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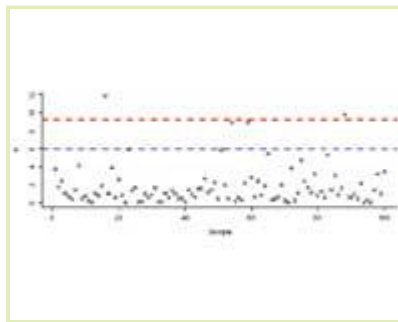
Stability Testing



Harry Yang

By

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Stability Testing Regulatory
Handbook

II. Major Regulatory Guidances A. US Food and Drug Administration Guideline for Submitting Documentation for the Stability of Human Drugs and Biologics I. INTRODUCTION This guideline is intended to provide sponsors/applicants with procedures acceptable to the agency for complying with regulations pertaining to the submission of adequate information on the production and control of new drug substances. This guideline addresses new drug substances manufactured by chemical synthesis, by fermentation, or by isolation from natural sources (and combinations thereof); it does not cover...

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