



STANDARD OPERATING PROCEDURE

Department: Production (External Preparation)	SOP No.:
Title: Operation and Cleaning of Roto Cube Blender - 500 Liters	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for Operation and Cleaning of Roto Cube Blender – 500 liters.

2.0 SCOPE:

This SOP is applicable for Operation and Cleaning of Roto Cube Blender – 500 liters installed in Ointment Section.

3.0 RESPONSIBILITY:

Officer / Executive - Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

BMR	Batch Manufacturing Record
QC	Quality Control
QA	Quality Assurance
RPM	Rotation Per Minute
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 OPERATION:

- 6.1.1 Ensure that the Roto cube Blender and surrounding area is clean. Take line clearance from QA as per “Line Clearance” SOP.
- 6.1.2 Affix Status label on the Roto cube Blender.
- 6.1.3 Bring the Roto cube Blender in up-right position.
- 6.1.4 Close the material outlet valve tightly.
- 6.1.5 Open the material inlet of the Roto Cube Blender and charge the materials.
- 6.1.6 Close the lid tightly.
- 6.1.7 Switch ‘ON’ the mains of Roto Cube Blender and set the timer and RPM as instructed in BMR.
- 6.1.8 Press the push button to start Roto Cube Blender.
- 6.1.9 At the end of the set time, the blender will automatically stop.



STANDARD OPERATING PROCEDURE

Department: Production (External Preparation)	SOP No.:
Title: Operation and Cleaning of Roto Cube Blender - 500 Liters	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

6.1.10 After the blending is over, keep the material inlet valve in upper side and outlet valve of the Roto cube Blender in downward position by Inching Push button.

6.1.11 Disconnect the electrical connection.

6.1.12 Unload the blend material into double polythene lined drum by slowly opening the material outlet valve.

6.1.13 Intimate to QA to collect the sample.

6.1.14 Affix status label "To be Clean" on Roto cube Blender.

6.2 CLEANING:

6.2.1 For Product Changeover (Type-B Cleaning):

6.2.1.1 Remove the remnants of previous batch / product from the surrounding area of the machine.

6.2.1.2 Disconnect the electrical supply to the equipment and clean the external surface of the control panel with clean dry lint free cloth and cover them with polythene bag.

6.2.1.3 De-dust the external parts of the Roto cube Blender with the help of dry lint free cloth.

6.2.1.4 Close the material outlet valve, add quantity of Purified water (as given in Table-1) in the Roto cube Blender as per capacity and close the Inlet valve tightly.

6.2.1.5 Connect the electrical connection, safety guard. Set the timer for 5 minutes, run at suitable RPM and press the start button After 5 minutes drain out.

6.2.1.6 Take 2.0% v/v solution of Extran MA-02 and add to the Roto cube Blender as per capacity, operate the equipment for 5 minutes & drain out the washed solution.

Table - 1

Capacity of Octagonal Blender	500 Ltrs.
Extran MA-02 Solution 2.0% v/v	4-5 Ltrs.
Purified water	350 Ltrs.

6.2.1.7 Again add the purified water in Roto cube Blender and operate for 5 minutes, examine the water visually & drain it.

6.2.1.8 Clean the lid by Purified water.

6.2.1.9 Finally rinse the Roto cube Blender with purified water and examine the rinsed water visually for any turbidity, then clean the outer part by dry lint free cloth.

6.2.1.10 If there is not any turbidity then Officer/Executive Production shall send rinse water intimation slip cum analysis report to Officer/Executive QA to collect rinse sample.



STANDARD OPERATING PROCEDURE

Department: Production (External Preparation)	SOP No.:
Title: Operation and Cleaning of Roto Cube Blender - 500 Liters	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

6.2.1.11 Officer / Executive QA shall collect rinse sample for Analysis.

6.2.1.12 If the rinse water is found turbid then repeat point (6.2.1.9) again and check the rinse sample as usual. Cover the Roto cube Blender with lid.

6.2.1.13 Use the Roto cube Blender after receiving rinse water intimation slip cum analysis report from QC showing pass.

6.2.1.14 If the QC report shows fail then repeat the step (6.2.1.6) to (6.2.1.9).

6.2.1.15 Affix the status label on the equipment.

6.2.2 For Batch Changeover (Type A Cleaning) :

6.2.2.1 Remove the remnants of previous batch / product from the surrounding area of the machine.

6.2.2.2 Clean the Roto cube Blender by moping with dry clean lint free cloth.

6.2.2.3 Check visually for absence of any residue of previous batch or any extraneous matter.

6.2.2.4 Affix the status label on the equipment.

6.2.2.5 Examine Roto cube Blender visually before use.

6.2.2.6 Maintain the Cleaning details in log book.

6.3 FREQUENCY OF CLEANING:

6.3.1 Frequency of Type- B cleaning:

6.3.1.1 Product to Product Changeover.

6.3.1.2 If cleaned equipment is kept idle for more than 05 days.

6.3.1.3 After 5 batch of the same product or 72 hours hold from batch to batch cleaning which is earlier.

6.3.1.4 After any Maintenance of Contact Parts.

6.3.1.5 Changeover of one Batch to Next Batch of the same Product with Descending Potency.

6.3.1.6 In case of colour change (any strength).

6.3.2 Frequency of Type-A cleaning:

6.3.2.1 Changeover from one Batch to Next Batch of the same Product with same Potency.

6.3.2.2 Changeover from one batch to next Batch of the same Product with Higher Potency.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production (External Preparation)	SOP No.:
Title: Operation and Cleaning of Roto Cube Blender - 500 Liters	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

7.0 ANNEXURES:

Not Applicable.

ENCLOSURE: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Production
- Master Copy Quality Assurance

9.0 REFERENCES:

- cGMP

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By