STANDARD OPERATING PROCEDURE

Department: Production	**SOP No.:**
Title: Cleaning and Operation of Cap Retorquer (PHARMA PACK)	**Effective Date:**
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1.0   OBJECTIVE:

To lay down a procedure for cleaning and Operation of Cap Retorquer (Pharma Pack).

2.0   SCOPE:

The procedure is applicable to the cleaning and operation of Cap Retorquer (Pharma Pack).

3.0   RESPONSIBILITY:

Technical Associate   : Cleaning and operation of bulk counter.

Officer, Executive-production : To prepare recipe and its compliance.

Officer, Executive-IPQA   : SOP compliance.

Manager–production   : SOP compliance

4.0   DEFINITION (S):

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 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 by dry lint free cloth.

5.1.7   Clean the product deposited 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:

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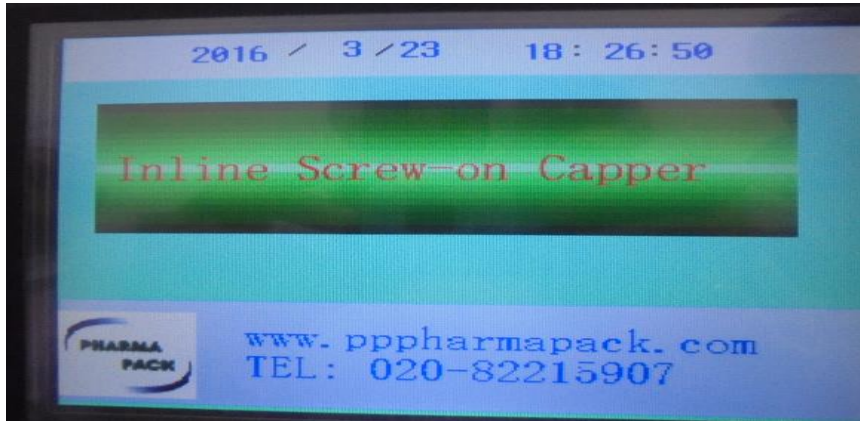| **Department:** Production	**SOP No.:**
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5.2.1   Switch ''ON'' the power supply, the following screen will be displayed:

5.2.2   Three different user has different rights assignment as mentioned below:

S.No.	Type of Functions	User Rights Assignment(Y/N)		
		Operator	**Supervisor**	**Administrator (Production Head)**
1.	Torque Value Setting	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 following :-

5.2.4   On the main operation interface following option will be shown.

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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 display torque of current bottle.

5.2.4.4   To display the name of current product group.

5.2.4.5   To display the minimum and maximum value of torque. Press the CLEAR ALARM and CLEAR for clearing any alarm at MMI interface.

5.2.4.6   REJECT QTY. Displays number of bottles rejected

5.2.5   Press PARAMETER for setting and MMI will display as follow:-

5.2.6   Parameter Interface: Before entering into Parameter Setting Interface, enter the right password.
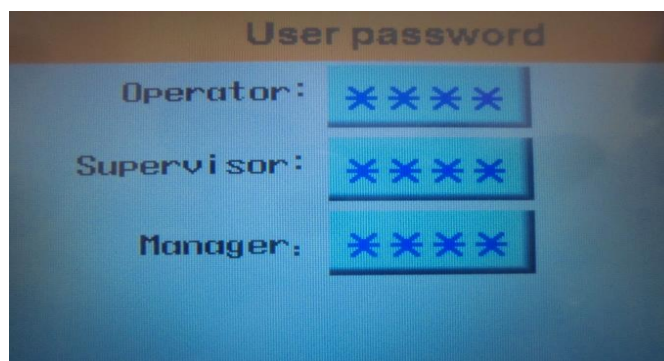
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5.2.7 **NOTE:** Password protection is of three levels and different rights are given to different levels as mentioned in 5.2.2.

5.2.8 **Different Parameters are displayed below:**
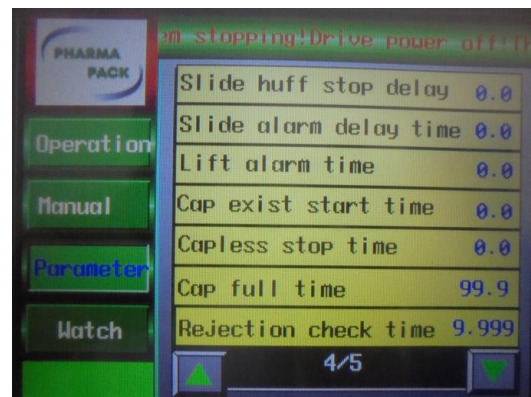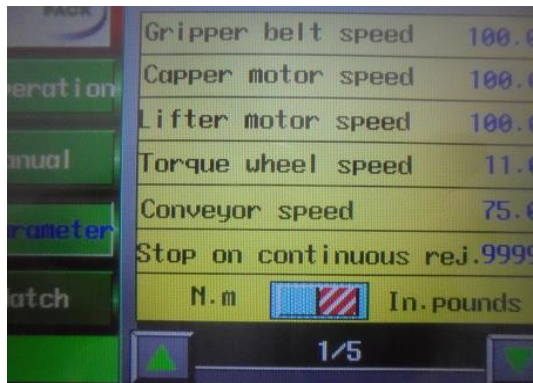
5.2.9 **Gripper belt speed:** Change running speed of gripper belt.

5.2.10 **Capper motor speed:** Change running speed of capper motor speed.

5.2.11 **Lifter motor speed:** Change running speed of lifter motor speed.

5.2.12 **Torque wheel speed:** Change running speed of torque wheel speed.

5.2.13 **Continuous rejection time for qualified torque:** When continuous rejection time for qualified torque reaches this value, the machine will give alarm and stop.

5.2.14 **Maximum Torque:** The upper torque limit of qualified bottle.

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5.2.15   **Minimum Torque:** The lower torque limit of qualified bottle.

5.2.16   **Rejection Action Time:** The lasting time of rejection.

5.2.17   **Torque value check time:** Checking time for maximum value from value checking device after torque triggering the sensor.

5.2.18   **Conveyor jam time:** Time for sensor on buffering conveyor continuously detecting bottles. After the time reaches the preset value, the bottle spacing wheel stop the bottle infeeding.

5.2.19   **Alarm information includes:**

(1) Emergency stop.

(2) Frequency invertor error.

(3) Conveyor stop.

(4) Continuous error !

(5) Back conveyor jam !

(6) Unqualified torque rejection !

(7) Power supply cut off !

(8) Safety door open

MMI will display as follow :

5.3   SETTING OF BOTTLE PRESENT OPTICAL SENSOR AND PRODUCT LEVEL OPTICAL SENSOR

5.3.1   SETTING OF ''BOTTLE PRESENT OPTICAL SENSOR'' :

5.3.1.1   Take a filled bottle with product and placed it on conveyor belt in front of optical sensor.

5.3.1.2   Set the position of sensor on conveyor guide that when it emit the ray of red light, will fall on outer surface of bottle neck.

5.3.1.3   Set the distance traveled by ray of red light by screwing the nut given on sensor clockwise (To increase the distance traveled) and anti-clockwise (To decrease the distance traveled)

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5.3.1.4   The sensor will blink with orange light when ray of red light will be reached on object and it will ''OFF'' when object is not present in front of sensor.

5.3.2   SETTING OF ''PRODUCT LEVEL OPTICAL SENSOR'':

5.3.2.1   Set the position of product level optical sensor at top of bottle that when it emit ray of red light, will fall on product inside the bottle.

5.3.2.2   Set the distance traveled by ray of red light by screwing the nut clockwise (To increase the distance traveled) and anti-clockwise (To decrease the distance traveled)

5.3.2.3   Take a filled bottle with desired count and remove half tablets from bottle that total height of product bed inside container remained approx half.

5.3.2.4   If any pack profile with cotton to be inserted into bottle follow as per given below:

5.3.2.5   Take a bottle filled with desired count and desired length of cotton.

5.3.2.6   Remove cotton from the bottle.

5.3.2.7   Now set the ray of red light by screwing the nut that it reached on product bed inside the bottle.

5.3.2.8   The sensor will blink with orange light when object will present.

NOTE:

In case of product bed height inside the container is very small, the ''EMPTY BOTTLE'' challenge test for that product shall not be applicable. Product with small product dimension, small pack size leads to small bed height.

5.4   CHALLENGE TESTS:

5.4.1   CHALLENGE TEST FOR ''BOTTLE PRESENT'':

5.4.1.1   Mark the empty bottle with marker to identify it and feed into conveyor belt of Inline Capper machine.

5.4.1.2   Challenge test 'PASS' if closure will be released for that bottle and bottle not rejected at rejection point of Inline capper machine.

5.4.1.3   Collect the same marked bottle and fall down the bottle on conveyor belt.

5.4.1.4   Now feed the fallen empty bottle through the conveyor belt into inline capper. machine.

5.4.1.5   Challenge test will be 'PASS', if no orange light blink, no closure will be released for that bottle and same bottle will be rejected at rejection point of Inline Capper machine.

Note: Frequency for challenge test of Inline Capper Machine shall be at start, after every 4 hours of operation and at end of operation.

5.4.2   **CHALLENGE TEST FOR ''PRODUCT LEVEL'':**

5.4.2.1   Mark the bottle with marker to identify it and filled it as per product packing profile then feed into the conveyor belt of Inline Capper machine.

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5.4.2.2 Challenge test will be 'PASS', if closure will be released for that bottle and bottle not rejected at the rejection point.

5.4.2.3 Get the same marked bottle and make empty the bottle to perform challenge test.

5.4.2.4 Now empty bottle feed into the conveyor belt of inline capper machine.

5.4.2.5 Challenge test will be 'PASS', if no orange light blink, no closure will be released for that bottle and if bottle will be rejected at rejection point.

Note: Frequency for challenge test of Inline Capper Machine shall be at start, after every 4 hours of operation and at end of operation.

6.0   ABBREVIATION (S):

SOP - Standard Operating Procedure

MMI – Man Machine Interface

7.0   REFERENCE (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 CAP RETORQUER (PHARMA PACK)

Annexure-II - CHALLENGE TEST FOR CAP RETORQUER (MAKE: PHARMA PACK)

9.0   DISTRIBUTION:

Master Copy   : Quality Assurance

Controlled Copy (S) : Production department, Quality Assurance

Reference Copy (S) : Production department

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ANNEXURE I
CLEANING CHECKLIST OF CAP RETORQUER
(PHARMA PACK)

Name of the Equipment	CAP RETORQUER (PHARMA PACK)		
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 dry lint free cloth.	
6.	Open guard and clean inside surface of machine, hopper and its area with dry 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.	

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

Checked By (Production)   **Verified By (QA)**
Sign/Date   **Sign/Date**

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ANNEXURE II

CHALLENGE TEST FOR CAP RETORQUER (MAKE: PHARMAPACK)

CHALLENGE TEST FOR FALLEN BOTTLE/CROSS CAP AND NO FOIL SENSOR

FREQUENCY: AT START, AFTER EVERY FOUR HOUR OF OPERATION, AT END OF OPERATION AND AFTER ANY MAINTENANCE

DATE	TIME	WITHOUT FOIL (SENSOR-I) #	CROSS CAP (SENSOR-II) #	FALLEN BOTTLE (SENSOR-III) #	CHECKED BY (Production)	VERIFIED BY (IPQA)

The result shall be ''OK'' if bottle rejected and ''NOT OK'' if bottle not rejected.