

Standard Operating Procedure

Title: Classification of Defects for Incoming Packaging Components

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Title	Classification of Defects for Incoming Packaging Components				
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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%)**.

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