

This document provides guidance on the inspection of non-sterile drug products and non-sterile medical devices for manufacturing and packaging defects.

1. Inspection Requirements for each type of product, container/closure configuration, and packaging configuration should be written, approved by the Site Quality Team and include and not be limited, to the following information:
 - Determination of the minimum number of product units that must be sampled and the frequency of inspection; and
 - Identification of physical attributes that are considered defects and their respective Acceptable Quality Limit (AQLs).
2. Inspection Personnel should be qualified prior to inspecting products during manufacturing or packaging operations including a test for color blindness and an annual vision test. Requalification should be performed as required.

Qualification should include, and not be limited to, the following:

- Identification and classification of defects for each product, container/closure configuration, and packaging configuration using photos, illustrations, or actual defects as training aids; and
 - Set-up challenge and operation of automated electronic inspection systems and line monitoring devices.
3. Manufacturing Defects include, and are not limited to, the following:
 - Broken or chipped tablets;
 - Twinning of tablets;
 - Unusually thick or thin tablets;
 - Uneven film coating of tablets;
 - Unusual appearance (e.g., off color, discolored, cloudy, foreign matter, suspension segregation); Empty or under-filled capsules; and
 - Missing or partially debossed logo or markings.
 4. Packaging Defects include, and are not limited to, the following:
 - Incorrect cap torque;
 - Cap out of alignment;
 - Fill weight/volume;
 - Cracked, chipped, or dented container;
 - Low or high fill volume;
 - Defective crimps;
 - Leaking container;
 - Incomplete packaging (e.g., missing product, missing desiccant, missing cotton, missing package insert);
 - Incorrect product and/or packaging materials;
 - Tamper resistant packaging is missing or in poor condition;
 - Incorrect or missing labels, labeling, or label information (e.g., lot number or expiration date); and