



Cleaning and Operation of Solution Holding Tank

1.0 OBJECTIVE

- 1.1. To lay down a procedure for cleaning of Cleaning and Operation of Solution Holding Tank.

2.0 SCOPE

- 2.1. This procedure is applicable to cleaning of Cleaning and Operation of Solution Holding Tank in production department.

3.0 RESPONSIBILITY

- 3.1. Technical Associates : Cleaning and Operation
3.2. Officer, Executive : Checking cleaning and operation
3.3. Head Production : SOP Compliance
3.4. IPQA : SOP Compliance

4.0 DEFINITION(S)

- 4.1. NA

5.0 PROCEDURE

5.1 "TYPE A" CLEANING

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

- 5.1.1 Affix dully filled "TO BE CLEANED" status label on equipment with date and signature of the Production Officer as per SOP ("Status labeling").
5.1.2 Clean the inner and outer surface of Solution Holding Tank with wet lint free cloth.
5.1.3 Wipe the inner and outer surface of Solution Holding Tank with 70% v/v IPA solution.
5.1.4 Replace the "TO BE CLEANED" status label with "CLEANED" status label with date and signature of the Production Officer/QA officer as per SOP ("Status labeling").
5.1.5 Record the cleaning activity in equipment usage and cleaning log sheet as per SOP ("Making entries in equipment usage and cleaning log sheet").

5.2 "TYPE B" CLEANING

This cleaning procedure for change over of product with difference actives / color / descending potency or after maintenance of contact parts.

- 5.2.1 Bring the solution holding tank to the coating wash area.
5.2.2 Affix dully filled "TO BE CLEANED" status label on equipment with date and signature of the Production Officer as per SOP ("Status labeling").
5.2.3 Cover the stirrer motor with the polybag.



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- 5.2.4 Dismantle the stirrer from the main shaft.
- 5.2.5 Clean the stirrer and top lid with purified water.
- 5.2.6 Scrub the stirrer and top lid with nylon brush till all the adhered residues of previous product get softened. Use 70% v/v IPA in case adhered material does not scrubbed out.
- 5.2.7 Flush enough purified water till all visible residues of previous product are washed away.
- 5.2.8 Rinse the stirrer and top lid with purified water.
- 5.2.9 Rinse the inner surface of solution holding tank with purified water.
- 5.2.10 Flush enough purified water till all the visible residues of previous product are washed away. Use 70% v/v IPA in case adhered materials dose not scrubbed out.
- 5.2.11 Finally rinse the equipment with 30-40 liters of purified water.
- 5.2.12 Wipe the outer surface of solution holding tank with wet lint free cloth.
- 5.2.13 Wipe the inner and outer surface of solution holding tank with dry lint free cloth.
- 5.2.14 Wipe the inner and outer surface of solution holding tank with 70% v/v IPA.
- 5.2.15 Bring the cleaned solution holding tank from coating wash.
- 5.2.16 Replace the “TO BE CLEANED” status label with “CLEANED” status label with date and signature of the Production Officer/QA officer as per SOP (“Status labeling”).
- 5.2.17 Record the cleaning activity in equipment usage and cleaning log sheet as per SOP (“Making entries in equipment usage and cleaning log sheet”).

5.3 Frequency

- 5.3.1 Type ‘A’ cleaning is applicable after completion of every batch of same product.
- 5.3.2 Type ‘B’ is applicable in case of change over / same product is run for seven days / after three batches of same product, which ever is earlier.
- 5.3.3 Cleaning is applicable in case of at the end of working day, clean the equipment with dry lint free cloth.

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 and cleaning log sheet as per SOP (“Making entries in equipment usage and cleaning log sheet”).

5.4 Precaution

- 5.4.1 After completion of operation, clean the equipment within 24 hours if not in use.

5.5 Operation



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- 5.5.1 Ensure the cleaning of equipment and area. Affix 'EQUIPMENT STATUS' label dully filled and signed on the solution holding tank and Record the activity in equipment usage and cleaning log sheet as per SOP ("Making entries in equipment usage and cleaning log sheet").
- 5.5.2 Attach the pipe for pneumatic supply to the equipment and open the valve of compressed air.
- 5.5.3 Set the RPM as required.
- 5.5.4 Ensure the discharge valve is closed.
- 5.5.5 Connect the discharge valve with the coating solution pipe.
- 5.5.6 Load the material in the solution holding tank as per sequence in the respective BMR.
- 5.5.7 Start the stirrer motor.
- 5.5.8 After completion of operation stop the stirrer motor.
- 5.5.9 Replace the "EQUIPMENT STATUS" label with "TO BE CLEANED" status label with date and signature of the Production Officer as per SOP ("Status labeling").

6.0 ABBREVIATION(S)

- 6.1. SOP : Standard operating procedure
- 6.2. BMR : Batch Manufacturing Record
- 6.3. v/v : Volume/Volume
- 6.4. IPA : Iso Propyl Alcohol

7.0 REFERENCE(S)

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

8.0 ANNEXURE(S)

- 8.1. Nil

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 (08)

10.0 REVISION HISTORY

S.No.	Revision No.	Change Control No.	Reason (S) For revision	Details of revision	Revision Date