

The instructions for in-process controls could be given in Batch Records, procedures or in separate in-process control records. The records must have space for entering and signing test results. All raw data generated must be maintained with these records.

Qualified production department personnel can perform in-process controls. Sufficient space and qualified testing equipment should be available for the in-process controls.

Whilst normally in-process controls have associated control limits there may be occasions when additional testing is conducted to gather additional information and there are no control limits. If such testing is carried out it must be identified as 'for information only' and the purpose of gathering the data should be clearly understood.

5.2 In-process Control Activities

Examples of quality characteristics that can influence the product quality and should be considered when establishing in process controls are:

- weight variations
- Disintegration time.
- Specific resistance of water for processing
- Moisture content
- Clarity of solutions
- pH in solutions
- Volume filled into finished product containers
- Appearance and correctness of packaged units
- Hardness
- Thickness
- Tablet physical appearance.
- Temperature
- Pressure
- Duration of a procedure or process step

Routine tests of such environmental conditions, which can influence the product quality should be considered when establishing in process controls are:

- counting of viable micro-organisms and non-viable particles.
- Hand and finger tip tests for viable micro-organisms
- surface tests for viable micro-organisms

In the context of API manufacture the acceptance criteria and type and extent of testing can depend on the nature of the intermediate or API being manufactured, the reaction or process step being conducted, and the degree to which the process introduces variability in the product's quality. Less stringent in-process controls may be appropriate in early processing steps, whereas tighter controls may be appropriate for later processing steps (e.g., isolation and purification steps).