STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Operation and Cleaning of Three Stage Semi Drier Tumbler	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0   OBJECTIVE:

To lay down a Procedure for Operation and Cleaning of Three Stage Semi Drier Tumbler.

2.0   SCOPE:

This SOP is applicable for Operation and Cleaning of Three Stage Semi Drier Tumbler used in Soft Gelatin Capsule Section.

3.0   RESPONSIBILITY:

Officer / Executive – Production

4.0   ACCOUNTABILITY:

Head – Production

5.0   ABBREVIATIONS:

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

6.0   PROCEDURE:

6.1   OPERATION:

6.1.1   Ensure that the machine & area are cleaned.

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 the machine.

6.1.4   Ensure that the temperature and relative humidity of area is within limit as specified in BMR.

6.1.5   Switch "ON" the machine.

6.1.6   Put the lint free cloths in each basket to removing the oil from the capsule.
6.1.7   Switch "ON" the blower.

6.1.8   Set the basket rotation time for 15 minutes.

6.1.9   Switch "ON" the basket by pressing the knob switch anticlockwise direction to rotate the basket Clockwise direction.

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6.1.10 Switch "ON" the basket by pressing the knob switch clockwise direction to rotate the basket anticlockwise direction.

6.1.11 Continue till the production is over.

6.1.12 Enter the operation details in "Machine Utilization report".

6.2   CLEANING:

6.2.1   For Product Change Over:

6.2.1.1 Check & ensure that the machine switch is "OFF".

6.2.1.2 Dismantle the baskets and transfer to the washing area.

6.2.1.3 Clean the baskets through 2.0% v/v Extran MA-02 solution with the help of nylon   brush.

6.2.1.4 Wash all the baskets with sufficient quantity of potable water.

6.2.1.5 Finally rinse all the baskets with sufficient quantity of purified water.

6.2.1.6 Take the baskets to the encapsulation area.

6.2.1.7 Assemble the baskets.

6.2.1.8 Start the blower and dry the baskets.

6.2.1.9 Affix the label as "Cleaned" on the machine.

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

6.2.2   For Batch Change Over:

6.2.2.1 Clean the machine with dry lint free cloth.

6.2.2.2 Affix the label as "Cleaned" 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 Type-B Cleaning shall be done in following cases:

    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.

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

    g. In case of colour change.

6.2.3.2 Type-A Cleaning shall be done in following cases:

    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:

<div align="center">CHANGE HISTORY LOG</div>

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