STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Operation and Cleaning of Homogenizer Mixer	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0 OBJECTIVE:

To lay down a Procedure for Operation and Cleaning of Homogenizer Mixer.

2.0 SCOPE:

This SOP is applicable to Operation and Cleaning of Homogenizer Mixer used in production department.

3.0 RESPONSIBILITY:

Officer / Executive – Production

4.0 ACCOUNTABILITY:

Head – Production

5.0 ABBREVIATIONS:

BMR	Batch Manufacturing Record
QC	Quality Control
QA	Quality Assurance
SOP	Standard Operating Procedure
Pvt.	Private
Ltd.	Limited
%	Percent
v/v	Volume by Volume

6.0 PROCEDURE:

6.1 OPERATION:

6.1.1 Ensure that the homogenizer mixer is 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 homogenizer mixer.

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

6.1.5 Lift the homogenizer mixer manually.

6.1.6 Take the bulk tank under the homogenizer mixer.

6.1.7 Transfer the materials to the bulk tank as per specified in respective BMR under the stirring.

6.1.8 Continue the mixing as per specified time which given in respective BMR.

6.1.9 After completion of the mixing switch "OFF" the homogenizer mixer.

6.1.10 Enter the operation details in "Machine Utilization Record"

6.2 CLEANING:

6.2.1 For Product Change over (Type B Cleaning):

6.2.1.1 Ensure that the mains switch is "OFF".

6.2.1.2 Wash the homogenizer mixer with potable water and collect the wash water in a container and drain it.

6.2.1.3 Wash the homogenizer mixer using 2 % v/v Extran MA-02 solution with the help of nylon brush and collect the wash water in a container and drain it.

6.2.1.4 Again wash the homogenizer mixer with potable water and drain it.

6.2.1.5 Finally wash the homogenizer mixer with purified water and drain it.

6.2.1.6 Dry the homogenizer mixer using dry lint free cloth.

6.2.1.7 Officer/Executive QA shall collect the swab/Rinse sample with intimation slip cum analysis report and send to QC for analysis.

6.2.1.8 Use the homogenizer mixer after receiving swab/Rinse test intimation cum analysis report from QC showing negative identification.

6.2.1.9 If the report shows positive identification then repeat the above procedure.

6.2.1.10 Affix a label as "Cleaned".

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

6.2.2 For Batch Change over (Type A Cleaning):

6.2.2.1 Clean the homogenizer mixer with Purified water.

6.2.2.2 Finally dry the homogenizer with lint free cloth.

6.2.2.3 Affix a label as "Cleaned".

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

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6.2.3 Frequency of Cleaning:

6.2.3.1 Type-B Cleaning shall be done in following cases:

6.2.3.1.1 Product to product changeover.

6.2.3.1.2 If cleaned equipment is kept idle for more than 24 hours.

6.2.3.1.3 After 5 batch of the same product in case of soft gel capsule.

6.2.3.1.4 After 3 batch of the same product in case of oral liquid.

6.2.3.1.5 After any Maintenance of product contact parts.

6.2.3.1.6 Changeover of one batch to next batch of the same product with descending potency.

6.2.3.1.7 In case of colour change (any strength).

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

6.2.3.2.1 Changeover from one batch to next batch of the same product with same potency & same color/flavor.

6.2.3.2.2 Changeover from one batch to next batch of the same product with higher potency with same composition.

6.2.3.2.3 If the cleaned equipment is kept idle upto 24 hours or Section Incharge and Officer / Executive QA shall decide as per physical status of the equipment.

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

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10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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