

Summary - Considerations for Selecting Packaging Lot Sizes During Packaging Validation

One of the industry standards in packaging validation indicates that: “A packaging validation lot must be representative of the typical packaging process and be of sufficient length such that packaging validation lot will exhibit normal packaging process variability”. In addition, a packaging validation run (e.g. entire lot or defined portion of a lot) shall be determined by the Validation Committee based on a technical evaluation and experience with the packaging process. For the purposes of validation it should be allowed a lot size to be determined that may not correspond to the full packaging order lot size.

A non-sterile, oral liquid dosage form is filled in pre-labeled plastic bottles, sealed with a tamper-evident seal and capped. The sealed bottle is directly printed with lot number and expiration date using an ink jet printer. The bottles are then placed manually in individual cartons; the cartons are then printed with the same lot number and expiration date. Groups of 6 cartons are shrink-wrapped together. The shrink-wrapped cartons are manually placed in a shipping container. It requires 9 shifts to fill and package all 200,000 units in the batch.

The filling, sealing and capping of the non-sterile liquid should be validated within the scope of the process validation. Subsequent to capping, the packaging process equipment includes a labeler, cartoner, another labeler and shrink-wrapper. The labeling equipment provides batch-record-specific information. Ensuring proper alignment on the bottle/carton is important for legibility.

The potential effect of heat from the shrink-wrapper on the product and packaging materials has already been assessed. The cartoner and shrink-wrapper have no direct impact on product quality. Proper timing of the inter-connected packaging equipment is important not only to the efficiency of the line, but also to prevent damaged bottles, cartons and labeling errors. Transfer of the shrink-wrapped cartons into the shipping container does not impact the quality of the product or affect any batch record specific labeling of the product.

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