

Gopal Narayan Singh University
Faculty of Pharmacy
Stability Studies of Formulations

Course code: BPHVA5

Objective: The purpose of stability testing is to provide evidence on how the quality of a drug substance or drug product varies with time under the influence of a variety of environmental factors such as temperature, humidity, and light, and to establish a re-test period for the drug substance or a shelf life for the drug

Unit I

06 hours

Drug development cycles and stability testing: Role and types of stability studies during different stages of drug and product development

Unit II

06 hours

Drug stability testing guidelines: International, Regional, and National drug stability guidelines.

Unit III

06 hours

WHO vs. ICH drug stability testing guidelines: Comparison of different aspects in WHO guideline, and critical comparison with ICH parent guideline Q1A (R2)

Unit IV

06 hours

Specific discussion on following ICH guidelines: Q1B, Q1C, Q1D, Q1E and Q5C 5. Additional topics: Stress testing and stability-indicating method development: Role, regulatory aspects, protocols/approaches, practical considerations

Unit V

06 hours

Stability testing of phytopharmaceuticals: Regulatory requirements Stability test equipment: Types of stability chambers (walk-in, stand-alone), design considerations, qualification and other critical issues. Stability testing for Shipping & Distribution: Stability testing during transport, Stability testing of drug delivery systems



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