



PHARMA DEVILS

PRODUCTION DEPARTMENT

Cleaning and Operation of Process Line in Liquid Orals

1.0 OBJECTIVE:

To lay down the procedure for Cleaning and operation of process line in liquid orals.

2.0 SCOPE:

This procedure is applicable for Cleaning and operation of process line in Liquid orals.

3.0 RESPONSIBILITY:

Operator- for Execution

Officer/ Executive Production - for verification and implementation of SOP

Head Production - shall ensure compliance of the SOP.

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 Cleaning

If next product is the same as previous product (campaign production), follow batch-to-batch cleaning procedure. If next product is different from previous product, follow product-to-product cleaning procedure.

5.1.1 Batch-to-Batch cleaning procedure (Type A):

5.1.1.1 After completion of the batch dismantle all the process lines, affix "TO BE CLEANED" label and transfer to wash area.

5.1.1.2 During cleaning, remove "TO BE CLEANED" label and affix "UNDER CLEANING" label as per reference SOP (Status labeling).

5.1.1.3 Clean the gasket, S.S pipes, Clamp with sufficient quantity of purified water and nylon brush.

5.1.1.4 Dry the S.S pipe, gasket, clamp with compressed air and clean the outer surface of S.S pipe line with dry lint free cloth.

5.1.1.5 Reassemble the process line after cleaning of the manufacturing tank.

5.1.2 Product-to-product cleaning procedure (Type B):

This procedure is applicable if -there is a change in product, if the batches have been processed for 7 consecutive days, if the equipment is taken for maintenance during processing and maintenance work continues for more than 24 hrs or maintenance work involves any part, which comes in direct contact with product, If the equipment is not used within 72 Hrs, after type "A" Cleaning and If the equipment not used within 240 hrs. (10 Days), after type "B" cleaning.

5.1.2.1 After completion of the batch dismantle all the process lines, affix "TO BE CLEANED" label and transfer



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to wash area.

- 5.1.2.2 During cleaning, remove “TO BE CLEANED” label and affix “UNDER CLEANING” label as per reference SOP (Status labeling).
- 5.1.2.3 Clean the gasket, SS pipes, Clamp with sufficient quantity of purified water and nylon brush.
- 5.1.2.4 Re-clean the gasket, SS pipes, Clamp with hot water and nylon brush.
- 5.1.2.5 Dry the SS pipe, gasket, clamp with compressed air and clean the outer surface of SS pipe line with dry lint free cloth.
- 5.1.2.6 Reassemble the process line after cleaning of the manufacturing tank.

5.1.3 Cleaning of silicon pipe use in liquid oral (Silicon pipe for all size):

- 5.1.3.1 Transfer the silicon pipe to the wash area and pass the purified water from one end and drain the water from the other end of the silicon pipe till the complete removal of the previous product from the silicon pipe.
- 5.1.3.2 Take 500 ml of purified water in a clean container and pour in to the silicon pipe from One end and collect the water from other end, repeat the process twice. Check the water in a glass flask for the traces of silicon pieces, If there is no pieces of silicon observed then perform next step and if any piece of silicon is observed then reject the silicon pipe.
- 5.1.3.3 Dry the silicon pipe with help compressed air from inside and clean the outer surface with the help of dry lint free cloth.
- 5.1.3.4 Hang the silicon pipe on the hanger in invert position for complete removal of water from the silicon pipe.

5.2 Operation:

5.2.1 Operation of process line between sugar dissolving tank and 1000 ltrs. manufacturing tank.

- 5.2.1.1 Close the valve no. 5.
- 5.2.1.2 Create the vacuum in 1000 ltrs. manufacturing tank by ‘ON’ the vacuum switch.
- 5.2.1.3 Open the outlet valve of sugar dissolving tank, outlet valve of basket assembly, valve No. 03 and valve No. 04.
- 5.2.1.4 Start vacuum to pass material through process line to 1000 ltrs. Manufacturing tank.

5.2.2 Operation of process line between sugar dissolving tank and 3000 ltrs. manufacturing tank

- 5.2.2.1 Close the valve no. 4.
- 5.2.2.2 Create the vacuum in 3000 ltrs. manufacturing tank by ‘ON’ the vacuum switch.
- 5.2.2.3 Open the outlet valve of sugar dissolving tank, outlet valve of basket assembly, valve No.03 and valve No.05.
- 5.2.2.4 Start vacuum to pass material through process line to 3000 ltrs. manufacturing tank.

5.2.3 Operation of process line between 3000 ltrs. manufacturing tank and 3000 ltrs. Holding tank



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- 5.2.3.1 Close the valve No.14, 16 and 17 or 20 (whichever required).
- 5.2.3.2 Open the valve No.15 and 17 or 20 (whichever required)
- 5.2.3.3 Attach outlet valve of 3000 ltrs. manufacturing tank to the inlet of process line and start process.
- 5.2.4 Operation of process line between 1000 ltrs. manufacturing tank and 3000 ltrs. manufacturing tank**
- 5.2.4.1 Close the valve no.14, 12, 06 and 07.
- 5.2.4.2 Create the vacuum in 3000 ltrs. manufacturing tank by 'ON' the vacuum switch.
- 5.2.4.3 Open the outlet valve of 1000 ltrs. manufacturing tank, valve No.19 and valve No.08.
- 5.2.4.4 Start vacuum to pass material through process line to 3000 ltrs. manufacturing tank.
- 5.2.5 Operation of process line between 3000 ltrs. manufacturing tank and 1000 ltrs. manufacturing tank**
- 5.2.5.1 Close the valve no.06, 08, 12 and 15.
- 5.2.5.2 Create the vacuum in 1000 ltrs. manufacturing tank by 'ON' the vacuum switch
- 5.2.5.3 Open the outlet valve of 3000 ltrs. manufacturing tank, valve No.14, valve No.19 and valve no.07.
- 5.2.5.4 Start vacuum to pass material through process line to 1000 ltrs. manufacturing tank.
- 5.2.6 Operation of solvent transfer process line**
- 5.2.6.1 Create vacuum in 1000 ltrs. and 3000 ltrs. manufacturing tank as per requirement.
- 5.2.6.2 Open the valve No. 09, 10 and close valve No.11 for transferring of solvent into 1000 ltrs. manufacturing tank.
- 5.2.6.3 Open the valve No. 09, 11 and close valve No.10 for transferring of solvent into 3000 ltrs. manufacturing tank.
- 5.2.6.4 Supply solution through solvent process line into 1000 ltrs. and 3000 ltrs. Manufacturing tank.
- 5.2.6.5 After transfer of material remove the pipe line and take it to wash area for cleaning.
- NOTE:**
- 5.3** After complete transfer of solution from the process pipe line, verify the pipe line for any remaining quantity of solution by opening the lower end of the pipe and if any solution remains in the pipe take it into the S.S container and transfer it to the respective tank.
- 6.0 ABBREVIATION (S):**
- 6.1 SOP : Standard Operating Procedure.
- 6.2 No. : Number.
- 6.3 NA : Not applicable.
- 6.4 S.S : Stainless steel.
- 7.0 REFERENCE(S):**
- NA



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8.0 ANNEXURE (S):

Nil

9.0 DISTRIBUTION:

9.1 Master Copy: Quality Assurance

9.2 Controlled Copy (s): Production department (01), Quality Assurance (01)

9.3 Reference Copy (s): Production department (01)

10.0 REVISION HISTORY:

S.No.	Revision no.	Change Control no.	Reason (s) for revision	Details of Revision	Revision date