

Guidance Number: 031

Table 1: Example of Bottle packaging defects

Defect class	Example AQL	Example Defect
Critical	0.01% None or reject with 1 ^(a)	<ul style="list-style-type: none"> • Incorrect or missing packaging material • Incorrect or missing bottle label • Objectionable foreign matter or incorrect product • Contamination (foreign material) • Wrong product insert/outsert or wrong revision • Incorrect/absence inner seal material • Non-functioning seal (misaligned, wrong dimensions) • Unengaged closure (squeeze and turn) <p>Others (one site example):</p> <ul style="list-style-type: none"> • Perforated bottle • Broken desiccant inside bottle • Bottle with flashing (impact personal injury) • Cotton/rayon/polyester outside the internal seal affecting sealing
Major	1.0% ^(b) (0.4- 1.5%)	<ul style="list-style-type: none"> • Short count (separate criteria may be developed, e.g. controlled substances) • Empty bottle • Obvious low or high fill (liquids)(separate criteria may be developed; e.g. controlled substances) • Bottle with leaks (liquids only) (lower AQL%)^(d) • Damaged or dirty container (package integrity not compromised or not in contact with product) • Damaged or dirty inserts/outserts (higher AQL%)^(d) • Missing or incorrect desiccant (lower AQL%) • Particulate matter in liquid product (lower AQL%) • Damaged product or closure (e.g. crimped or torn closure s) • Cotton /rayon/polyester present- none or double • Cotton/rayon/polyester - contaminated • Cotton/rayon/polyester- protruding from under seal^(c) • Closure removal torque- out of specifications (lower AQL%) • Incomplete inner seal • Detached closure/foam liner (squeeze and turn) • Missing batch number or expiration date • Outsert or label not adhering completely • Wrinkle in label causing illegible print (lower AQL%)
Minor	2.5% ^(b) (1.5% - 4.0%)	<ul style="list-style-type: none"> • Loose bundles • Improper amount of cotton/rayon/polyester (if amount is specified) • Scratched closure • Color variation in closure

Footnotes:

(a) Setting AQLs of 0.01% may require larger sample sizes in order to claim that level of quality. Depending on batch and sample size, no critical defects ('None' or 'Reject with 1') may be the limit. Alternate

sampling plans may be more appropriate for inspection of certain critical attributes, but the AQL for critical defects is 0.01% (2).

(b) Other Major AQLs such as 0.4% - 1.5% and Minor of 4.0% have also been used by some sites.

(c) Could be critical if affecting stability.

(d) Lower or higher AQLs mean that defect may have AQLs beyond the range provided, depending on the specific nature and description of the defect.

Table 2: Example of Blister packaging defects

Defect class	Example AQL	Defect
Critical	0.01% None ^(a)	<ul style="list-style-type: none"> • Same as bottles (e.g. incorrect or missing material, foreign material, product) • Failing leak tests, holes in blisters or foil • Extra tablet/capsule in blister • Cavities with improper depth • Missing/ incomplete, incorrect, or illegible control number or expiration date.
Major A ^(b)	0.4% (0.25- 0.65%)	<ul style="list-style-type: none"> • Empty blister card • Non-objectionable foreign matter (dark specs) • Heat marked or burned product • Missing or incomplete perforations • Crushed or broken tablets/capsules • Damaged blister or foil
Major B	1.0% (0.65% – 1.5%)	<ul style="list-style-type: none"> • Non-functional die cut • Excessive powder in cavity • Peel too loose or too tight (separation of units to tear-off) • Die-cut-is out of register • Defective tablets due to discoloration or general appearance • Damaged/ smeared labeling or coding (legible) • Soiled package • Blister with some empty cavities.
Minor	2.5% (1.5- 4.0%)	<ul style="list-style-type: none"> • Minor perforations imperfections • Surface blemishes/scratches/flaws (bubbles, discolor) • Print/coding off-registration • Difficult to open

(a) See footnotes – Table 1

(b) Major A and B. Two different levels in major category to allow for more differentiation of defects, AQLs and sample sizes.

Table 3: Example of Package Insert, Display forming, Heat Seal Card (HSC), or Intermediate Folding Carton (IFC) Inspections, Labeling, or Pre-printed literature

Defect class	EXAMPLE AQL	Defect
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Defect class	Example AQL	Defect
Critical	0.01 % None ^(a)	<ul style="list-style-type: none"> • Copy information- incorrect, missing, illegible • Incorrect material • Missing insert • Foreign items • Missing or illegible critical copy (e.g. product/active ingredient, manufacturer's name, NDC code, indications and precautions), especially Japan. • Incorrect or missing lot number or expiration date
Major	1.5% (0.25- 1.5%)	<ul style="list-style-type: none"> • Foreign material on non-product contact surfaces • Missing or illegible non-critical copy • Poor adhesion (not properly adhered to bottle) • Improperly assembled component (for HSC) • Double printing • Printed with clear legibility, but with broken lettering • Box with single sticky tape (sealed one side) • Components with readability defects that do not affect function, literature or label.
Minor	4.0% (2.5% -4.0%)	<ul style="list-style-type: none"> • Cosmetic defects • Copy information damaged (legible) • Print defect- legible with scuff, scratches, or smear • Light printing of lot number or expiration date (legible) • Label- off center (quantitative measurements may be specified) • Cartons- not properly closed or glued shut

(a) See footnotes – Tables 1, 2

Table 4: Example of Shippers and Print & Apply Labeling

Defect class (a)	Example AQL	Defect
Critical	None ^(b) (0.01%)	<ul style="list-style-type: none"> • Foreign display in shipper • Incorrect lot number or expiration date • Foreign shipper (if preprinted shippers are used) • Incorrect product/strength/identification- GTIN (Global Trade Identification Number)⁽⁸⁾ • Foreign shipper label • Missing or illegible lot number or expiration date
Major A	0.65%	<ul style="list-style-type: none"> • Missing or illegible shipper label^{(b)(d)}

Defect class (a)	Example AQL	Defect
Major B	1.5%	<ul style="list-style-type: none"> • Particulate matter on non-product contact surfaces^(c) • Incorrect quantity of displays in shipper (wrong count) • Incorrect shipper component • Incorrect pallet pattern (could cause over or under shipment quantities)
Minor	4.0% (2.5% -4.0%)	<ul style="list-style-type: none"> • Loose/flagging shipper

(a) In one example, there is no formal classification for shippers, just inspection criteria such as number of allowed defects (e.g. 3 defects allowed out of sample size of 50).

(b) See footnote b – Table 1

(c) One site classifies this defect as minor

(d) One site classifies this as minor since case labels have no compliance ramifications but potential charge back from customers and are printed by a validated case label system⁽¹¹⁾
Also, since consumers (end users) are not buying case quantities, the definition in Appendix I may not apply.

Table 5: Example of Bar code reader or scanner

Defect class	Example AQL	Defect
Critical	None ^(a) (0.01 %)	<ul style="list-style-type: none"> • Incorrect lot number, expiration date, or NDC (National Drug Code or GTIN) number. • NDC code or other primary label barcodes that are not machine readable.
Major	0.65% (0.25- 1.5%)	<ul style="list-style-type: none"> • Primary and secondary labels have to meet ANSI barcode quality of Grade C or better⁹⁾ • Shipping case label barcodes meet ANSI barcode quality Grade C or better.
Minor	2.5% (2.5- 4.0%)	<ul style="list-style-type: none"> • No readings after repeated attempts

(a) See footnote a – Table 1

Appendix I – Defect Classification Criteria

Impact of Defect**	Critical	Major	Minor
Effect on Consumer Safety	Will cause personal injury or illness. (Alternate*: Would result in hazardous or unsafe conditions for an individual using the product)	May cause personal injury or illness. (Alternate*: May result in failure of the product, or may materially reduce the usability of the product, for its intended purpose)	Will not cause personal injury or illness. (Alternate*: Would not cause injury (appearance, elegance, cleanliness or neatness issues))
Effect on Conformance to Regulations	Fails to conform to regulations for safety, purity, efficacy, toxicity, or identity.	Fails to conform to regulations on weight, count, or volume.	Fully conforms to regulations and specifications.
Effect on Use	Will render the product totally unfit for use.	May render the product difficult or unfit for use and may cause Rejection* by user (e.g., removal from package, objectionable appearance).	Will not affect usability of the product; may affect appearance.
Consumer Relations	Will offend consumers due to odor or appearance. Will very likely result in Complaints* . (Alternate: Will result in lost customers or losses greater than the value of the product (recall, litigation, etc.)	May be noticed by consumer, may be an annoyance and reduce product salability. May result in complaints. (Alternate: May be rejected by the consumer or construed as tampering. Will be noticed by the consumer. May cause lost customers or losses greater than the value of the product (recall, litigation, etc)	Unlikely to be noticed by consumers, and of little concern if noticed. Not likely to result in complaints. (Alternate: May or may not be noticed by the consumer. Little or no concern to the consumer. Not likely to cause lost customers. May cause losses equal to the value of the product (replacement of product))
Loss to Company	Will lose consumers and may result in losses greater than value of product. This will include productivity or	May lose consumers and may result in losses equal to or greater than value of product. This will include productivity or yield issues related to	Unlikely to result in loss.

Impact of Defect**	Critical	Major	Minor
	yield issues related to components.	components.	

* Alternate- one sites description in these categories ⁽¹¹⁾.

**When multiple impacts (e.g. Loss to Company, Effect on Conformance to Regulations), it is recommended to use the most conservative classification of defect