



# Procedure

## Packaging and Labeling

### AUTHOR

Quality Assurance Assistant	Signature.....
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### VERIFICATION

Quality Assurance Manager	Signature .....
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### AUTHORIZATION

Quality Assurance Manager	Signature ..... Date 07.01.2014
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**Expiry Date      07/01/2016**



## Re-Approvals Form

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EXPIRES ON \_\_\_\_\_  
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## 0. Revision Matrix

REVISION	DATE	UPDATE CARRIED OUT AND REASON FOR UPDATE
01	07/01/2014	Inclusion of use of temporary identification label (FORM 73) to be affixed to the aluminum drum for packaging for each shipment. More details regarding the packaging of the product for the micronization.  Date Rev. 00 Withdrawn 09/01/2014
02		   Date Rev. 01 Withdrawn
03		   Date Rev. 02 Withdrawn
04		   Date Rev. 03 Withdrawn
05		   Date Rev. 04 Withdrawn
06		   Date Rev. 05 Withdrawn
07		   Date Rev. 06 Withdrawn
08		   Date Rev. 07 Withdrawn
09		   Date Rev. 08 Withdrawn



## 1. Scope and Application

To standardize all operations of packaging and labeling for finished products and intermediates.

To determine the content and method of preparation and compilation of the Master Warehouse Record and Batch Warehouse Record, which are the documents containing the instructions and information required for the packaging of products.

## 2. Responsibility

Production or Warehouse operators for execution; QA, Production Manager/Assistant or Supervisor as supervisors.

Writing of the Master Warehouse Record: Production Manager/Assistant.

Approval and Verification of the Master Warehouse Record: Quality Assurance.

## 3. Procedure

This procedure outlines the steps to be followed for sampling and packaging of the products coming from the stage of drying and for packaging of the products for shipment.

Sampling and packaging operations of products from drying step are carried out in the drying room 12E of the finishing area.

The operations of packaging of the products for shipment are carried out inside the packaging room 12W of the finishing area.

Every operation carried out inside the packaging room 12W of the finishing area shall be recorded in FORM 69.

### 3.1 Preliminary Checks

The operator, or warehouse keeper, must perform the following checks:

- cleaning of the premises and equipment;
- the absence of any material / product / documentation relating to previous operations;
- compliance of the environment: Temperature between 20 and 25 ° C and relative humidity below 60%.
- compliance of pressure differences between the various rooms of the finishing area according to the procedure established in P.SOP.016;
- that the balance is labeled with the calibration status and is level;
- identity, referring to the processing sheet or document provided by Logistic in the case of preparation of the product to be packaged for shipment;
- integrity, cleanliness and amount of packaging material and identification labels provided with the processing sheet or document provided by Logistic in the case of preparation of the product to be packaged for shipment;
- the availability, integrity and cleanliness of Personal Protective Equipment.
- before handling a product within the finishing area it is necessary for at least 25 minutes have elapsed since the previous manipulation of another substance.



### 3.2 Sampling Operations

- Take a sample by mixing the product taken from the two points where the dryer was recorded the highest and lowest temperature, identified on the basis of the results obtained from the dryer validation (see protocol P.SOP.013/SOI.01 and its report). Whenever it is necessary to take further samples, this must be indicated in the processing sheet of the product in question.

### 3.3 Packaging Operations

- The packaging material is transferred from the SAS Packaging Materials (12EM) in the finishing area. Before the transfer, the drums are properly cleaned by operators with paper soaked in detergent described in specifications and the polyethylene bags are placed in a sealed bag to prevent contamination.
- The products to be shipped to customers must be packaged in two antistatic polyethylene bags, placed in aluminum drums, which are finally inserted inside a cardboard box. In the case where stability data for the product stored in drums of different materials is available, it is also possible to package the product in question and its intermediates in drums made out of these materials.
- Products which absorb water must be packaged with silica gel, for which the double envelope of antistatic polyethylene is inserted in a third antistatic polyethylene bag containing silica gel. Quality Control is responsible for communicating which products are packed with silica gel.
- Different products or different batches of the same product cannot be packed in the same room at the same time.

#### **Packaging of the product obtained from the drying stage**

- Before initiating packaging, to be carried out in accordance with the provisions defined in this procedure, label each drum with the identification labels "INTERNAL PRODUCTION", provided with the Batch Production Record by Quality Assurance (or in his absence by the Production Supervisor).
- Each individual polyethylene bag used for packaging products must be closed individually gooseneck using releasable cable ties; releasable cable ties are used also to close the outer bag.
- Finished filling of drums close them and seal them. The packaged product remains in the packaging area, while the Batch Production Record is forwarded, with all the accompanying documentation, to Production Manager/Assistant or Supervisor or Quality Assurance for verification.
- After verification, the Production Manager/Assistant or Supervisor or Quality Assurance deliver a copy of the bill of weights/materials to Warehouse to communicate the number of containers to be transferred to the Finished Goods Warehouse 12MF in the quarantine area. This is carried out by Warehouse



personnel in accordance with M.SOP.001 "Receipt of Goods in Warehouse". Upon taking charge, Warehouse stores data sheet stock of the product in question.

### **Packaging of the product for shipment**

- The packaging is made according to the provisions provided by Logistic.
- For shipments of product quantities exceeding 100 g must be issued and filled in the corresponding BWR according to the procedures defined in Section 3.6.
- Any additional labels required by the customer are provided by Logistic and are attached on the drums and boxes as required. The labeling on each drum and box must be identical. All drums and boxes must contain the following labels (labeling on drums and boxes must be the same):
  - Numbered Shipment label;
  - Destination label which is not numbered.

A copy of all labels must be attached to BWR.

- The product must be packed in double antistatic polyethylene bags, the inner bag containing the product must be subjected to heat seal, the outer bag must be properly folded gooseneck and be closed with a cable tie that is not releasable and identified by its serial number. The shipment label must be attached to the outer bag. In the case of products that absorb moisture, the double envelope of antistatic polyethylene bags, heat-sealed and bearing the label on the outer surface, are inserted in a third antistatic polyethylene bag containing silica gel. This outer bag must be labeled (as the second bag), carefully folded gooseneck and closed with a non-releasable cable tie.
- The packaging methods described apply to product quantities exceeding 100g, for quantities less than or equal to 100g, the heat seal shall be carried out on both the inner bag and the outer bag and the shipment labels shall be attached according to the shipping instructions provided by Logistics.
- The product (packaged in the polyethylene bags) is then inserted in the aluminum drum and two anti-tampering stickers with Sterling logo are attached at the seal. Attach on each aluminum drum the temporary identification label FORM 73. Carry the drums in the shipping area, attach over the label FORM 73 the final label for shipment issued by Logistics, then plug the drums into boxes for shipment.
- In the case that a product is intended for micronization, each polyethylene bag used for packaging must be closed individually gooseneck, using releasable cable-ties, while the outer bag must be closed with a non-releasable, numbered cable-tie. The shipping label must be attached on the outer bag. In the case of products that absorb moisture, the double antistatic polyethylene bags closed with releasable cable tie and bearing the label on the outer bag, must be inserted in a third antistatic polyethylene bag, containing silica gel. This outer bag must be labeled (as the second bag), carefully folded gooseneck and closed with the provided cable tie numbered and not releasable.



Products that absorb water and are intended for micronization must be packaged according to QC.SOP.010 "Products Stored in Silica Gel", providing the amount of silica gel required for the packaging of micronized product.

The products to be shipped to the micronization must be packed in double antistatic polyethylene bags, and included all inside a cardboard box.

Moreover, in order to trace any possible manipulation of the packaging and/or product, micronized and non-fractionated products must be packed in the same manner as products prepared for shipment, the inner bag containing the product must be heat-sealed while the outside bag is closed with a non-releasable cable-tie. The company responsible for micronization is provided with a fair amount of non-releasable cable ties, which are identifiable through their serial numbers.

If the micronized product should be fractionated, the company responsible for micronization will be required to package the product in antistatic polythene bags, folded gooseneck and closed by releasable cable ties, this bag will be placed in a second antistatic polyethylene bag, folded gooseneck and closed with a suitable non-releasable cable-tie, identifiable by its serial number.

In this case, at the time of fractionation, the non-releasable cable-tie on the outer polyethylene bag will have to be cut and the amount of product required withdrawn, subsequently sealing the outer bag with a releasable cable-tie and carefully closing the bag.

- The serial numbers of all the numbered cable ties used for each packaging operation is recorded in the dedicated column on the warehouse record sheet for internal production (FORM 53).

- The serial numbers of the cable ties used for the packaging of products intended for micronization should be recorded as well as in the relevant column in the warehouse record sheet for internal production (FORM 53) and also in the specific column in the warehouse record sheet for micronized product (FORM 54). The serial number of the cable ties supplied to the micronizer and the number of cable ties sent but not used by the micronizer, then returned in Sterling, have to be registered in FORM 54. The cable ties returned in Sterling shall be thrown.

- At the end of each single packaging operation, label each outer bag, drum and box with the shipment labels provided by Logistic. Logistic also provides destination labels, which must be attached on the drums and boxes. Both the shipment labels and the destination labels must be verified by QA before being applied.

The Warehouse attaches a copy of all labels to the pertinent BWR.

- At the end of the packaging process QA verify the correct execution of operations. QA sign for verification in the "Shipment Labels Emission Register" FORM 20, and the BWR for its verification.

- The "Shipment Labels Emission Register" (FORM 20) is issued by QA. Each register is assigned a serial number by QA.



### 3.4 Identification Labels for intermediates and finished products

These are issued by Quality Assurance and are transported with the Batch Production Records.

All labels issued must be recorded in the "Labels Issue Register" (FORM 35) by Quality Assurance.

The Labels Issue Register (FORM 35) is issued by QA that assign a serial number to the register.

This register must contain the following information:

- Date of issue of labels;
- Manufacturing Order Number, the product name and batch number for which the labels are issued;
- No. of labels "INTERNAL PRODUCTION" (FORM 58) issued;
- No. of labels "SAMPLE" labels (CQ.SOP.003/SOI.01/All.01) issued;
- Signature of Production Supervisor for the issue;
- Signature of Quality Assurance as a supervisor.

These labels are applied during the packaging of containers prior to their loading as defined by the procedure M.SPC.001.

In the event that the product returns from micronization, Quality Assurance is responsible for compiling, affixing signing and dating, the "quarantine" labels from internal production and attaching them on the drums containing the micronized product. Quality Assurance is responsible for tick, affixing signature and date, the labels "approved" attached on the drums containing the product from the company that performed the micronization. The unique labels to take into consideration are therefore those internal identifying the state of Quarantine. The product obtained from the micronization must be analyzed by Quality Control for the final release. In the meanwhile, it is stored in the Quarantine area of the Finished Goods Warehouse.

### 3.5 Shipment Labels

These are numbered labels issued by Logistic and verified by QA prior to their use, in accordance with procedure G.SOP.003. QA records all labels issued into the "Shipment Labels Emission Register" (FORM 20) for each shipment. This reports the number of labels issued broken down by bags, drums and boxes.

The information to be reported in this register, for each shipment, is the following:

- Progressive Number of the first and last shipment label issued for bags;
- Progressive Number of the first and last shipment label issued for drums;
- Progressive Number of the first and last shipment label issued for boxes;
- Destination;
- Product;
- Invoice Number;
- Date of Shipment;
- QA Signature.

In the case when a quantity less than 100g of product is being shipped, and for which a BWR is issued, the labels prepared by Logistic are not numbered.





### 3.6 Master Warehouse Record (MWR) and Batch Warehouse Record (BWR)

#### Master Warehouse Record (MWR)

The Master Warehouse Record is the original document that contains all the information required for the packaging and shipment of products.

Upon issuance, it must be approved and signed (with data) on the title page and the first page by the personnel referred to above.

Each Master Warehouse Record is kept by Quality Assurance who use it to issue the Batch Warehouse Records by reproducing it.

The Master Warehouse Record is set out to clearly indicate the operation steps, verifications and controls to be carried out. It is desirable that individual operations are listed and numbered consecutively and each point has clear spaces to input the necessary data, including the date and time of execution, the initials of the operator and the Supervisor control.

Any change to the packaging method must be approved by the same functions who approved the original method.

Upon issuance, all copies of the previous edition should be withdrawn.

The first two pages of the Master consist of the cover page and the matrix of revisions, as described in procedure G.SOP.001 "Documentation Management".

Additional information to be included in the Master are:

- Master code (MWR), date of issue, revision level;
- Page number in the form "Page X of Y ", where X is the sequence number and Y is the total

All pages of the Master should be arranged to record:

- Product identification data: name, code and batch number;
- Shipment Order Number: This is assigned progressively from Quality Assurance/Warehouse personnel at the time of compiling FORM 19 "List of Consigned Orders". FORM 19 consists of 10 pages and is issued by QA who sign and date the form upon its issue.

The Master is organized in four sections:

- Documentation Table of Contents,
- Bill of weights/materials,
- Work Instructions,
- Preparation for Shipment Record (Attachment #1 to the shipment preparation)

- Documentation Table of Contents

The Documentation Table of Contents contains the following information:

- List of documents attached to the shipment documentation;
- Space for checking for compliance by Warehouse and a space for a compliance check by Quality Assurance.



- Bill of Weights/Materials

This is set out in a tabular form and contains the following information for each material to be used in the process:

- Code, Name, and Batch Number;
- Assigned amount;
- Balance used;
- Quantity used for the packaging with date and signature of the operator;

### **Checks and Inspections**

- Description of the operation and identity of the main machinery and equipment to be used;
- Description of work clothing and any Personal Protective Equipment to be used;
- Description of preliminary tests to be performed on premises, equipment, environmental conditions, products, materials, availability of personal protective equipment provided and any printed materials (refer to the relevant standard operating procedures) with spaces designed for registering the verification;
- When multiple operations are shown, the operator carrying out the operations has the task of coordinating these activities as they are performed.

- Work Instructions containing:

- The activities to be performed, the method of handling/transfer the product and operating conditions to be applied;
- Precautions to be taken;
- The materials to be used during the operation.

There will also be a space for notes at the end of each process stage in which any anomalies or deviations from the approved instructions are to be reported.

In particular if it is necessary to ship all the product present in stock and in the event that at the end of the packaging operation it results that a smaller amount of product was packaged, Warehouse records the actual amount packaged in the weighing record sheet, signaling as a note that the difference is due to losses occurring during the packaging operations. Finally at the end of the packaging is required to disclose the discrepancy between the amount prepared for shipment and that stated in the instructions by sending a scanned copy of the compiled, signed and dated record sheet to the client.

### **Batch Warehouse Record (BWR)**

The Batch Warehouse Record is an operational document for each Master Warehouse Record that faithfully reproduces the original Master.

The Batch Record Warehouse must be issued:

- for the preparation of the shipment of a quantity of product greater than 100 g (MWR.01);
- for the preparation of products for third parties (MWR.02).



The Batch Warehouse Record is issued by Quality Assurance and must include the following information at the time of issue:

- Date of issue;
- Product Name;
- Code;
- Batch Number of the product to be packaged;
- Date of preparation;

Quality Assurance signs each page, no further changes are allowed.

From the moment of issue, the Batch Warehouse Record materially follows all the various stages of shipment and is compiled in full, in real time.

**Preparation for Shipment Record (Attachment # 1 to the shipment preparation):**

This must be prepared by Quality Assurance at the time of issue of the BWR. You may attach more than one copy in order to provide sufficient space to record all the packaging materials required for preparation and delivery.

Attachment # 1 is issued by Quality Assurance along with BWR. Quality Assurance inputs the product code, batch No., date, and prepare a suitable number of columns, one for each drum to be prepared during packaging.

Closing the Batch Warehouse Record: at the end of the expedition the Batch Warehouse Record must be verified and approved (signed and dated) by Quality Assurance. Quality Assurance is responsible for checking the Batch Warehouse Record, particularly in matching the labels with the order, correspondence with the information contained in the BWR, the integrity of the packaging and affixing the signature and date for approval.

The following attachments must be present with each Batch Warehouse Record:

- The packaging instructions received;
- Attachment # 1 "Preparation for Shipment Record"
- A copy of the labels prepared by Logistic and used for shipment. In the case of labels with the destination address, one copy of these is attached to the Batch Warehouse Record, indicating the number of labels printed and used during packaging.

Packaging instructions must contain:

- The delivery address;
- The name of product;
- The amount;
- The batch number of the product shipped;
- The date of manufacture;
- The expiry date;
- The internal code;
- The shipment code;
- The type of packaging;
- The size of bags;
- The labeling;
- Any additional information relating to the packaging of samples.



Instructions, once signed and dated by Logistic, are transmitted to the Warehouse. Warehouse is required to store the instructions as an attachment to the BWR.

The documents making up each Batch Warehouse Record shall be collected and assembled in a binder with documentation flow as the title, in order to avoid confusion between documents from different batches.

The Batch Warehouse Records are stored by shipment number and are kept in a secure and controlled access area by Quality Assurance for 10 years.

### **Shipments of samples equal to or less than 100 g**

As defined above, the Batch Warehouse Record is not issued for the preparation of the shipment of a quantity of product equal to or less than 100 g: Warehouse and QA are responsible to verify and supervise such shipments, in particular, Warehouse and QA are required to cross-check of all shipping documents and to store a copy of the shipping labels and shipping instructions, affixing signature and date to prove the check.