



**STANDARD OPERATING PROCEDURE**

<b>Department:</b> Production (Softgel)	<b>SOP No.:</b>
<b>Title:</b> Cleaning of Utensils and Accessories	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

**1.0 OBJECTIVE:**

To lay down the procedure for Operation and Cleaning of Fluidizer Tumbler Dryer.

**2.0 SCOPE:**

This procedure is applicable for the Operation and Cleaning of Fluidizer Tumbler Dryer in Softgel Department.

**3.0 RESPONSIBILITY:**

Technician/ Officer/ Executive/ Manager.

Head of Department: To ensure execution & compliance.

Head QA: To ensure the compliance.

**4.0 PROCEDURE:**

**4.1 Operation**

4.1.1 Ensure cleanliness of the equipment and area.

4.1.2 Ensure that environmental conditions are within the limit as given in the BMR.

4.1.3 Ensure that all the doors are closed and no chance of cross-contamination.

4.1.4 Ensure BMR is available and all the entry is completed properly till this stage.

4.1.5 Ensure that "CLEANED" label affix on the Fluidizer Tumbler Dryer.

4.1.6 Update the "AREA STATUS BOARD" with duly filled and signature of production officer.

4.1.7 Take line clearance from QA personnel as per SOP.

4.1.8 Remove "CLEANED" label from the Fluidizer Tumbler Dryer and affix the "STATUS LABEL" with duly filled and signature of production officer.

4.1.9 Enter the operation start time in equipment usage log book as per SOP.

4.1.10 Attach the Fluidizer Tumbler Dryer with Encapsulation Machine in such a way that the capsules comes out from the Encapsulation Machine are feed into the inlet of the Fluidizer Tumbler Dryer.



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4.1.11 The Fluidizer Tumbler Dryer is controlled by a control panel which has a PLC to control the working of the Fluidizer Tumbler Dryer baskets. The six baskets provided rotate in clockwise and anticlockwise direction. The optimum working capacity of each basket is 10 Kg capsules.

4.1.12 At the base of the each rotating baskets of the Fluidizer Tumbler Dryer blower is attached for cooling.

4.1.13 Set the timing for the rotation of each basket to forward and backward direction.

4.1.14 Adjust the timers for both baskets such a way that total drum rotation time as per requirement.

4.1.15 Switch 'ON' the main supply on the panel.

4.1.16 Switch 'ON' the Fluidizer Tumbler Dryer.

4.1.17 Turn first black knob in "Auto" position for both basket.

4.1.18 Timer setting display will be in the form of XXX.Y for first basket & XX.YY for second basket.

$$\text{Total time} = (\text{XXX}+\text{Y}) + (\text{XX}+\text{YY}) \text{ minutes}$$

4.1.19 Automatic operation will take care of separation and removal of excess lubrication and good shape attained of capsules.

4.1.20 Collect the separated capsules in a clean SS container transfer the capsules into Degreasing Pan for polishing and oil removing.

4.1.21 Switch "OFF" the Fluidizer Tumbler Dryer after batch completion.

4.1.22 Enter the operation complete time in equipment usage log book as per SOP.

4.1.23 Remove "STATUS LABEL" and affix the "TO BE CLEANED" label on the equipment with duly filled and signature of production officer.

4.1.24 Update the "AREA STATUS BOARD" with duly filled and signature of production officer.

#### **4.2 DISMANTEL OF TUMBLER DRYER**

4.2.1 Switch "OFF" the mains before starting any maintenance operation.

4.2.2 Remove the inlet chute and outlet chute.

4.2.3 Remove both acrylic covers.



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4.2.4 Remove the baskets and place them on work bench.

4.2.5 Cladding is removed by unbolting it.

**4.3.1 Cleaning procedure Type A**

**Change over from one batch to next batch of the same product and potency and of similar product with ascending potency.**

4.3.1.1 Remove “TO BE CLEANED” label and affix “UNDER CLEANING” label to the machine with date and signature of the production officer as per SOP.

4.3.1.2 Enter the cleaning start time in equipment usage log book as per SOP.

4.3.1.3 Operating panel shall be covered with polythene bag.

4.3.1.4 Take out the Acrylic cover from the top of the Fluidizer Tumbler Dryer.

4.3.1.5 Lift up and take out the cylindrical perforated basket, which are freely mounted on the gear.

4.3.1.6 Remove all capsules from the perforated basket of Fluidizer Tumbler Dryer.

4.3.1.7 Wipe out the outer surface, inner surface and oil collecting tray of tumbler dryer with clean dry lint free cloth.

4.3.1.8 Soak clean lint free cloth in 70% v/v IPA and wipe out the outer, inner surface and oil collecting tray of the Fluidizer Tumbler Dryer.

4.3.1.9 Clean the Acrylic cover with clean dry lint free cloth followed by 70% v/v IPA solution.

4.3.1.10 Clean the area as per SOP.

4.3.1.11 Replace the “UNDER CLEANING” status label with “CLEANED” status label with date and signature of the Production Officer.

4.3.1.12 Record the cleaning complete time in equipment usage log book as per SOP.

**4.3.2 Cleaning procedure Type B**

**This is a cleaning procedure for Changeover of product with different active/colour/descending potency or after maintenance of contact parts.**

4.3.2.1 Replace the “TO BE CLEANED” status label with “UNDER CLEANING” status label with date and signature of the Production officer and enter cleaning time in log book.

4.3.2.2 Enter the cleaning start time in equipment usage log book as per SOP.

4.3.2.3 Operating panel shall be covered with polythene bag.



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- 4.3.2.4 Take out the acrylic cover from the top of the Fluidizer Tumbler Dryer.
- 4.3.2.5 Lift up and take out the cylindrical perforated basket, which are freely mounted on the gear.
- 4.3.2.6 Remove the capsules and slugs from the perforated baskets.
- 4.3.2.7 Keep the perforated basket, capsule inlet/outlet chutes, oil collecting tray and capsule collecting box on the trolley and transfer to the washing area.
- 4.3.2.8 Clean the all equipment with purified water to clean oil and medicament.
- 4.3.2.9 Use 1.0 % v/v Teepol solution and scrubber for proper cleaning of equipment. Rinse with purified water to remove the traces of Teepol solution.
- 4.3.2.10 Dry the perforated basket, capsule inlet/outlet chutes, oil collecting tray and capsule collecting box by compressed air.
- 4.3.2.11 Then clean with dry lint free cloth followed by 70% v/v IPA solution.
- 4.3.2.12 Clean the outer and inner body of Fluidizer Tumbler Dryer, acrylic cover by dry clean lint free cloth followed by 70% v/v IPA.
- 4.3.2.13 Assemble the cylindrical perforated drum in the Fluidizer Tumbler Dryer.
- 4.3.2.14 Put an acrylic covers on the top of cylindrical perforated drum and assemble inlet/outlet chute of capsule.
- 4.3.2.15 Clean the area as per SOP.
- 4.3.2.16 Replace the “UNDER CLEANING” status label with “CLEANED” status label with date and signature of the production officer.
- 4.3.2.17 Record the cleaning complete time in equipment usage log book as per SOP.

**5.0 ANNEXURE (S) :**

Nil

**6.0 REFERENCE (S):**

SOP: Procedure of filling of equipment log book.

SOP: Procedure for Area Line clearance.

SOP: Preparation, approval, distribution control, revision and destruction of standard operating procedure.



# PHARMA DEVILS

PRODUCTION DEPARTMENT

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SOP: Cleaning and Sanitization of Production department.

SOP: Status Labeling in Production department,

### 7.0 ABBREVIATION (S) / DEFINITION (S):

BMR	: Batch Manufacturing Record
SOP	: Standard Operating Procedure
SS	: Stainless Steel
IPA	: Iso Propyl Alcohol
v/v	: Volume/Volume
ml	: Milliliter
QA	: Quality Assurance
NA	: Not Applicable
PLC	: Programmable Logic Controller

### REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	---	---	New SOP	---