

	<b>Standard Operating Procedure</b>		<b>SOP Number B-704</b>	<b>Revision 2</b>
	<b>Perforated Pan Coating</b>		<b>Effective Date</b> 07/14/21	<b>Page Page 1 of 6</b>
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## 1.0 Purpose

The purpose of this procedure is to outline the process and operation of perforated pan coating utilizing aqueous film coatings.

## 2.0 Scope

This procedure applies to all perforated pan coating machines in operation at Ion Labs, Inc.

## 3.0 Responsibility

- 3.1 It is the responsibility of production personnel to follow this procedure.
- 3.2 It is the responsibility of the compression manager and production supervisor to implement this procedure and ensure that the procedure is followed.
- 3.3 It is the responsibility of the QC Inspectors to inspect and assure the procedure is being followed.

## 4.0 Definitions

- 4.1 **IPA** – 70% Isopropyl Alcohol
- 4.2 **DI Water** – Deionized Water, Distilled or Purified Water is a sufficient substitute
- 4.3 **QC** – Quality Control
- 4.4 **Minor Clean** – A clean between batches of the same product
- 4.5 **Major Clean** - A clean between batches of different products or before long-term storage
- 4.6 **Viscosity** – a measure of the resistance to deformation of a fluid. Typically measured in poise or centipoise. 1 Poise (P) = 1 g•cm<sup>-1</sup>•s<sup>-1</sup>. 1 Centipoise (cP) = 1/100<sup>th</sup> Poise
- 4.7 **kPa** – Kilopascal. 1000 Pascals, the SI unit of pressure. 1 Pascal = 1 N•m<sup>-2</sup>.

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- 4.8 **Plenum** – Air reservoir between the pan and the ducting.
- 4.9 **Zahn Cup** – A basic instrument for measuring kinematic viscosity of liquids.
- 4.10 **RPM** – Rotations Per Minute
- 4.11 **IR** – Infrared
- 4.12 **Jog** – Interval tumbling of the tablet bed
- 4.13 **BPR** – Batch Production Record

## **5.0 References**

- 5.1 B-111, SOP, Cleaning of Manufacturing/Production Areas and Equipment

## **6.0 Procedure**

- 6.1 Set Up
  - 6.1.1 Obtain the batch record for the product to be coated.
  - 6.1.2 Ensure the coating suite is clean and dry.
  - 6.1.3 Fill out the batch coating form for the specific pan being utilized.
  - 6.1.4 Assemble the spray guns.
    - 6.1.4.1 Ensure all functions of the guns are operating as designed.
  - 6.1.5 Assemble the coating suspension pump.
  - 6.1.6 Assemble the coating suspension tank.
    - 6.1.6.1 Inspect the Teflon bushing for wear and replace as needed to prevent metal on metal contact.
  - 6.1.7 Prepare the coating suspension by following the mix instructions included in the batch record. Mix instructions are raw material and/or formulation specific.
  - 6.1.8 Utilize a Zahn Cup to ensure the viscosity of the solution meets the specifications set forth in the coating mix instructions.

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6.1.9 Determine the total spray rate for all guns in grams per minute (g/min) and utilize coating form to generate a spray-rate slope to interchange machine Hertz (Hz) settings with actual grams per minute spray rates.

## 6.2 Machine Loading

6.2.1 Determine the appropriate pan size based on the batch yield. If tableting is still in process use the blending yield to approximate tableting yield. Record pan size on batch coating form.

6.2.2 Before loading, make sure the filter is clean.

6.2.3 Load tablets into the machine gently.

6.2.4 Determine optimal pan speed (RPM) based on load, tablet core friability, and exhibited cascade.

6.2.5 Aim the spray guns and set the gun to bed distance to the desired value.

## 6.3 Coating Operation

6.3.1 Turn on the Main Motor.

6.3.2 Set the hot air inlet temperature. Record this on coating form.

6.3.3 Turn on the Hot Inlet Air and Outlet Air pumps.

6.3.4 Adjust the inlet and outlet air valves to the maximum while sustaining the desired inlet temperature and pressure differential (kPa). Record this on the batch coating form.

6.3.5 Begin to jog the pan as the tablets warm to ensure even heating.

6.3.6 Monitor the tablet bed temperature with an IR thermometer. Record this on coating form.

6.3.7 Commence coating spray once the tablet bed temperature had risen to the desired value. Atomization air must be turned on prior to turning on the suspension pump. Record this information on coating form.

6.3.8 Once the spray guns have been activated check to ensure all guns are operating correctly with the desired spray pattern.

- 6.3.9 Monitor the coating operation parameters including Inlet Temperature, Outlet Temperature, Pressure Differential, Pan Speed, Spray Rate, Gun to Bed Distance, Bed Temperature, etc... and record the readings on coating form every 5-10 minutes (remain consistent). Obtain samples of tablets concurrently with operational parameter recordings as required.
- 6.3.10 Adjust parameters as necessary to ensure product quality. Record all changes on coating form.
- 6.3.11 The end point is reached when all tablets have a complete coating and are uniform in color from tablet to tablet. Once this point is reached stop the spray, reduce the pan speed to 1 RPM or jog, turn off the heat, and begin cool down procedures.
- 6.3.12 Continue to monitor the tablet bed temperature with an IR thermometer until the desired temperature has been reached. Record this on coating form.
- 6.4 Machine Unloading
- 6.4.1 Line all buckets with food grade liners.
- 6.4.2 Stop pan rotation by reducing RPM to 0.
- 6.4.3 Remove spray gun arm from the coating pan.
- 6.4.4 Install and secure the inner and outer tablet chutes. If a tablet chute is not available the tablets may be hand scooped from the machine.
- 6.4.5 Turn the pan rotation on to begin unloading tablets.
- 6.4.6 Fill buckets near maximum capacity.
- 6.4.7 Seal the buckets by twisting the excess liner several times then placing a lid on the buckets ensuring that it is completely secure.
- 6.5 Cleaning Procedure
- 6.5.1 Minor Clean
- 6.5.1.1 Remove all containers, utensils, and paperwork from the previous batch.
- 6.5.1.2 Tag the room "Minor" to indicate a minor clean is needed or in process.

- 6.5.1.3 Vacuum excess powder from pan and equipment floor.
- 6.5.1.4 Complete the cleaning and sign the room usage and equipment cleaning log per SOP B-111.
- 6.5.1.5 Dispose of any coating solution held for >24hr unless otherwise dictated or approved with stability data (approval in BPR or list by QC Laboratory.)

**6.5.2 Major Clean**

- 6.5.2.1 Remove all containers, utensils, and paperwork from the previous batch.
- 6.5.2.2 Tag the room "Major" to indicate a major clean is needed or in process.
- 6.5.2.3 Dispose of any remaining coating suspension and move the coating mix vessel to the wash area to be cleaned.
- 6.5.2.4 Vacuum out any loose powder.
- 6.5.2.5 Turn on the drain pump.
- 6.5.2.6 Thoroughly rinse the interior of the machine. Utilize hot water if available.
- 6.5.2.7 Generate NLT ½ gallon of citranox solution and run this solution through the spray guns and into the coater. Citranox must be utilized on stainless steel product contact surfaces to maintain a passive layer of chromium oxide.
- 6.5.2.8 Tag out the machine's power.
- 6.5.2.9 Remove the spray gun arm from the machine and disassemble the spray guns.
- 6.5.2.10 Remove the hoses and soak in a food contact approved cleaning solution.
- 6.5.2.11 Disassemble the suspension pump.
- 6.5.2.12 Remove the air plenums and move to wash room to be cleaned.

6.5.2.13 Spray all interior surfaces of the machine with citranox and allow to sit for NLT 3 minutes.

6.5.2.14 Rinse the interior of the machine with room temperature water until no citranox residue is present.

6.5.2.15 Spray the interior of the machine with 70% IPA.

6.5.2.16 Use the standard parts cleaning procedure to clean the mixing vessel and plenums. See SOP B-111.

## 6.6 Preventative Maintenance

### 6.6.1 Filters

6.6.1.1 Inspect every day/shift and clean or replace as needed.

### 6.6.2 Hoses

6.6.2.1 Replace after solutions that are a different color.

### 6.6.3 Tanks

6.6.3.1 Bushing at the bottom of agitator is to be inspected after each major clean. Replace once excessive wear is noted.

### 6.6.4 Spray Guns

6.6.4.1 Inspect every major clean and replace as needed.

### 6.6.5 Ducting

6.6.5.1 Inspect every 6 months and clean as needed.

## 7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	02/24/14	New procedure.	N/A	S. Grimes
1	04/30/18	Complete rewrite to generalize procedure for all perforated coating pans.	18-0151	C. Fryman
2	06/17/21	Scheduled revision: updated solution holding time and hose replacement.	CC-21-0237	K. Blozousky