

Company Procedure

Title: Daily Quality Audit Number: R12-PR-100-001
Owner: Eric Downs Revision: 03

Effective Date: 5/1/2017 Page: 1 of 5



1.0 Purpose

The procedure is in place to ensure that all products being produced meet the approved specifications for the Repackaging Facility at Giles Chemical.

2.0 Scope

This procedure will be performed starting at 6AM and continuing every two hours until production ends for the day.

3.0 Responsibility

The Quality Unit is responsible for this audit to be performed correctly. Quality personnel will be performing the audit throughout the course of production in the Repackaging area.

4.0 Safety Considerations

Steel toe shoes, safety glasses, hair net, and standard safety attire for Repackaging.

Safety is a condition of employment. Employees are not authorized to work in an unsafe manner and are prohibited from harming the environment of the facility or community.

5.0 Materials/Equipment

- Pouches/Cartons in production
- Quality Station with scale for pouches/cartons and fragrance barrel
- Black ink pen
- Master Copy or Quality Released placard from the pallet of pouches/cartons
- Nalgene beaker to weigh the fragrance.

6.0 Procedure

1. Record time of product, line number, Auditor, and date before starting the audit.

2. Weight Check:

- Take three pouches from the conveyor line and bring them to the quality station to be weighed. The operator of the machine has a spec sheet that indicates the proper weight.
- After performing the weight check inform the operator the test results. If the weights fall inside the allotted specs, relay the information to the operator.



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- If the test results show that the weight is below the weight limits, then the pallet at the machine in production will be quarantined and an audit will be performed.
- The audit will back check pouches to verify the weights. Once the weights are approved the product that failed the weight check will be disposed of following the Rework/Reprocess procedure (*R12-PR-100-007*).

3. Metal Detection:

- Following the Weekly Metal Detector Inspection Procedure (R17-PR-100-066), run the same three pouches or cartons used for the weight checks on Daily Quality Audit Form (R12-PR-100-F001) through the metal detector. This will apply to USP products only.
- If a pouch and/or carton is rejected, collect and run three additional samples.
- If one of the additional samples are rejected, proceed with placing all product from that line on Quality Hold and audit appropriately following Quarantine and Auditing of *Products*(*Q12-PR-100-012*)

4. Drop Test:

The drop test will be performed from the pouches that were used for the weight check. *Pouch* Drop Test Procedure (R12-PR-100-004) gives the details on how a drop test is performed at each machine.

5. Incoming Salt Inspection Form:

Verify the salt lot number from the Incoming Salt Inspection Form R12-FM-100-006 at the stations by the hoppers.

6. Dispersion Test:

Open 1 of the 3 pouches that were weighed and check the dispersion of fragrance. Only fragrance pouches are to be tested. Lay the pouch down on its back side and cut the front of the pouch off. Grab a handful of salt from the bottom, middle, and top of the pouch, and then squeeze the salt in your hand. The salt should clump up in your hand. If the salt clumps there



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is fragrance. If the salt does not clump the fragrance did not disperse evenly. Indicate on the audit sheet yes for dispersion or describe where there was no fragrance.

• Once a month "between" (1st-5th) days of the month, perform a Kool-Aid test on the machine that are using fragrance. The information will be recorded on the *Daily Quality Audit Form* (R12-PR-100-F001) in the comments section.

7. Fragrance Test:

- Check the dosage of fragrance that is being dispensed into the pouch of salt following Fragrance Dosing Check (R12-PR-100-020). Use the appropriate fragrance weight form to document the results.
- On Auto #1 check the fragrance barrel weight. The procedure *Auto Machine Scent Weight Check (R12-PR-100-005)* explains how to perform the weight check.

8. Appearance:

- Verify the pouch is sealed and no salt can escape from the pouch.
- To check for leaking, squeeze the pouch and turn it upside down and shake it. If no salt leaves the pouch it is sealed correctly.
- If the seal is not good and the pouch leaks, dispose of the pouch.
- Check the artwork and print on the pouch/carton. Ensure that there is a green Quality Release
 Tag on the pallet of pouches/cartons.
- If the pouches/cartons do not have a quality release tag, quality will quarantine the pouches/cartons and compare to the Master pouch or carton.
- Check the legibility of the printed date code. Make sure the pouch/carton is legible.
- If pouch/carton date code is legible continue with production.



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• If the pouch/carton is not legible, quality will stop production on that specific line and back audit production. Any product that failed the appearance check will be disposed of following the *Rework/Reprocess* procedure (*R12-PR-100-007*). Also, the date code must be fixed by the lead operator.

9. Document Check:

• Look over the paper work to make sure the operator has used the correct paper work and everything is filled out correctly.

10. Record the Product Date Code:

- Document the date code that is on the pouch, carton and all packing boxes. The operator will have a change over form that will have the correct date code written on it. The operator should refer to appropriate *Start-Up/Change over Form*.
- Make sure the correct date code is on the product and the packing boxes.
- If the date code is wrong on any of the products, the product will be quarantined and a separate audit will be performed.
- 11. There is an area for comments to be documented.
- 12. The audit sheets are saved and filed daily by quality.

7.0 Reference Documents

Incoming Salt Inspection Form (R12-FM-100-006)

Pouch Drop Test (R12-PR-100-004)

Fragrance Dosing Check (R12-PR-100-021)

Auto Machine Scent Weight Check (R12-PR-100-005)

Daily Quality Audit (R12-PR-100-F001)



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Rework/Reprocess

(R12-PR-100-007)

Weekly Metal Detector Inspection Procedure (R17-PR-100-066)

Appropriate Start-Up/Change-Over Form

Carton Weight Sheet

Pouch Weight Sheet

8.0 Change Information

Changed / Up-dated document to reflect current practice and form titles