STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Cleaning and Operation of Tablet and Capsule Inspection Belt	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Vernacular SOP: No

1.0 OBJECTIVE:

To lay down a procedure for operation and cleaning of tablet and capsule inspection belt.

2.0 SCOPE:

This procedure is applicable to operation of tablet and capsule inspection belt in production department.

3.0 RESPONSIBILITY:

Technical Associate : Operation
Officer/ Executive Production : Supervision
Head Production : SOP Compliance
IPQA : Line Clearance

4.0 DEFINITION (S):

NA

5.0 PROCEDURE:

5.1 "TYPE A" CLEANING:

Change over from one batch to next batch of the same product, same potency and are of similar product.

5.1.1 Affix dully filled "TO BE CLEANED" status label on equipment with date and signature of the Production Officer as per SOP (Status labeling).

5.1.2 Turn off the power supply to the machine.

5.1.3 Remove the tablets/capsules from the rejection box. Dedust the machine with clean lint free cloth.

5.1.4 Clean the area as per SOP (Cleaning of production area).

5.1.5 Remove the "TO BE CLEANED" label and affix "CLEANED" label to the machine as per SOP (Status labeling).

5.1.6 Cleaning (Dedusting of machine with dry lint free cloth) is applicable in case of at the end of working day.

5.1.7 Record the cleaning observations in the equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet). After completion of cleaning process, get it checked by production officer.

5.2 "TYPE B" CLEANING:

This is a cleaning procedure for Changeover of product with different actives/color/ ascending potency/descending potency of products or after maintenance of contact parts.

5.2.1 Follow the step no. 5.1.1 to 5.1.3

5.2.2 Dismantle the hopper, dust collection box, rejection collection box, Dust/ Tablet Collection tray, Hopper View glass, lid, Tablet/Capsule guide brush and rubber rollers.

5.2.3 Put all the dismantled parts on the SS pallets or trays and affix dully filled "TO BE CLEANED" status label on all the dismantled parts and send them to the washing area.

5.2.4 Wash the hopper and rejection collection box, dust collection box and Dust/Tablet Collection tray with 40-60 liters of purified water and scrub with nylon brush to remove any adhered material on the surface.

5.2.5 Clean the rubber rollers with wet lint free duster dipped in purified water. Ensure no any remnants of previous product presence.

5.2.6 Wash the Hopper View glass, lid, and Tablet/Capsule guide brush with 5 – 10 liters of purified water and scrub with nylon brush to remove any adhered material on the surface.

5.2.7 Clean the cleaned parts with 2% sodium lauryl sulfate before final rinsing of equipment/parts in case of previous product API is Efavirenz. (For 1 liter 2% Sodium Lauryl Sulphate, take 20 g Sodium Lauryl Sulphate and dissolve in 1 liter of purified water)

5.2.8 Rinse the hopper, dust collection box, rejection collection box, Dust/Tablet Collection tray, Hopper View glass, lid, and Tablet/Capsule guide brush and rubber rollers with 10-20 liters of Purified water.

5.2.9 Dry all the above parts with compressed air.

5.2.10 Clean the Mirror, acrylic guards and gasket with the wet lint free cloth.

5.2.11 Visually check all the above cleaned parts for its cleanliness and any damage.

5.2.12 Covered all dismantle cleaned parts with fresh poly bag and bring in the designated area or cleaned area.

5.2.13 Wipe the machine and all parts with 70 % v/v IPA solution.

5.2.14 Clean the area as per SOP (Cleaning of production area).

5.2.15 Remove the "TO BE CLEANED" label and affix "CLEANED" label to the machine as per SOP (Status labeling).

5.2.16 Record the cleaning observations in Equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).

5.2.17 The cleaned equipment is idle for 72 hours, after this period Wipe all the parts of equipment with 70% v/v IPA solution before use. And should be a counter sign on previous "CLEANED" label by production & QA officer with date as per SOP (Status labeling).

5.3 Operation

5.3.1 Ensure the cleanliness of equipment and area.

5.3.2 After line clearance from QA, put the ''UNDER PROCESS'' label duly filled and signed on the machine and record the observations on the equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).

5.3.3 Turn 'ON' the main switch from the panel board.

5.3.4 Load the tablets/capsules into the hopper with the help of L & P device and switch on the machine.

5.3.5 Adjust the vibration of the hopper to the optimum level so that the tablets/capsules passes freely from the hopper and to avoid the over flow of the tablets/capsules.

5.3.7 Check out for the defective tablets like broken, capping, chipping, oil or black spots, sticking, mottling, orange peel appearance etc.

5.3.8 Check out for the defective capsules like unlocked, telescopic, dented appearance etc.

5.3.9 Stop the belt by using leg brakes and remove the defective tablets/capsules and collect it into the SS trays provided with recovery label.

5.3.10 After inspection, check the weight of defective and correct tablets/capsules.

5.3.11 Record the observations in the equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).

5.3.12 Switch 'OFF' the main power supply from electric panel.

5.3.13 Affix duly filled and signed "TO BE CLEANED" label on the machine as per SOP (Status labeling).

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5.4 Precaution:

5.4.1 Ensure that the checker/inspector should be changed at every four hours during tablet/capsule inspection.

5.4.2 Ensure the rotation of belt in forward direction.

5.4.3 Ensure the proper rolling of tablet/capsule on the belt.

5.4.4 Check the integrity of inspection roller before and after use.

6.0 ABBREVIATION(S):

6.1 BMR : Batch Manufacturing Record

6.2 IPC : In-process Container

6.3 QA : Quality Assurance

6.4 SS : Stainless Steel

6.5 v/v : Volume/Volume

6.6 L & P : Lifting And Positioning Device

7.0 RERERENCE (S):

7.1 SOP: Making entries in equipment usage and cleaning log sheet.

7.2 SOP: Cleaning of Production area.

7.3 SOP: Status Labeling

8.0 ANNEXURE (s):

Annexure No.	Title of Annexure	Format No.	Mood of Execution
Annexure I	Cleaning Checklist of Tablet/ Capsule Inspection Belt		Checklist

9.0 DISTRIBUTION:

9.1 **Master Copy :** Quality Assurance

9.2 **Controlled Copy (S):** Production Department, Quality Assurance

9.3 **Reference Copy (S) :** Production Department

10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason (S) for Revision	Details of Revision	Effective Date
1.	00	NA	New SOP	NA	NA

PHARMA DEVILS

PRODUCTION DEPARTMENT

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ANNEXURE I
CLEANING CHECKLIST OF TABLET/CAPSULE INSPECTION BELT

Name of the Equipment		**Tablet/Capsule Inspection Belt**	
Equipment ID No.:		**Previous Product**	
Batch No.:		**Date**	

S.No.	Activity	Activity performed
1.	Turn off the power supply to the machine.	
2.	Remove the Tablets/Capsules from the rejection box. Dedust the machine with clean lint free cloth.	
3.	Dismantle the hopper, dust collection box, rejection collection box, Dust/ Tablet Collection tray, Hopper View glass, lid, Tablet/Capsule guide brush and rubber rollers.	
4.	Put all the dismantled parts on the SS pallets or trays and affix dully filled “TO BE CLEANED” status label on all the dismantled parts and send them to the washing area.	
5.	Wash the hopper and rejection collection box, dust collection box and Dust/ Tablet Collection tray with 40-60 liters of purified water and scrub with nylon brush to remove any adhered material on the surface.	
6.	Clean the rubber rollers with wet lint free duster dipped in purified water. Ensure no any remnants of previous product presence.	
7.	Wash the Hopper View glass, lid, Tablet/Capsule guide brush with 5-10 liters of purified water and scrub with nylon brush to remove any adhered material on the surface.	
8.	Clean the cleaned parts with 2% Sodium Lauryl Sulfate before final rinsing of equipment/parts in case of previous product API is Efavirenz. (For 1 liter 2% Sodium Lauryl Sulphate, take 20 g Sodium Lauryl Sulphate and dissolve in 1 liter of Purified water)	
9.	Rinse the hopper, dust collection box, rejection collection box, Dust/Tablet Collection tray, Hopper View glass, lid, Tablet/Capsule guide brush and rubber rollers with 10-20 liters of Purified water.	
10.	Dry all the above parts with Compressed air.	
11.	Clean the Mirror, acrylic guards and gasket with the wet lint free cloth.	
12.	Visually check all the above cleaned parts for its cleanliness and any damage.	
13.	Covered all dismantle cleaned parts with fresh poly bag and bring in the designated area or cleaned area.	
14.	Wipe the machine and all parts with 70 % v/v IPA solution.	

Checked By (Prod.)
Sign/Date

Verified By (QA)
Sign/Date

Note: Put ‘√’ mark if activity is performed and put ‘X’ if activity is not performed.