



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Octagonal Blender 3000 Ltrs.	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 Octagonal Blender 3000 liters.

2.0 SCOPE:

2.1 This procedure is applicable to cleaning and operation of octagonal blender 3000 liters located in manufacturing area.

3.0 RESPONSIBILITY:

- 3.1 Technical Associate : Cleaning and Operation of Blender
3.2 Production Officer / Executive : Checking Cleaning and Operation of Blender
3.3 IPQA Person : Line clearance
3.4 Head Production/ IPQA : SOP Training and 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 same potency and of similar product with ascending potency.**

5.1.1 Remove “EQUIPMENT STATUS” label and affix dully-filled “UNDER CLEANING” label to the machine.

5.1.2 Enter the cleaning start time in equipment usage and cleaning log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).

5.1.3 Ensure that power supply is turned “OFF”.

5.1.4 De-dust the outer body of equipment with lint free dry cloth.

5.1.5 De-dusting the powder from platform and surroundings using vacuum cleaner.

5.1.6 Remove the remnants of the previous batch from the equipment and the area with vacuum cleaner as per SOP Cleaning and operation of vacuum cleaner.

5.1.7 Ensure that there is no remnant of previous batch in product transfer pipes.

5.1.8 Reassemble the lid assembly.

5.1.9 Affix duly filled status label on octagonal blender 3000 liters.



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5.1.10 Record the cleaning completion time in equipment usage and cleaning log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).

5.2 **“TYPE B” CLEANING: This is a cleaning procedure for Changeover of product with different actives/ color/ descending potency or after maintenance of contact parts.**

5.2.1 Follow the procedure from step 5.1.1 to 5.1.6

5.2.2 Dismantle the product transfer pipes from the blender.

5.2.3 Fix the water spray valves on the top of octagonal blender and start the high pressure jet cleaner machine (As per SOP) using 150-200 liters of purified water.

5.2.4 Clean product transfer pipe with 50-60 liters of purified water using nylon brush.

5.2.5 Wash inside, and outside of blender with a nylon scrubber using 50-60 liters of purified water. Clean the platform with purified water by using high pressure jet cleaner.

5.2.6 Wash the pneumatic butterfly valve and with a nylon scrubber using 5-10 liters of purified water.

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 Finally rinse all parts of octagonal blender with 100-120 liters of purified water.

5.2.9 Wash the PCS as per SOP (Cleaning and operation of pneumatic conveying system).

5.2.10 Dry all parts, outer surface and inner surface of octagonal blender with compressed air.

5.2.11 Ensure that all parts should be completely dry.

5.2.12 Wipe out the control panel with dry lint free cloth.

5.2.13 Assemble the product transfer pipes and lid to octagonal blender 3000 liters

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

5.2.15 Record the cleaning completion time in equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).

5.2.16 Record the cleaning activity in Annexure-I (Cleaning checklist for Octagonal Blender 3000 Liters).

5.3 **Frequency:**

5.3.1 Type ‘A’ cleaning is applicable after completion of every batch of same product, same potency and of similar product with ascending potency. If same product is processed for more than seven days then follow the procedure of type – B cleaning as per SOP (Cleaning Verification).



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5.3.2 Type 'B' cleaning is applicable in case of changeover of product with different actives / color / descending potency or after maintenance of contact parts or same product is run for more than seven days cleaning Type -B done after completion of batch as per SOP (Cleaning verification).

NOTE: After Type - B cleaning, if machine is not used within 72 hours, clean the outer surface of octagonal blender "before use", with the lint free duster dipped in 70% v/v IPA solution followed by dry lint free duster and dully sign the "CLEANED" label again. Record the activity in equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).

5.4 **OPERATION:**

5.4.1 **Machine setting:**

5.4.2 Ensure 'CLEANED' label duly filled and signed is affixed on the equipment.

5.4.3 Ensure cleanliness of area and the equipment. Record the observations in the equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).

5.4.4 Affix 'UNDER PROCESS' label duly filled and signed on the equipment.

5.4.5 Ensure that the pneumatic butterfly valve is closed and product pipes are attached with PCS.

5.4.6 Ensure that the safety guard is in place.

5.4.7 Switch ON the power supply of the blender.

5.4.8 Ensure the Compressed air pressure should be NLT 5 kg/cm².

5.4.9 Set the PCS time on control panel with the help of up and down keys.

5.4.10 Turn the CHG MODE knob to PCS.

5.4.11 Enter the process start time in the Equipment Log Book as per SOP (Making entries in equipment usage and cleaning log sheet).

5.4.12 Put the product pipe in the IPC (containing sifted/resized/dried material) and start the PCS as per SOP (Cleaning and operation of pneumatic conveying system).

5.4.13 Load the batch material in the Octagonal Blender with PCS by turning the PCS switch clockwise. Load the complete lot/batch material into the blender.

5.4.14 Switch off the PCS by turning the PCS switch anti-clock wise. Remove the product pipes from blender and PCS.

5.4.15 Turn the CHG MODE knob to BLD.

5.4.16 Enter the blending time and blender RPM in HMI as per the respective batch manufacturing records using up and down keys.

5.4.17 Turn the BLENDER knob to RUN to start the blending.



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5.4.18 After completion of blending, place the IPC or blender 600/1200 liters beneath the discharge butterfly valve of the blender by turning the BF VALVE to OPEN.

5.4.19 Unload the batch/lot material in IPC or blender 600/1200 liters.

5.4.20 Ensure complete discharge of batch material to IPC or blender 600/1200 liters.

5.4.21 Enter the process stop time in the Equipment Log Book as per SOP (Making entries in equipment usage and cleaning log sheet).

6.0 ABBREVIATION (S):

6.1 IPA : ISO-Propyl Alcohol

6.2 PCS : Pneumatic Conveying System

6.3 HMI : Human Machine Interface.

7.0 REFERENCE (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.

7.4 SOP: Cleaning and operation of high pressure jet cleaner.

7.5 SOP: Cleaning and operation of pneumatic conveying system.

7.6 SOP: Cleaning Verification.

8.0 ANNEXURE (S):

Annexure no.	Title of Annexure	Format no.	Mode of Execution
Annexure I	Cleaning Checklist of Octagonal Blender 3000 Liters.		Logbook

9.0 DISTRIBUTION:

9.1 **Master Copy** : Quality Assurance

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

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

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	



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ANNEXURE I

CLEANING CHECKLIST OF OCTAGONAL BLENDER 3000 LITERS

Name of the Equipment		OCTAGONAL BLENDER 3000 LITERS	
Equipment ID No.		Previous product	
Batch No.		Date	

S.No.	Activity	Activity performed
1	Wash inside of blender with water spray valves using 150-200 liters of purified water.	
2	Clean product transfer pipe with 50-60 liters of purified water using nylon brush	
3	Wash the lower butterfly valve and upper frame with a nylon scrubber using 5-10 liters of purified water.	
4	Finally rinse all parts of octagonal blender with 100-120 litres of purified water	
5	Dry all parts, outer surface and inner surface of octagonal blender with compressed air.	
6	Ensure that all parts should be completely dry.	
7	Wipe out the control panel with dry lint free cloth.	
8	Assemble the product transfer pipes, butterfly valve and upper assembly to octagonal blender 3000 liters	

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

Checked By (Prod.)
Sign/Date

Verified By (QA)
Sign/Date