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Regulatory requirements of stability studies

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The main aim is to compare the stability data of various countries for registration of IND, NDA, and ANDA. Stability plays important role in drug development process. Stability studies ensuring the maintenance of product quality, safety and efficacy throughout the shelf life are considered as prerequisite for the acceptance and approval of any pharmaceutical product. Stability protocols are the mainly required for registration of drug substances and drug products and it contains all the data such as various tests, storage conditions and special tests. Many regions in the world developed their own regulatory stability studies guidelines according to their environmental conditions and their requirements. Most of the stability requirements for WHO, ASEAN, and EMEA are similar to the ICH guideline, except for the parameters like selection of batches and storage conditions. All the regulatory authorities (USFDA, EMA, ASEAN, LATAM and JAPAN) developed their own guidelines, but some countries in those regulatory authorities have different stability data for registration of drug substance and drug product in their particular region. Therefore, stability tests are carried out so that recommended storage conditions and shelf life can be included on the label to ensure that the medicine is safe and effective throughout its shelf life.

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