

This document provides guidance for the stability testing for drug products [including: marketed human and animal prescription products and consumer Over-The-Counter (OTC) drug products, consumer non-drug products (e.g., cosmetics), Active Pharmaceutical Ingredients (API), API Intermediates for Sale, and medical devices manufactured at GMP facilities.

1. Stability Testing for Finished APIs (including API Intermediates for Sale) and Drug Products is required for, but is not limited to, the following situations, unless there is documented rationale approved by the Site Quality Authority for not performing stability testing:
  - Routine required monitoring as per established protocol;
  - Establishment of expiration or reevaluation dates;
  - A change in the reevaluation date of the API or the API Intermediate for Sale; and/or
  - When required by the Regulatory Authority for the specific market, such as:
    - A change in the qualitative and/or quantitative composition of the primary packaging material;
    - A change in packaging that may affect stability (e.g., headspace, surface-to-volume ratio of the container); or
    - A change in the manufacturing process of the finished API, API Intermediate for Sale or drug product that may affect stability (e.g., a change in batch or lot size, change in manufacturing Site, process, equipment, raw material (RM) specification, RM supplier, product formulation).
2. Protocols for Stability Studies should, at a minimum, include the following information and should be approved by the Site Quality Authority before use:
  - Product name;
  - Product strength or concentration, if applicable;
  - Storage conditions including temperature and humidity;
  - Testing intervals (typically expressed in months);
  
  - Tests to be performed;
  - Acceptance criteria or a reference to the acceptance criteria;
  - Special instructions (e.g., upright, inverted, or reconstituted methods);
  - 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