Standard Operating Procedure

Title: Classification of Defects for Incoming Packaging Components

Department	Warehouse		Document no	WAR-110	
Title	Classification of Defects for Incoming Packaging Components				
Prepared by:		Date:		Supersedes:	
Checked by:		Date:		Date Issued:	
Approved by:		Date:		Review Date:	

1.0 **DOCUMENT OWNER**

Warehouse / Quality Manager

2.0 **PURPOSE**

Define the classification of defects found during the inspection of incoming packaging components.

3.0 **SCOPE**

This SOP explains the Acceptable Quality Limit (AQL) levels and categories of defects for all incoming packaging components received and tested at a GMP site.

It also determines the responsibility levels for the acceptance or rejection when an Out of Specification (OOS) result occurs.

4.0 **RESPONSIBILITY**

It is the responsibility of the Incoming Goods Inspectors to identify and evaluate the extent of a defect when inspecting a packaging component.

It is the responsibility of the Quality Assurance Manager to accept or reject the defective packaging component that falls outside its AQL level.

5.0 **PROCEDURE**

All deliveries of packaging components undergo thorough sampling and inspection against artwork and the Packaging Material Specification (PMS).

When a defect is found during the inspection:

5.1 **Determine the type of problem**, defects or failure for any characteristics of the component whether it's related to the delivery, appearance, dimension, printing, assembly, weight or material.

5.2 **Refer** to the Tables of Defects (**Appendix A**) and find the listed defect that corresponds to the type of problem determined.

5.3 If the defect is listed in:

5.3.1 **Appendix 1** – It is a **Critical** defect: a defect that would result in hazardous or unsafe conditions for individual using, maintaining or depending upon the product. (**AQL of 0.0%**).

5.3.2 **Appendix 2** – It is a **Major** defect: a defect that is likely to result in failure or that would materially reduce the usability of the product for its intended purpose. (**AQL of 0.4%**).

5.3.3 **Appendix 3** – It is a **Minor** defect: a defect that is not likely to materially reduce the usability of the product for its intended purpose. (**AQL of 1.5%**).

5.7 Where only part of a delivery is to be rejected the lot will be sub-lotted.

5.8 Write in the History Supplier Folder that the batch is approved but, in the comment section, write that a part of the lot. (i.e. knifes number…) has been rejected under the creation of sublot.

5.9 The next delivery from the same supplier will have to follow a tighter inspection plan.

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MAJOR DEFECTS (AQL OF 0.4%)

DELIVERY	- Seals not present - Missing polyethylene liner bag - Missing, illegible or incorrect pallet markings. - Missing plastic protection bag - Wrong delivery quantity - Not labelled with site order no / code no / component description
APPEARANCE	- Pin hole, pitting, scuffing, streak, nicks, embedded foreign matter, splits. - Cracks, chips, blisters - Water damaged - Gloss free area missing - Component is not the correct shape (square, triangle, rectangular etc.) - Visual defect which affects the use or elegance - Anti-counterfeit labels are not in the quantity specified, not positioned as per artwork / are easily removed.
DIMENSION	- Core inside diameter is under or exceed specification - Dimensions are too large or too small - Wind is too loose or too tight - Volume is under or exceeds specification - Incorrect angle (bottles)
PRINTING	- Colour is out of colour standard - Registration marks is not correct or in the exact position - Barcode / EAN / Pharmacode is incorrect, unreadable or in the incorrect position - Colour misplaced / not used as per specification - Tape test failed - Missing colour - Spelling is incorrect - Edge Barcode is not showing - Missing or unreadable printing which may not be detrimental for the consumer - Incorrect printing
ASSEMBLY	- Glue line becomes unstack during testing - Cartons not opening correctly - Bottles threads malformed - Uneven base - Folded incorrectly - Not Uni Bi-oriented as per specification - Knifing / cutting is not as per artwork - Doesn't assemble properly
WEIGHT	N/A
MATERIAL	- Material is different than specified - Mixed / Incorrect ID number (PM#) used - Incorrect type of board / paper / foil / PVC / PVDC / Shrink wrap - Component split / break / crack during inspection - Negative ID using Pyridine spot test

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APPENDIX B

SWITCHING SAMPLING INSPECTION LEVELS

1. Tightened Inspection to Normal Inspection

When tightened inspection is in effect, normal inspection will apply for the next delivery when five (5) consecutive lots of packaging materials have been considered acceptable from a given supplier for a given class of products.

2. Normal Inspection to Tightened Inspection

When normal inspection is in effect, tightened inspection will apply for the next delivery when two (2) out of five (5) consecutive lots of packaging materials from the same supplier have been rejected for a given class of products (only original lots considered, not re-submitted lots).

3. Normal Inspection to Reduced Inspection

When normal inspection is in effect, reduced inspection will apply to the subsequent delivery if the previous ten (10) or more consecutive lots of packaging materials from the same supplier have been approved on normal inspection for a given class of products.

4. Reduced Inspection to Normal Inspection
When reduced inspection is in effect, normal inspection will apply if any of the following occur:

1. A lot of packaging material is rejected.
    - When the previous delivery of packaging materials from an approved supplier occurred more than 12 months ago.
    - If a lot of packaging materials is tested on reduced inspection and found to exceed the accepted level of defects but is below the reject level, it will be accepted but the next delivery will be tested on normal inspection.

    If Quality Assurance advises that normal inspection should be applied for the given supplier.

A critical nonconformity is:

A. one which judgment and experience indicate is likely to result in hazardous or unsafe conditions for individuals using, handling, or storing the product;

B. one which qualified judgment and experience indicate will cause the product to be in violation of any applicable federal and/or state law or federal regulation.

1.2 Major (AQL: 0.4~0.65%, accumulated major nonconformities: 0.65%)
A major nonconformity is:

A. one other than Critical, which would result in obvious failure of the product to fulfil its intended purpose;

B. one other than Critical, which, though unrelated to function, is likely to reduce the saleability of the product; i.e., the major appearance nonconformity;

C. a packing, packaging, or labelling nonconformity, other than Critical, which is likely to result in either product damage or transport, storage, or inventory error;

D. one other than Critical, which judgment and experience indicate will impair the function of downstream automatic processing equipment;

1.3 Minor (AQL: 1.0~4.0%, accumulated minor nonconformities: 4.0%)
A minor nonconformity is:

A. one which has no significant effect, discernible or otherwise, on the product's function, but does prevent the product from being what it is supposed to be;

B. one which is not likely to reduce the product's saleability but does indicate poor workmanship;

C. one other than Critical or Major which, though related to the function of the product, does not adversely affect the usability and/or saleability of the product; e.g., a process control nonconformity discernible only to the manufacturer and knowledgeable inspectors;

1.4 OVERALL accumulated nonconformities (max AQL: 4.65%)

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Table B:

SINGLE SAMPLING PLANS FOR NORMAL INSPECTION

Sample Size Code Letter	Sample Size	Acceptable Quality Levels (Normal Inspection)																					
		0.065		0.10		0.15		0.25		0.40		0.65		1.0		1.5		2.5		4.0		6.5	
		Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re
A	2																					0	1
B	3																			0	1		
C	5																	0	1				
D	8															0	1					1	2
E	13													0	1					1	2	2	3
F	20											0	1					1	2	2	3	3	4
G	32									0	1					1	2	2	3	3	4	5	6
H	50							0	1					1	2	2	3	3	4	5	6	7	8
J	80					0	1					1	2	2	3	3	4	5	6	7	8	10	11
K	125			0	1					1	2	2	3	3	4	5	6	7	8	10	11	14	15
L	200	0	1					1	2	2	3	3	4	5	6	7	8	10	11	14	15	21	22
M	315					1	2	2	3	3	4	5	6	7	8	10	11	14	15	21	22		
N	500			1	2	2	3	3	4	5	6	7	8	10	11	14	15	21	22				
P	800	1	2	2	3	3	4	5	6	7	8	10	11	14	15	21	22						
Q	1250	2	3	3	4	5	6	7	8	10	11	14	15	21	22								
R	2000	3	4	5	6	7	8	10	11	14	15	21	22										

↑ Use first sampling plan above arrow, if sample size equals or exceeds lot or batch size, do 100 percent inspection.

↓ Use first sampling plan below arrow

Ac : Acceptance number **Re** : Rejection number

