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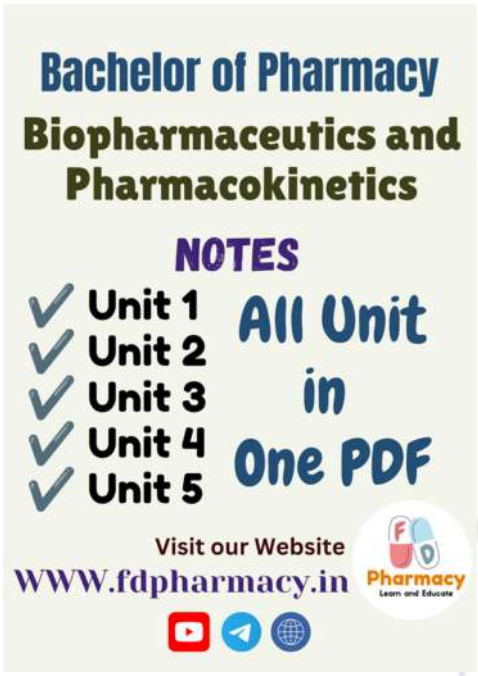
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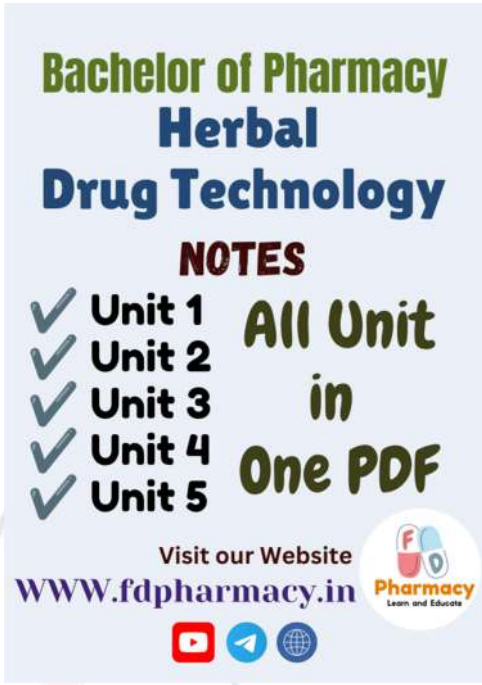
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PHARMACEUTICAL QUALITY ASSURANCE

UNIT 1

TOPIC :

- **ICH Guidelines :** purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines

International Council for Harmonisation (ICH)

→ ICH stands for International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.
→ ICH is an international organization that brings together regulatory authorities and the pharmaceutical industry to develop common guidelines for the development, registration, and manufacture of medicines.
→ The main aim of ICH is to harmonize pharmaceutical regulations worldwide so that medicines meet the same standards of quality, safety, and efficacy in different countries.

History and Need of ICH

- Before 1990, different countries had different drug regulations.
- Pharmaceutical companies had to repeat the same studies and clinical trials for approval in different countries.
- This resulted in increased cost, delay, and duplication of work.
- To solve these problems, ICH was established in **1990** by regulatory authorities and pharmaceutical industries of the USA, Europe, and Japan.
- Initially known as the International Conference on Harmonisation (ICH).
- Later renamed as the International Council for Harmonisation (ICH).
- The ICH Secretariat is located in Geneva.

Objectives of ICH

1. Harmonize global pharmaceutical regulations.
2. Ensure quality, safety, and efficacy of medicines.
3. Reduce duplication of testing and clinical trials.
4. Accelerate availability of medicines worldwide.
5. Reduce research and development costs.
6. Promote public health protection.
7. Facilitate international drug registration.

Members of ICH

Japan

- Ministry of Health, Labour and Welfare (MHLW)
- Japan Pharmaceutical Manufacturers Association (JPMA)

Europe

- European Commission (EC)
- European Federation of Pharmaceutical Industries and Associations (EFPIA)

USA

- U.S. Food and Drug Administration (FDA)
- Pharmaceutical Research and Manufacturers of America (PhRMA)

Categories of ICH Guidelines

ICH guidelines are divided into four major categories:

Code	Category
Q	Quality
S	Safety
E	Efficacy
M	Multidisciplinary

ICH Quality Guidelines (Q-SERIES)

→ The Q-Series guidelines deal with the quality of pharmaceutical products.
→ They ensure that medicines are consistently manufactured, stable, pure, safe, and effective throughout their shelf life.

Objectives of Quality Guidelines

1. Ensure high-quality medicines.
2. Maintain batch-to-batch consistency.
3. Control impurities.
4. Establish international standards.
5. Protect patient safety.

Important ICH Quality Guidelines

Q1 – Stability Testing

Purpose

→ To determine how long a drug remains stable under different environmental conditions.

Sub-Guidelines

Q1A(R2) – Stability Testing of New Drug Substances and Products

- Long-term studies
- Intermediate studies
- Accelerated studies
- Determines shelf life and expiry date

Q1B – Photostability Testing

- Studies effect of light exposure
- Identifies light-sensitive drugs
- Helps decide protective packaging

Q1C – Stability Testing for New Dosage Forms

- Used when dosage form changes
- Example: Tablet converted into syrup

Q1D – Bracketing and Matrixing

- Reduces number of stability studies
- Saves time and cost

Q1E – Evaluation of Stability Data

- Statistical analysis of stability results
- Helps determine expiry date

Q1F – Stability Data Package for Climatic Zones III and IV

- Applicable for hot and humid countries
- Important for countries like India

Q2 – Validation of Analytical Procedures

Purpose

→ To ensure analytical methods produce accurate and reliable results.

Parameters Evaluated

- Accuracy
- Precision
- Specificity
- Linearity
- Range
- Robustness

Importance

- Ensures correct testing of identity, purity, and potency.

Q3 – Impurities

Purpose

→ To control harmful impurities in pharmaceutical products.

Types

Q3A

- Impurities in Drug Substances

Q3B

- Impurities in Drug Products

Q3C

- Residual Solvents

Q3D

- Elemental Impurities

Q3E

- Extractables and Leachables

Importance

- Ensures medicines are free from toxic contaminants.

Q4 – Pharmacopoeial Harmonisation

Purpose

To harmonize standards among pharmacopoeias such as:

- United States Pharmacopeia (USP)
- British Pharmacopoeia (BP)
- Japanese Pharmacopoeia (JP)
- Indian Pharmacopoeia (IP)

Importance

Provides uniform quality standards worldwide.

Q5 – Quality of Biotechnological Products

Purpose

Ensures quality of biotechnology-derived medicines.

Covers

- Viral safety
- Cell substrates
- Stability studies
- Manufacturing processes

Examples

- Insulin
- Vaccines
- Monoclonal antibodies

Safety Guidelines (S-SERIES)

→ Safety guidelines evaluate the toxicological safety of medicines before human use.

Areas Covered

- Acute toxicity
- Chronic toxicity
- Genotoxicity
- Carcinogenicity
- Reproductive toxicity
- Toxicokinetics

Importance

- Ensures drugs do not cause serious harmful effects.

Efficacy Guidelines (E-SERIES)

→ Efficacy guidelines ensure that medicines work effectively in humans.

Covers

- Clinical trial design
- Good Clinical Practice (GCP)
- Dose selection
- Benefit-risk assessment
- Clinical safety reporting

Importance

- Ensures medicines provide intended therapeutic benefits.

Multidisciplinary Guidelines (M-SERIES)

→ These guidelines address topics common to all areas of drug development.

Covers

- Common Technical Document (CTD)
- Medical terminology
- Electronic submissions
- Data standards

Importance

- Facilitates communication between regulatory agencies and pharmaceutical companies.

Stability Testing

→ Stability testing is the study of how the quality of a drug substance or drug product changes with time under the influence of environmental factors such as temperature, humidity, and light.

→ It helps determine:

- Shelf life
- Expiry date
- Storage conditions

Types of Stability Studies

1. Long-Term Stability Study

- Conducted under recommended storage conditions.
- Determines actual shelf life.

Storage Conditions

- 25°C ± 2°C / 60% RH ± 5%
  or
- 30°C ± 2°C / 65% RH ± 5%

2. Intermediate Stability Study

Storage Condition

- 30°C ± 2°C / 65% RH ± 5%

Purpose

- Performed when significant changes occur during accelerated testing.

3. Accelerated Stability Study

Storage Condition

- 40°C ± 2°C / 75% RH ± 5%

Purpose

- Predicts long-term stability in a shorter time.

Climatic Zones

ICH classifies the world into climatic zones:

Zone	Climate
I	Temperate
II	Subtropical/Mediterranean
III	Hot and Dry
IV	Hot and Humid

Importance of Stability Testing

1. Determines shelf life and expiry date.
2. Establishes storage conditions.
3. Ensures drug safety and efficacy.
4. Supports regulatory approval.
5. Prevents product degradation.
6. Maintains product quality during storage and transport.
7. Protects patient health.