Summary - Inspection Attributes in Packaging Validation of Non-Sterile Drug Products

This procedure provides examples and guidance on classification of defects for packaged non-sterile drug products.

General criteria for inspection and control of defects are described in Appendix 1. Three classifications: critical, major, and minor are used to classify packaging defects. The Tables below on defects and attributes can be used as a starting point for those new to defect classification during packaging validation.

Sample size of multiple plans is less than double sampling plans, which in turn is less than the single sample plans. Once determined, the total sample size is divided by the number of sampling intervals to determine the number of samples per interval (e.g. 200 bottles (sample size) /24 intervals = 9 bottles/interval).

Each application is suggested to be evaluated on a case-by-case basis to determine which defects are critical, major and minor, for that specific package or product line. Depending on the specific package and dosage form, some of the attributes or defects listed below may not be applicable, additional defects may be warranted, or the description of the defect further specified. Definitions of defects may vary from site to site, so the classification is highly dependent on the interpretation and specific definition of the defect. The concepts of AQL (Acceptable Quality Level) and UQL (Unacceptable Quality Level) may be non-uniformly applied in setting acceptance or statistical quality control criterion.

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