

handbook of stability testing pdf

Handbook of Stability Testing in Pharmaceutical Development Kim Huynh-Ba Editor Handbook of Stability Testing in Pharmaceutical Development Regulations, Methodologies, and Best Practices

Handbook of Stability Testing in Pharmaceutical

Other Stability Programs. Latest regulations for stability testing, including cGMP requirements, ICH guidelines, and global guidances from WHO, ASEAN, EMRO, and other regions. Post-approval considerations and regulatory filing strategies to support a global supply chain. Methodologies, including development of a stability-indicating method,...

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drug product stability and safety can be quite complicated, and stability profile can impact many functional

areas, including analytical testing, formulation development, toxicology, quality and regulatory affairs. This handbook is the first to cover all aspects of stability testing in pharmaceutical development.

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