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				
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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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