Drug Stability

ICH Guidelines for Stability Testing of Drug Substances and Drug Products

Definition

- Stability testing is the process of evaluating how the quality of a drug substance or drug product changes over time under the influence of environmental factors such as temperature, humidity, and light.

Objectives

- To determine the shelf life of a drug substance or drug product.
- To establish recommended storage conditions.
- To evaluate the effect of temperature, humidity, and light on product quality.
- To ensure that the product remains safe, effective, and acceptable throughout its shelf life.

Important ICH Stability Guidelines

A. ICH Q1A(R2)

- ICH Q1A(R2) provides guidance for stability testing of new drug substances and drug products.
- It explains the requirements for long-term, intermediate, and accelerated stability studies.

B. ICH Q1B

- ICH Q1B provides guidance for photostability testing.
- It studies the effect of light exposure on drug substances and drug products.

C. ICH Q1C

- ICH Q1C provides guidance for stability testing of new dosage forms.
- A new dosage form means a different pharmaceutical form of an already approved drug substance.

D. ICH Q1D

- ICH Q1D provides guidance on bracketing and matrixing designs for stability testing.
- These designs help reduce the number of stability samples while still giving useful stability information.

E. ICH Q1E

- ICH Q1E provides guidance for evaluation of stability data.
- It helps in estimating shelf life and retest period using stability results.

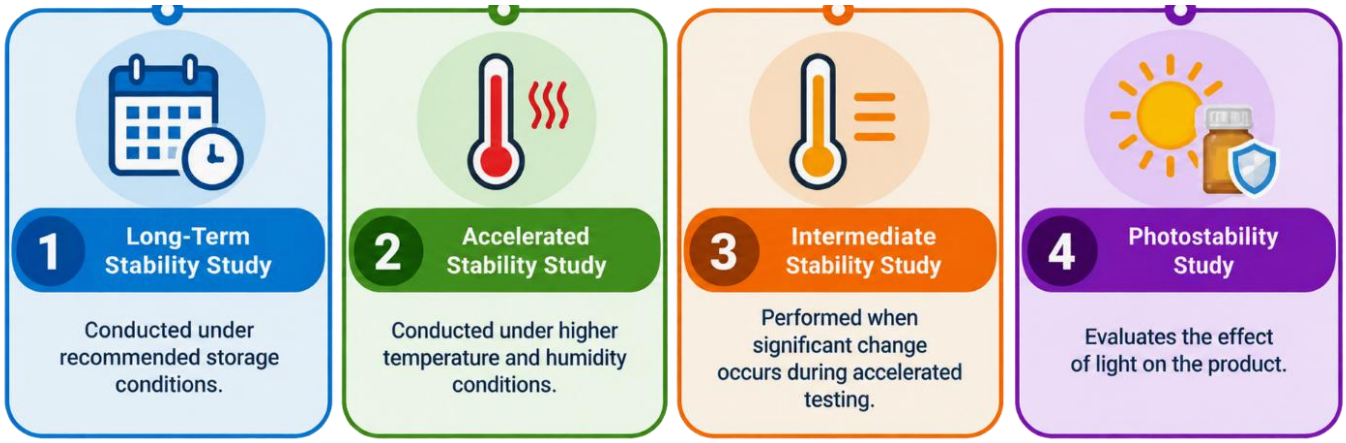
First Hope

Copyright by Engacy Learning Private Limited. All rights reserved. Reproduction or distribution without written consent is strictly prohibited.

F. ICH Q1F

- ICH Q1F was related to stability testing for climatic zones III and IV.
- This guideline has been withdrawn, but its concepts are still useful for understanding stability requirements in hot and humid regions.

Types of Stability Studies



1. Long-Term Stability Study

- Long-term stability study is conducted under recommended storage conditions.
- It provides real-time data about how the product behaves during its proposed shelf life.

2. Accelerated Stability Study

- Accelerated stability study is conducted under higher temperature and humidity conditions.
- It helps predict possible degradation and supports shelf-life estimation.

3. Intermediate Stability Study

- Intermediate stability study is performed when significant change occurs during accelerated testing.
- It helps evaluate product stability under moderate stress conditions.

4. Photostability Study

- Photostability study evaluates the effect of light on the product.
- It helps determine whether special light-protective packaging is required.

Parameters Studied During Stability Testing

- Appearance of the product is checked for changes in color, odor, shape, or physical condition.
- Assay is performed to measure the amount of active ingredient present.
- Degradation products are measured to detect breakdown of the drug.
- Dissolution testing is performed for tablets and capsules.
- pH is measured for liquid preparations.

Copyright by Engacy Learning Private Limited. All rights reserved. Reproduction or distribution without written consent is strictly prohibited.

- Moisture content is checked when water may affect stability.
- Microbial quality is evaluated when required.

Importance in Pharmaceutical Industry

- Stability testing ensures that medicines remain safe and effective until the expiry date.
- It helps select suitable packaging materials.
- It supports regulatory approval of pharmaceutical products.
- It helps define proper storage conditions for patients and healthcare providers.

Study of ICH Q8

Definition

- ICH Q8 is an international guideline that provides a scientific and systematic approach for pharmaceutical product and process development.

Objectives

- To develop high-quality pharmaceutical products.
- To understand the relationship between formulation, manufacturing process, and product quality.
- To improve process consistency.
- To support continuous improvement.

First Hope

Main Concepts of ICH Q8

1. Pharmaceutical Development

- Pharmaceutical development includes the study of formulation, dosage form, manufacturing process, container closure system, and product performance.
- The aim is to design a product that consistently meets patient needs and quality requirements.

2. Quality Target Product Profile

- Quality Target Product Profile is a planned summary of the quality characteristics that the final product should have.
- It includes dosage form, route of administration, strength, release pattern, stability, and intended use.

3. Critical Quality Attributes

- Critical Quality Attributes are physical, chemical, biological, or microbiological properties that must be controlled to ensure product quality.

Copyright by Engacy Learning Private Limited. All rights reserved. Reproduction or distribution without written consent is strictly prohibited.

- Examples include assay, content uniformity, dissolution, impurity level, sterility, and moisture content.

4. Critical Material Attributes

- Critical Material Attributes are important properties of raw materials that can affect product quality.
- Examples include particle size, moisture content, polymorphic form, and purity of the drug substance.

5. Critical Process Parameters

- Critical Process Parameters are process variables that can affect Critical Quality Attributes.
- Examples include mixing time, granulation speed, drying temperature, compression force, and coating temperature.

6. Design Space

- Design space is the approved range of material attributes and process parameters that ensures product quality.
- Working within the design space is not considered a regulatory change, but movement outside the design space usually requires regulatory approval.

Importance

- Product development becomes more scientific and systematic.
- Manufacturing problems are reduced.
- Product quality becomes more predictable.
- Regulatory flexibility may increase when product and process understanding is strong.

Quality by Design

Definition

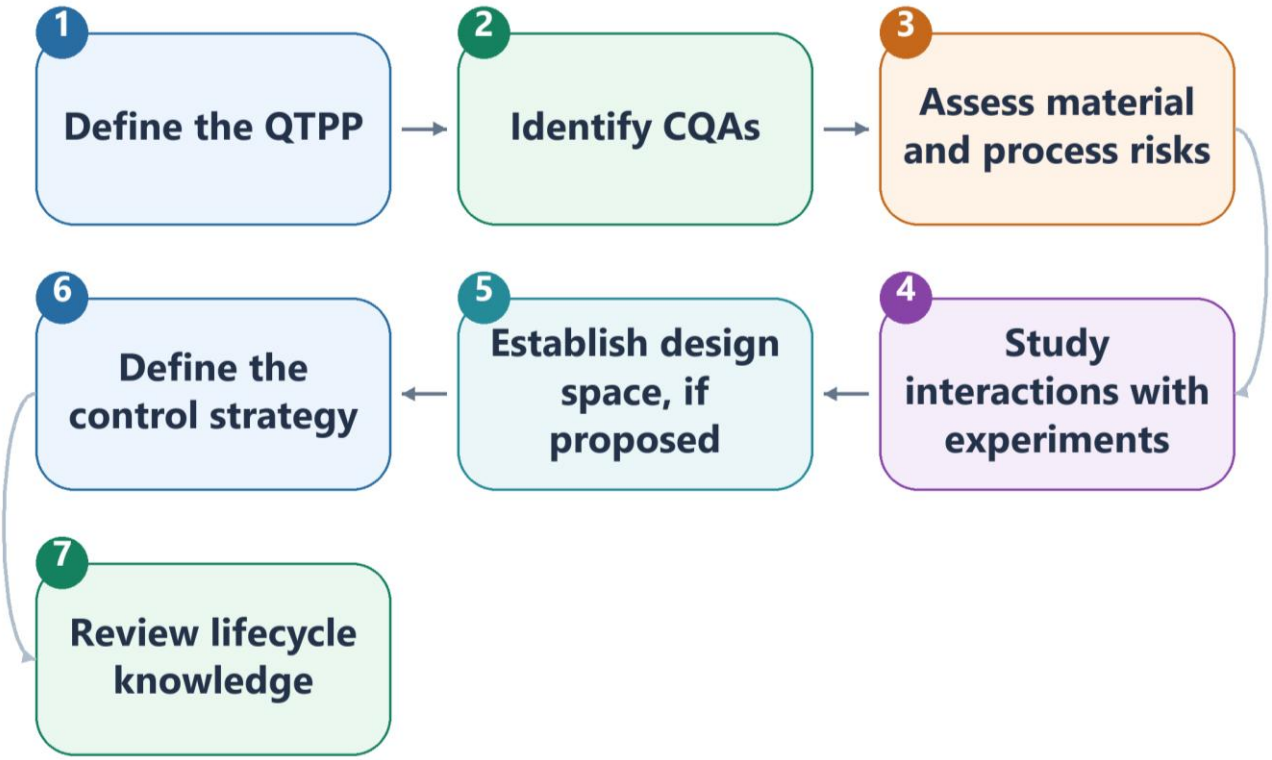
- Quality by Design is a development approach that begins with predefined quality objectives and emphasizes product and process understanding based on scientific knowledge and risk management.

Objectives

- To build quality into the product.
- To reduce manufacturing variability.
- To improve product consistency.
- To minimize product defects.
- To improve regulatory compliance.

Copyright by Engacy Learning Private Limited. All rights reserved. Reproduction or distribution without written consent is strictly prohibited.

Key Elements of Quality by Design



Quality by Design connects target quality, scientific understanding, risk assessment and lifecycle controls

A. Quality Target Product Profile

- Quality Target Product Profile defines the desired characteristics of the final product.
- It acts as a guide for product development.

B. Critical Quality Attributes

- Critical Quality Attributes are product properties that must remain within limits to ensure quality.
- These attributes are selected based on their impact on safety and effectiveness.

C. Risk Assessment

- Risk assessment is used to identify which materials and process steps may affect product quality.
- It helps prioritize the most important factors for control.

D. Design of Experiments

- Design of Experiments is a scientific method used to study the effect of multiple variables at the same time.
- It helps identify the best formulation and process conditions.

E. Design Space

- Design space defines the safe working range for process parameters and material attributes.

First Hope

Copyright by Engacy Learning Private Limited. All rights reserved. Reproduction or distribution without written consent is strictly prohibited.

First Hope

FREE PREVIEW

Click here to visit our website

PHARMACY PREMIUM NOTES

Complete subject and semesters are available on FirstHope app only.

Scan or click here

Click here to get the app >

Available on Google Play

JOIN THE FIRSTHOPE COMMUNITY

Join our Telegram channel

Click here to join Telegram >

Scan or click here

@FirstHopeNotes

Instagram

@firsthope.official

Click here to follow >

YouTube channel

FirstHope-Pharmacy / Live streams

Click here to watch >

WhatsApp channel

Follow FirstHope on WhatsApp

Click here to join >

FirstHope website

firsthope.co.in

Click here to visit >

B.Pharm / D.Pharm / M.Pharm / Pharm.D

Preview notes. Complete subjects and semesters in the FirstHope app.