SOP: LFA 00066
SOP For Automatic Coating System (NEOCOTA 48″)

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1 Objective

Procedure for the Operation of the Automatic Coating System (NEOCOTA 48″)

2 Scope

Applicable for the Automatic Coating System (NEOCOTA 48″) in the coating area in the Production Department

3 Responsibility

Execution Operator

Checking Production Pharmacist and Above

4 Accountability

HOD Production / Assigned Designee

5 Procedure

5.1. Before starting the coating process, check to make sure that the equipment including the coating pan, spray gun assembly, pressure vessel, liquid hose and other parts and areas is clean. Label the equipment as "cleaned".

5.2. Before starting the production operation, the personnel must get a line clearance from the Q.A. staff by providing the status label of the product?s name, batch detail and equipment as per BMR.

5.3. Put the main and panel switch to the "ON" position.

5.4. Press the manual mode in the microprocessor screen and then press the bypass of PDM indicator.

5.5. Set the following in the microprocessor screen as required: Enter in data log

5.5.1. Batch Number

5.5.2. Inlet Temperature

5.5.3. Outlet Temperature

5.5.4. Bed Temperature

5.5.5. Pan Speed

5.5.6. Printing Cycle

5.5.7. Spray "ON" and "OFF" as per requirement.

5.5.8. Set the atomization air limit switch; this will set the "OFF" spray system. If the atomization air pressure falls below, manually set the air pressure.

5.6. Remove the liquid vessel lid and load the required coating solution. Close the lid and activate the stirrer by opening the compressed air supply knob.

5.7. To set the dosing percentage of the feed pump as per the requirement, rotate the knob located on the top of the pump.

5.8. Turn the knob to the right side to set the dosing RPM of the peristaltic pump, then remove the spray gun assembly arm outside the pan and then charge the core tablets into the pan.

5.9. Set the spray gun for liquid volume flow and spray pattern as follows:

5.9.1. Put "OFF" the compressed air supply valve of the zender filter.

5.9.2. Push the selector switch on the PDM bypass.

5.9.3. Push the selector switch on manual position.

5.9.4. Hold the measuring cylinder under each of the nozzle. Put "ON" the spray switch and measure the coating solution volume collected in the cylinder after one minute of cycle. Do volume correction by using the screw located on top of the gun.

5.9.5. Put the filter valve and spray switch to "ON". Hold the filter paper in front of the gun and check the spray pattern by checking the filter paper.

5.10. Coating Process

5.10.1. Start the pan, inlet damper and the exhaust blower to maintain the bed temperature (as per BMR) by pressing the heater to the "ON" position.

5.10.2. Push the hot air blower switch to start the hot air blower.

5.10.3. Start the coating pan and then adjust the distance between the gun and the tablet bed.

5.10.4. Move the spray gun assembly to the coating pan. Keep the gun close to the tablet bed distance between 8 -12 cm for non-aqueous and 7-10cm for aqueous coating. Afterwards, close and lock the window. 5.10.5 Before loading, check the weight of the 20-core tablet. Check the weight again after drying and record the weight gain.

5.10.5. Auto-mode - Press the auto-mode selection.

5.10.6. Push the "OFF" button of the heater switch.

5.10.7. Set the spray "ON" and "OFF" time in the microprocessor screen as per the requirement.

5.10.8. Set the Pause timer as per the requirement.

5.10.9. To start the film coating, push "ON" for "Auto cycle" and "Film coating cycle".

5.10.10. Check and monitor the inlet air temperature and outlet exhaust temperature throughout the coating process.

5.10.11. Once the film coating is completed, allow the tablets to roll in the pan until the exhaust temperature reaches 3 to 5°C for the drying of the tablets.

5.11. Remove the tablets from the pan by using the following equipment:

5.11.1. Set the pan speed (RPM) as per the requirement.

5.11.2. Fix the scoop assembly on the pan mouth with the scoop in between the two opposite baffles. Check to make sure that the scoop assembly is fixed by pulling it outward.

5.11.3. Fix the discharge hopper over the front window and unload the tablets. Place drums containing polythene bags below the hopper.

5.12. Record in the "Equipment Log Book".

5.13. Once processing is done, Push to "OFF" the main.

5.14. Affix a "TO BE CLEANED" label on the equipment.

6 Abbreviations

SOP Standard Operating Procedure

BMR Batch Manufacturing Record

Q.A Quality Assurance

HOD Head of Department