

E SOP 0500 Cleaning Verification

Date Implemented: 10/17/2019

Last Revision 07-19-2026

Version 3

- I. Objective:** To provide a procedure to ensure that any required pre or post-batch cleaning is being verified by a scientifically sound and approved procedure.
- II. Scope:** All employees who perform cleaning and cleaning verifications in the production processing areas.
- III. Definitions:**
 - a. ATP Swab - Adenosine Triphosphate - A molecule that is found in all living cells, including bacteria, food residues, and organic matter
 - b. RLU – Relative Light Units – Light that is measured from ATP reaction with the swab enzyme
 - c. QA/QC – Quality Assurance/Quality Control
 - d. SOP - Standard Operating Procedure
 - e. GMP - Good Manufacturing Practices
- IV. Procedure:**
 - A. ATP Testing**
 - 1. ATP testing must be performed on at least one piece of equipment that will be used in production/batching **prior** to beginning.
 - a. Multiple pieces of equipment that undergo the same cleaning methods should be rotated so that every piece of equipment that is being used is tested at least once per week.
 - 2. Results of the ATP test are recorded on the batch/packaging record in the designated area.
 - 3. ATP machine Operating Instructions.
 - a. Begin by selecting the appropriate User ID
 - b. Turn the unit on and allow it to finish the 15-second self-calibration.
 - c. Once calibrated, press the “*” button. “USER ID” will now be visible.
 - d. Press “OK.” “USER: #” will begin flashing.
 - e. Press the up or down arrows to find the correct User ID.
 - f. If the correct User ID does not appear, contact QA to ensure all the appropriate training is completed before conducting the test.
 - g. Press “OK” to confirm your selection.
 - h. Press the “*” button to exit the menu.
 - 4. Select a test location
 - a. Turn the unit on and allow it to finish the 15-second self-calibration.

- b. Once calibrated, press the “P” button. “PROG #” will begin flashing.
 - c. Using the up or down arrows, find the desired test location and press “OK” to select. The swab may now be inserted for measurement.
 - 5. ATP Sample Procedure
 - a. Turn the unit on and allow it to finish the 15-second self-calibration.
 - b. Remove the swab from the test tube and collect a sample.
 - i. Use a back-and-forth, and then cross-cross motion across the surface being swabbed.
 - ii. Using the above swab technique, swab multiple locations on the equipment, ensuring that product contact surfaces are adequately represented as recommended below.
 - c. Place the swab back in the test tube.
 - d. Snap the bulb by bending back and forth and squeezing to expel the liquid reagent into the swab tube.
 - e. Lightly shake for 5 seconds, bathing the swab in the reagent liquid.
 - f. Place the swab test in the luminometer and close the lid.
 - g. Hold the luminometer upright during the test.
 - h. Press “OK” and the reading will appear in 15 seconds.
 - i. Readings that show a check mark indicate a Pass result. Nothing more needs to be done.
 - ii. Readings that show an exclamation point indicate a Caution result. Generally, this does not indicate anything more needs to be done; however, if multiple tests return with Caution results for the same process, QA must investigate the effectiveness of cleaning methods.
 - iii. Readings that show an ‘X’ indicate a Fail result. QA must be contacted, and all product contact machines must be recleaned and retested until a Pass result is obtained. Increased testing may be required as a preventative measure.
 - 6. Test limits
 - a. Pass: 0-10 RLU
 - b. Caution: 11-30 RLU
 - c. Fail: >30 RLU
- B. Typical Swab Locations:
 - 1. SureKap Filler – Hold Tank and Nozzles.
 - 2. All Fill Filler – Drive Blade, Head Hopper, Tote Hopper, Auger, and Auger Tube.
 - 3. Simplex Filler – Hold Tank, Piston Tube, Piston, and Nozzle.
 - 4. Mateer Powder Filler – Head Hopper and Drive Blade.
 - 5. Pump – Inside Fan Blades and Encasement
 - 6. Masterflex Filler – Tubing
 - 7. Pasteurizer – Hold Tank.

8. 2000-Gal Tank – Tank Wall, Impeller Blade, and Cover.
9. 600-Gal Tank – Tank Wall, Impeller Blade, and Cover.
10. Lightnin Mixer – Impeller Blade, Pivot point for motor
11. Premier Mills Dispersator – Mixing Shaft and Blade.
12. pH Meter – Shaft and Sensor
13. Thermometer – Shaft.
14. Mixing Drum – Drum Walls and Lid.
15. Pump Innards – Hoses and impeller
16. Vacuum Feeder – Hoses and Wand
17. Utensils

C. Internal Audits

1. Quality Assurance conducts a monthly site internal audit that includes verifications of cleaning practices.
2. QC technicians perform weekly GMP/Sanitation audits that verify cleaning is being conducted, see GMP Internal Audits SOP.
3. All site cleaning records must be signed and turned in to the Sanitation Supervisor and kept on file in the Quality Cleaning binder location, see Sanitation of Building and Facilities SOP.

IV. Monitoring: The production supervisor, warehouse lead and the Quality team will monitor compliance with this SOP.

V. Corrective Action:

- A. The quality team will verify if cleaning records are being completed and turned in to the Sanitation Supervisor. If records are not being turned in and audits are verifying that cleaning is not taking place, then the pertinent managers shall be notified for corrective actions.
- B. If ATP results are not being logged on the proper batch/packaging record locations, then the pertinent managers must be notified for corrective actions.

VI. Verification and Record Keeping:

- A. Use the Monthly Quality internal audit and weekly GMP/Sanitation audits to verify proper cleaning.

VII. History

Originator	Date	Description	Approved	Version #
Q Morrill	10/17/2019	Created SOP	K Turner	1
S Bowler	9/11/2024	Changed SOP number from C 0390 to E SOP 0500. (CC22108-5) Added column for version #. (CC24324-3)	D Duersch	2
D Duersch	07-19-2026	Added a definition section and removed CLS equipment numbers that were referenced	T Quinones	3

Originated By 

Date 07-19-2026

Approved By _____

Date _____

Effective Date _____