
	Standard Operating Procedure		SOP Number B-703	Revision 4
	Solid Coating Pan		Effective Date 06-08-20	Page Page 1 of 3
Written by/ Date C. ... 01-02-21-20		Reviewed by/ Date ... re off/uct	Approved by/ Date  04-27-20	
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1.0 Purpose

The purpose of this procedure is to outline the process for the operation and cleaning of the solid coating pan utilizing volatile solvent film coatings.

2.0 Scope

This procedure applies to all solid "candy" coating pans in operation at Ion Labs, Inc.

3.0 Responsibility

3.1 It is the responsibility of production (coating) personnel to follow this procedure.

3.2 It is the responsibility of the department supervisor to implement this procedure and ensure that the procedure is followed.

4.0 Definitions

4.1 IPA - Isopropyl Alcohol

4.2 DI Water = Deionized Water

4.3 QC = Quality Control

4.4 **Minor Clean** - A clean between batches of the same product (refer to SOP B-111 Cleaning of Manufacturing/Production Areas and Equipment)

4.5 **Major Clean** - A clean between batches of different products or before long-term storage (refer to SOP B-111 Cleaning of Manufacturing/Production Areas and Equipment)

5.0 References

5.1 C-104-F7, Form, Coating Record

5.2 B-111-F1, Form, Cleaning of Manufacturing/Production Areas and Equipment

5.3 B-103, Form, Small Parts Cleaning and General Sanitation

6.0 Procedure

6.1 Operation

6.1.1 Bring tablet cores into coating room.

6.1.2 Ensure all coating materials are in the room and have not expired.

6.1.3 Open the coating pan door and load the tablet cores into the pan.

6.1144 Start the coating pan by adjusting the speed control. The optimal speed is dependent on pan charge and produces a smooth cascade.

Note: Softer tablet cores are best tumbled at lower speeds.

6.1155 Adjust the air inlet and vacuum controls then briefly close the door to remove any residual dust.

6.1166 Measure the coating solution, typically 300-500ml for a 24" pan. Optimal coating volume per pan is dependent on operator's discretion and experience with the specific product being coating.

6.1177 Temporarily turn off the air inlet, open the door, and slowly and consistently pour the coating solution back and forth across the tablet bed until all coating solution has been applied to the tablet cores.

6.1188 Turn on the air inlet and close the door, allowing tablet cores to tumble. Adjust pan speed as required.

6.1199 Run the coating pan for 5-20min, occasionally checking the tablets for cured coating. Coating time per pan is at the operator's discretion and experience with the specific product being coated.

6.1.110 Once the tablet cores have been coated turn off the inlet air.

6.1.111 Open the coating pan door and with the pan still rotating apply a small amount of talc to the tablet cores to prevent sticking.

6.1.112 Utilize a clean scoop to empty the coating pan. If the tablet cores are known to be soft stop the coating pan to empty it. If the tablet cores are sufficiently durable the pan speed may be reduced to a minimum and the tumbling action utilized to aid in scooping the tablets out.

6.1.113 Once all tablet cores in the batch have been coated complete the coating yield.

6.1.114 If any comments may be made about the coated tablet cores, e.g. high instance of breakage, record them in the comments section at the bottom of form C-104-F7.

6.1.115 Initial and date form C-104-F7.

6.1.116 Remove the coated tablets from the coating room and label them quarantine pending QC release.

6.2 Cleaning Procedure

6.211 Remove all product and paperwork from the previous batch.

6.222 Refer to SOP B-111 Cleaning of Manufacturing/Production Areas and Equipment to follow the cleaning procedure applicable to this type of equipment.

6.233 Document cleaning in the cleaning logbook.

6.244 Contact a QC inspector to verify equipment cleanliness and to check the cleaning logbook.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	08/20/10	New	-	-
1	03/17/11	Made some minor changes	-	-
2	06/20/12	Changed SOP title. Made SOP more detailed.	12-105	M. Wienke
3	11/10/16	Updated format. Changed title, Rewrote to pertain to only the 24" coater and not act as a general coating procedure.	16-0779	C. Fryman
4	03/26/20	Revised and updated for cleaning procedure	66-20-02 r3	E. Hubbell