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Handbook of Stability Testing in Pharmaceutical Development

Kim (Ed.) Huynh-Ba

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This handbook is the first to cover all aspects of stability testing in pharmaceutical development. It presents a scientific understanding of regulations and balances methodologies and best practices. Comprising 17 chapters, it provides a wealth of resources for pharmaceutical companies, educational institutions, and manufacturing laboratories to use as either a supplementary text for stability training courses or as a reference book for pharmaceutical practitioners. Topics covered include: (1) Latest regulations for stability testing, including cGMP requirements, ICH guidelines, and global guidances from WHO, ASEAN, EMRO, and other regions. (2) Post-approval considerations and regulatory filing strategies to support a global supply chain. (3) Methodologies, including development of a stability-indicating method, method validation and transfer. Physical stability, non-chromatographic methodologies, and spectroscopic applications are also discussed. (4) Setting specifications, monitoring impurities, and establishing shelf-life of pharmaceutical products. (5) Data management, including stability reports, CMC and discussion of Out-of-Specification (OOS) and Out-of-Trend (OOT). (6) USP-NF testing in support of stability purposes. (7) Current industry best practices on stability operation, validation and calibration of stability chambers including considerations for photo-stability testing. (8) Discussion of matrixing and bracketing to support reduced stability testing. (9) Overview of stability programs for biologics and drug-in-devices pharmaceutical products. This collective work was written by a group of prominent international experts, who have been directly responsible for instituting industry best practices and establishing the current stability guidelines.

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