

	Standard Operating Procedure	SOP Number B-201	Revision 5
	Tooling Control and Cleaning	Effective Date 03/06/24	Page Page 1 of 5
Written by/ Date <i>Janis Nielsen 09/25/23</i>	Reviewed by/ Date <i>M. J. 09/25/23</i>	Approved by/ Date <i>K. Bunn 09/25/23</i>	
Title: Maintenance and Engineering Manager	Title: Chief Operating Officer	Title: Quality Assurance Director	

1.0 Purpose

The purpose of this procedure is to define the cleaning and control of tooling.

2.0 Scope

This procedure applies to all tooling used in production at Ion Nutritional Labs.

3.0 Responsibility

- 3.1 It is the responsibility of Production personnel to follow this procedure.
- 3.2 It is the responsibility of the Tooling Attendant to follow this procedure.
- 3.3 It is the responsibility of Production & Maintenance Management to implement this procedure and to ensure that the procedure is being followed.
- 3.4 It is the responsibility of Production and/or Maintenance & Engineering to keep this procedure aligned with current practices.

4.0 Definitions

- 4.1 **IPA** – 99% Isopropyl Alcohol
- 4.2 **R&D** – Research and Development
- 4.3 **Tooling** – Punches and Dies
- 4.4 **PQV** – Process Quality Verification

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5.0 References

- 5.1 A-106, SOP, Documentation Guidelines for cGMP Records
- 5.2 C-501, SOP, Document Control
- 5.3 C-502, SOP, Record Storage, Retention, and Destruction
- 5.4 B-201-F1, Form, Tooling Usage Log

6.0 Procedure

6.1 Tooling Logging

- 6.1.1 Once the operations team determines that tooling is needed for a machine, they will report to the tooling cage and ask that tooling attendant to assist in gathering the tooling needed to run the machine that is scheduled.
- 6.1.2 The operator must bring the production room information and all the batch information to the cage at this time to log out the tooling.
- 6.1.3 Once the tooling attendant has all the information, they will assist the operator to gather all the tooling needed in the proper sizes and quantities based on the information they provide.
- 6.1.4 The operations team will locate form B-201-F1 Tooling Usage Log and log all tooling that is being removed from the tooling cage, ensuring that the tooling is being logged correctly and completely. They will need to know what production room they are setting up, what batch name & number is running, the sizes they need, & the quantities needed. They will also apply their initials and the date they are removing the tooling from the tooling cage.
- 6.1.5 Once the log is complete, the tooling attendant will unload the tooling totes and load the tooling onto a transport cart. While loading the cart, the tooling attendant will do a visual inspection of the tooling to ensure they are ready to use. The

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tooling attendant will also give the operator any other pieces/parts that may be needed with the tooling (ex. dust cups).

6.1.6 Once the production run is complete, the operator will remove all the tooling from the machine and clean any excess powders from the tooling prior to returning it to the tooling cage. The operator is responsible for logging the tooling back into the log book and the tooling attendant can begin the cleaning & maintenance needed prior to storing into the tooling totes.

6.2 Tooling Cleaning and Maintenance

6.2.1 Materials Needed

6.2.1.1 IPA

6.2.1.2 Stainless steel wire brush (wheel type and pencil type)

6.2.1.3 Natoli Barrel-Lube H-1/Natoli Food Grade White Mineral Oil H-1 (or equivalent)

6.2.1.4 Natoli Synthetic Food Grade Grease H-1 (or equivalent)

6.2.1.5 Cotton wheel for polishing

6.2.1.6 Gloves

6.2.1.7 Safety Glasses

Note: Always wear gloves and safety glasses when handling tooling. Punch tips are very delicate so treat them accordingly. Avoid punch tip contact with any part of another punch, any part of the press, metal tools and equipment, and any part of the metal storage container.

6.2.2 Punches and dies removed from a press by the operator, should be wiped with a clean dry cloth to remove any remaining product /oils.

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6.2.3 If any product remains then use a clean dry cloth, soak with 99% IPA, wring out the cloth and wipe any remaining product/oils from tooling.

6.2.4 Continue process until tooling is free of any product/oils buildups. Wipe off any excess IPA and place on the transport cart. Return the tooling to the tooling attendant and check in anything being return into the log book.

6.3 Tooling polishing & Inspection

6.3.1 The tooling attendant will repeat the same process as above, until the punches are free of material. Use IPA and a cotton cloth to ensure punches and dies are thoroughly cleaned.

6.3.2 Dry with a clean cotton cloth.

6.3.3 If needed, use the cotton wheel with polishing compound to polish punches to a mirror shine.

6.3.4 After polishing, inspect the tooling to determine if there is any damage or wear that is beyond repair using the proper tooling drawing. Place emphasis on the punch tips. Look for bruising outside of the punch tips and check the tips for raised burrs and abrasion.

6.3.5 Check for scoring or binding on the punch barrels and stems. Visually inspect the punch bodies for corrosion.

6.3.6 Inspect the die bores for compression rings in the bores, wear or binding in the bores, corrosion, and burrs or bruising.

6.3.7 Notify Maintenance Management if any wear is found.

6.4 Storage Preparation

6.4.1 Prior to storage, apply a light coating of Natoli Barrel Lube H-1 or Natoli Food Grade White Mineral Oil H-1 (or equivalent) to the punch barrels and dies.

6.4.2 Apply a light coating of Natoli Synthetic Food Grade Grease H-1 (or equivalent) to the punch heads.

6.4.3 Measure each punch for wear consistency. Notify Maintenance and Operations Management for any inconsistent punch measurement.

6.4.4 Place tooling in the appropriate tooling tote with the punch tips pointed downwards.

6.5 Documentation Requirements

6.5.1 Logbooks will be assigned and distributed as outlined in SOP C-501 Document Control.

6.5.2 A PQV check must be performed for each completed logbook page as outlined in SOP A-106 Documentation Guidelines for cGMP Records.

6.5.3 Documents will be maintained following SOP C-502 Record Storage, Retention, and Destruction.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	02/23/11	New	-	-
1	04/01/13	Updated SOP format.	13-204	B. Mosall
2	06/18/15	Biennial Review. Updated SOP format.	15-0530	E. Cummings
3	02/08/17	Improved clarity and precision of procedure	17-0145	C. Fryman
4	06/20/19	Change from 70% IPA to 99% IPA. Clarified procedure.	19-0394	L. Dush
5	09/23/23	Added in logging information and proper department notifications. Added form B-201-F1 to log tooling. Updated logo and format. Added documentation requirements. Changed SOP title.	CC-23-0109	J. Mireles

