



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Triple Roller Mill	Effective Date:
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1.0 OBJECTIVE:

To lay down a Procedure for Operation and Cleaning of Triple Roller Mill.

2.0 SCOPE:

This SOP is applicable to Operation and Cleaning of Triple Roller Mill used in Soft Gelatin Capsule Section.

3.0 RESPONSIBILITY:

Officer / Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

BMR	Batch Manufacturing Record
IPA	Isopropyl Alcohol
LTD.	Limited
PVT.	Private
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
SS	Stainless Steel

6.0 PROCEDURE:

6.1 OPERATION:

- 6.1.1** Ensure that the area and Triple Roller Mill is clean.
- 6.1.2** Take the line clearance from QA as per "Line Clearance" SOP and enter the details in BMR.
- 6.1.3** Affix the status label on Triple Roller Mill.
- 6.1.4** Ensure that the temperature and humidity of area is within limit as specified in BMR.
- 6.1.5** Switch "ON" the Triple Roller Mill and set the distance of between rollers with the help of setting key.
- 6.1.6** Put the SS tray below Triple Roller Mill.
- 6.1.7** Load the medicament (paste) on the Triple Rollers and collect the grinded medicament (Paste) in SS container.
- 6.1.8** Repeat the process again and collect the medicament in SS container through the sieve as per specified in respective BMR.



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6.1.9 After completion of the process, cover the medicament with lid and mark the status label.

6.1.10 Switch “OFF” the Triple Roller Mill.

6.1.11 Enter the operation details in “Machine Utilization Record”.

6.2 CLEANING:

6.2.1 For Product Changeover (Type B Cleaning):

6.2.1.1 Ensure that mains switch is “OFF”.

6.2.1.2 Clean the Triple Roller Mill with potable water followed by 2 % v/v Extran MA-02 solution with the help of nylon brush.

6.2.1.3 Collect the wash water in a container and drain it to the washing area.

6.2.1.4 Take the SS tray of Triple Roller Mill to washing area and wash 2 % v/v Extran MA-02 solution.

6.2.1.5 Wash the Triple Rollers & SS trays with the sufficient quantity of potable water.

6.2.1.6 Finally wash the Triple Rollers & SS trays with the sufficient quantity of purified water.

6.2.1.7 Dry the Triple Roller Mill with dry lint free cloth.

6.2.1.8 Mop the Triple Roller Mill with 70% v/v IPA solution.

6.2.1.9 Officer/Executive QA shall check visually & collect the swab sample with intimation slip cum analysis report and send to QC for analysis.

6.2.1.10 Use the Triple Roller Mill after receiving swab test intimation slip cum analysis report from QC showing negative identification.

6.2.1.11 If the QC report shows positive identification then repeat the above procedure.

6.2.1.12 Affix the label as “Cleaned” on the machine.

6.2.1.13 Maintain the cleaning record in “Machine Utilization Record”.

6.2.2 For Batch Changeover (Type A Cleaning) :

6.2.2.1 Clean the equipment by mopping with dry clean lint free cloth.

6.2.2.2 Affix the status label on the machine.

6.2.2.3 Enter the cleaning details in “Machine Utilization Record”.

6.2.3 Frequency of Cleaning:

6.2.3.1 For B Type Cleaning:



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- (a) Product to Product Changeover.
- (b) After 5 batch of the same product.
- (c) If cleaned equipment is kept idle more than 72 hours.
- (d) If Dirty equipment is kept idle more than 24 hours.
- (e) After any Maintenance of Product Contact Parts.
- (f) Changeover of one Batch to Next Batch of the same Product with Descending Potency.

6.2.3.2 For A Type Cleaning:

- (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.

7.0 ANNEXURES:

Not Applicable

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:

Not Applicable

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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