



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning and Operation of CAP Retorquer (Make: CVC Technology)	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
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1.0 **OBJECTIVE:**

To lay down a procedure for cleaning and Operation of cap retorquer.

2.0 **SCOPE:**

This procedure is applicable for the cleaning and Operation of cap retorquer machine in production area.

3.0 **RESPONSIBILITY:**

Technical Associate : Cleaning and Operation

Production Officer / Executive : Supervision

IPQA Person : Line Clearance

Head 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 CLEANED" 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 S.S surface of machine by 70% v/v IPA solution using lint free cloth.
- 5.1.6 Open guard and clean inside S.S. surface of the machine, hopper and its assembly by dry lint free cloth.
- 5.1.7 Clean the product deposit 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.



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### 5.2 OPERATING PROCEDURE FOR MODEL 1206 H2:

5.2.1 Switch "ON" the power supply, the following screen will be displayed:



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5.2.2 Press the “MAIN WIN” key and “MAIN MENU SCREEN” will be displayed as :



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5.2.3 Press the “LOGIN” key on “MAIN MENU SCREEN” and login screen will be as displayed :

5.2.4 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



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5.2.5 Press "LOGIN" key on main screen, the login screen will be displayed as follows :



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5.2.6 Press the numeric field to call out the numeric keypad for entering the “USER ID PASSWORD”, press “ENTER” to confirm it and then enter the “PASSWORD” it will be shown hidden as an asterisk “\*” and then press “ENTER” to confirm it.

5.2.7 Press [RUN] , this key to start the machine.

5.2.8 Press [STOP],this key to stop the machine.



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5.2.9 Press [TQ REC],this key to display torque records of capped bottle.

5.2.10 Press [RESET],this key to to connect the motive power after powering “ON” the machine also to reset the machine and to remove the error message.

5.2.11 Press [ALARM],this key to check the alarm message when machine stop with error.

5.2.12 Press [MESSAGE], this key to check the error message when machine error occurred.

5.2.13 [PCS/MIN],it display average output speed.

5.2.14 [PCS], it display total output of machine.

5.2.15 [PCS], it display total output of machine.



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5.2.16 Press [MAIN MT SPD],the numeric field of this screen to call out the keypad for entering the speed value, Setting range :10 □30(M/min.)





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5.2.17 [Capping SPD]:To call out the numeric keypad for entering speed value (Capping speed is responsible for controlling the capping speed control)  
Setting range : 30 □ 100 (M/min.)



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5.2.18 [TQ Setting]: Press the numeric field of this screen to call out the keypad for entering the torque value,  
Setting range : 3 □40(lb)



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5.2.19 [OFS HIGHER] / [OFS LOWER]: Press the numeric field of the UPPER/LOWER torque limit to call out for setting of upper/lower limit. 0  5(lb)



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5.2.20 [ALARM]: After pressing the alarm icon the alarm message will be shown on screen and press “RESET” to resume the machine.

5.2.21 [MESSAGE]: After pressing the this, the prompt message will be shown on screen.

5.2.22 Press [MSG CLR] to clear the message.



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5.2.23 Select the “COUNTER” key at bottom of screen and following screen will be displayed



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5.2.24 Press [Remain] key, to call out the numeric keypad to enter the total batch size.

5.2.25 Press the [SET] key to confirm the setting, the “REMAIN” value range is 0 □9999999.



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5.2.26 Product : The total product output at a batch.

5.2.27 Good output : Good product output at a batch

5.2.28 Rejected :Rejected product at a batch.

5.2.29 TQ ERR REJ: Torque error rejected product of a batch.

5.2.30 Foil/Cap Rej: Foil or cap rejection at a batch.

5.2.31 BTL DIM Rej: Bottle diameter rejection at a batch.

5.2.32 No Check Rej: No check bottle rejection.

5.2.33 Press [RST CNT] key to resetting the counter number except “REMAIN” & “TOTAL PRODUCT”

5.2.34 Manual interface: Different keys enabling to actuate the following functions manually:

5.2.34.1 Press [CAP REJ] to actuate the reverse cap reject, the indicator will be lit.

5.2.34.2 Press[CAPPING FOIL] to actuate the capping foil sensor manually, the indicator will be lit.

5.2.34.3 Press[Chute empty] to actuate the chute empty sensor manually, the indicator will be lit.

5.2.34.4 Press[EVT Feed] to actuate the sensor of hopper of cap elevator manually, the indicator will be lit.

5.2.34.5 Press[Foil Cap] to actuate the foil/ cap missing sensor manually, the indicator will be lit.



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5.2.34.6 Press[BTL DIM CHECK] to enable the function of bottle diameter check.





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5.2.35 On this interface, the operator can manually operate motor and electromagnetic valve, when the machine un-automatically runs, which offers convenient maintenance and commission.

5.2.36 Press [UP/DN EN] key, to enable the function of lift/lower the machine firstly.

5.2.37 Press [M/C UP] OR [M/C DN] key, to upper or lower the machine in jog mode respectively.

5.2.38 Alarm interface:



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5.2.39 Alarm information includes:

- (1) Emergency stop.
- (2) Elevator
- (3) Conveyor stop.
- (4) Conveyor jam !
- (5) Unqualified torque rejection !
- (6) Power supply cut off !
- (7) Safety door open

5.3 **OPERATING PROCEDURE FOR MODEL1206 SE:**

5.3.1 Switch "ON" the power supply and wait for few seconds ,the following screen will be displayed:



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5.3.2 Touch the ‘‘MAIN’’ and ‘‘SCREEN’’ will be displayed as following:

5.3.3 Touch ‘‘Ready’’ key on ‘‘MAIN SCREEN’’ and login screen will be as displayed :



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5.3.4 Touch “LOGON” key on “ SCREEN” and login screen will be as displayed

5.3.5 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



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5.3.6 After login the screen will display as following:

5.3.7 Touch TQ SET for Torque setting it will display as following:

Enter the parameters as per BPR.



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5.3.8 Touch TQ REC from screen 5.3.6, this key to display torque records of capped bottle.

5.3.9 Touch 'COUNTER', it will display as following:

5.3.10 Remain: Batch size of product in no. of bottles.

5.3.11 Product: The total product output of batch.

5.3.12 Good OUT: Good product output of batch.

5.3.13 Rejected: Rejected product of batch.

5.3.14 TQ ERR REJ: Torque error rejected product of batch.

5.3.15 Foil/Cap REJ: Foil or cap rejection of batch.

5.3.16 BTL DIM REJ: Bottle diameter rejection of batch.

5.3.17 No Check REJ: No check bottle rejection.



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5.3.18 Touch RESET key to resetting the counter number except “Remain” & Total Product”.

5.3.19 Touch on MANUAL it will display as following:

5.3.20 Touch on Machine UP to move the machine in upward direction

5.3.21 Touch on Machine DN to move the machine in downward direction



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5.3.22 Touch on SETTING it will display as following:

Add the required parameters as per BPR (if any).





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5.3.23 Touch on 'MEMORY' it will display as following:

5.3.24 [ALARM]: After touching the alarm icon the alarm message will be shown on screen and Touch the "RESET" to resume the machine.



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5.3.25 Alarm information includes:

- (1) Emergency stop.
- (2) Elevator
- (3) Conveyor stops.
- (4) Conveyor jam!
- (5) Unqualified torque rejection!
- (6) Power supply cut off!
- (7) Safety door open

### 5.4 CHALLENGE TESTS

#### 5.4.1 CHALLENGE TEST FOR “FALLEN BOTTLE SENSOR”:

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

5.4.1.2 It must be passed through the machine.

5.4.1.3 Now place a fallen bottle on conveyor belt and pass it through the machine.

5.4.1.4 The bottle must be rejected by the rejection system and fall into rejection box.

#### 5.4.2 CHALLENGE TEST FOR “CROSS CAP BOTTLE SENSOR”

5.4.2.1 Mark a normal capped bottle with marker to identify it and pass it through machine.

5.4.2.2 The bottle must be passed through the machine.

5.4.2.3 Now take the bottle with incomplete cap and pass it through the machine.

5.4.2.4 The bottle must be rejected by the rejection system and fall into rejection box.

#### 5.4.3 CHALLENGE TEST FOR “FOIL PRESENT SENSOR”:

5.4.3.1 Mark a bottle with marker to identify it and it shall be capped with foil and is feed into conveyor belt of Inline Capper machine.

5.4.3.2 The bottle must be passed through the machine.

5.4.3.3 Now take the capped bottle with no foil and pass it through the machine.

5.4.3.4 The bottle must be rejected by the rejection system and fall into rejection box.



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**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 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 Cap Retorquer)

### 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 (MAKE: CVC)

<b>Name of the Equipment</b>	<b>CAP Retorquer</b>
<b>Equipment I.D. No.</b>	<b>Date</b>
<b>Previous Product:</b>	
<b>Batch No.</b>	

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.	

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

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

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



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### ANNEXURE II

#### 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.