
	GILES CHEMICAL ~ PREMIER MAGNESIA		
	Company Procedure		
	Title: Daily Batch Record	Number: R12-PR-100-012	
	Owner: Jeff Hill	Revision: 01	
	Effective Date: 05/24/13	Page: 1 of 3	

1.0 Purpose

To establish uniform guidelines and responsibilities for keeping track of the batch records.

2.0 Scope

The batch record for Giles Chemical Repackaging is a daily production record and its supporting documents.

3.0 Responsibility

The Quality Unit will collect and assemble the daily batch record for products produced and ensure traceability. The documents will be submitted by production personnel and audited by the Quality Unit to insure proper cGMP procedures are being followed.

4.0 Safety Considerations

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

N/A

6.0 Procedure



1. The *Recon Sheet (R12-FM-100-010)* will provide an accurate reproduction of the appropriate master production and control record. This form will be filled out by the shift supervisor, reviewed by production personnel and quality personnel. This form will also calculate yield of bulk salt for the day
2. *Incoming Salt Inspection Form (R12-FM-100-006)* serves as a tracking component for the incoming raw material (Bulk Salt). Information related to the manufacturing of this raw material is transferred to the form. The bulk salt is inspected and reviewed prior to use/release in the manufacturing process.

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3. *Start-Up/Change Over* Form ensures that all customer and quality requirements are being met and that all materials (packaging and labeling) used to produce said finished product is accurate, provide the proper expiry date or salt lot number (Batch Code) that should be applied to the product, and corrugated shipper that product is packed in. As well as ensure inventories of pouches and cartons remain accurate, and ensure that all previous ran materials were removed at the end of the day and before a change over occurs.
4. *Daily Production Report (R12-PR-100-F002)* the production report identifies each individual line of equipment used within that day. Each production line will need to have a production report form to identify what products were made or produced.
5. *Weight Sheets* The weight sheet is the location where operator inspections are recorded. The weight sheets are specific for each weight class of products. The weight sheet allows for a visual inspection to product weight trends and allows operator/supervisor to maintain the product within the specification of each weight class.
6. *Fragrance Weight Sheets* The fragrance weight sheet is the location where operator inspections are recorded. The fragrance weight sheets are specific for each product. The fragrance weight sheet allows for a visual inspection to fragrance weight trends and allows operator/supervisor to maintain the product within the specification.
7. *Daily Quality Audit (R12-PR-100-F001)* form is used by quality personnel to provide assurance that proper containers and labels are being used during production. This audit forms provided a place to document audit finding and any possible deviation. This audit also is a secondary check on weights and measures on product and fragrance if needed.

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8. *Drop Test Forms*: Used to verify the pouches maintain their integrity when dropped from 36 inches.
9. *Auto Summary Forms*: Used to track key process points on the auto lines.
10. *Date Code Sign-off Form*: (R12-FM-100-009). *These forms are used to ensure there is a date code on every pouch or carton. They are completed each hour the line is running.*
11. *Salt Delivery Forms*: These forms keep up with salt inventory that is received daily and needed to calculate daily salt usage.
12. *Daily Batch Record (R12-PR-100-F012)* is a form that shows all applicable expiry date of salt lots. (Batch codes) for cartons and pouches produced daily. The form also shows the salt lot numbers used that day.

7.0 Reference Documents

<i>Recon Sheet</i>	(R12-FM-100-010)
<i>Incoming Salt Inspection Form</i>	(R12-FM-100-006)
<i>Start-Up/Change Over Form</i>	
<i>Daily Production Report</i>	(R12-PR-100-F002)
<i>Weight Sheet</i>	
<i>Fragrance Weight Sheet</i>	
<i>Daily Quality Audit</i>	(R12-PR-100-F001)
<i>Drop Test Form</i>	
<i>Auto Summary Form</i>	
<i>Date Code Sign-off Form</i>	(R12-FM-100-009)
<i>Salt Delivery Form</i>	
<i>Daily Batch Record</i>	(R12-PR-100-F012)

8.0 Change Information

Updated procedure following *SOP Template Instructions (Q12-PR-100-004)* and *Document Numbering (Q12-PR-100-003)*

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