



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning & Operation of Homogenizer	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

### 1.0 OBJECTIVE:

- 1.1. To lay down a procedure for Cleaning and operation of homogenizer.

### 2.0 SCOPE:

- 2.1. This procedure is applicable to cleaning and operation of homogenizer.

### 3.0 RESPONSIBILITY:

- 3.1. Technical Associate: Operation of Homogenizer
- 3.2. Officer/ Executive Production: Supervision of cleaning & operation
- 3.3. Head Production: SOP Compliance
- 3.4. IPQA: Line Clearance

### 4.0 DEFINITION (S):

- 4.1. NA

### 5.0 PROCEDURE:

#### 5.1. Cleaning

##### 5.1.1. Batch-to-Batch change over procedure (type A)

- 5.1.1.1. Remove "UNDER PROCESS" label and affix dully-filled "TO BE CLEANED" label to the machine, panel.
- 5.1.1.2. Cleaning procedure for Tablet /Capsule Manufacturing Area.
- 5.1.1.3. Load the 15 liters purified water in the tank.
- 5.1.1.4. Switch on the homogenizer and Run the homogenizer with 15 liters of Purified water for 5 minutes to recirculate the water and drain the water into drain with the help of silicon pipe(if required) and follow the procedure as defined from step No. 5.1.1.6 to 5.1.1.9.
- 5.1.1.5. For Liquid oral manufacturing area -Clean the homogenizer with the cleaning of the manufacturing tank by recirculating the water for 5 minutes whichever the tank is under cleaning (Manufacturing tank 1000, 3000,200 liters).
- 5.1.1.6. Switch off the electric supply and rub the reachable area with clean lint free cloth.
- 5.1.1.7. Wipe the outside of homogenizer with a clean cloth.
- 5.1.1.8. Remove the "TO BE CLEANED" and Label Put "CLEANED" status on the equipment as per reference SOP, "Status labeling".



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<b>Issue Date:</b>	<b>Page No.:</b>

- 5.1.1.9. Record the details of machine cleaning in equipment usage log sheet as per reference SOP, "Making entries in equipment usage and cleaning log sheet".
- 5.1.1.10. Product-to-product change over procedure (type B):
- 5.1.1.11. Switch OFF the electric supply and disconnect the plug.
- 5.1.1.12. Remove "UNDER PROCESS" label and affix dully-filled "TO BE CLEANED" label to the machine, panel.
- 5.1.1.13. Cleaning procedure for Tablet /Capsule Manufacturing Area.
- 5.1.1.14. Dismantle & Clean the SS rod, re-circulation pipe, rotor, Stator and Blades with purified water and scrub inside and outside with nylon scrubber. Clean with 30-40 liters of purified water. Drain the water taken for cleaning and flush the cleaned parts with purified water.
- 5.1.1.15. **For Liquid oral manufacturing area-** Clean the homogenizer with the cleaning of the manufacturing tank by recirculating the water for 5 minutes whichever the tank is under cleaning (Manufacturing tank 1000, 3000,200 liters). Dismantle the SS ordure-circulation pipe, rotor, stator and blades and clean them purified water using nylon scrubber and clean the inside and outside surface of homogenizer with lint free cloth. Follow the procedure as defined from the step No. 5.1.1.9 to 5.1.1.13.
- 5.1.1.16. Wipe the body of the homogenizer with a wet lint free duster followed by dry lint free cloth.
- 5.1.1.17. Reassemble the homogenizer with cleaned parts.
- 5.1.1.18. Connect the plug and switch ON the equipment and rinse the homogenizer again with 15 liters of Purified Water and drain off the water with the help of silicon pipe.
- 5.1.1.19. Wipe the inside and outside of homogenizer with a clean dry lint free cloth.
- 5.1.1.20. Wipe the entire machine with 70% v/v IPA solution.
- 5.1.1.21. Inform QA personnel to collect swab/ rinse sample after step No. 5.1.3.8 (if required).
- 5.1.1.22. Remove the "TO BE CLEANED" and Label Put "CLEANED" status on the equipment as per SOP, "Status labeling".
- 5.1.1.23. Record the details of machine cleaning in equipment usage log sheet as per SOP, "Making entries in equipment usage and cleaning log sheet".
- 5.1.2. **Frequency**
- 5.1.2.1. Type 'A' cleaning is applicable after completion of every batch of same product. If same product is processed for more than a week then follow the procedure of type - B cleaning.



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<b>Issue Date:</b>	<b>Page No.:</b>

5.1.2.2. Type 'B' cleaning is applicable in case of changeover of product with different actives / color / descending potency or equipment is taken for maintenance during processing and maintenance work continues for more than 24 hrs. or maintenance work involves any parts which comes in direct contact with product or same product is run for more than seven days.

**NOTE:** After Type - B cleaning, if machine is not used within 72 hours, clean the machine "before use", with the lint free duster dipped in 70% v/v IPA solution followed by dry lint free duster and dully sign the "CLEANED" label again. Record the activity in equipment usage log sheet as per SOP, "Making entries in equipment usage and cleaning log sheet".

### 5.2. Machine Set up and operation

5.2.1. **Ensure that homogenizer is cleaned and availability of purified water in cooling pot.**

5.2.2. Take line clearance from QA, and then put the 'UNDER PROCESS' label on machine.

5.2.3. Connect the pipe of cooling pot to the port of seal of homogenizer.

5.2.4. Connect the homogenizer with the tank with s.s pipe or silicon pipe (if required). Fixed properly both rotor & stator with the main shaft of motor.

5.2.5. Connect the plug with electric socket and keep main switch ON Start the homogenizer by pressing green button.

5.2.6. Set the RPM of homogenizer as per batch requirement. Check the homogenizer for correct direction of rotation (i.e. clock wise).

5.2.7. On completion of the process, stop the Homogenizer by pressing Red button.

5.2.8. After completion of batch affix the "TO BE CLEANED" labels.

5.2.9. Enter operation details in Equipment Usages Log Sheet as per SOP, "Making entries in equipment usage and cleaning log sheet".

### 5.3. Precaution:

5.3.1. Check that homogenizer runs first and then product is fed.

5.3.2. Check that homogenizer should stop at the time of product unloading.

5.3.3. Never put oil or grease inside the main housing.

5.3.4. Ensure air pressure NLT 3.0 Kg/cm<sup>2</sup> in cooling pot.



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<b>Issue Date:</b>	<b>Page No.:</b>

5.3.5. After completion of activity of homogenizer remove the connection of cooling pot from homogenizer and clean the pot using purified water by attaching purified water to top of pot and drain the water from outlet of pot for up to 2 - 3. Minutes.

### 6.0 ABBREVIATION(S):

- 6.1. RPM : Revolution per minute.
- 6.2. QA : Quality Assurance
- 6.3. SOP : Standard operating procedure
- 6.4. No. : Number
- 6.5. NA : Not applicable
- 6.6. SS : Stainless steel
- 6.7. IPA : Isopropyl Alcohol
- 6.8. % : Percentage
- 6.9. v/v : Volume / Volume

### 7.0 REFERENCE(S):

- 7.1. SOP: Status labeling
- 7.2. SOP: Making entries in equipment usage and cleaning log sheet.

### 8.0 ANNEXURE(S) :

Annexure no.	Title of Annexure	Format no.	Mode of Execution
Annexure I	Cleaning checklist of Homogenizer		Log Book

### 9.0 DISTRIBUTION:

- 9.1. **Master copy:** Quality Assurance.
- 9.2. **Controlled copy (s):** Production department (02), Quality Assurance (01)
- 9.3. **Reference copy (s) :** Production department (02)



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### ANNEXURE I

#### CLEANING CHECKLIST OF HOMOGENIZER

<b>Name of the Equipment</b>	<b>HOMOGENIZER</b>		
<b>Equipment I.D. No.</b>		<b>Previous Product</b>	
<b>Batch No.</b>		<b>Date</b>	

S.No.	Activity	Activity performed
1.	Switch OFF the electric supply and disconnect the plug.	
2.	Dismantle & Clean the SS rod, circulation pipe, rotar, Stator and Blades with purified water (30-40liters)and scrub with nylon scrubber, drain the water after cleaning and flush the clean parts with purified water.	
3.	Cleaning of homogenizer is done with the cleaning of manufacturing tank, whichever tank is under cleaning by recirculating for 5 minutes in liquid oral manufacturing area.	
4.	Dismantle the parts –SS rod, circulation pipe,rotor,stator and blades and cleaning with hot purified water using nylon scrubber, drain the use water and flush the parts with purified water.	
5.	Wipe the body of the homogenizer with a wet lint free duster followed by dry lint free cloth.	
6.	Reassemble the homogenizer with cleaned parts.	
7.	Rinse the homogenizer with 15 liters of purified water .	
8.	Wipe the out side of homogenizer with a clean lint free cloth.	
9.	Wipe the entire machine with 70% v/v IPA solution.	

Checked By (Prod.)		Verified By (QA)	
Sign and Date		Sign and Date	

**Note:** Put '√' mark if activity is performed and put 'X' if activity is not performed.