STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Bulk Counter Machine (Make: Pharma Pack)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Vernacular SOP: No

1.0   OBJECTIVE:

1.1   To lay down a procedure for Cleaning and Operation of Bulk Counter Machine (Make: Pharma Pack PP-12).

2.0   SCOPE:

2.1   The procedure is applicable to the cleaning and operation of Bulk Counter Machine (Make: Pharma Pack PP-12).

3.0   RESPONSIBILITY:

3.1   Technical Associate   : Cleaning and operation of bulk counter machine.

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

3.3   Officer, Executive-IPQA   : Line Clearance and verification of Cleaning and operation of bulk counter machine.

3.4   Manager–production : SOP compliance of Cleaning and operation of bulk counter machine

4.0   DEFINITION (S):

4.1   NA

5.0   PROCEDURE:

5.1   **Cleaning**

5.1.1   **TYPE A CLEANING: This is a cleaning procedure for change over from one batch to next batch of the same product, same potency.**

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

5.1.1.2   Remove "EQUIPMENT STATUS" label and affix "UNDER CLEANING" label on the machine with date and sign of the production officer.

5.1.1.3   Clean the control panels of machine with dry lint free cloth.

5.1.1.4   Clean the control panel of camera inspection system monitor and wiring panel with dry lint free cloth.

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

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

5.1.1.7   Clean the product deposit area on top and parts by vacuum cleaning followed by dry lint free cloth.

5.1.2   **Machine Dismantling Procedure:**

5.1.2.1   Remove the dust collector pipe and S.S guards of machine of front, center, sides and back.

	PHARMA DEVILS	
	PRODUCTION DEPARTMENT	

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Bulk Counter Machine (Make: Pharma Pack)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.1.2.2   Switch 'OFF' the vibratory lock in PLC to release the vibratory plates In-feeding system.

5.1.2.3   Remove hopper, three level vibratory plate's In-feeding system.

5.1.2.4   Switch 'OFF' all the utility supply to machine.

5.1.2.5   Remove the individual product rejection assembly from machine.

5.1.2.6   Remove the pneumatic connection from the memory flap cylinder assembly.

5.1.2.7   Remove the channel divide above the sensor head.

5.1.2.8   Remove the air purging nozzle assembly of individual rejection of product by loosing the clump.

5.1.2.9   Remove the sensor port from the sensor assembly and small sensor port from memory flap cylinder unit.

5.1.2.10   Remove the sensor head carefully above the cover of memory flap cylinder unit.

5.1.2.11   Remove the safety cover of memory flap cylinder unit.

5.1.2.12   Remove the memory flap cylinder unit from the memory flap support.

5.1.2.13   Remove the memory flap support plate and S.S. funnel from main gate cylinder.

5.1.2.14   Remove the product feeding nozzle from locking system.

5.1.2.15   Remove the base S.S. plate of bulk counter machine to which hopper, vacuum suction pipe, three-level vibratory plates In-feeding system attached.

5.1.2.16   Clean the S.S. guards of machine of center, sides and back, hopper, three-level vibratory plates In-feeding system, memory flap support plate, Individual product rejection assembly, SS funnel, product feeding nozzle, base SS plate of hopper and vacuum suction pipe with dry lint free cloth.

5.1.2.17   Clean the machine surface and product deposit area by dust collector pipe followed by dry lint free cloth.

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

5.1.2.19   Record the cleaning activity in equipment usage log as per SOP, "Making entries in equipment usage and cleaning log sheet".

5.1.2.20   Clean the surrounding area as per SOP, "Cleaning of production area".

5.1.3   **"TYPE B" CLEANING:** This is a cleaning procedure for Change over of product with different actives/color/ascending potency/descending potency or after maintenance of contact parts.

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

5.1.3.2   Remove "EQUIPMENT STATUS "label and affix "UNDER CLEANING" label on the machine with date and sign of the production officer.

5.1.3.3   Clean the control panel of machine with dry lint free cloth.

	PHARMA DEVILS	
	PRODUCTION DEPARTMENT	

STANDARD OPERATING PROCEDURE		
Department: Production	**SOP No.:**	
Title: Cleaning and Operation of Bulk Counter Machine (Make: Pharma Pack)	**Effective Date:**	
Supersedes: Nil	**Review Date:**	
Issue Date:	**Page No.:**	

5.1.3.4   Clean the control panel of camera inspection system monitor and wiring panel with dry lint free cloth.

5.1.3.5   Remove "EQUIPMENT STATUS" label and affix "UNDER CLEANING" label on the machine with date and sign of the production officer.

5.1.4   **Machine Dismantling Procedure**

5.1.4.1   Remove the dust collector pipe and S.S. guard of machine of front, center, sides and back.

5.1.4.2   Switch 'OFF' the vibratory lock in PLC to release the vibratory plates In-feeding system.

5.1.4.3   Remove hopper, three-level vibratory Plates In feeding System.

5.1.4.4   Switch 'OFF' all the utility supply to machine.

5.1.4.5   Remove the individual product rejection assembly from machine.

5.1.4.6   Remove the pneumatic connection from the memory flap cylinder assembly.

5.1.4.7   Remove the channel divide above the sensor head.

5.1.4.8   Remove the air purging nozzle assembly of individual rejection of product by loosing the clump.

5.1.4.9   Remove the sensor port from the sensor assembly & small sensor port from memory flap cylinder unit.

5.1.4.10   Remove the sensor head carefully above the cover of memory flap cylinder unit.

5.1.4.11   Remove the safety cover of memory flap cylinder unit.

5.1.4.12   Remove the memory flap cylinder unit from the memory flap support.

5.1.4.13   Remove the memory flap support plate, S.S funnel from main gate cylinder.

5.1.4.14   Remove the product feeding nozzle from the locking system.

5.1.4.15   Remove the S.S. base plate of bulk counter machine in which hopper, vacuum suction pipe, three-level vibratory plates In-feeding system attached.

5.1.4.16   Transfer the S.S. guards of machine of center, sides and back, hopper, three-level vibratory plates In-feeding system, memory flap support plate, SS funnel, feeding nozzle, dust collector pipe, individual product rejection assembly, S.S. base plate of vacuum suction pipe to washing area in virgin poly bag for cleaning.

5.1.4.17   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.

5.1.4.18   **NOTE:** 2% Sodium Lauryl Sulphate solution shall be used for scrubbing with nylon brush if API is Efavirenz before final rinsing of equipment/parts.

5.1.4.19   Rinse all the change parts with 40-50 litters of purified water.

5.1.4.20   Clean the parts by mopping with dry lint free cloth.

5.1.4.21   Wipe the all parts with 70% v/v IPA solution followed by mopping with dry lint free cloth.

	PHARMA DEVILS	
	PRODUCTION DEPARTMENT	

STANDARD OPERATING PROCEDURE

Department: Production	**SOP No.:**
Title: Cleaning and Operation of Bulk Counter Machine (Make: Pharma Pack)	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

5.1.4.22   Transfer all the parts from washing area to cubicle area in fresh virgin poly bag.

5.1.4.23   Clean the control panels with dry lint free cloth.

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

5.1.4.25   Clean the machine guards with dry lint free cloth.

5.1.4.26   Assemble all the dismantled parts by following 5.2.1 to 5.2.20.

5.1.4.27   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.

5.1.4.28   Replace the ''TO BE CLEAN" status label by "CLEANED" status label on the machine with date and sign of the production officer.

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

5.1.4.30   Record the cleaning activity in equipment usage log as per SOP, "Making entries in equipment usage and cleaning log sheet".

5.1.4.31   Clean the surrounding area as per SOP, "Cleaning of production area".

5.2   **Machine Operation**

5.2.1   Insert the MMI key and 'ON' the MMI.

5.2.2   System shows four type of user login level and has specific rights assignment. Following table given according to 'USER RIGHT'

S.No.	Function	Rights assignment			
		Operator (Level-I)	Foreman (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

5.2.3   Enter password for different levels.

5.2.4   Level 1 is for operation of the same product.

5.2.5   Start the machine by pressing Green Button on console panel of MMI.

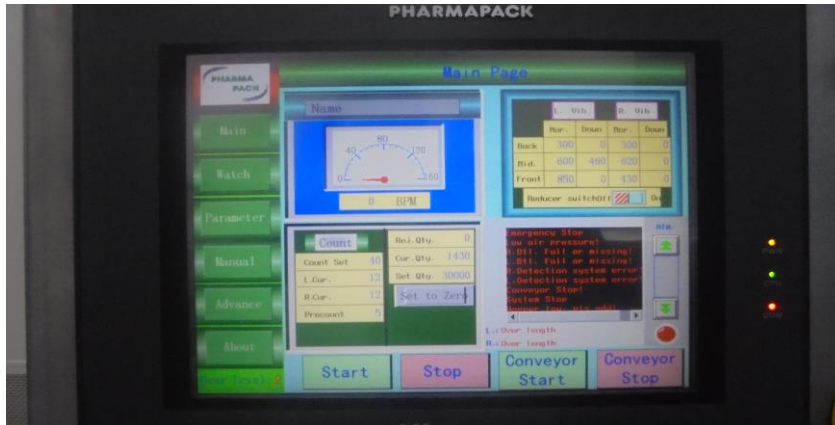5.2.6   Start the conveyor belt by pressing conveyor start and then press start for staring the machine

STANDARD OPERATING PROCEDURE		
Department: Production	**SOP No.:**	
Title: Cleaning and Operation of Bulk Counter Machine (Make: Pharma Pack)	**Effective Date:**	
Supersedes: Nil	**Review Date:**	
Issue Date:	**Page No.:**	

5.3   **For New product setting**

5.3.1   Enter password for level 3

5.3.2   Main screen open.

5.3.3   Start conveyor belt by pressing conveyor start.

5.3.4   Press Manual button on main screen.

5.3.5   ON any one-vibrator left hand or righthand side.

5.3.6   Go to main screen by pressing Main button on the MMI.

5.3.7   Set counting quantity as per pack size, i.e. tablets quantity for each bottle, by small numeric keyboard.

5.3.8   Start the machine by pressing start.

	PHARMA DEVILS	
	PRODUCTION DEPARTMENT	

STANDARD OPERATING PROCEDURE		
Department: Production		**SOP No.:**
Title: Cleaning and Operation of Bulk Counter Machine (Make: Pharma Pack)		**Effective Date:**
Supersedes: Nil		**Review Date:**
Issue Date:		**Page No.:**

5.3.9　　Press watch button and observe Maximum Length and Minimum Length for 3 to 4 bottles of the selected side vibrator.

5.3.10　　Add 1 to 3 values to the Maximum Length and subtract 1 to 3 values from the Minimum Length of respective head enter in respective production.

5.3.11　　Press parameter button on main screen.

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

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

5.3.14　　Enter Delay parameter.

5.3.15　　Enter Filling delay----This parameter stands for time interval (millisecond) for tablet falling from tablet gate to bottle. It is input by small numeric keyboard.

5.3.16　　Enter Lock Bottle Delay Time ------. This parameter stands for time interval from the moment when cylinder discharges one bottle to the moment when cylinder clamps the next one. It is input by small numeric keyboard.

5.3.17　　Enter No bottle delay----This parameter stands for time interval (millisecond) from the moment when sensor detects fallen bottle to the moment when filling tablets stops. It is input by small numeric keyboard.

5.3.18　　Enter Conveyor Speed----It is input by small numeric keyboard.

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

5.3.20　　Enter Rejection parameter.

5.3.21　　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.

5.3.22　　Enter Reject Switch ---- Select switch for using rejection function or not. This value can be input by small keyboard.

	PHARMA DEVILS	
	PRODUCTION DEPARTMENT	

STANDARD OPERATING PROCEDURE

Department: Production	**SOP No.:**
Title: Cleaning and Operation of Bulk Counter Machine (Make: Pharma Pack)	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

5.3.23   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).

5.3.24   Minimum Gate Closing Tablet Interval ---- It stands for distance between tablets when tablets gate closes. The value is larger; the filling is more accurate, while the rejection rate will be larger (10 to 20).

5.3.25   Adjust the vibration of vibrating plates on main screen.

5.3.26   Save the file in Product management by product name.

5.3.27   Run the machine by calling product file by follow step No.5.3.3.

6.0   ABBREVIATION (S):

6.1   SOP - Standard Operating Procedure

6.2   MMI – Man Machine Interface

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   REFERENCE (S):

7.1   SOP: Making entries in Equipment Usage and Cleaning Log Sheet.

7.2   SOP: Cleaning of Production Area

8.0   ANNEXURE (S):

Annexure No.	Title of Annexure	Format No.	Mode of execution
Annexure - I	Cleaning check list of bulk counter machine.		Log book

9.0   DISTRIBUTION:

9.1   **Master Copy   :** Quality Assurance

9.2   **Controlled Copy (S) :** Production department (02), Quality Assurance (01)

9.3   **Reference Copy (S) :** Production department (02)

STANDARD OPERATING PROCEDURE

Department: Production	**SOP No.:**
Title: Cleaning and Operation of Bulk Counter Machine (Make: Pharma Pack)	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

10.0   REVISION HISTORY:

S. No.	Version No.	Change Control No.	Reason (s) For Revision	Details Of Revision	Effective Date
1.	00		New SOP	NA	

STANDARD OPERATING PROCEDURE

Department: Production	**SOP No.:**
Title: Cleaning and Operation of Bulk Counter Machine (Make: Pharma Pack)	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE I

**CLEANING CHECKLIST OF BULK COUNTER MACHINE
(MAKE: PHARMA PACK PP-12)**

Name of the Equipment		Bulk Counter Machine (**MAKE:** PHARMA PACK PP-12)	
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 plate 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 SS 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	

STANDARD OPERATING PROCEDURE

Department: Production		**SOP No.:**
Title: Cleaning and Operation of Bulk Counter Machine (Make: Pharma Pack)		**Effective Date:**
Supersedes: Nil		**Review Date:**
Issue Date:		**Page No.:**

S. No.	Activity	Activity Performed
	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. **NOTE:** 2% Sodium Lauryl Sulphate solution shall be used for scrubbing with nylon brush if API is Efavirenz before final rinsing of equipment/parts.	
17.	Rinse all the change parts with 40-50 litters purified.	
18.	Clean the parts by mopping with dry lint free cloth.	
19.	Wipe the all parts with 70% v/v IPA solution followed by mopping with dry lint free cloth.	
20.	Transfer all the parts from washing area to cubicle area in fresh virgin poly bag.	
21.	Clean the machine surface and product deposit area by dust collector pipe followed by dry lint free cloth.	
22.	Replace the "TO BE CLEANED" status label by "CLEANED" status label on the machine with date and sign of the production officer.	
23.	Record the cleaning activity in equipment usage log as per SOP.	
24.	Clean the surrounding area as per SOP.	

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

Checked By (Prod.)   **Verified By (QA)**
Sign/date   Sign/date