

Guidance 082 Stability Testing

- Rationale for the study should be included in the protocol if a new protocol is generated for the specific stability study;
 - Author's signature; and
 - Signature of testing Site representative, if testing Site is different from the production Site.
3. Samples should be stored at conditions that do not compromise the product during the time period (maximum of thirty calendar days) from the actual pull date of the samples to the completion of chemical and physical testing (i.e., samples stored at 5°C must not be stored at 25°C during this period).
 4. For Countries with Requirements Different from Conditions Defined in ICH Q1A (R2) Stability Testing of New Drug Substances and Products, the responsible Country Regulatory Affairs Manager should negotiate with the local Regulatory Authority for acceptance of the data. If ICH data are not accepted by the local Regulatory Authority, the manufacturing Site Quality Authority should ensure that the required data are generated.
 5. An Assessment of the Labeled Storage Conditions should be made after stability data have been collected. If the stability data indicate the product could not withstand the storage conditions, an assessment of the possible actions (e.g., a reduction in shelf-life, a need for more protective packaging, a need for more restrictive label storage conditions, Market Action) should be made.