



STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning of Auto-coater 60'' (Bectochem)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

1.0 OBJECTIVE :

To lay down a procedure for cleaning of Autocoater 60'' (Make: Bectochem).

2.0 SCOPE :

This procedure is applicable to cleaning method of Autocoater 60'' (Make: Bectochem) in coating area.

3.0 RESPONSIBILITY:

Production: Officer /Executive/Assistant Manager.

Head Production: To ensure execution & compliance.

Head QA: To ensure the compliance.

4.0 PROCEDURE:

4.1 CLEANING : TYPE A

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

4.1.1 Remove the 'TO BE CLEANED' status label and affix the label "UNDER CLEANING".

4.1.2 Ensure that the power supply is switched OFF.

4.1.3 Clean the coating pan, inlet air blower duct and the exhaust air blower duct by using compressed air and a lint free cloth.

4.1.4 Ensure that there is no coating solution of the previous batch is left in the solution tank and the solution line.

4.1.5 Clean the solution tank with purified water.

4.1.6 Dry the solution tank with using compressed air and lint free cloth.

4.1.7 Affix the status label 'CLEANED' with date and signature of the production officer and enter cleaning details in equipment sequential log.

4.1.8 Record the cleaning activity in equipment sequential log as per SOP.

4.2 TYPE B:

This is a cleaning procedure for Change over of product with different actives/color/



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descending potency or after maintenance of contact parts.

- 4.2.1 Follow the procedure from step 4.1.1 to 4.1.2.
- 4.2.2 Cover all the electrical parts including HMI with poly bag.
- 4.2.3 Insert the gun gun arm inside the coating pan.
- 4.2.4 Connect the washing pipe from valve of purified water to WIP.
- 4.2.5 Open the valve of purified water and start the WIP on HMI.
- 4.2.6 Open the side covers and unclamp the inlet and out let plenum.
- 4.2.7 Clean the unloading assembly, inlet and outlet plenum, with 40-50 Kg of purified water by using nylon scrubber.
- 4.2.8 Fill the solution tank with purified water and start dosing in HMI.
Note: In case of cleaning after enteric coated products fill the solution tank with 20 Liters of 1N Sodium hydroxide solution (1 N NaOH)
(For preparations of 1N NaOH solution refer SOP)
- 4.2.9 Allow the purified water / 1 N sodium hydroxide solution to wash on the perforated pan.
Finally rinse with the purified water till no residue of sodium hydroxide remains.
- 4.2.10 Ensure that no coating residue is present inside and outside of the silicon tube.
- 4.2.11 The flexibility of silicon tubing used for coating solution transfer shall be replaced if any sign of deformation observed.
- 4.2.12 Transfer the silicon tube to washing area, and wash the silicon tube by using purified water and dry the silicon tube by using compressed air and hang the silicon tube in inverted position so as to allow complete drain of water.
- 4.2.13 Take out the gun arm outside the auto coater.
- 4.2.14 Open the nozzles and wash nozzle guns with purified water / 1 N Sodium Hydroxide Solution in case of cleaning after enteric coating, by using nylon scrubber.
- 4.2.15 Clean the baffles with 20-30 Kg of purified water by using nylon scrubber.
- 4.2.16 Clean the solution tank with 30-40 Kg of purified water by scrubbing with nylon scrubber.
Finally rinse the machine and parts with 50-60 kg of purified water.
- 4.2.17 Dry all the cleaned parts with compressed air and cleaned dry lint free cloth.
- 4.2.18 Keep all the cleaned dismantled parts on a SS pallet.



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- 4.2.19 Wipe the auto coater as well as all the cleaned parts with the cleaned lint free cloth dipped in 70 % V/V IPA solution.
- 4.2.20 Assemble all dismantled parts to the auto coater.
- 4.2.21 Put the ‘CLEANED’ status label with the date and signature of the production officer.
- 4.2.22 Enter cleaning activity in equipment sequential log as per SOP.
- 4.2.23 Get it certified by Quality Assurance Department.

5.0 ANNEXURE (S):

Annexure- I: Cleaning check list of Autocoater 60” (Bectochem).

6.0 REFERENCE (S):

SOP: Procedure for line clearance.

SOP: Preparation, approval, distribution control, revision and destruction of Standard Operating Procedure (SOP).

7.0 ABBREVIATION (S) /DEFINITION (S) :

IPA : Iso Propyl Alcohol

HMI : Human Machine interface

SOP : Standard Operating Procedure

SS : Stainless Steel

WIP : Wash in place

V/V : Volume / Volume

Kg : Kilogram

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	---	---	New SOP	---