UNIT – 4

Evaluation of Herbal Drugs: WHO & ICH Guidelines, Stability Testing, Patenting, and Regulatory Requirements

Evaluation of Herbal Drugs: WHO & ICH Guidelines:

1. WHO Guidelines:

- **Quality Control:** Emphasis on quality, safety, and efficacy.
- **Identification:** Methods for authentication and identification.
- **Pharmacopoeial Standards:** Reference to pharmacopoeias for herbal drugs.
- **Good Agricultural and Collection Practices (GACP):** Guidelines for cultivation and collection.
- **Good Manufacturing Practices (GMP):** Manufacturing standards.

2. ICH Guidelines:

- **Safety and Efficacy:** Emphasis on safety studies and efficacy assessment.
- **Clinical Trials:** Guidelines for conducting clinical trials on herbal medicines.
- **Quality:** Addressing issues related to the quality of herbal products.
- **Registration:** Procedures for the registration of herbal medicines.

Stability Testing of Herbal Drugs:

1. Definition:

- **Stability Testing:** Evaluating the chemical and physical changes in a drug over time under various conditions.

2. Parameters Studied:

- **Physical Characteristics:** Color, odor, appearance.
- **Chemical Characteristics:** Degradation, impurities.
- **Biological Characteristics:** Microbial contamination.

3. Conditions for Testing:

- **Temperature:** Varied temperatures to simulate real-world conditions.
- **Humidity:** Testing under controlled humidity levels.
- **Light:** Exposure to different light conditions.

4. Importance:

- **Determine Shelf Life:** Predict how long the drug will remain stable.
- **Quality Assurance:** Ensures product consistency.

- **Regulatory Compliance:** Required for regulatory approvals.

Patenting and Regulatory Requirements of Natural Products:

a) Definition of Terms:

1. Patent:

- **Definition:** Legal protection granted to inventors for their inventions.
- **Purpose:** Prevents others from making, using, or selling the patented invention.

2. IPR (Intellectual Property Rights):

- **Definition:** Legal rights that result from intellectual activity.
- **Includes:** Patents, copyrights, trademarks.

3. Farmers' Right:

- **Definition:** Recognizes the contributions of farmers in conserving biodiversity.
- **Protection:** Ensures fair and equitable benefit-sharing.

4. Breeder's Right:

- **Definition:** Protects the rights of plant breeders over their new plant varieties.
- **Encourages Innovation:** Promotes the development of new and improved plant varieties.

5. Bioprospecting and Biopiracy:

- **Bioprospecting:** Exploration of biodiversity for valuable genetic and biochemical resources.
- **Biopiracy:** Unauthorized use or patenting of these resources without proper compensation or consent.

b) Patenting Aspects of Traditional Knowledge and Natural Products:

1. Traditional Knowledge:

- **Challenge:** Difficulty in patenting due to existing traditional knowledge.
- **Protection:** Implementing systems to protect traditional knowledge.

2. Natural Products:

- **Patenting Challenges:** Identifying novel aspects to meet patentability criteria.
- **Case-by-Case Evaluation:** Each natural product's patentability assessed individually.

Case Study of Curcuma & Neem:

- **Curcuma (Turmeric):**
    - **Challenges:** Traditional use, widespread knowledge.

- **Solution:** Patenting specific formulations or methods.

- **Neem:**
    - **Challenges:** Long-standing traditional uses.
    - **Solution:** Patenting specific applications or processes.

Regulatory Issues - Regulations in India:

1. ASU DTAB (Drugs Technical Advisory Board):

- **Role:** Advises the central government on technical matters.
- **Functions:** Formulating standards for drugs, advising on drug-related issues.

2. ASU DCC (Ayurveda, Siddha, Unani Drugs Consultative Committee):

- **Role:** Advises the central government on issues related to ASU drugs.
- **Functions:** Examines matters referred by the DTAB.

3. Regulation of Manufacture of ASU Drugs - Schedule Z of Drugs & Cosmetics Act:

- **Includes:** Regulations related to the manufacture, sale, and distribution of Ayurvedic, Siddha, and Unani drugs.
- **Ensures:** Compliance with quality and safety standards.

In summary, the evaluation of herbal drugs follows WHO and ICH guidelines, emphasizing quality, safety, and efficacy. Stability testing assesses the physical, chemical, and biological characteristics of herbal drugs under various conditions. Patenting and regulatory requirements involve protecting intellectual property rights, addressing challenges related to traditional knowledge and natural products. In India, regulatory bodies like ASU DTAB and ASU DCC play key roles in formulating standards for Ayurvedic, Siddha, and Unani drugs. The regulation of manufacturing falls under Schedule Z of the Drugs & Cosmetics Act, ensuring compliance with quality standards.