



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production (External Preparation)	SOP No.:
Title: Cleaning, Sanitization & Operation of Multi Mix Plant with Load Cell-75 Kg	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a Procedure for Cleaning , Sanitization & Operation of Multi Mix Plant with Load Cell-75 Kg.

2.0 SCOPE:

This SOP is Applicable to Cleaning , Sanitization & Operation of Multi Mix Plant with Load Cell-75 Kg in Ointment Section.

3.0 RESPONSIBILITY:

Officer/Executive – Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

No.	Number
PLC	Programmable logic control
QC	Quality control
RPM	Rotation Per Minute
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 CLEANING:

6.1.1 A Type Cleaning (Batch to Batch & Sift End Cleaning)

6.1.1.1 Ensure that the Equipment has a “TO BE CLEANED” Status Label.

6.1.1.2 Previous Product residue removes from Multi-Mixer, wax vessel and water vessel with Purified Water use until previous residue remove.

6.1.1.3 Take Purified Water approx. 50.00 kg in Multi-Mixer and 30 kg in each of wax vessel and water vessel manually and heat up to 75°C to 80°C under Stirring and then Start the Stirrer/Homogenizer for 05 Min.

6.1.1.4 Now open the Drainage Valve and Drain the Hot Purified Water with the help of Transfer Pump.

6.1.1.5 Dry mop the outer surface of Multi-Mixer with Lint Free Cloth.



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6.1.1.6 Affix a “CLEANED” Status Label on the Vessel.

6.1.1.7 Make an entry of Cleaning Time in Equipment Log.

6.1.1.8 A - Type Cleaning is to be done.

1. Batch to Batch change over of the same Product.
2. Change over to higher strength of same colour.

6.1.2 B Type Cleaning (Product to Product Cleaning)

6.1.2.1 Ensure that the Equipment has a “TO BE CLEANED” Status label on it.

6.1.2.2 Previous Product residue removes from Multi-Mixer, wax vessel and water vessel with Purified Water.

6.1.2.3 Take Purified Water approx. 50.00 kg in Multi-Mixer and 30 kg in each of wax vessel and water vessel manually and heat up to 75°C to 80°C under Stirring and then Start the Stirrer/Homogenizer for 05 Min.

6.1.2.4 Now open the Drainage Valve and Drain the Hot Purified Water with the help of Transfer Pump.

6.1.2.5 Clean the inner surface of Multi-Mixer, wax vessel, water vessel with 1-2 liters of Extran MA 02 solution 2% v/v by sprinkling it inside and scrub the inner surface of the vessel with the help of scrubber to remove any adhered residual of previous product.

6.1.2.6 Final rinse all vessels with 50.0 Kg hot purified water.

6.1.2.7 Dismantle all parts of Multi-Mixer, wax vessel and water vessel for Cleaning.

6.1.2.8 Wrap the dismantle parts with polybag and then transfer to the wash area for cleaning.

6.1.2.9 Clean the parts with Extran MA 02 solution 2% and Hot Purified Water and dry them with Compressed Air.

6.1.2.10 Collect the cleaned & dry parts and assemble them.

6.1.2.11 Again wash and flush the Multi-Mixer with Purified Water.

6.1.2.12 Ensure the cleanliness of Vessels visually.



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6.1.2.13 Affix a “CLEANED” Status Label on the Vessel.

6.1.2.14 Make an entry of Cleaning Time in Equipment Log.

6.1.2.15 B-Type Cleaning is to be done.

1. After 48 hrs of type A-Type cleaning.
2. Product Change Over.
3. Change over to Lower strength of same product.
4. After maintenance or major breakdown.
5. Change over to upper strength with different colour.
6. If the Equipment is not used within 72 hrs clean the equipment before use.
7. After every 5 batches of same product in case of campaign product.

6.2 HOT WATER SANITIZATION:

6.2.1 Ensure that the Equipment has a “CLEANED” status label.

6.2.2 Collect 2 x 30 kg Purified Water in water vessel and wax vessel manually.

6.2.3 Heat up to 80°C to 85°C, transfer the wax vessel purified water and water vessel purified water into the multimixer & recirculation for 15 Minutes with the help of Re-circulation system.

6.2.4 Now open the Drainage Valve and Drain the Hot Purified Water with the help of Transfer Pump.

6.2.5 Dry mop the outer surface of Multi-Mixer with Lint Free Cloth.

6.2.6 Affix the “CLEANED” Status Label on the Multi Mixer.

6.2.7 Make an entry in respective log book.

6.2.8 Intimate to IPQA person for collection of Rinse water sample along with intimation. IPQA person shall verify the cleanliness visually and after satisfactory cleaning, IPQA person shall collect the rinse water sample from the exit chute of the vessel and then send the Sample to Quality Control Lab for Chemical Testing.

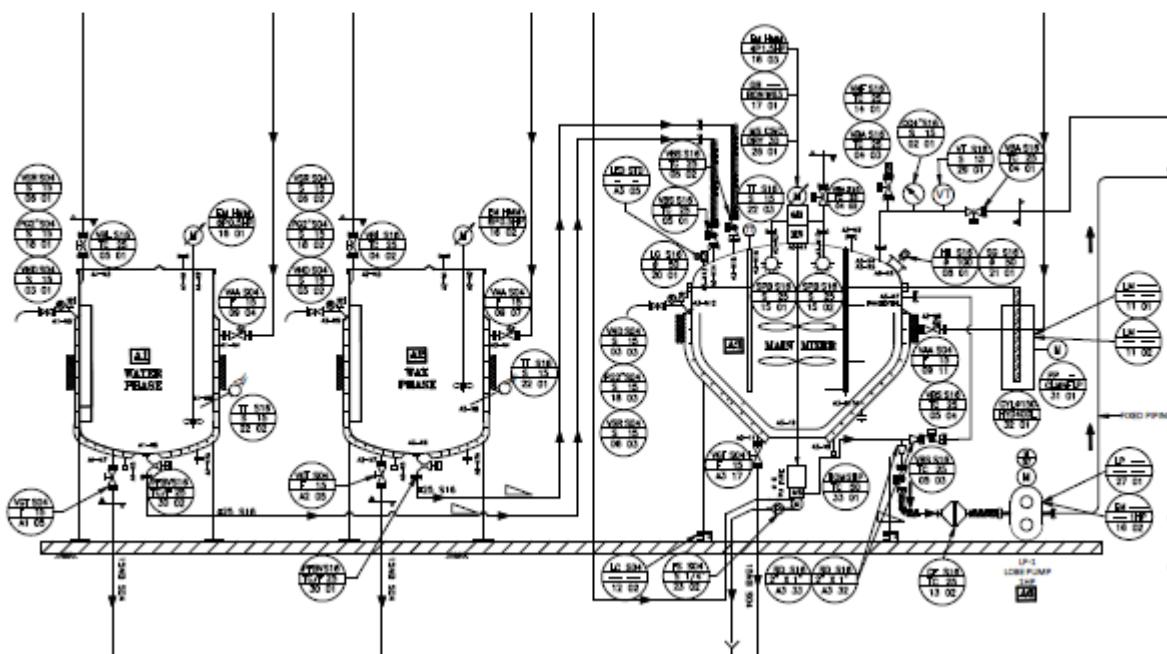


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6.2.9 If Testing Results not complies with Reference Specification, again flush & clean the Vessel with 2 x 30 kg. Of Purified water or till satisfactory & send the sample to QC Department.
Frequency for sanitization: After every B Type Cleaning.

6.3 OPERATION:



6.3.1 PROGRAMMABLE LOGIC CONTROL (PLC) OPERATION SYSTEM FOR MUTIMIX PLANT -75 kg IN MANUFACTURING NO.- 03:

1. The Operation shall be through PLC.
2. Quantity of purified water required during manufacturing shall weight in electronic balance and is transferred manually.
3. Non aqueous materials are add manually in wax phase vessel.
4. Aqueous base material are add manually in water phase vessel.
5. Both are phase heat by steam,when required and mixing with stirrer appropriated RPM.
6. Molted materials are transfer in to multi mixture through appropriated vaccume.
7. Appropriated run time and RPM mixing and homogenizer in PLC.



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8. After completion of batch unloading the batch through pump or manually in holding tank.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Multi Mix Plant With Load Cell Sanitization Record	

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance Department
- Controlled Copy No. 02 Production Department
- Master Copy Quality Assurance Department

9.0 REFERENCES:

Not Applicable

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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

