

Steps using packaging equipment should be evaluated to determine which steps or pieces of equipment are considered critical. Examples of potential critical packaging steps/equipment systems may include:

- Reject systems (e.g. vision systems, weighing systems)
- Product and/or lot specific labeling systems
- Bottle and blister filling equipment
- Filling and capping equipment
- Induction seal units
- Tamper resistant packaging equipment
- Tablet and capsule feeding equipment
- Lot and bar coding equipment (both printing and reading of bar codes)
- Desiccant or other material feeders
- Bottle cleaning equipment (e.g. blowers and vacuums)
- Re-torque equipment
- Outserters and Inserters
- Other related to packaging (storage tanks prior to packaging, blow-fill-seal machines)

Equipment is subject to routine maintenance, calibration, challenges, etc. to ensure it is properly functioning. These practices should be taken into account when determining the criticality.

Potential CPPs and CQAs for these equipment and systems were addressed for some common packaging processes for solid dosage forms in Tables 1-3. Depending on the specific dosage form, product or packaging, some of the attributes listed below may not be applicable or additional attributes could be warranted. The following tables can be used as a starting point for the selection of CPPs and CQAs for an assessment of packaging validation requirements.

**Table 1: [Bottle Packaging – Common Potentially Critical Process Parameters](#)**

**Table 2: [Blister Packaging – Common Critical Process Parameters](#)**

**Table 1: [Other Packaging Steps – Common Critical Process Parameters](#)**

#### **Packaging Validation Protocol and Report**

The protocol should include or reference the following items at a minimum:

- Validation approach to be used (e.g. concurrent, bracketing and matrixing, continuous verification) and the related rationale for that approach
- Description of product, including product name, dosage form, strength where applicable, packaging instructions, bill of materials, and package configuration;
- Packaging process description with a list of major systems involved, process flow chart, and description of individual unit operations;