



STANDARD OPERATING PROCEDURE

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| Department: Production | SOP No.: |
| Title: Operation and Cleaning of Inline Homogenizer | Effective Date: |
| Supersedes: Nil | Review Date: |
| Issue Date: | Page No.: |

1.0 OBJECTIVE :

To lay down the procedure for Operation and Cleaning of Inline Homogenizer.

2.0 SCOPE :

This procedure is applicable to Operation and Cleaning of Inline Homogenizer in medicament manufacturing area.

3.0 RESPONSIBILITY:

Technician/Officer /Executive/Manager-Production.

Head of Department: To ensure execution & compliance.

Head QA: To ensure the compliance.

4.0 PROCEDURE:

4.1 Operation

4.1.1 Ensure cleanliness of the equipment and area.

4.1.2 Ensure that environmental conditions are within the limit as given in the BMR.

4.1.3 Ensure that all the doors are closed and no chance of cross-contamination.

4.1.4 Ensure that BMR is available and all the entry is completed properly till this stage.

4.1.5 Ensure that all containers are properly cleaned and labeled. It kept properly on pallets in a proper place.

4.1.6 Ensure that chilled water supply and other utilities are available as per requirement.

4.1.7 Check the proper working of Rotor, Stator, Mechanical seal and operating Panel.

4.1.8 Ensure that "CLEANED" label affix on the Inline Homogenizer.

4.1.9 Update the "AREA STATUS BOARD" duly filled and signature of production officer.

4.1.10 Take line clearance from QA personnel.

4.1.11 Remove "CLEANED" label from the Inline Homogenizer and affix the "STATUS LABEL" with duly filled of signature of production officer.

4.1.12 Switch "ON" the main supply of the Inline Homoginizer.

4.1.13 Before starting the machine, check the rotor shaft can rotate freely by hand, check the



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tightness of the nut that hold the stator head in place.

4.1.14 Connect outlet of Medicament Preparation Vessel with inlet of Inline Homogenizer and the outlet of Inline Homogenizer connect with Medicament Preparation Vessel inlet.

4.1.15 Inline Homogenizer suck the medicament and pass in to Rotor and Stator.

4.1.16 Rotor is a dynamic part of Inline Homogenizer unit with slotted veins and mounted on a shaft and maintains a close working clearance inside the chamber with stator. Rotor of Inline Homogenizer mix the medicament inside the chamber.

4.1.17 The rotor is accelerated to the medicament towards the blade periphery and it expelled into the body of the mixer through the stator opening where it undergoing to an intensive mechanical and hydraulic shearing action.

4.1.18 Then the medicament is expelled through the outlet of the Inline Homogenizer to Medicament Preparation Vessel.

4.1.19 The medicament is to be re-circulate through the Inline Homogenizer for a specific time period as per mentioned in BMR.

4.1.20 The Inline Homogenizer is use for proper mixing, homogenizing the medicament, disintegrating of solid and suspending lumps. It also use to transfer the medicament into Medicament Holding Tank.

4.1.21 At the end of process check that no medicament is left inside the Inline Homogenizer and in medicament transfer pipe.

4.1.22 After batch completion close the all opened valve and switch "OFF" the main supply of the Inline Homogenizer.

4.1.23 Enter the process complete time in equipment usage log book as per SOP.

4.1.24 Remove "STATUS LABEL" and affix the "TO BE CLEANED" label on the equipment with duly filled and signature of production officer.

4.2 CLEANING PROCEDURE

4.2.1 Cleaning procedure Type A

Change over from one batch to next batch of the same product and same potency and of similar product with ascending potency.



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- 4.2.1.1 Remove "TO BE CLEANED" label and affix "UNDER CLEANING" label to the machine with date and signature of the production officer as per SOP.
- 4.2.1.2 Enter the cleaning start time in equipment usage log book as per SOP.
- 4.2.1.3 Soak clean lint free mop in 70 % v/v IPA and wipe out the outer surface of the Inline Homoginizer.
- 4.2.1.4 Clean the area as per SOP.
- 4.2.1.5 Replace the "UNDER CLEANING" status label with "CLEANED" status label with date and signature of the Production Officer.

4.2.2 Cleaning procedure Type B

This is a cleaning procedure for Change over of product with different actives/color/descending potency or after maintenance of contact parts.

- 4.2.2.1 Replace the "TO BE CLEANED" status label with "UNDER CLEANING" status label with date and signature of the Production officer and enter cleaning time in log book.
- 4.2.2.2 Enter the cleaning start time in equipment usage log book as per SOP.
- 4.2.2.3 Take 1.0 % v/v Teepol solution and dip all dismantle parts of the Inline Homoginizer into the Teepol solution.
- 4.2.2.4 Properly clean the adhered medicament and oil from all parts of the Inline Homoginizer.
- 4.2.2.5 Then clean with sufficient quantity of Purified Water to remove traces of Teepol solution from all parts.
- 4.2.2.6 Dry the dismantle parts of Inline Homoginizer with compressed air.
- 4.2.2.7 Finally mop with 70% v/v IPA solution and assemble the dismantle parts of Inline Homoginizer.
- 4.2.2.8 Clean the area as per SOP.
- 4.2.2.9 Replace the "UNDER CLEANING" status label with "CLEANED" status label with date and signature of the Production Officer.
- 4.2.2.10 Record the cleaning complete time in equipment usage log book as per SOP.

4.3 Precautions



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4.3.1 Never leave the machine with material overnight or for a long time.

5.0 ANNEXURE (S) :

Nil

6.0 REFERENCE (S):

SOP: Procedure of filling of equipment log book.

SOP: Preparation, approval, distribution control, revision and destruction of standard operating procedure.

7.0 ABBREVIATION (S) / DEFINITION (S):

BMR : Batch Manufacturing Record

SOP : Standard Operating Procedure

IPA : Iso Propyl Alcohol

v/v : Volume/Volume

NA : Not Applicable

REVISION CARD

| S.No. | REVISION No. | REVISION DATE | DETAILS OF REVISION | REASON (S) FOR REVISION | REFERENCE CHANGE CONTROL No. |
|-------|--------------|---------------|---------------------|-------------------------|------------------------------|
| 1 | 00 | --- | --- | New SOP | --- |