



STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Operation and Cleaning of Roto Cube Mixer

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 Mixer.

2.0 SCOPE:

This SOP is applicable for Operation and Cleaning of Roto Cube Mixer used in Hard Gelatin Capsule & Tablet Sections.

3.0 RESPONSIBILITY:

Officer / Executive Production

4.0 ACCOUNTABILITY

Head Production

5.0 ABBREVIATIONS:

BMR	Batch Manufacturing Record
Ltd.	Limited
Pvt.	Private
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 OPERATION:

- 6.1.1 Ensure that the Roto Cube Mixer 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 Mixer.
- 6.1.3 Bring the Roto Cube Mixer in up-right position (Outlet valve portion is at the bottom) by using the manually by using hand wheel.
- 6.1.4 Close the material outlet valve tightly.
- 6.1.5 Open the material inlet of the Roto Cube Mixer and load the materials.
- 6.1.6 Close the lid tightly and close the safety guard.



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- 6.1.7 Switch 'ON' the mains of Roto Cube Mixer and set the timer as instructed in BMR.
- 6.1.8 Press the push button to start blending.
- 6.1.9 At the end of the set time, the blender will automatically stop.
- 6.1.10 After the blending is over, keep the material outlet valve of the Roto Cube Mixer in downward position by Inching Push button.
- 6.1.11 Switch "OFF" the electric supply and open the safety guard.
- 6.1.12 Unload the blend material into polythene lined drum by slowly opening the material outlet valve.
- 6.1.13 Intimate QA to collect sample of mixed/lubricated granules.
- 6.1.14 Affix a label "To be Cleaned" on Roto Cube Mixer.
- 6.1.15 **Enter the operation details in "Machine Utilization Record" and BMR.**

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 Switch 'OFF' the mains 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 Dedust the external parts of the Roto Cube mixer with the help of dry clean cloth.
- 6.2.1.4 Close the material outlet valve tightly, adds quantity of Potable water (as given in table-1) in the Roto Cube mixer as per capacity and close the Inlet valve tightly.
- 6.2.1.5 Switch 'ON' the mains electric supply, close the safety guard .Set the timer for 5 minutes and press the start button. Drain the washed water.
- 6.2.1.6 Take 2.0% v/v solution of Extran MA-02 (as given in table-1) as per capacity and add to the Roto Cube mixer, operate the equipment for 5 minutes & drain it.

TABLE – 1

TABLE – 1	
Capacity of Roto Cube Mixer	625 Ltrs.
Potable Water	60 Ltrs.
Extran MA-02 Solution 2.0% v/v	25 Ltrs.
Purified water	25 Ltrs.



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6.2.1.7 Add Potable water (quantities defined in table -1) in Roto Cube mixer and operate for 5 minutes, examine the water visually & drain it.

6.2.1.8 Clean the lid & outer surface of Roto Cube mixer with Potable water followed by rinse with purified water.

6.2.1.9 Finally rinse the Roto Cube Mixer with purified water (quantities defined in table -1) and examine the rinsed water visually for any turbidity, then clean the outer part by a wet cloth followed by clean dry lint free cloth.

6.2.1.10 If there is no any turbidity then Officer / Executive Production send rinse water intimation slip cum analysis report to Officer / Executive QA to collect the rinse water.

6.2.1.11 Officer / Executive QA shall collect rinse sample and send to QC 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 Mixer with lid.

6.2.1.13 Use the Roto Cube Mixer after receiving rinse water intimation slip cum analysis report from QC showing negative identification.

6.2.1.14 If the QC report shows positive identification then repeat the step **(6.2.1.6)** to **(6.2.1.11)**.

6.2.1.15 Affix a label as "CLEANED" on the Roto Cube mixer.

6.2.1.16 Enter the cleaning details in "Machine Utilization Record".

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 Mixer by moping with dry clean lint free cloth.

6.2.2.3 Check visually for any extraneous matter.

6.2.2.4 Affix a label as "CLEANED" on the Roto Cube mixer.

6.2.2.5 Examine Roto Cube Mixer visually before use.

6.2.2.6 Enter the cleaning details in "Machine Utilization Record".

6.3 FREQUENCY OF CLEANING:

6.3.1 Frequency of cleaning as per step-6.2.1

(a) Product to Product Changeover.

(b) After 10 batch of the same product.



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- (c) After any Maintenance of Product Contact Parts.
- (d) Changeover of one Batch to Next Batch of the same Product with Descending Potency.

6.3.2 Frequency of cleaning as per step-6.2.2

- (a) Changeover from one Batch to Next Batch of the same Product with same Potency.
- (b) Changeover from one batch to next Batch of the same Product with Higher Potency.

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

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure – I	Cleaning Record of Roto Cube Mixer	

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

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

9.0 REFERENCES:

Operating Manual

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

