3 ROI : Region of Interest
- 6.4 TOL : Tolerance

7.0 REFERENCES:

NA

8.0 ANNEXURE (S):

Annexure no.	Title of Annexure	Format No.	Mode of execution
Annexure-I	Challenge test for camera Operation		Logbook

9.0 DISTRIBUTION:

- 9.1 **Master Copy** : Quality Assurance



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9.2 **Controlled Copy (s) :** Production department (2), Quality Assurance (1)

9.3 **Reference Copy (s) :** Production department (2)

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	NA



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ANNEXURE I

CHALLENGING TEST FOR CAMERA OPERATION

DATE	TIME	WITHOUT TABLET/CAPSULE #	WITH BROKEN TABLET#	MULTIPLE TABLET/CAPSULE#	DONE BY	CHECKED BY

Write OK or NOT OK, where:

OK : If the Camera rejects the defective blister.

NOT OK : If the Camera accepts the defective blister.