Pharmaceutical – Format Changeover Procedure in Tablet Packaging Lines			
Document ID	SOP-FRCHGOV-TPL-100	**Version**	1
Reviewed by	Michelle Salas (Production Supervisor)	**Approved by**	Nathaly Mcallister (Manufacturing Manager)
Revision date	19/06/2024	**Release Date**	25/10/2024

Pharmaceutical – Format Changeover Procedure in Tablet Packaging Lines

1. Purpose

To standardize the format **changeover process in tablet packaging lines** to ensure product integrity and compliance.

2. Scope

Applicable to **all tablet packaging lines in the pharmaceutical manufacturing facility.**

3. Objectives

- Ensure correct format parts are installed.
- Prevent cross-contamination between products.
- Maintain GMP compliance.

4. Tools and Materials

- Format parts (chutes, feeders, blister molds)
- Cleaning tools and agents
- Torque wrenches
- PPE: gloves, masks, gowns

5. Applicable Regulations

- FDA 21 CFR Part 211
- EU GMP Annex 15
- Internal SOPs for line clearance

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6. Procedure

1. Preparation

1. **Review batch record and format change instructions:** Confirm the upcoming production batch and verify all format change requirements as per the batch record, product specification, and standard operating instructions. Review equipment setup drawings or changeover guides to ensure correct configuration for the new product format.

2. **Verify availability of new format parts:** Check that all required format parts (e.g., forming plates, sealing tools, feeders, guiding components, and change parts) are available, cleaned, and in good condition. Inspect for any wear or damage that could affect product quality or machine performance.

3. **Perform line clearance:** Ensure complete removal of the previous batch materials from the production line, including product residues, packaging components, and printed materials. Clean and inspect all work areas to confirm compliance with line clearance standards. QA or production supervision must verify and sign off before proceeding.

2. Disassembly

1. **Stop the line and perform lockout/tagout:** Safely stop all equipment in accordance with standard shutdown procedures. Apply lockout/tagout (LOTO) to isolate electrical, pneumatic, and mechanical energy sources. Confirm that no residual movement or stored energy remains before handling any components.

2. **Remove current format parts and clean them:** Carefully disassemble and remove the existing format components following the manufacturer's or internal setup guide. Clean all parts using approved cleaning agents to remove product residue or lubricant buildup. Label and store parts in designated racks or storage areas to avoid mix-ups and maintain traceability.

3.Installation

1. **Install new format parts as per instructions:** Assemble and install the new format components according to the changeover checklist, ensuring that each part is correctly positioned and secured. Follow torque specifications, assembly diagrams, and any special setup notes provided by equipment engineering or technical support.

2. **Verify alignment and secure with torque wrenches:** Check alignment of critical components such as sealing jaws, forming cavities, and feeding systems. Use calibrated torque wrenches to tighten bolts and fasteners to specified torque values. Confirm that all moving parts operate smoothly and that no interference occurs.

4. Testing

1. **Run empty blisters to verify alignment:** Start the machine with empty blisters or packaging materials to verify correct alignment and motion synchronization. Observe feeding, sealing, and cutting operations for stability, ensuring that components operate without friction or collision.

2. **Perform trial run with tablets and inspect output:** Conduct a short production trial using actual tablets or product units. Inspect the first several packs for alignment, sealing integrity, fill accuracy, and visual quality. Record results in the changeover log and obtain QA approval before initiating full production.

7. Documentation

a. **Record changeover details**: Document all relevant information regarding the format changeover in the equipment or batch logbook, including date, time, equipment ID, product name, and personnel involved. Record all format part numbers installed, torque verification results, and visual inspection findings.

b. **Capture verification and approval:** Production and maintenance personnel must sign off upon completion of installation and testing steps. Quality Assurance (QA) shall verify correct setup, perform visual inspection of the first article, and approve the line before production restart.

c. **Archive supporting data:** Store torque measurement sheets, alignment checks, and any deviation reports in accordance with document control policies. This ensures traceability and compliance with audit and validation requirements.

8. Multimedia Aids

1. Flow diagrams of CIP/SIP system
2. Video tutorial of cleaning process
3. Audio safety instructions

9. Quality Controls

1. **Mechanical alignment verification:** Confirm that all tooling and format parts are properly aligned, using alignment gauges or reference marks where applicable. Improper alignment can lead to product rejection, mechanical wear, or packaging defects.

2. **Trial run inspection**: Evaluate the initial trial run output for accuracy in filling, sealing, labeling, and cutting. Inspect for defects such as misalignment, incomplete seals, or damaged units. QA must verify and approve the first acceptable pack before full-scale production.

3. **Cross-check with batch documentation**: Ensure that product code, batch number, and packaging material codes match the new format setup. Verify that all materials correspond to the approved documentation to prevent cross-contamination or labeling mix-ups.

10. Problem Resolution

1. **If misalignment detected**: Stop the equipment immediately and identify the source of misalignment (e.g., tooling, feeder, or sealing station). Recalibrate or reassemble the affected section following setup guides, and perform another empty-run verification before restarting.

2. **If defective output continues**: If trial runs show repeated defects, report the issue to maintenance and QA. Conduct root cause analysis (mechanical, material, or parameter-related). Rework or replace defective format components as required.

3. **If deviation occurs:** Document all deviations in the deviation log, including description, cause, corrective actions, and responsible personnel. QA and Maintenance must jointly assess the impact on quality and determine if revalidation of the line setup is necessary.