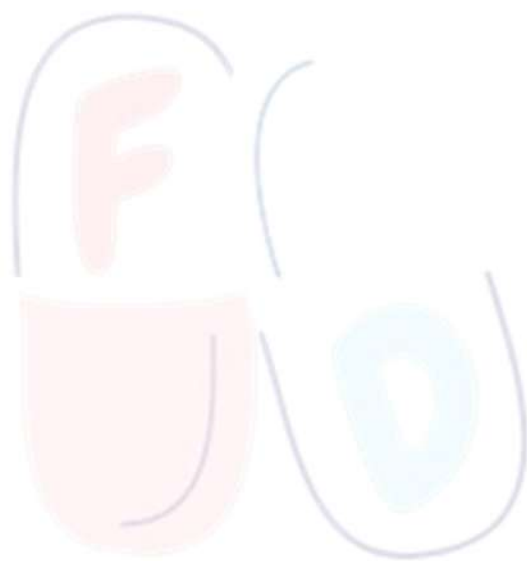


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HERBAL DRUG TECHNOLOGY

UNIT 4

TOPIC :

- **Evaluation of Drugs WHO & ICH guidelines for the assessment of herbal drugs Stability testing of herbal drugs.**



Evaluation of Herbal Drugs

→ Herbal drugs are medicinal products obtained from plants and are widely used in traditional and modern systems of medicine. Since herbal drugs contain complex mixtures of chemical constituents, proper evaluation is necessary to ensure their:

- Quality
- Safety
- Efficacy
- Purity
- Stability

→ International organizations such as the World Health Organization and International Council for Harmonisation have established guidelines for assessment and standardization of herbal drugs.

Objectives of Evaluation of Herbal Drugs

1. Identification and authentication of herbal drugs
2. Detection of adulteration and contamination
3. Assurance of quality and purity
4. Determination of safety and efficacy
5. Standardization of herbal formulations
6. Maintenance of batch-to-batch consistency

Need for Evaluation of Herbal Drugs

Evaluation is necessary because:

- Herbal drugs may vary due to climate and cultivation conditions
- Risk of adulteration and substitution exists
- Herbal products may contain contaminants
- Active constituents vary among plant species
- Proper therapeutic effect depends on quality control

WHO Guidelines for The Assessment of Herbal Drugs

- World Health Organization has developed guidelines for the evaluation, quality control, safety, efficacy, and standardization of herbal drugs and herbal medicines.
- These guidelines help ensure that herbal products are safe, effective, pure, and of good quality for human use.

Objectives of WHO Guidelines

1. To ensure quality and purity of herbal drugs
2. To ensure safety and efficacy of herbal medicines
3. To prevent adulteration and contamination
4. To standardize herbal products
5. To promote safe use of herbal medicines worldwide

Need for WHO Guidelines

- Herbal drugs vary due to environmental and cultivation conditions.
- Risk of adulteration and substitution exists.
- Herbal products may contain contaminants and toxic substances.
- Proper evaluation is necessary for therapeutic effectiveness and safety.

Important WHO Guidelines For Herbal Drugs

WHO guidelines include:

1. Authentication and identification
2. Quality control of herbal materials
3. Physicochemical evaluation
4. Phytochemical evaluation
5. Toxicological evaluation
6. Microbial contamination testing
7. Stability testing
8. Good Agricultural and Collection Practices (GACP)

Advantages Of WHO Guidelines

1. Ensure quality and safety of herbal drugs
2. Prevent adulteration and contamination
3. Improve therapeutic efficacy
4. Promote international acceptance
5. Improve quality control and standardization

ICH Guidelines For The Assessment Of Herbal Drugs

- International Council for Harmonisation guidelines are international standards developed for ensuring the quality, safety, efficacy, and stability of pharmaceutical products including herbal drugs.
- These guidelines help in proper evaluation, standardization, manufacturing, and quality control of herbal medicines.

Objectives of ICH Guidelines

1. To ensure quality and purity of herbal drugs
2. To ensure safety and efficacy of herbal formulations
3. To standardize manufacturing and analytical methods
4. To control impurities and contamination
5. To improve international acceptance of herbal products

Need For ICH Guidelines in Herbal Drugs

- Herbal drugs contain complex chemical constituents.
- Variation occurs due to climate, cultivation, harvesting, and storage conditions.
- Herbal medicines may contain contaminants and impurities.
- Proper quality control is required to ensure therapeutic effectiveness.

Important ICH Guidelines Related to Herbal Drugs

1. ICH Q1 – Stability Testing
2. ICH Q2 – Validation of Analytical Procedures
3. ICH Q3 – Impurity Testing
4. ICH Q7 – Good Manufacturing Practice (GMP)
5. ICH E6 – Good Clinical Practice (GCP)

Advantages of ICH Guidelines

1. International standardization of herbal products
2. Improved quality and safety
3. Better therapeutic effectiveness
4. Increased global acceptance
5. Improved patient safety

Stability Testing of Herbal Drugs

- Stability testing is the process of evaluating a herbal drug or herbal formulation under different environmental conditions such as temperature, humidity, and light to determine its shelf life, storage conditions, and stability.
- It ensures that the herbal product maintains its:
 - Quality
 - Safety
 - Purity
 - Strength
 - Efficacy throughout the storage period.

Objectives of Stability Testing

1. Determine shelf life of herbal products
2. Establish suitable storage conditions
3. Detect physical, chemical, and microbial changes
4. Ensure safety and therapeutic effectiveness
5. Maintain product quality during storage

Need for Stability Testing of Herbal Drugs

Stability testing is important because herbal drugs:

- Contain complex phytoconstituents
- Are sensitive to heat, moisture, oxygen, and light
- May undergo degradation during storage
- May lose potency with time
- Are prone to microbial contamination

Methods of Stability Testing

1. Real-Time Stability Testing

→ The product is stored under normal storage conditions and tested over a long period.

Conditions

- Room temperature
- Normal humidity

Duration

- 1 to 5 years

Advantages

- Accurate results
- Reliable shelf-life prediction

Disadvantages

- Time consuming

2. Accelerated Stability Testing

→ The product is stored under stressed conditions to speed up degradation.

Conditions

Usually:

- $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$
- $75\% \pm 5\% \text{ RH}$

Duration

- 6 months

Advantages

- Faster results
- Predicts long-term stability quickly

Disadvantages

- May not perfectly simulate natural conditions

3. Retained Sample Testing

→ Samples from marketed batches are tested periodically throughout shelf life.

4. Cyclic Temperature Stress Testing

→ Product is exposed to alternating high and low temperatures.

Purpose:

- Detect instability due to temperature changes

Stability Testing Procedure

Step 1 – Selection of Samples

- Herbal formulation samples are selected.

Step 2 – Storage Under Specified Conditions

- Samples are stored at required temperature and humidity.

Step 3 – Periodic Evaluation

- Samples are tested at regular intervals.

Example

- 0 month
- 3 months
- 6 months
- 9 months
- 12 months

Step 4 – Data Analysis

- Results are analyzed to determine shelf life and stability.

Importance of Stability Testing

1. Ensures product safety
2. Maintains therapeutic efficacy
3. Determines expiry date
4. Improves quality assurance
5. Prevents degradation and contamination

Advantages of Stability Testing

1. Ensures consistent product quality
2. Helps in proper packaging selection
3. Increases consumer confidence

Limitations

1. Time-consuming process
2. Expensive testing procedures
3. Difficult standardization due to natural variability of herbal drugs

Role of Stability Testing In Herbal Industry

- Helps maintain quality control
- Supports export and international marketing
- Ensures compliance with WHO and ICH guidelines
- Improves shelf life and storage recommendations