

# Standard Operating Procedure

## Title: Sampling Inspection and Release of Packaging Materials

Department	Warehouse	Document no	WAR-090
Title	Sampling Inspection and Release of Packaging Materials		
Prepared by:		Date:	
Checked by:		Date:	
Approved by:		Date:	

### 1.0 DOCUMENT OWNER

Warehouse / Quality Manager

### 2.0 PURPOSE

This procedure explains how to sample, inspect and [release packaging materials](#) (except roll feed labels) into the Packaging Store Area. This procedure is GMP critical.

### 3.0 SCOPE

The scope of this SOP is packaging materials used during the manufacture of products at the GMP facility.

These include, but are not limited to:

Materials used to package the various dosage forms (e.g. tablets, capsules, liquids and pastes) into saleable units (e.g. cartons, labels, bottles, blister film, foil, syringes, containers and stickers).

They also include materials used to package saleable units during transportation or shipment of orders (e.g. shippers, shrink film or shipper labels).

### 4.0 RESPONSIBILITY

4.1 All deliveries of incoming packaging materials at GMP site must undergo thorough inspection and proper sampling in the Inspection / Sampling Laboratory before they can be released for use.

4.2 Primary packaging materials that come into contact with product are sampled in the Sampling Booth, if sampling is required.

4.3 Each batch or lot of packaging materials from a supplier is regarded as a unique delivery and identified by a unique site Lot Number.

4.4 Components / containers that are damaged or found contaminated during inspection must be referred to Quality Assurance immediately. Appropriate measures are taken to sub-lot the unacceptable portion and separate lot disposition is performed.

4.5 All printed packaging materials are sampled on priority and then placed in the secure packaging store area for printed packaging materials.

4.6 Before carrying out any sampling or inspection of packaging materials, the required Packaging Material Specification (PMS) must be printed. Refer to [TEM-150 Packaging Material Specification](#) and Test Report. (**APPENDIX E**).

4.7 Only the current version of PMS is to be used for carrying out inspection of packaging materials.

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5.7 Locate the lot that has to be sampled in the Receiving Warehouse. Ensure that the Lot Number on the ERP System ID label on the containers matches the details on [Form 855 - Inspection of Goods](#) on Delivery. Refer to [WAR-095 - Status Labels while working on this process](#).

5.8 Check C of A to see if the manufacturer's lot number has been received previously or whether it is the first delivery of the batch.

5.9 Check that the physical quantities of the lot match the quantities receipted and recorded by the Receiving Warehouse Operators on [Form 850 Inspection of Goods on Delivery and on ERP System](#).

5.10 If there are quantity discrepancies, first review the receipted Item / Lot / Quantity with the Receiving Warehouse Operators. If the quantities cannot be reconciled with the Purchase Order and other delivery documents, then contact the Warehouse Manager. Ensure that the ERP System records match physical quantities for the lot before proceeding with sampling and inspection.

5.11 Determine the Sampling Plan

There are three (3) possible packaging material inspection plans available to sample a lot of packaging materials:

Refer to **APPENDIX A, B and C** respectively for guidance on Switching the sampling Plan, AQL Limits and Sampling plans.

1. Packaging Materials Single Sampling Plan - Reduced
2. Packaging Materials Single Sampling Plan - Normal
3. Packaging Materials Single Sampling Plan - Tightened

Follow the rules below to determine the required level of inspection:

5.11.1 For a new supplier of packaging materials, use tightened inspection.

5.11.2 For an existing approved supplier of packaging materials, use either normal inspection or reduced inspection.

5.11.3 To determine the appropriate level of inspection for a particular packaging material delivery, review the "Future Decision" column of the history chart for the previous delivery of this class of component from the supplier. The QA Sampling Inspector would have recorded this along with defect levels when performing the previous inspection.

Refer to **APPENDIX A**, Switching Sampling Inspection Levels, for details of the switching procedure between normal, reduced and tightened inspections.

5.12 Determining the Sampling Requirements Based on Sampling Plan (**APPENDIX C**) and Number of Containers in the Delivered Lot and if Manufacturer's Samples Are Acceptable.

After determining which sampling plan is to be used, check the particular sampling plan table to determine how many containers (cartons / shippers) need to be opened for sampling based on the number of containers in the delivery.

Use the same sampling plan to determine how many samples are to be drawn from the given lot.

Where the supplier is certified, samples provided by the supplier can be used for inspection and checking. The list of certified suppliers is found with Quality Assurance "Qualified Supplier and Sampling List".

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Complete the Sampling transaction in the ERP System.

This reduces the inventory in ERP System by the quantity of sample drawn for the given item / lot.

**Note:** In the case of supplier-provided samples, the sampling quantities are accounted for in ERP System, either at the outset whilst inventory is booked into ERP System or during the sampling process on a case-by-case basis and is determined by the commercial agreements between GMP site and the supplier as to how samples are accounted / paid for. In all circumstances, the ERP System inventory must reflect physical inventory once samples are removed from any given delivery.

### 5.15 Test Samples

Once the samples have been collected, take them into the Inspection and Sampling Laboratory to check the samples against specifications in the PMS and in accordance with the test procedure for that material.

In the case of printed packaging material, check the sample material against the controlled copy of the artwork.

Perform each test as specified in the PMS ([TEM-150 Packaging Material Specification and Test Report](#)). (**APPENDIX E**). Ensure that you record the results directly onto the PMS at the appropriate locations for each test. Where the method specified is "C of A", record "Complies" in results column if it complies with the test method.

For example: consider a case where 125 samples of printed cartons have been sampled for inspection and 2 defects are noticed (e.g. print smudge). Record the number of samples with defect on PMS and whether it is Critical, Major or Minor and record comments.

Wherever the PMS requires you to check and record length, width, depth or height, refer to the Test Procedure on the PMS and record dimensions accordingly.

The PMS should be signed and reviewed by a second person for correctness before an assessment can be made on suitability for release.

For detailed information about the individual test procedures, refer to the Test Procedure Methods File at QA Laboratory directory location:

### 5.16 Determine if the Sample Complies and if the Lot Can Be Released or Not

Once all the test procedures on the sample materials have been completed, determine whether to release, reject or quarantine the delivery of packaging materials.

SOP [WAR-110 Classification of Defects for Incoming Packaging Components](#) is to be followed if a defect is found during testing.

The *lot can be released* if the total number of recorded major and minor defects is less than or equal to the pre-determined acceptance number specified in the sampling plan.

The *lot should be rejected* when there are greater than allowed critical defects or if the total number of recorded major or minor defects is greater than the allowed rejection numbers in the sampling plan.

**Note:** If you find any discrepancies in the PMS while conducting a particular test procedure leave the delivery of packaging materials in quarantine and contact Quality Assurance immediately.

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5.19 File Documents: PMS, History Chart and Receiving Report.

5.19.1 Ensure a copy of the Purchase Order is attached to the filled out sheets of PMS.

5.19.2 Return these documents to the product file.

5.19.3 Return the History Chart to the Supplier file.

5.19.4 Transfer released material to the packaging warehouse in ERP System and physically to locations in the packaging store racks using RF scanners or the ERP System console.

5.19.5 Immediately transfer Rejected materials to the reject cage physically and in ERP System.

5.19.6 Immediately transfer Quarantine-Hold material to the Q-Hold cage physically and in ERP System.

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### APPENDIX B

#### AQL:

Acceptable quality level (AQL) is defined as the “quality level that is the worst tolerable process average when a continuing series of lots is submitted for acceptance.” (Ref. ISO 2859)

Once a manufacturer has studied their process capabilities, the repeatability of what they make, and the statistical ability to trap and capture defects, this is then used to set the Upper limit on any specific defect type. It is then linked to the US Military statistical sampling plan as the process to set the number and frequency of sampling goods to capture the defects from a given production size.

The definitions of the type of defect and the Acceptable maximum level we use are those set by the US Plastic Closure Manufacturers Associations. The below is a simplified version describing the AQL process.

The AQL tells you how many defective components are considered acceptable during random sampling quality inspections. It is usually expressed as a percentage or ratio of the number of defects compared to the total quantity.

It is important to note that AQLs are NOT specifying a quantity of any defect that will always be present in these manufactured goods. They identify that when an issue happens in manufacture. It is the largest quantity of a defect a customer could experience at one point in time.

Key points to remember:

- The acceptable quality level (AQL) is the worst quality level that is tolerable for a product.
- The AQL is used in conjunction with the sampling plans from ISO 2859 to determine
  - The number of cartons to be opened
  - The sample size
  - The number of defects that are acceptable / not acceptable.
- The AQL differs depending on the type of defect being sampled. Critical defects (ones that may represent a greater risk) will have a lower AQL than those considered as minor defects.

#### FOR EXAMPLE:

A particular lot of product is found to have short-shot during molding.

Lot size:	250,000 pieces
Total Number of Cartons:	100
If AQL:	0.4 (Major defect as per Site Non Conformance definitions)

AS 1199.1-2003 tells us that:

- For a given lot size with 100 cartons, 10 cartons chosen randomly will need to be sampled.
  - For a lot size of 250 000, 800 pieces over those 10 cartons sampled are inspected. i.e., random @80 pieces to be picked from 10 cartons.
  - For an AQL of 0.4 (at a normal inspection level), the lot will be rejected if 8 or more defective items are found during sampling. If 7 or fewer defective items are found, the lot is accepted.
  - This acceptance criterion will change if the inspection level is set at tightened or reduced.
- AQLs for various nonconformities are defined below and/or can be listed separately in the finished items specification (FIS) as agreed with the customer.

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### APPENDIX C

#### SAMPLING PLAN: (ISO 2859)

Example: for a hypothetical inspection of a production with 4,000 units, the site inspector has selected level II normal inspection and AQL of 2.5.

In Table A below, the intersection of the respective Lot Size and General Inspection Level indicates sample size code letter L. Then, referring to Table B, we locate row L, which indicates the required sample size of 200 units.

To comply with AQL 2.5, no more than 10 units from that sample size can fail inspection. (Table B).

Table A:

SAMPLE SIZE CODE LETTERS							
Lot Size	General Inspection Levels			Special Inspection Levels			
	I	II	III	S1	S2	S3	S4
2 to 8	A	A	B	A	A	A	A
9 to 15	A	B	C	A	A	A	A
16 to 25	B	C	D	A	A	B	B
26 to 50	C	D	E	A	B	B	C
51 to 90	C	E	F	B	B	C	C
91 to 150	D	F	G	B	B	C	D
151 to 280	E	G	H	B	C	D	E
281 to 500	F	H	J	B	C	D	E
501 to 1200	G	J	K	C	C	E	F
1201 to 3200	H	K	L	C	D	E	G
3201 to 10000	J	L	M	C	D	F	G
10001 to 35000	K	M	N	C	D	F	H
35001 to 150000	L	N	P	D	E	G	J
150001 to 500000	M	P	Q	D	E	G	J
500001 and over	N	Q	R	D	E	H	K

ANSI/ASQ Standard Z1.4 - 2008

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### APPENDIX D: Inspection of Goods on Delivery Form

<p>Item No: _____ Receiving Date: ____/____/____</p> <p>Description of Product: _____</p> <p>_____ Identification Labels Printed _____</p> <p><b>Receiving Use Only:</b></p> <p><b>Receiving Statement:</b>          "The description of the goods received matches the <b>Purchase Order</b>. The goods are in their original containers and marked with _____ supplier details. There is <b>NO</b> physical damage, <b>NO</b> contamination evident, and <b>NO</b> soiling."  <input type="checkbox"/> Yes, I agree</p> <p>Purchase Order No: _____</p> <p>Supplier Name: _____</p> <p>Receiving Report No: _____</p> <p>Manufacturing Lot No: _____</p> <p>MAPS Lot No: _____</p> <p>Expiry Date: _____</p> <p>Quantity Received: _____</p> <p>No. of Pallets: _____</p> <p>No. of Containers: _____</p> <p>Location: _____</p> <p>Accept: <input type="checkbox"/> Reject <input type="checkbox"/> (Tick the appropriate box)</p> <p>Comments: _____</p> <p>Signature: _____ Date: ____/____/____</p>	<div style="border: 1px solid black; height: 300px; margin-bottom: 10px;"></div> <p style="text-align: center;">Attach Identification Label Here</p>																																								
<p><b>Sampling Use Only:</b></p> <p>Laboratory Samples (if applicable): _____</p> <p>Revised Quantity: _____</p> <p>Comments: _____</p> <p>Signature: _____ Date: ____/____/____</p>	<p style="text-align: center;"><b>CHECKLIST</b></p> <ul style="list-style-type: none"> <li>GO TO S:\Document Control\RAW MATERIAL SPECIFICATION TEST REPORTS</li> <li>PRINT relevant RMSTR</li> <li>READ RMSTR</li> </ul> <table border="1" style="width: 100%; border-collapse: collapse; font-size: 0.8em;"> <thead> <tr> <th style="text-align: left;">Legend: Y = Yes / N = No / NS = Not Shown</th> <th style="text-align: center;">(Check) Delivery Docket</th> <th style="text-align: center;">(Check) Container Labels</th> <th style="text-align: center;">(Check) C of A</th> <th style="text-align: left;">Comments</th> </tr> </thead> <tbody> <tr style="background-color: #ffffcc;"> <td>Description Correct?</td> <td style="text-align: center;">Y / N / NS</td> <td style="text-align: center;">Y / N / NS</td> <td style="text-align: center;">Y / N / NS</td> <td>.....</td> </tr> <tr style="background-color: #ffffcc;"> <td>Grade Correct?</td> <td style="text-align: center;">Y / N / NS</td> <td style="text-align: center;">Y / N / NS</td> <td style="text-align: center;">Y / N / NS</td> <td>.....</td> </tr> <tr style="background-color: #ffffcc;"> <td>Supplier Correct?</td> <td style="text-align: center;">Y / N / NS</td> <td style="text-align: center;">Y / N / NS</td> <td style="text-align: center;">Y / N / NS</td> <td>.....</td> </tr> <tr style="background-color: #ffffcc;"> <td>Manufacturer Name Correct?</td> <td style="text-align: center;">Y / N / NS</td> <td style="text-align: center;">Y / N / NS</td> <td style="text-align: center;">Y / N / NS</td> <td>.....</td> </tr> <tr style="background-color: #ffffcc;"> <td>Manufacturing Plant Correct?</td> <td style="text-align: center;">Y / N / NS</td> <td style="text-align: center;">Y / N / NS</td> <td style="text-align: center;">Y / N / NS</td> <td>.....</td> </tr> <tr style="background-color: #d9ead3;"> <td>READ Lot Number on Containers. Does Lot Number Match?</td> <td style="text-align: center;">Y / N / NS</td> <td style="text-align: center;">Y / N / NS</td> <td style="text-align: center;">Y / N / NS</td> <td>.....</td> </tr> <tr style="background-color: #d9ead3;"> <td>READ Manufacturing and Expiry Dates on Containers. Do they Match?</td> <td style="text-align: center;">Y / N / NS</td> <td style="text-align: center;">Y / N / NS</td> <td style="text-align: center;">Y / N / NS</td> <td>.....</td> </tr> </tbody> </table> <p>Signature: _____ Date: ____/____/____</p>	Legend: Y = Yes / N = No / NS = Not Shown	(Check) Delivery Docket	(Check) Container Labels	(Check) C of A	Comments	Description Correct?	Y / N / NS	Y / N / NS	Y / N / NS	.....	Grade Correct?	Y / N / NS	Y / N / NS	Y / N / NS	.....	Supplier Correct?	Y / N / NS	Y / N / NS	Y / N / NS	.....	Manufacturer Name Correct?	Y / N / NS	Y / N / NS	Y / N / NS	.....	Manufacturing Plant Correct?	Y / N / NS	Y / N / NS	Y / N / NS	.....	READ Lot Number on Containers. Does Lot Number Match?	Y / N / NS	Y / N / NS	Y / N / NS	.....	READ Manufacturing and Expiry Dates on Containers. Do they Match?	Y / N / NS	Y / N / NS	Y / N / NS	.....
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