



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Ultrasonic Water Bath	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:
To lay down the procedure for Operation and Cleaning of Ultrasonic Water Bath.

2.0 SCOPE:
This procedure is applicable for the Operation and Cleaning of Ultrasonic Water Bath in the 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 indicated 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 “CLEANED” label affixed on the Ultrasonic Water Bath.
- 4.1.6 Update the “AREA STATUS BOARD” with duly filled and signature of production officer.
- 4.1.7 Take the line clearance from QA personnel.
- 4.1.8 Remove “CLEANED” label from the Ultrasonic Water Bath.
- 4.1.9 Enter the start time of the Ultrasonic Water Bath in equipment usage log book as per SOP.
- 4.1.10 Fill the water bath with purified water up to $\frac{3}{4}$ th level.
- 4.1.11 Put the main switch “ON”.
- 4.1.12 Set the required temperature and timer of Ultrasonic Water Bath as per mentioned in the BMR by press the button of Ultrasonic Water Bath.



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- 4.1.13 Allow the bath to reach the set temperature.
- 4.1.14 Open the lid on the top and keep the sample container inside the water and continue the dissolving of material till schedule time mentioned in BMR.
- 4.1.15 Switch "OFF" the main supply after completion of operation.
- 4.1.16 Remove "STATUS LABEL" and affix the "TO BE CLEANED" label on the Ultrasonic Water Bath
- 4.1.17 Update the "AREA STATUS BOARD" 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.

- 4.2.1.1 Remove "TO BE CLEANED" label from the equipment and machine and update the "AREA STATUS BOARD" with duly filled and signature of production Officer.
- 4.2.1.2 Enter the cleaning start time in equipment usage log book as per SOP.
- 4.2.1.3 Fill the Purified water in Ultrasonic water bath.
- 4.2.1.4 Switch ON" the main power supply of Ultrasonic water bath.
- 4.2.1.5 Scrub the inside and outside of Ultrasonic water bath.
- 4.2.1.6 Finally wash the inside and outside with Purified water.
- 4.2.1.7 Dry the Ultrasonic water bath with the help of Compressed air.
- 4.2.1.8 Mop up the inner and outer surface with dry lint free duster and finally mop with 70% v/v IPA solution.
- 4. 2.1.9 Switch "OFF" the main power supply from electric panel.
- 4.2.1.10 Clean the area as per SOP.
- 4.2.1.11 Affix "CLEANED" label on the equipment and machine and update the "AREA STATUS BOARD" with duly filled and signature of production officer.
- 4.2.1.12 Record the cleaning complete time in equipment usage log book as per SOP.

4.2.2 Cleaning procedure Type B

Dismantle and cleaning procedure of equipment parts for product changeover of



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different product/ active/ colour/ descending potency

- 4.2.2.1 Remove "TO BE CLEANED" label from the equipment, machine and update the "AREA STATUS BOARD" with duly filled and signature of production officer.
- 4.2.2.2 Enter the cleaning start time in equipment usage log book as per SOP.
- 4.2.2.3 Remove the lid of Ultrasonic water bath.
- 4.2.2.4 Fill the Purified water in Ultrasonic water bath.
- 4.2.2.5 Scrub the inside and outside of Ultrasonic water bath.
- 4.2.2.6 Finally wash the inside and outside with Purified water.
- 4.2.2.7 Dry the Ultrasonic water bath with the help of Compressed air.
- 4.2.2.8 Mop up the inner and outer surface with dry lint free duster and finally mop with 70% v/v IPA solution.
- 4.2.2.9 Clean the area as per SOP.
- 4.2.2.10 Affix label with "CLEANED" label with duly filled and signature of the production officer.
- 4.2.2.11 Record the cleaning complete time in equipment usage log book as per SOP.

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):
SOP : Standard Operating Procedure
BMR : Batch Manufacturing Record
IPA : Iso Propyl Alcohol



PHARMA DEVILS

PRODUCTION DEPARTMENT

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v/v : Volume/Volume
Q.A : Quality Assurance
NA : Not Applicable

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S)FOR REVISION	REFERENCE CHANGE CONTROL No.