

6. Quality Properties of the Final Packages produced at the both the upper and lower process parameter range limits should be considered for evaluation, including and not limited to:

For forming/assembling:

- Package completely formed/assembled,
- Product fits appropriately into package, and
- Essential dimensions met.

For sealing:

- Total continuous seal width,
- Punctures or tears,
- Material de-lamination or separation, and
- Channels or open seals.

For other closure system:

- Continuous closure,
- Punctures or tears,
- Material delamination or separation.

7. Final Package Visual Evaluation should be performed under specified conditions of distance, illumination, illumination source, time and magnification (if required).

The external surface of the final package should be inspected for defects such as:

- Irregularities in or on the sterile barrier materials, such as tears, cracks, holes or fractures;
- Presence of foreign material;
- Dimensional accuracy;
- Seal integrity (open or incomplete seals); and
- Presence of humidity, moisture or staining.

8. Sealing Equipment Commissioning and/or Qualification should include, and not be limited to:
- Verification that the sealing equipment is installed according to design criteria;
 - Verification of mechanical operation (e.g., valves, hydraulic vacuum pumps, heating elements);
 - Identification of utilities and instruments and elements (I/Es);
 - Calibration of I/Es;
 - Testing of alarm systems; and
 - Verification that equipment operates properly throughout the Normal Operating Ranges (NOR).
9. Packaging System Sealing Process Studies should include, at least, the following:
- Successful seal strength tests such as Tensile Seal Strength tests and Burst/Creep Pressure tests on three (3) separate container lots;