

Evaluation of Drugs

WHO Guidelines for the Assessment of Herbal Drugs

- The **World Health Organization (WHO)** provides guidelines for evaluating the **quality, safety, and efficacy** of herbal medicines.
- These guidelines help establish a regulatory framework ensuring their proper use based on traditional knowledge and scientific evidence.

Objectives:

- Promote the **safety, efficacy, and quality** of herbal medicines.
- Guide the assessment of **botanical, chemical, pharmacological, and toxicological** aspects.
- Provide methodologies for **research and evaluation** of herbal drugs.
- Support the **standardization and regulation** of herbal medicines.
- Encourage the **conservation of medicinal plants** and respect for indigenous knowledge.

Key Aspects of Assessment:

1. Quality Assessment

- Evaluates the physical, chemical, and biological properties of plant material.
- Uses macroscopic, microscopic, organoleptic, and chromatographic techniques.

2. Safety Assessment

- Determines the toxicological profile of herbal drugs.
- Includes acute, sub-acute, chronic toxicity, genotoxicity, and carcinogenicity studies.

3. Efficacy Assessment

- Examines therapeutic properties through pharmacological and clinical tests.
- Uses animal models, human clinical trials, and systematic reviews.

4. Standardization

- Establishes specifications for plant materials and finished products.
- Uses reference standards, marker compounds, and chemical fingerprinting.

5. Manufacturing

- Ensures compliance with Good Manufacturing Practices (GMP).
- Covers the preparation, processing, and quality control of herbal drugs.

ICH Guidelines for the Assessment of Herbal Drugs

- The International Conference on Harmonisation (ICH) provides guidelines for evaluating the quality, safety, and efficacy of herbal drugs.
- These guidelines help harmonize regulatory requirements across different regions.

Objectives:

- Establish a harmonized regulatory framework for herbal drugs.
- Provide guidance on assessing **active pharmaceutical ingredients (APIs)** of herbal origin.
- Standardize procedures for **clinical evaluation** of herbal medicines.
- Recommend approaches for **preclinical safety evaluation**.
- Identify and address potential **public health risks**.

Key Aspects of Assessment:

1. Quality Assessment

- Evaluates physical, chemical, and biological properties.
- Uses **macroscopic, microscopic, organoleptic, and chromatographic** methods.

2. Safety Assessment

- Assesses toxicological profile using acute, sub-acute, chronic toxicity, genotoxicity, and carcinogenicity studies.

3. Efficacy Assessment

- Examines therapeutic properties using pharmacological and clinical tests such as animal models, human trials, and systematic reviews.

4. Standardization

- Establishes **specifications** for plant materials and finished products.
- Uses reference standards, marker compounds, and chemical fingerprinting.

5. Manufacturing

- Ensures compliance with **Good Manufacturing Practices (GMP)** for herbal drug preparation and processing.

Key ICH Guidelines by Category:

1. Quality Guidelines (Q):

- Ensure product quality. Key guidelines:
 - **Q1A (R2):** Stability Testing of New Drug Substances and Products
 - **Q2 (R1):** Validation of Analytical Procedures
 - **Q3A (R2):** Impurities in New Drug Substances

- **Q5A (R1):** Viral Safety Evaluation for Biotechnology Products

2. **Safety Guidelines (S):**

- Ensure drug safety. Key guidelines:
 - **S1A:** Need for Carcinogenicity Studies
 - **S2 (R1):** Genotoxicity Testing
 - **S5 (R3):** Toxicity to Reproduction and Male Fertility

3. **Efficacy Guidelines (E):**

- Ensure therapeutic efficacy. Key guidelines:
 - **E3:** Structure and Content of Clinical Study Reports
 - **E6 (R2):** Good Clinical Practice
 - **E9:** Statistical Principles for Clinical Trials

4. **Multidisciplinary Guidelines (M):**

- Cover cross-category aspects. Key guidelines:
 - **M3 (R2):** Nonclinical Safety Studies for Human Clinical Trials and Marketing Authorization
 - **M7 (R1):** Control of DNA Reactive (Mutagenic) Impurities

Stability Testing of Herbal Drugs

- Stability testing evaluates the **physical, chemical, and microbiological** properties of herbal drugs over time under different storage conditions.
- The primary goal is to determine the **shelf life** and ensure the drug maintains its quality throughout its intended duration.

Objectives of Stability Testing

- To determine the shelf-life of herbal formulations.
- To assess changes in physical, chemical, and biological properties over time.
- To recommend appropriate storage conditions.

Types of Stability Testing

1. **Real-Time Stability Testing**

- Conducted under normal storage conditions for an extended period (e.g., 12-24 months).
- Helps determine actual shelf-life.

2. **Accelerated Stability Testing**



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