Summary - Potential Critical Process Parameters, Quality Attributes and Validation Practices in Packaging Validation

Quality risk assessments are suggested to be used for determining the level of criticality of equipment and parameters. See guidance on Risk Assessment in Validation. Each packaging application should be evaluated on a case-by-case basis to determine impact assessments and which parameters are critical. Critical packaging process parameters and normal operating ranges, including justification or reference for these ranges, are to be determined before validation and included in the packaging validation protocol. Some examples of critical
process parameters ranges to be determined in pre-studies, line trials or qualifications may include:

- Time
- Temperature
- Pressure
- Torque
- Speed
- Count quantity
- Fill Weight and Variation
- Inert atmosphere (liquid)
- Environmental Humidity

A solid dosage form is compounded in various strengths affecting its overall shape and size. Solid dosage units are packaged with the same tools in the same type of container/closure. One validation run for each tablet strength should be included in the validation matrix.

Bracketing of the packaging processes can be performed when there is a range of process extremes of parameters. Different products may be bracketed due to similarities of package components, critical packaging process parameters, packaging lines, and product attributes.

Number of Validation Runs (or segments)
A packaging validation run should be representative of the typical packaging process and be of sufficient length such that the packaging validation run will exhibit normal packaging process variability such as equipment variability, operator and mechanic variability, material variability, start-ups, shut downs, shift changes, and environmental conditions. Some sites use a minimum run time such as 10 hours to capture any potential effects of a shift change.

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