



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning and Operation of Bulk counter machine with Single/Double Counting Head (Make: CVC 1220)	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

**Vernacular SOP:** No

### 1.0 OBJECTIVE:

- 1.1 To lay down a procedure for cleaning and operation of bulk counter Machine with single/double counting head (Make: CVC).

### 2.0 SCOPE:

- 2.1 This procedure is applicable for cleaning and operation of bulk counter machine with single/double counting head (Make: CVC) in production department.

### 3.0 RESPONSIBILITY:

- 3.1 Technical Associate: Cleaning and operation of bulk counter.  
3.2 Officer/ Executive-Production: Supervision.  
3.3 IPQA: Verification of cleaning and operation.  
3.4 Head-Production: SOP compliance.

### 4.0 DEFINITION (S):

- 4.1 NA

### 5.0 PROCEDURE:

#### 5.1 TYPE A CLEANING:

##### **Change over from one batch to next batch of the same product and potency.**

- 5.1.1 Ensure that all the materials of previous batch are removed from the packing cubicle.  
5.1.2 Remove "EQUIPMENT STATUS" label and affix "UNDER CLEANING" label on the machine with date and sign of the production officer.  
5.1.3 Clean the control panel with dry lint free cloth.  
5.1.4 Clean the top and outer surface of machine with the dry lint free cloth.  
5.1.5 Open guard and clean inside surface of machine, hopper and its assembly by dry lint free cloth.  
5.1.6 Clean the product deposit area on top and parts by vacuum cleaning followed by dry lint free cloth.

#### 5.1.7 Dismantle the change parts from machine:

- 5.1.7.1 Bulk Counter Machine With Single Counting Head:  
5.1.7.1.1 Switch 'OFF' all the utility supply to machine.



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- 5.1.7.1.2 Remove the dust collector pot and S.S guards of machine of front, sides and back.
- 5.1.7.1.3 Remove hopper, three level vibratory plates In-feeding system.
- 5.1.7.1.4 Open the S.S door to open the memory flap cylinder units.
- 5.1.7.1.5 Remove the pneumatic connection from the memory flap cylinder assembly.
- 5.1.7.1.6 Remove the channel divide above the sensor head.
- 5.1.7.1.7 Remove the sensor port from the sensor assembly and small sensor port from memory flap cylinder Unit 3.
- 5.1.7.1.8 Remove SS vacuum suction pot beside the channel divide at the sitting fork of sensor head.
- 5.1.7.1.9 Remove the sensor head carefully above the cover of memory flap cylinder unit.
- 5.1.7.1.10 Remove the safety cover of memory flap cylinder unit.
- 5.1.7.1.11 Remove the memory flap cylinder unit from the memory flap support.
- 5.1.7.1.12 Remove the memory flap support plate and S.S. funnel from main gate cylinder.
- 5.1.7.1.13 Remove the product feeding nozzle from locking system.
- 5.1.7.1.14 Remove the hopper, vacuum suction pipe, three-level vibratory plates In-feeding system attached.
- 5.1.7.1.15 Clean the S.S. guards of machine of sides and back, hopper, three-level vibratory plates In-feeding system, S.S vacuum suction cylinder, memory flap support plate, SS funnel, product feeding nozzle and vacuum suction pipe with dry lint free cloth.
- 5.1.7.1.16 Clean the machine surface and product deposit area by dust collector pipe followed by dry lint free cloth.
- 5.1.7.1.17 Replace the "UNDER CLEANING" status label by "CLEANED" status label on the machine with date and sign of the production officer.
- 5.1.7.1.18 Record the cleaning activity in equipment usage log as per SOP.
- 5.1.7.1.19 Clean the surrounding area as per SOP.
- 5.1.7.2 **Bulk Counter Machine With Double Counting Head:**
- 5.1.7.2.1 Followed the same procedure for double counting head machine from point no. 5.1.1 to point no.5.1.7.1.19
- 5.2 TYPE B" CLEANING:**
- This is a cleaning procedure for change over of product with different actives/colour/ descending potency/ascending potency and If the same product processed for more than a week or after maintenance.**
- 5.2.1 Ensure that all the materials of previous batch are removed from the packing cubicle.



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- 5.2.2 Remove "EQUIPMENT STATUS " label and affix "UNDER CLEANING" label on the machine with date and sign of the production officer.
- 5.2.3 **Dismantle all the change parts of the machine**
- 5.2.3.1 Bulk Counter Machine With Single Counting Head
- 5.2.3.1.1 Switch 'OFF' all the utility supply to machine.
- 5.2.3.1.2 Remove the dust extractor pipe and S.S guard of machine of front, sides and back.
- 5.2.3.1.3 Remove hopper, three-level vibratory Plates In feeding System.
- 5.2.3.1.4 Open the S.S door to open the memory flap cylinder units.
- 5.2.3.1.5 Remove the pneumatic connection from the memory flap cylinder assembly.
- 5.2.3.1.6 Remove the channel divide above the sensor head.
- 5.2.3.1.7 Remove the sensor port from the sensor assembly & small sensor port from memory flap cylinder unit.
- 5.2.3.1.8 Remove S.S. vacuum suction cylinder beside the channel divide at the sitting fork of sensor head.
- 5.2.3.1.9 Remove the sensor head carefully above the cover of memory flap cylinder unit.
- 5.2.3.1.10 Remove the safety cover of memory flap cylinder unit.
- 5.2.3.1.11 Remove the memory flap cylinder unit from the memory flap support.
- 5.2.3.1.12 Remove the memory flap support plate, S.S funnel from main gate cylinder.
- 5.2.3.1.13 Remove the product feeding nozzle from the locking system.
- 5.2.3.1.14 Remove the hopper, vacuum suction pipe, three-level vibratory plates In-feeding system attached.
- 5.2.3.1.15 Transfer the S.S. guards of machine of sides and back, hopper, three-level vibratory plates In-feeding system, SS vacuum suction cylinder, memory flap support plate, SS funnel, feeding nozzle, dust extractor pipe to washing area in virgin double poly bag for cleaning.
- 5.2.3.1.16 In the washing area flush all change parts with purified water sufficient to remove the powder. To remove the adhered particulate scrub the equipment/parts with nylon brush using purified water.
- 5.2.3.1.17 **NOTE:** 2% Sodium Lauryl Sulphate solution shall be used for scrubbing with nylon brush if API is Efavirenz before final rinsing of equipment/parts.
- 5.2.3.1.18 Rinse all the change parts with 40-50 liters purified water.
- 5.2.3.1.19 Clean the parts by mopping with dry lint free cloth.
- 5.2.3.1.20 Wipe the all parts with 70% v/v IPA solution followed by mopping with dry lint free cloth.



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5.2.3.1.21 **Note:** Visual inspection shall be done for wear and tear of teflon coating on S.S. plate of hopper gate after B type cleaning.

### 5.2.3.2 **Bulk Counter Machine With Double Counting Head**

5.2.3.2.1 Follow the same procedure for double counting head machine from point no. 5.2.1 to point no.5.2.3.1.21.

5.2.3.2.2 Transfer all the parts from washing area to cubicle area in virgin double poly bag.

5.2.3.2.3 Clean the control panel with dry lint free cloth.

5.2.3.2.4 Clean the surface of the machine with dry lint free cloth using 70% v/v IPA solution.

5.2.3.2.5 Clean the machine guards with dry lint free cloth.

5.2.3.2.6 Assemble all the dismantled parts.

5.2.3.2.7 If machine is idle for 72 hours after cleaning, re-clean the machine by mopping with lint free cloth using 70% v/v IPA solution before use.

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

5.2.3.2.9 Do the cleaning as per Annexure-I Cleaning checklist of Bulk Counter Machine.

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

5.2.3.2.11 Clean the surrounding area as per SOP.

5.2.3.2.12 **Note:** Visual inspection shall be done for wear and tear of teflon coating on S.S. plate of hopper gate after B type cleaning.

### 5.3 **Operating procedure:**

5.3.1 Bulk Counter Machine With Single Counting Head:

5.3.1.1 Switch on the machine by pressing the green button in bulk counter machine.

5.3.1.2 System shows three type of user login level and have specific rights assignment.



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S.No.	Function	Meaning of Function	Operator	Supervisor	Administrator (Production Head)
1.	Set new job	New Product recipe define	----	Y	Y
2.	Load from previous job	To make a new reference from previous job	Y	Y	Y
3.	Online change in vibration frequency	To get more counting accuracy of vibratory plate.	---	Y	Y
4.	Manually Setting of machine	-General gate – Up/Down movement. -Product Max./Min. value change. -Flap working. -Vibratory lock working.	Y	Y	Y
5.	Parameters Value Setting	-Setting value for count/pre-count. -change value of other parameter to get accuracy	---	Y	Y
6.	Setting of frequency parameter of vibratory plates	To get more accuracy in product counting.	---	Y	Y
7.	Delete of recipe	When the product shifted to another area.	---	----	Y
8.	Edit of recipe	When the any change in process	---	-----	Y

5.3.1.3 Enter “USER LOGIN” and “PASSWORD”.

5.3.1.4 Welcome screen will appear as given below

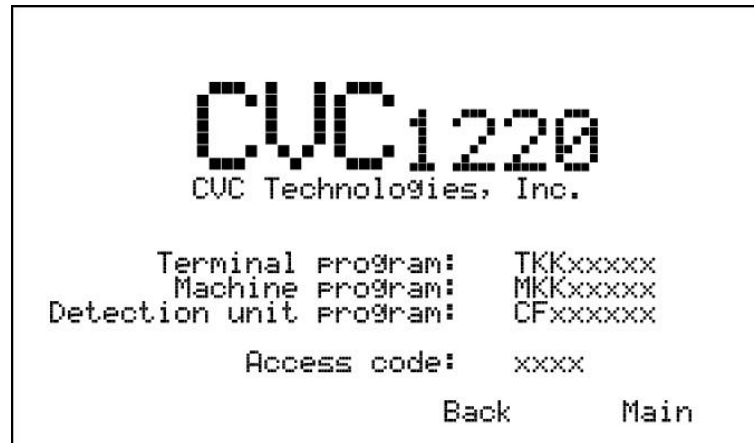


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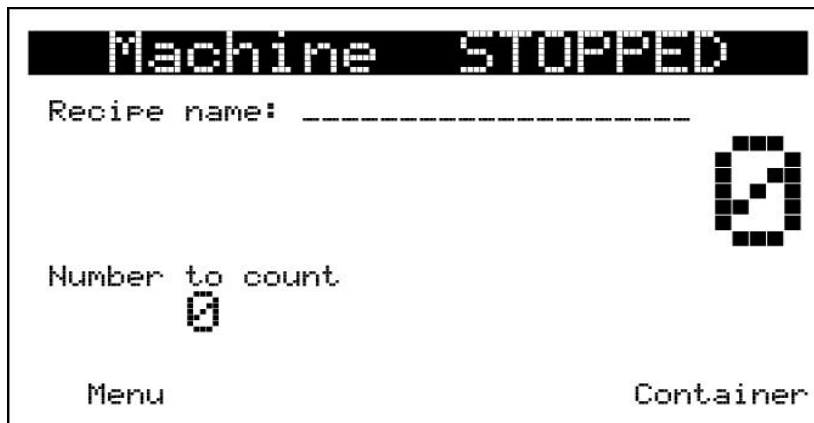
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5.3.1.5 After 3 seconds screen will appear as follows



5.3.1.6 Press the menu button for operation of the product.

5.3.1.7 Main screen open as given below.





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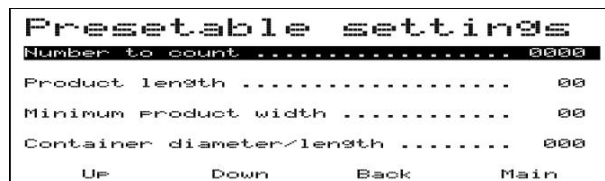
<b>Department:</b> Production	<b>SOP No.:</b>
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5.3.1.8 Press Manual button of setting menu on main screen.

5.3.1.9 Following screen will appear



5.3.1.10 Presentable setting required for count setting of product ,product length, min product width, container diameter/length, maximum rejects/minutes, Number of containers, Counting mode, Translucent product if any, Product number as given below screen;-





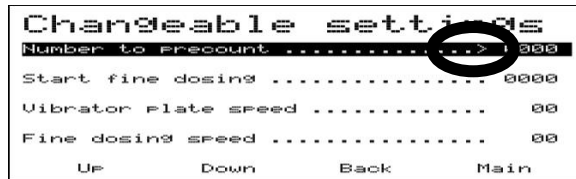
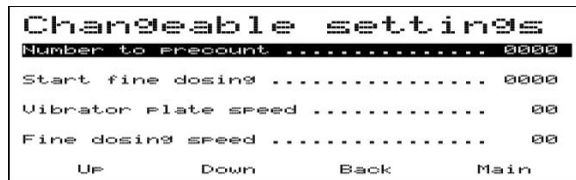
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5.3.1.11 Changeable setting required for no. of pre count, start fine dosing, vibrator plate speed, fine dosing speed, hopper plate speed, hopper plate pulse time, hopper plate interval. Discharge time and dipping nozzle mode. as given below screen;-



5.3.1.12 Manual setting required for ruler hopper gate, ruler indexing gate 1, ruler indexing gate 2, nozzle ID number, nozzle insert quantity as given below screen;-







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5.3.1.13 Recipe file manager consist for recipe name, load recipe files in case of another products, save, delete and edit the recipe file. as given below screen

```
Recipe file manager
Recipe name          Edit recipe file
Load recipe file
Save recipe file
Delete recipe file
Back                Main
```

5.3.1.14 Service menu is a part of engineering department where the engineering person may detect the cause of problem when machine in breakdown it consist of detection unit test, input test ,output test ,keyboard test, memory flap test1 , memory flap test2, and special access as given below screen.

```
Service menu
Detection unit test  Memory flap test 1
Input test           Memory flap test 2
Output test          Special access
Keyboard test
Back                Main
```

5.3.1.15 Detection unit test used for voltage of machine with respect to product length, minimum product width, free fall distance between product and bottles.

```
Detection unit test
Product length ..... 00
Minimum product width ..... 00
Free-fall distance ..... 00
-----
4: x.xxV  3: x.xxV  2: x.xxV  1: x.xxV
8: x.xxV  7: x.xxV  6: x.xxV  5: x.xxV
12: x.xxV 11: x.xxV 10: x.xxV  9: x.xxV
Back                Main
```



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5.3.1.16 Input test consist of incoming the inputs in IR sensor which sense the product detection channel from 1 to 12 with respect to the channel.

```
Input test
Input 01 - Detection channel 1 ..... [1]
Input 02 - Detection channel 2 ..... [1]
Input 03 - Detection channel 3 ..... [1]
Input 04 - Detection channel 4 ..... [1]
UP           Down       Back       Main
```

5.3.1.17 Output test consist of outgoing the inputs in IR sensor which sense the product detection channel from 1 to 12 with respect to the channel

```
Output test
Output 01 - Memory flap 1 ..... [0]
Output 02 - Memory flap 2 ..... [0]
Output 03 - Memory flap 3 ..... [0]
Output 04 - Memory flap 4 ..... [0]
UP           Down       Back       Main
```

5.3.1.18 Keyboard test used for the verification of functioning of the key board.

```
Keyboard test
LKEY1                                RKEY1
LKEY2                                RKEY2
Key pressed: NO KEY
LKEY3                                RKEY3
LKEY4                                RKEY4
BKEY1      BKEY2      BKEY3      Back
```



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5.3.1.19 Memory flap test 1 and 2 used for no. of counts of tablets which delivered the tablet in to bottle.

```
Memory flap test 1
Output 01 - Memory flap 1 ..... [0]
Output 02 - Memory flap 2 ..... [0]
Output 03 - Memory flap 3 ..... [0]
Output 04 - Memory flap 4 ..... [0]
Up      Down      Back      Main
```

```
Memory flap test 2
Output 01 - Memory flap 1 ..... [0]
Output 02 - Memory flap 2 ..... [0]
Output 03 - Memory flap 3 ..... [0]
Output 04 - Memory flap 4 ..... [0]
Up      Down      Back      Main
```

5.3.1.20 Special Access for vendors use only.

```
Special access
Free-fall distance ..... 00
Back      Main
```

5.3.1.21 System menu used for system information, password menu and language selection as per given below-

```
System menu
System information
Passwords
Language selection
Back      Main
```

5.3.1.22 System information consists of general information regarding to model no and machine make.

5.3.1.23 Password menu consists of password setting, service and system.



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5.3.1.24



5.3.1.25

Machine function required for run empty process, machine level adjustment and indexing of container. The screen shows as follows



5.3.1.26

Run empty system use for the unloading of batch after completion of batch or any major breakdown.



5.3.1.27

Machine level adjustment used for setting of the height of product falling.





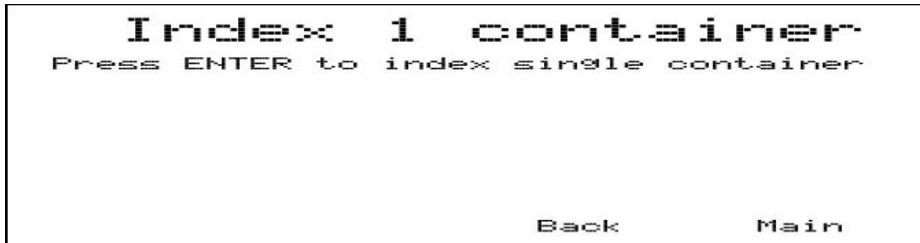
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5.3.1.28 Index 1 container process used for one by one container filled with product and run on the conveyer belt.



5.3.1.29 Press parameter button on main screen.

5.3.1.30 Start machine and check 3 to 4 bottles for count check.

5.3.1.31 If any problem persists then adjust the value of Gate delay .By pressing respective gate delay by small numeric keyboard.

5.3.1.32 Enter Delay parameter.

5.3.1.33 Discharge time setting required for proper filling of tablets in to bottles according to feeding count in TST.

5.3.1.34 Set the container diameter by adjust the bottle getting gate for proper flow of tablets/capsules in to the bottle.

5.3.1.35 Enter Feeder nozzle vibration frequency for big tablets switch ON the Nozzle vibration for big tablets.

5.3.1.36 Enter Rejection parameter.

5.3.1.37 Enter Remain Time ---- It stands for time interval for rejection valve from pushing out to pulling back. This value can be input by small keyboard.

5.3.1.38 Gate Interval ---- It stands for time interval from the moment when gate opens to the moment when gate closes. The value is larger; the filling is more accurate, while the rejection rate will be larger (150 to 225).

5.3.1.39 Adjust the vibration of vibrating plates on main screen.

5.3.1.40 Save the file in Product management by product name.

5.3.1.41 Run the machine by calling product file by follow step No.5.3.

5.3.1.42 **NOTE:** During start the batch 2 bottles will be rejected by bulk counter machine for proper count setting.

### 5.3.2 Bulk Counter Machine With Double Counting Head :

5.3.2.1 Follow the same procedure for double counting head machine from point no. 5.3.1 to point



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no.5.3.1.42.

### 6.0 ABBREVIATION (S):

- 6.1 SOP - Standard Operating Procedure
- 6.2 TST- Touch screen terminal
- 6.3 S.S- Stainless Steel
- 6.4 V/V – volume/volume
- 6.5 IPA- Isopropyl alcohol
- 6.6 SLS- Sodium Lauryl Sulphate

### 7.0 REFERENCES (S):

- 7.1 SOP No.: Making entries in equipment usage and cleaning log sheet.
- 7.2 SOP No.: Cleaning of production area.

### 8.0 Annexure (S):

8.1

Annexure no.	Title of Annexure	Format no.	Mode of Execution
Annexure- I	Cleaning checklist of bulk counter machine with single/double counting head.(make cvc 1220)		Log Book

### 9.0 DISTRIBUTION (S):

- 9.1 **Master Copy** : Quality Assurance
- 9.2 **Controlled copy (S)** : Production department (01),QA department (01)
- 9.3 **Reference copy (S)** : Production department (01)



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### 10.0 REVISION HISTORY:

S.No.	VERSION No.	CHANGE CONTROL No.	REASON (S) FOR REVISION	DETAIL OF REVISION	EFFECTIVE DATE
1.	00		New SOP	NA	



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### ANNEXURE I CLEANING CHECKLIST OF BULK COUNTER MACHINE WITH SINGLE/DOUBLE COUNTING HEAD (MAKE CVC 1220)

Name of the Equipment		Bulk Counter Machine	
Equipment ID No.		Previous Product	
Batch No.		Date	

S.No.	Activity	Activity Performed
1.	Ensure that all the material of previous product removed from the packing cubicle.	
2.	Switch 'OFF' all the utility supply to machine.	
3.	Remove hopper, three level vibratory plates In-feeding system.	
4.	Open the SS door to open the memory flap cylinder units.	
5.	Remove the pneumatic connection from the memory flap cylinder assembly.	
6.	Remove the channel divide above the sensor head.	
7.	Remove the sensor port from the sensor assembly and small sensor port from memory flap cylinder unit.	
8.	Remove SS vacuum suction pot beside the channel divide at the sitting fork of sensor head.	
9.	Remove the sensor head carefully above the cover of memory flap cylinder unit.	
10.	Remove the safety cover of memory flap cylinder unit.	
11.	Remove the memory flap cylinder unit from the memory flap support.	
12.	Remove the memory flap support plate and S.S. funnel from main gate cylinder.	
13.	Remove the product feeding nozzle from locking system.	
14.	Remove the hopper, vacuum suction pipe, three-level vibratory plates In-feeding system attached.	
15.	Transfer the S.S. guards of machine of sides and back, hopper, three-level vibratory plates In-feeding system, SS vacuum suction cylinder, memory flap support plate, SS funnel, feeding nozzle, dust extractor pipe, S.S. base plate of vacuum suction pipe to washing area in virgin poly bag for cleaning pipe with dry lint free cloth.	
16.	Flush all change parts with purified water sufficient to remove the powder. To remove the adhered particulate scrub the equipment/parts with nylon brush using purified water.	
17.	<b>NOTE:</b> 2% Sodium Lauryl Sulphate solution shall be used for scrubbing with nylon brush if API is Efavirenz before final rinsing of equipment/parts.	
18.	Rinse all the change parts with 40-50 liters purified.	
19.	Clean the parts by mopping with dry lint free cloth.	
20.	Wipe the all parts with 70% v/v IPA solution followed by mopping with dry lint free cloth.	
21.	Visual inspection shall be done for wear and tear of Teflon coating on S.S. plate of hopper gate after B type cleaning.	
22.	Transfer all the parts from washing area to cubicle area in fresh virgin poly bag.	





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S.No.	Activity	Activity Performed
23.	Clean the machine surface and product deposit area by dust collector pipe followed by dry lint free cloth.	
24.	Replace the "UNDER CLEANING" status label by "CLEANED" status label on the machine with date and sign of the production officer.	
25.	Record the cleaning activity in equipment usage log as per SOP.	
26.	Clean the surrounding area as per SOP.	

**Checked By(Prod.)**  
**Sign/Date**

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

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