

If a change requires validation, "One validation batch must be placed on stability regardless of whether or not it is a batch designated for commercial distribution and whether or not stability information is required for a regulatory filing. The number of batches to be placed on stability and the type of study required shall be documented and justified."

Note that local regulations or commitments may require that the first three validation lots be placed on stability – these commitments take precedence over this guidance requirement.

4.3. Assignment of Retest or Expiry Dating for Affected Lots

ICH Q7A states that the potential for critical changes to affect retest or expiry dates should be evaluated. Accelerated stability conditions may be used to obtain data quickly (e.g. 3 months accelerated study) to support batch release for lots involved with planned or unplanned changes.

Without the support of these data, retest or expiry dating would be based only on available stability data from the new process – often resulting in shortened dating assignments until additional stability data are generated. If accelerated data are equivalent for lots produced before and after the change, then stability data from the original process can be used to support the retest or expiry dating for lots produced after the change.

5. Use of Stability Data

Stability studies can be initiated after batch release if the data will be used to fulfil annual stability commitments or if the data are for information only (e.g. analysis of a proposed package change or some other non-process related change). Batch release may need to wait until completion or partial completion of a stability study if the data are intended to (Note: this is not intended to be an all-inclusive list):

- Support a registered process change
- Support batch release

The amount of stability data required prior to batch release (e.g. completion of an accelerated study, 6 months of real-time data, etc.) should be determined and documented prior to initiation of the study.

Stability data generated for some deviation lots may only be intended to support batch release of the affected lots. Data from this kind of special stability study are not typically combined with data from annual stability lots to calculate retest or expiry dating for lots produced by the registered process. If stability data supporting a deviation are not consistent with historical stability data, then the affected batches may require rejection, rework or reprocessing prior to release.