



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

| | |
|--|------------------------|
| Department: Production | SOP No.: |
| Title: Cleaning and Operation of Sachet Desiccant Inserter with Camera inspection system, Model: PID-20 | Effective Date: |
| Supersedes: Nil | Review Date: |
| Issue Date: | Page No.: |

1.0 OBJECTIVE:

To lay down the procedure for Cleaning & Operation of Sachet Desiccant inserter machine with Camera Inspection System, Model: PID-20.

2.0 SCOPE:

This procedure is applicable for Cleaning and Operation of Sachet Desiccant inserter machine in production department.

3.0 RESPONSIBILITY:

Technical Associate: Responsible for cleaning & operation of sachet desiccant, Production Officer, Executive: Supervision.

IPQA Officer/Executive: Verification.

Managers Production: Responsible for SOP compliance.

4.0 DEFINITION (S):

Not Applicable

5.0 PROCEDURE:

5.1 CLEANING

5.1.1 Ensure that all the materials of previous batch are removed from the packing cubicle.

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

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

5.1.4 Clean the control panel with clean and dry lint free cloth.

5.1.5 Clean the top and outer surface of machine with the dry lint free cloth.

5.1.6 Open guard and clean inside surface of machine, hopper and its assembly by dry lint free cloth.

5.1.7 Replace the 'UNDER CLEANING' status label by 'CLEANED' status label on the machine with date and sign of the production officer.

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

5.1.9 Clean the surrounding area as per SOP.

5.1.10 Replace the 'UNDER CLEANING' status label by 'CLEANED' status label on the machine with date and sign of the production officer.



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5.2 Machine Setting Procedure

- 5.2.1 Adjust the insertion assembly height by rotating height adjusting wheel until the desired height is obtained for different bottles height.
- 5.2.2 Adjust the conveyor guides (front and rear) and container gates, such that the containers move freely in line with center line of the insertion assembly.
- 5.2.3 The sachet desiccant inserter is composed of Desiccant dispensing device, Length control device, Length transmit device, Desiccant cut device, Lift system and PLC control system.
- 5.2.4 Desiccant dispensing device is composed of desiccant installation plate; fasten device; and each guide roller.
 - 5.2.5 Set the chute position as per bottle diameter.
 - 5.2.6 Check and adjust bottle presence sensor position.
 - 5.2.7 Check and ensure the gauge of the chute cylinder is in the defined values.

5.3 MMI Setting

- 5.3.1 Switch on the power supply, the following screen will open:
- 5.3.2 Click the first interface, input the password, and then comes to Main Operation Interface, as follows.

There are three 'users' with their rights assignments as :

| S.No. | Function | Rights Assignment | | | |
|-------|---|--------------------|-------------------|------------------------|---------------------------------|
| | | Operator (Level-I) | Forman (Level-II) | Supervisor (Level-III) | Administrator (Production Head) |
| 1. | To make recipe. | N | N | Y | Y |
| 2. | Online change in vibration frequency. | Y | Y | Y | Y |
| 3. | Machine setting (Manual setting)e.g. General gate, Product Max./Min. Value, Flap working. | Y | Y | Y | Y |



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5.3.3 Click button [Interface], [Function], [Alarm] to switch to these different interfaces.

From this 'Main Operation Interface' operator can 'START' or 'STOP' the machine by pressing [START] or [STOP] icons.

This interface also displays current output, Current running speed.

From this interface operator can select auto or manual mode of operation by pressing at Auto or Manual in MMI screen.





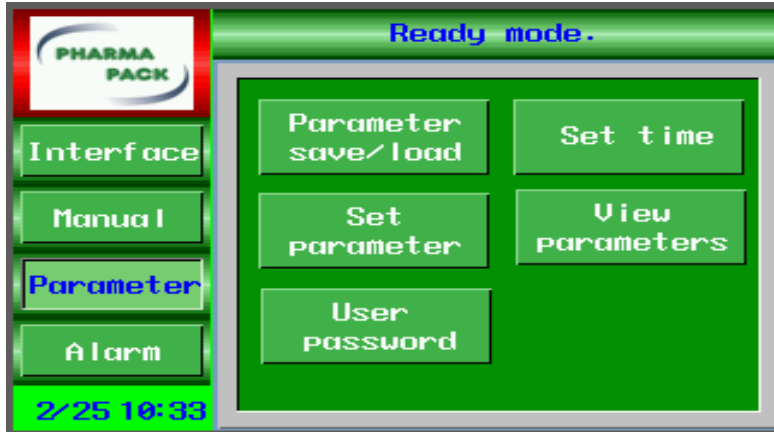
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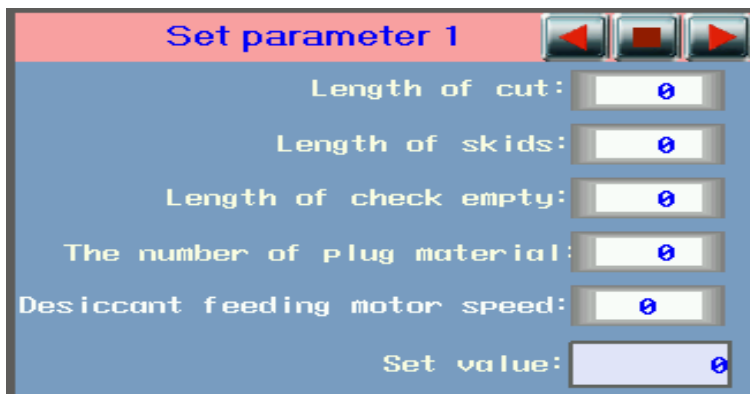
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5.3.4 The bottom of interface dynamically display alarm information of the machine.



5.3.5 Parameter: By pressing [Parameter] icon in touch screen at Operation Interface following will be displayed.



5.3.7 Press [Set Parameter] for setting the parameter. Before entering parameter set interface, operator has to input correct password.

In this Parameter set Interface, parameters can be set by touching these icons [Length parameter]; [Time parameter 1]; [Time parameter 2]; [Option setup].

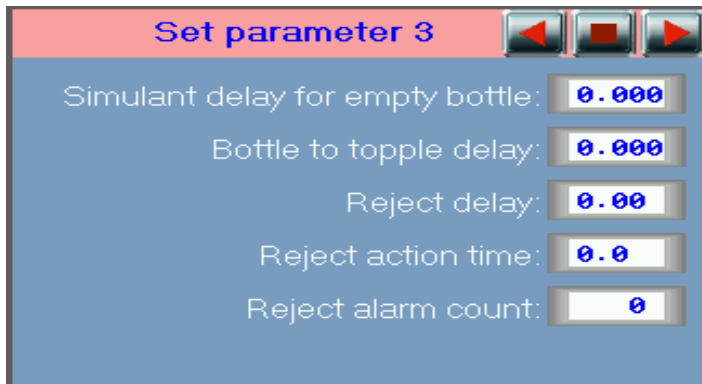


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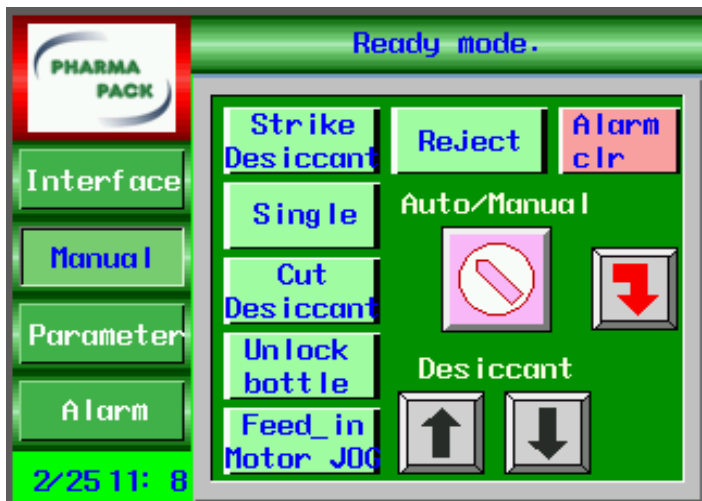
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[Option setup] : Press [Option setup] icon in 'Parameter option Interface'.

In this interface, when it is 'Off-line', the machine can automatically run without conveyor working.

When it is 'On-line' the machine can work only if conveyor starts up.



5.3.8 Press [Manual control] icon in Machine Function Interface' to switch to manual operations.



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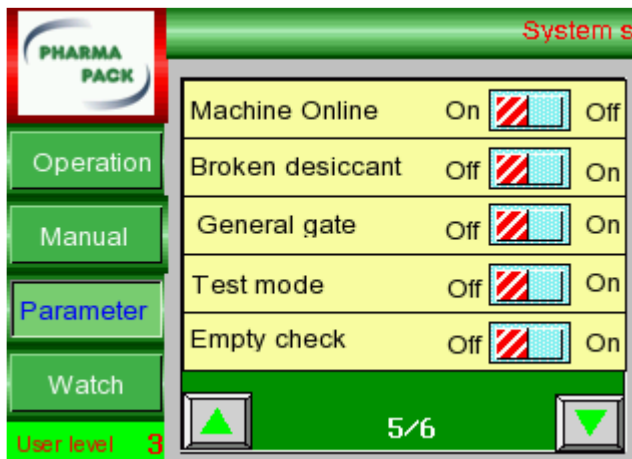
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On this interface operator can perform different manual operations during machine setting like—unlock bottles, cut desiccant, strike desiccant, transport desiccant, moving desiccant upward and circulating single stop.

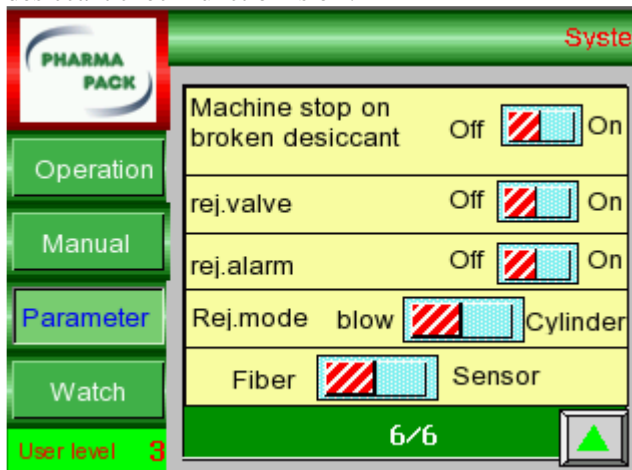
Setting of Camera Inspection System For Sachet:



Broken desiccant: When this button is OFF, broken desiccant detect function is off. when this button is ON, broken desiccant will be detected and rejected

General gate: When this button is ON, general gate works. Otherwise, general gate does not work.

Empty check: When this button is ON, machine stops in case of empty desiccant. Otherwise, empty desiccant check function is off.



Machine stop on broken desiccant: when this button is OFF, broken desiccant detect function is off. When this button is ON, broken desiccant will be detected and rejected.

Rejection valve: When reject valve is on, unqualified products will be rejected. Otherwise, reject function is off.

Rejection Alarm: When reject alarm is ON, machine alarms and stops in case of machine alarm. When this button is OFF, reject alarm function is off.

Rejection mode: Rejection mode of blow and cylinder are available to be chosen.



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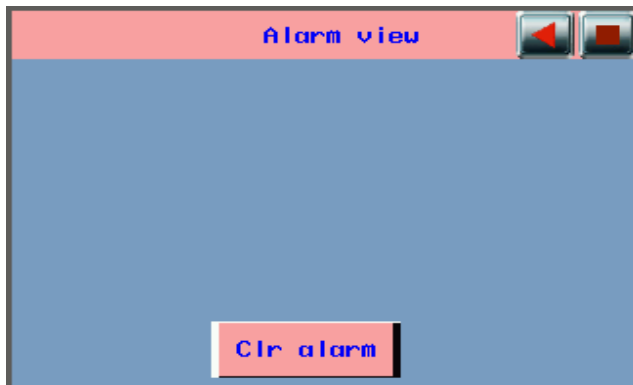
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Fiber/Sensor: Original position of Fiber and Sensor detect are available to choose.

- 5.3.11 Press [View parameter] in Machine Function Interface' to switch to the display parameter interface. This interface displays the set parameters (Parameter preview).
- 5.3.12 Press [Black] in Machine Function Interface to go the first screen 'DESICCANT INSERTER'.
- 5.3.13 Press [Alarm] in 'Main Operation Interface' or 'Machine Function Interface' to switch to the Alarm interface to see the alarm information.

Press 'Clear alarm' button to eliminate alarm list.



5.4 Machine Operation

- 5.4.1 Load pre-set parameters by pressing [Parameter save/load] icon in 'machine function Interface' & check operation as per desired requirements, if required do changes by switching to "Parameter set" interface. After final setting, press "START" icon. Keep "Option setup" 'On-line'. Press 'Auto' in MMI. Press "START" icon to run the machine. Any partially cut or uncut sachet shall not be cut manually and shall be rejected. Any torn or irregular cutting during process shall be rejected.
- 5.4.3 For stopping the machine or after completion of packing activity, press "STOP" icon.
- 5.4.4 Press 'black push button' of control panel to switch OFF the power of machine.

Setting of Camera Inspection System:



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Camera Challenge Test

Pass the good sachet in front of camera.

Now cut the sachet with scissor from its edge and pass the bad sachet from the camera.

It must be rejected by camera and general gate must be closed with holding the broken sachet into it till not all are cleared and machine shall be stopped with alarm system.

6.0 ABBREVIATION (S):

SOP : Standard Operating Procedure

MMI : Man machine interface

IPQA : In process Quality Assurance

PLC : Programmable logic Controller

7.0 REFERENCES (S):

SOP No. : Making Entries in equipment usage and Cleaning Log Sheet.

SOP No. : Cleaning of Production area.

8.0 ANNEXURE (S):

Annexure I (Cleaning Checklist of Sachet Desiccant inserter)

9.0 DISTRIBUTION:

9.1 **Master Copy** : Quality Assurance

9.2 **Controlled copy (S)** : Production department, QA department

9.3 **Reference copy (S)** : Production department



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ANNEXURE I

FREQUENCY: At Start, after every four hours and at End of Operation

| DATE | TIME | CHALLENGE TEST FOR 'NO POUCH-NO PRODUCT' SENSOR (Sensor-I) | | CHALLENGE TEST FOR 'PRODUCT LEVEL SENSOR IN HOPPER' (Sensor-II) | | RESULT OK/NOT OK | CHECKED BY (Production) | VERIFIED BY(IPQA) |
|------|------|--|--|---|---|------------------------|----------------------------|----------------------|
| | | * CHALLENGE WITH POUCH (OK/NOT OK) | # CHALLENGE WITHOUT POUCH (OK/NOT OK) | **PRODUCT LEVEL UP-TO THE SENSOR (OK/NOT OK) | ## PRODUCT LEVEL LOWER TO THE SENSOR (OK/NOT OK) | | | |
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Sensor-I: *Mark 'OK' in observation if product filling occurs and # mark 'OK' in observation if product filling not occurs.

Sensor-II: * *Mark 'OK' in observation if machine run and ## mark 'OK' in observation if machine stop.