
	GILES CHEMICAL ~ PREMIER MAGNESIA		
	Company Procedure		
	Title: Daily Batch Record	Number: R12-PR-100-012	
	Owner: Brook Vaughn	Revision: 04	
	Effective Date: 08/01/2016	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 ensure 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

Batch records are reviewed by the Quality Unit for completeness and GDP's. Additionally, a critical review is conducted to ensure compliance with all established procedures prior to release of the lot. This review and approval will be completed before each lot is released.

1. *Daily Batch Record (R12-PR-100-F012)* shows all applicable expiry dates of salt lots, and batch codes for cartons and pouches produced daily. The form also shows the salt lot numbers used that day.
2. The *Recon Worksheet (R12-FM-100-010a)* is an excel spreadsheet and will provide an accurate reproduction of the appropriate master production and control record. The *Recon Calculations Summary (R12-FM-100-010b)* is the hand calculation for the *Recon Worksheet*. These forms will be completed by the shift supervisor, reviewed by



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production personnel and quality personnel. This form will also calculate yield of bulk salt for the day.

3. *Start-Up/Change Over Form (Specific to product)* 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 previously ran materials were removed at the end of the day and before a change over occurs.
4. *Expiry Date Sign-off Form (R12-FM-100-009)* is used to ensure there is a date code on every pouch or carton. They are completed each hour the line is running.
5. *Daily Production Report (R12-PR-100-F002)* the production report identifies each individual product produced on that line on that day. Each production line will need to have a production report form to identify what products were made or produced.
6. *Weight Sheet (Specific to product)* is where operator inspections are recorded. The weight sheets are specific for each weight class of products. The weight sheet allows for a visual inspection of product weight trends and allows operator/supervisor to maintain the product within the specification of each weight class.
7. *Fragrance Weight Sheet (Specific to product)* is where operator inspections are recorded. The fragrance weight sheets are specific for each product. The fragrance weight sheet allows for a visual inspection of fragrance weight trends and allows operator/supervisor to maintain the product within the specification of each weight class.
8. *Auto Scent & Weight Check (R12-PR-100-F005)* is used to track the weight of the pouches, the amount of fragrance being dispensed, and whether the drop test is passed.
9. *Compactor Waste Form (R13-FM-100-044)* is used to track salt that is wasted, and salt that can be recovered.
10. *Auto Summary Form (R13-FM-100-039)* is used to track key process points on the auto lines.

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11. *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.
12. *Daily Quality Audit (R12-PR-100-F001)* is used by quality personnel to provide assurance that proper containers and labels are being used during production. This audit form provides a place to document audit findings and any possible deviations. This audit form also provides a secondary check on weights and measures of product and fragrance.
13. *Certificate of Analysis* are received with each truck load of incoming magnesium sulfate. The CoA's are collected and retained with the daily batch record.

7.0 Reference Documents

<i>Daily Batch Record Form</i>	<i>(R12-PR-100-F012)</i>
<i>Recon Worksheet</i>	<i>(R12-FM-100-010a)</i>
<i>Recon Calculations Summary</i>	<i>(R12-FM-100-010b)</i>
<i>Start-Up/Change Over Form</i>	<i>(Specific to product)</i>
<i>Expiry Date Sign-off Form</i>	<i>(R12-FM-100-009)</i>
<i>Daily Production Report</i>	<i>(R12-PR-100-F002)</i>
<i>Weight Sheet</i>	<i>(Specific to product)</i>
<i>Fragrance Weight Sheet</i>	<i>(Specific to product)</i>
<i>Auto Scent & Weight Check</i>	<i>(R12-PR-100-F005)</i>
<i>Compactor Waste Form</i>	<i>(R13-FM-100-044)</i>
<i>Auto Summary Form</i>	<i>(R13-FM-100-039)</i>
<i>Incoming Salt Inspection Form</i>	<i>(R12-FM-100-006)</i>
<i>Daily Quality Audit</i>	<i>(R12-PR-100-F001)</i>
<i>Certificate of Analysis</i>	<i>(lot specific for salt received for use in production)</i>

8.0 Change Information

Added batch record review information to the Procedure section.
Updated # 2 of the procedure to include document numbers for the *Recon Worksheet* and *Recon Calculations Summary* forms.
Added # 13 to the procedure for receipt of CoA's.

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