
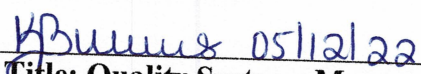
	Standard Operating Procedure NP-250 Rotary Tablet Press		SOP Number B-207	Revision 4
			Effective Date 04/08/22	Page Page 1 of 10
Written by/ Date <i>James Mirellin</i> 04/28/22 Title: Maintenance Manager	Reviewed by/ Date  05/09/22 Title: Production Manager	Approved by/ Date  05/12/22 Title: Quality Systems Manager		

1.0 Purpose

The purpose of this procedure is to define the process for the setup, operation, and cleaning of the NP-250 Rotary Tablet Press.

2.0 Scope

This procedure applies to all NP-250 Rotary Tablet Presses in operation at Ion Labs, Inc.

3.0 Responsibility

- 3.1 It is the responsibility of Production (Compression) personnel to follow this procedure.
- 3.2 It is the responsibility of the department supervisor/manager to implement this procedure and to ensure that this procedure is being followed.

4.0 Definitions

- 4.1 **QC** – Quality Control
- 4.2 **IPA** – 70% Isopropyl Alcohol
- 4.3 **Alconox** – A powdered precision concentrated cleaning anionic detergent

5.0 References

- 5.1 Tablet Press Owner's Manual
- 5.2 B-111, SOP, Cleaning of Manufacturing/Production Areas and Equipment
- 5.3 B-103, SOP, Small Parts Cleaning and General Sanitation

6.0 Procedure

6.1 General Operations Break Down

6.1.1 Tools needed

6.1.1.1 Forked Punch Removal Tool

6.1.1.2 Plastic Tipped Steel Rod

6.1.1.3 T-Handled Allen Wrench or Standard Allen Wrench

6.1.1.4 7/16th Wrench

6.1.1.5 Flat Head Screw Driver

6.1.1.6 Short Shank 90° Allen Key 5/16th for the Upper Punch Take-out Plate

6.2 Operating Steps:

6.2.1 Turn Press off and lock out and tag out (LOTO) power.

6.2.2 Remove Dust Collector Hose from Dust Collector Nozzle & move Dust Collector with Press Cart for cleaning.

6.2.3 Remove Hopper and place into Press Cart.

6.2.4 Remove Feed Frame with Hand Crank and place into Press Cart – check lower section of Feed Frame for wear. Report any wear including pits or metal scrapings or any distinguishable marking on Feed Frame or Turret Head to immediate Supervisor.

6.2.5 Open Lower Swing Arm by loosening Hand Crank.

6.2.6 Remove Upper Punch Take-out Plate by loosening bolt and tapping free with plastic end of Plastic Tipped Steel Rod. Once free, remove bolt and pry out plate. Place plate and bolt inserted onto Press Cart.

Note: Be careful while handling and removing punches and dies. They can be damaged if dropped or handled incorrectly.

6.2.7 Remove upper punches lined up with the take out plate section individually and place on press cart for cleaning (Punch fork removal tool).

6.2.7.1 ROUND PUNCHES – Move to next step.

6.2.7.2 SHAPED PUNCHES – Remove the Phenolic Lower Punch Retainer Pins from spring slots and place onto Cart for cleaning and storage.

6.2.8 Remove Lower Punch Drop Out Plug – BE CAREFUL while removing so the Punch in the first location does not fall onto ground and get damaged.

6.2.9 CAREFULLY rotate head with counter balance and remove each Lower Punch individually (Punch Removal Forked Tool) - may need assistance.

6.2.10 Place dirty lower Punches in Press Cart for cleaning.

6.2.11 Loosen Die Locking Screws individually by rotating press with counter balance (T Handled Allen Wrench).

6.2.12 Remove dies for die seats individually by inserting Plastic Tipped Steel Rod up through Lower Punch Drop-out Plug and place Dies & Die Lock Screws into Press Cart with Punches for cleaning (Plastic Tipped Rod).

6.2.13 Move Dust Collector and Hoses, Tablet Deduster and Press Cart into Maintenance Shop for storage during cleaning.

6.3 Cleaning

6.3.1 Refer to SOPs B-111 Cleaning of Manufacturing/Production Areas and Equipment and SOP B-103 Small Parts Cleaning and General Sanitation for applicable cleaning procedures for this type of equipment.

6.4 Tablet Setup & Operation

6.4.1 Setup and Operation procedure will be used for after a preventative maintenance, cleaning or machine storage.

6.4.2 Tools needed:

6.4.2.1 90 Weight Gear Oil

6.4.2.2 Barrel Oil

6.4.2.3 H1 Food Grade Grease

6.4.2.4 Die Alignment Tool

6.4.2.5 Plastic Tipped Steel Driving Rod

6.4.2.6 Short Shank 90° Allen Key

6.4.2.7 15lbs per foot Torque Wrench

6.4.2.8 Allen Key Set

6.4.3 Setup Procedure

6.4.3.1 Tooling Lubrication:

- Barrel Oil
- A light film of H1 Food Grade Grease is recommended for the punch heads. DO NOT use an excessive amount of grease.
- A light film of Barrel Oil (1-2 drops) should lubricate the punch barrels beginning 1" above the punch tip and up to the punch neck. NEVER use grease on the punch barrel.

6.4.3.2 Die Installation (Round) – Punches and Dies need to be handled with the utmost care in order to prevent damage to finish.

- Double check die pockets to be sure die pockets are clean of all residues from previous cleaning process (Die Alignment Tool).
- Utilizing the Die Alignment Tool to keep dies straight, place each die into pockets.
- Tap down the die until it is solidly seated into the pocket utilizing the Plastic Tipped Steel Driving Rod. This is done by placing the Driving Rod through the corresponding Upper Punch Guide and tapping (Plastic Tipped Steel Driving Rod).
- Utilize the counter balance to rotate the turret and install all punches in the same format.
- Tighten all of the die lock screw using a torque wrench provided. Be sure the wrench is rated at 15lbs per foot of torque. DO NOT OVER TIGHTEN, strike each die one last time and retighten the die screws individually, using the counter balance to manually rotate the head. DO NOT INSTALL WITHOUT LIGHT MINERAL OIL LUBRICATION ON THREADS.

6.4.3.3 Lower Punch Installation (Round)

- Do not install punch without making sure the punches are lubricated as the procedure stated above.
- Rotate the counter balance until each lower punch guide is aligned with the plug and install each punch into the corresponding location.
- When installing the last punch be sure it is pushed high enough so the drop out plug can be reinstalled. Check to see if the plug is seated properly before beginning operation.
- Reinstall gear guard cover (Lower Swing Arm).

6.4.3.4 Upper Punch Installation (Round)

- Do not install punch without making sure the punches are lubricated as the procedure stated above.
- Without force, install punches through upper punch guides rotating the head to make available each punch guide. Lower each punch gently until it reaches the dwell cam.
- Reinstall the Upper Punch take out.

6.4.3.5 Installation of Shared Tooling – This type of tooling must be installed in a different than round tooling. The upper punch guides of the turret have key ways and the upper punches are keyed. This keeps the punches and dies accurately aligned.

- Do not install punch without making sure the punches are lubricated as the procedure stated above.

Note: If punches do not slide freely into punch guides by the force of their own weight, examine them for nicks, burrs or dirt. NEVER force the punches.

- In the gap left by the removal takeout plate, insert the punches individually. As with round punches check for the free movement of the punches.
- Place the die under the punch and insert the punch in the die.
- Lower both the punch and die in the die pocket keeping clockwise pressure on the punch head, this is the direction of force during normal operation (Die Alignment Tool).
- Use the punch to begin seating the die until the punch head comes close to contacting the turret. Remove the punch and tap the die

down with the plastic tipped steel driving rod until fully seated in the die seat (Plastic Tipped Steel Driving Rod).

- Carefully lower the punch back into the die. Make sure to maintain clockwise pressure to check for proper alignment. The punch should enter the die without any difficulty.
- If the punch has difficulty, remove the punch and die and reinstall with instructions above.
- After all punches and dies are installed, install the takeout plate, making sure to line it up carefully with the cam body and tighten the screw securely.
- After correcting the alignment, tighten but do not force the die lock screw with the punch remaining in the die. Use the 15lbs per foot torque wrench to tighten the die, DO NOT OVER TIGHTEN (15lbs per foot Torque Wrench). DO NOT INSTALL WITHOUT LIGHT MINERAL OIL LUBRICATION ON THREADS.
- Align each set the same way and tighten all die screws.
- After all lower punches are installed; return the lower dropout plug into its proper place.
- Lower punch installations refer to the Lower Punch Installation (Round) procedure.
- Install the lower gear guard swing arm and install the remaining parts:
 - Prepare the feed frame.
 - Prepare the hopper.

6.5 Operation Sequence Procedure

- 6.5.1 Before operating check to see if these steps have been completed:
 - 6.5.1.1 All moving parts have been thoroughly lubricated.
 - 6.5.1.2 Check to make sure the tonnage overload spring pressure indicating system is on the proper setting for your tools.
 - 6.5.1.3 All adjustments described in previous section have been made.
 - 6.5.1.4 Hopper has been filled and flow adjusted.
 - 6.5.1.5 The press has been turned through at least one revolution by hand compression.
- 6.5.2 General Operating Factors
 - 6.5.2.1 The quality of the punches and dies
 - 6.5.2.2 The material being compressed
 - 6.5.2.3 Free flowing material that does not stick to punch faces, pack in the feed frames or bind in the dies
 - 6.5.2.4 Tablet size & shape
 - 6.5.2.5 Proper adjustment of fill, compression point, pressure, hopper and feed frame
 - 6.5.2.6 Correct operating speed
 - 6.5.2.7 Proper Lubrication
- 6.5.3 Installation and Adjustments of Feed Frames
 - 6.5.3.1 Set the feed frame on the leveling screw in its correct position.
 - 6.5.3.2 Tighten feed frame clamp, set screws.

6.5.3.3 The scraper blades are held in place by spring and should be free to float. Be sure to check them periodically during operation.

6.5.3.4 Adjust the table take off bar so that they just clear the lower punch. This should enable to excess granulation to enter the feed frame for use again.

6.5.3.5 By hand, rotate the press through one cycle to ensure the punches, dies or feed frames are not colliding with anything prior to use.

6.5.4 Hopper Setting

6.5.4.1 Install the hopper onto the hopper spindle.

6.5.4.2 Adjust the hopper spindle nuts to the correct adjustment so there is enough granulation gravity fed to keep the feed frame filled with powder without overflowing the feed frame.

6.5.4.3 Tighten the hand lock knob located on the hopper bracket to ensure there is no further movement.

Note: If the feed frame is not provided with enough powder, the tablet made will be underweight and inconsistent weight. Too much material will cause an overflow, so watch feed frame level during normal operation and adjust hopper as needed.

6.5.5 Lower Pressure Roller Adjustment

6.5.5.1 Turn the hand wheel to rotate the turret until the filled die passes between the upper and lower pressure rolls.

6.5.5.2 There should be resistance. If not, adjust the pressure adjusting wheel toward increase pressure.

6.5.5.3 AFTER the punches and dies have passed between the rolls, turn the adjusting wheel until a tablet of the desired density has been

accomplished. If necessary, small adjustments can be made during normal operation. Note: Increasing pressure will decrease tablet thickness.

6.5.6 Adjusting Upper Punch penetration and Lower Punch Height Adjuster

6.5.6.1 See Owner's Manual

6.5.7 Lubrication

6.5.7.1 Fill the upper oil reservoir to half height with 90 weigh gear oil.

6.5.7.2 Upper & Lower Pressure Rolls after cleaning, between batches and during storage.

6.5.7.3 Ring and worm gear after cleaning, between batches and during storage.

6.5.7.4 Worm bearing after cleaning, between batches and during storage.

6.5.7.5 Pivot Pins after cleaning, between batches and during storage.

6.5.7.6 All thread and Hinge Points at after cleaning, between batches and during storage.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	08/02/10	New	-	-
1	04/02/13	New format, update SOP setup, Operation, Cleaning and Maintenance, changed SOP name	13-205	B. Mosall
2	09/28/15	Biennial Review: updated SOP format.	15-0547	P. Zittere
3	01/14/19	Scheduled review: Added reference to SOP B-1111 and SOP B-103. Revised section 6.3.	19-0041	K. Burris
4	04/15/22	Revise machine model numbers to reflect what we currently have on-site and use in production.	CC-22-0187	J. Mireles