
	GILES CHEMICAL ~ PREMIER MAGNESIA		
	Company Procedure		
	Title: Daily Batch Record	Number: R12-PR-100-012	
	Owner: Eric Downs	Revision: 06	
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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 pouches produced daily. This 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 Verification Worksheet (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 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. This form also provides the proper Expiry Date and Salt Lot Number(Batch Code) that should be applied to the product along with Corrugated Materials that product is packed in. The bottom portion of this form also ensures that inventories of pouches are properly reconciled, remain accurate and that all previously ran materials were removed at the end of the day and/or before a Changeover occurs.
 4. *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 ensure the product stays within the proper specifications of each weight class.
 5. *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 ensure the product stays within the proper specification of each weight class.
 6. *Auto Scent & Weight Check (R12-PR-100-F005)* is used to track the weight of the pouches, Lot Code Verification, the amount of fragrance that is being dispensed, whether the Drop Test Passes/Fails and if the product is Properly Sealed or contains Dry Additives.
 7. *Compactor Waste Form (R13-FM-100-044)* is used to track salt that is wasted, salt that cannot be recovered or disposed of and how many labels are discarded of for each line per shift.
 8. *Incoming Salt Inspection Form (R12-FM-100-006)* serves as a tracking component for the Incoming Raw Materials(Bulk Salt). Information related to the manufacturing of this

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Raw Material is transferred to the form. All of the Bulk Salt is Inspected and reviewed prior to release/use in the Manufacturing Process.

9. *Daily Quality Audit (R12-PR-100-F001)* is used by Quality Personnel to provide proof that all proper materials are being used including but not limited to labels and containers. This form also provides secondary Weight Checks, Fragrance Verification and confirmation of proper Seals and Date Codes. The *Daily Quality Audit* form has a place to document any audit findings and/or possible deviations that have occurred including possible introduction of metal into product via Metal Detection Checks.(USP Only)
10. *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 Verification Worksheet</i>	<i>(R12-FM-100-010b)</i>
<i>Start-Up/Change Over Form</i>	<i>(Specific to product)</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>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

Change Owner

Updated *Recon Calculations Summary* name to *Recon Verification Worksheet*.

Removed *Expiry Date Sign-Off Form* from procedure since it has been archived and is no longer used.

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