Regulatory Requirements for Herbal Medicine in India.

Raut Ajit V., Gandhade Sairaj S., dherange Aaditya V., Gorade Prasad L.

MATOSHRI MIRATAI AHER COLLEGE OF PHARMACY

Vithal nagar, Kokate vasti, Karjule Harya, (Takali Dhokeshwar), Nagar kalyan highway, Tal-Parner, Dist-Ahmednagar.

Abstract

The regulatory requirements for herbal medicine in India encompass a framework defined by the Ayurveda, Siddha, and Unani Drugs Technical Advisory Board, along with the Central Council of IndianMedicine. These guidelines emphasize the need for standardized manufacturing processes, quality control,and safety assessments. Herbal medicines must comply with the Drugs and Cosmetics Act, ensuring proper licensing, labeling, and adherence to Good Manufacturing Practices. Additionally, documentation of traditional use, phytochemical analysis, and toxicity studies are integral components for regulatory approval, contributing to the overall safety and efficacy of herbal products in the Indian market.

Key words :*Good manufacturing practices,Phytochemical analysis, Emphasized*

INTRODUCTION

- The term grass comes from Latin words. Herbs and the Old French word Herby.
- India is known for traditional Ayurveda, Siddha and Unanni system of medicine.
- The system of medicine is mentioned even in our ancient Vedas and other manuscripts.It is
- the oldest and still the most commonly used systemic drug in the world.
- In India, herbal medicines are regulated by the Ministry of Ayurveda, Yoga and Naturopathy, Unanni, Siddha and Homeopathy. [2]
- Herbal medicines and herbal medicines are also known as herbal medicines. Use plant parts, leavesroot steam flowers and seeds for medical thermolysis purposes.
- Three types of herbal medicines according to WHO :

1. Plant material line
2. sustain plant material
3. Herbal medicine.[3]

Definition

Plants or plant parts that have been used to make pyrotechnics by a simple process involving harvesting, drying and storage.[1]

LITERATURE SURVEY:

1) Gohil K J, Patel J (2017). To conduct a systematic review of the literature on interactions between traditional medicines and various medicinal plants. Herb-drug interactions are a harsh reality today. Therefore, appropriate case reporting, careful vigilance, evidence-based evaluation, and continuously updated assessments of such herb-drug interactions are essential to advance systematic research.[3]

2) Richa Shah. In this study, the author has tried to present information about herbal medicines and regulatory requirements of medicines used in India since Vedic times and documented in Rig-Veda.

3) the government. Indian Ministry of Health, Indian Pharmacopoeia of Homeopathy, Volume 1, Controller's Edition (1971). This study contains information about the Homeopathic Pharmacopoeia ofIndia (Hpi). From Hpi This author has taken information about herbal medicines.

4) Government of India, Ministry of Health, India, Pharmacopoeia of Homeopathy, Volume 1, Delhi, Family Welfare. In this study, rules and regulations are related to family welfare and use of herbal medicines. Information related to the traditional dosage form.[7]

5) Department of Indian System of Medicine and Homeopathy, Volume 8, Controller Publication 2000. Traditional medicinal systems based on medicinal herbs play an important role in providing health servicesto a large part of the population, especially in developing countries. Interest in using them and herbal products made from them is also growing in developed countries. A minimum entry level is required to understand and get the most out of these systems and how they work. Indian systems of medicine are known traditional systems of medicine. This review has attempted to provide general information on various aspects of these systems.

6) Government of India, Ministry of Health, Ayurvedic Pharmacopeia for Family Welfare, Volume 4, Comptroller New Delhi 2004. This publication of the pharmacopoeia contains information on the

standardization of herbal medicines and their methods. And family welfare health regulations.[4]

7) Dr. Priyanka Goswami, In this study, the author tried to get information about herbal drug interactions. Both schedule T and schedule Y. Whose guidelines relate to quality control of herbal medicines.

8) Anupam K Sachan et al. Medicinal plants are an important source in the preparation of medicines. Medicinal plants and herbal medicines form an important part of the pharmaceutical market. As the side effects of synthetic medicine have become more and more obvious, most of the dosage forms are made from herbs. However, herbal medicines suffer from the lack of normative parameters. The biggest limitation is the lack of standardization of raw materials, processing methods and final products, dosage formula and lack of quality control criteria. Regulatory measures must be put in place for herbal medicines to ensure the quality, safety and efficacy of herbal medicines using modern techniques, applyingappropriate standards and good manufacturing.[10]

AIM AND OBJECTIVE

AIM: To study the regulatory requirement for herbal medicine in India. Objetive:

• Quality control of herbal drug

• Authorization storage of parts of plant, regional status, botanical identity like Phyto micro- ology, microscopical and histological analysis

• Foreign matters- herbs converted should be free from soil insect part or animal etc. • Organic evaluation

• Volatile matter- moisture content contamination

• Chromatographic evaluation and spectroscopic evaluation ex. Cadmium, lead, arsenic etc. • Microbial contamination

• Radioactive contamination

• Herbal medicine - Regulated under drug and cosmetic act 1940 And rules 1945. Where regulatory provision for Ayurveda, unanni and siddha medicine clearly laid down.

• DandC act extends the control.

NEED OF HERBAL DRUG

- Toxic side effect - Drugs of modern medicine
- Lack of Medicine - for many chronic illness
- Most disease - Multifactorial
- Needs therapeutic – innervations[9]

CLASSIFICATION

1)Category 1st - Indigenous herbal medicines-

This category of herbal medicines is historically used in local community of re-join and its very well-known though long usages by local population in terms of its composition treatment dosage.

2)Category 2"nd - Herbal medicines in system

Medicines in the category have been used for long time and are documented with their special theories and concept and accept by countries. Ex. Ayurveda, unanni and siddha, would fall in the category

3)Category 3rd- Modified herbal medicines

This are herbal medicines as described above in categories one and two except that they have been mode of administration herbal medicines ingredients method of preparation and medical indication.

4)Category 4th - Imported products with an herbal medicine base. This category covers all imported herbal medicines, row material and product imported medicines must be registered marketed in the countries of origin.[13]

Herbal Drug Regulation Of India

• Herbal medicine - regulated by the Narcotics and Cosmetics Act 1940 and Regulations 1945. The provisions of Ayurveda, Unanni and Siddha medicine are clearly defined.

• The D and C Act expands licensing, formulation, manufacturing, labeling, packaging, and quality and export controls.[5]

WHO Guidelines

• Quality control of herbal medicines

• Repository of plant part licenses, regional status, botanical identity such as phytomicrobiology, microscopic and histological analysis

• Foreign matter - modified herbs must not contain soil insects or animal parts, etc.

• Organic assessment.

• Pollution caused by the moisture content of volatile substances.

• Chromatographic and spectroscopic evaluation, e.g. cadmium, lead, arsenic etc.

• Microbial contamination

• Radioactive contamination.[7]

WHO Guidelines for Herbal Drug Standardization

The subject of standardization of herbal medicines is extremely broad and deep. The guidelinesestablished by the WHO can be summarized as follows:

• Reference to drug identification data.

• Reference to the physico-chemical properties of the drug.

• Reference to pharmacological parameters. Toxicity information. Microbiological parameters.

• Radioactive contamination.[4]

Herb drug interactions:

- Many herbs and drugs are therapeutic in one dose and poisonous in another.
- Interactions between herbs and drugs can increase or decrease the pharmacological or toxicological effects of both components.
- Synergistic therapeutic effects may complicate the administration of long-term medications.For
- example, herbs traditionally used to lower glucose in diabetes can theoretically cause hypoglycemia when taken with conventional medications.
- Herbal medicines are ubiquitous: underreporting of adverse events and interactions is likely due to underreporting and the benign nature of most medicinal plants used. o increase or decrease the effectof blood thinners such as warfarin and cause bleeding or dangerous blood clot formation;
- reduces the effect of blood pressure medication, causing high blood pressure and stroke; reduces the
-

effect of the anti-infective agent so that the infection does not get out of control; or -increases the effect of diabetes medications and lowers blood sugar to dangerously low levels.[2]

EXAMPLES:

Herb drug interactions Garlic

• Allium sativum (garlic) decreased the plasma surface of saquinavir but not ritonavir and paracetamol(acetaminophen) in volunteers. concentration–time curve (AUC) and

• A. sativum increased the international normalized ratio of warfarin clotting time and caused hypoglycemia when co-administered with chlorpropamide.[11]

Herb drug interactions Ginkgo

• Ginkgo biloba (ginkgo biloba) has caused bleeding when combined with warfarin or aspirin (acetylsalicylic acid), increased blood pressure when combined with a thiazide diuretic, and even coma when combined withtrazodone.[10]

Schedule T

Good Manufacturing Practice (GMP) is prescribed in Part I and |l as follows to ensure that:

- The raw materials used in the manufacture of medicines are genuine, of certain quality and unpolluted.The
- production process is designed to maintain standards.
- Appropriate quality control measures are implemented.
- Produced medicine that is released for sale with acceptable quality.
- To achieve the objectives listed above, each licensee must develop methods and procedures to follow theprescribed drug manufacturing process. These should be documented as a guide and kept for reference and inspection. However, under IMCC Act 1970 registered Vaidya's, Siddhas and Hakeems who prepare medicines on their own to dispense to their patients and not selling such drugs in the market are exempted from the purview of G.M.P.[7]

PART-I

GOOD MANUFACTRING PRACTICES

Factory Premises:

There must be enough space in the production area: -

(1) Receiving and storage of raw materials

(2) Production process areas

(3) Quality Control Department

(4) Trading in finished products

(5) Office

(6) Abandoned goods/drug sales.

- General Requirements: -
- Location and surroundings
- Buildings
- Water supply
- Disposal of waste
- Containers' cleaning
- Stores Raw materials
- Packaging material
- Finished goods stores
- Working space
- Heath, clothing, sanitation and hygiene of workers
- Medical services
- Machinery and equipment's
- Batch manufacturing records
- Distribution records
- Record of market complaints
- Quality control
- Requirement for sterile product
- Manufacturing areas
- Precautions against contamination and mix.[3]

Schedule Y for Herbal Drugs:

All the basic ethical principles of human participation in research apply equally to the study of herbal medicines and their compounds.

Consent must be obtained, the selection of experimental subjects must be fair, the risks and benefitsmust be weighed and favorable to the potential participant, and the experimental design must be reasonable.

Problems specific to clinical trials of herbal products include: product adulteration (is this documented?)

Interactions between herbal preparations and other organisms (rarely understood) Data on reproductive toxicity and organ toxicity (may be minimal) Previous dose detection (probably incomplete).

- 1st class: already used for more than 5 years
- 2nd class: used for less than 5 years
- Class 3: new drugs.
- For those herbal medicines and medicinal plants that need to be clinically evaluated for use in allopathic systems and which can later be used in allopathic hospitals, the prescriptions of the Bureauof Allopathic Medicines (Office of Allopathic Medicines) of the Drug Controller of India is followed .
- If a plant extract or a compound isolated from a plant needs to be clinically evaluated for a therapeutic effect that was not originally described in the texts of traditional systems or the methodof preparation is different, it must be considered as a new substance or a new chemical entity (NCE) must be presented according to regulatory agency requirements before it can be approved for clinicalevaluation.).
- An extract or compound isolated from a plant that has never been used and never mentioned in ancient literature must be considered a new drug and therefore must pass all regulatory requirementsbefore clinical evaluation.
- The document also contains general guidelines on medicinal plant clinical trials, toxicity studies, needfor standardization and adherence to GCP in all clinical trials. Some suggestions include:
- Clinical trials with herbal preparations must be carried out only after standardization and identification of markers, so that the evaluated substances are always the same.

- Plants and herbal medicines must be produced strictly in the same way as described in the literatureand include GMP standards in the standard.
- For herbal products, phase 1 studies should be conducted to verify maximum tolerated dose (MTD)and early measurement of drug activity.
- If there are reports suggesting toxicity or if the herbal product is intended for use over 3 months,toxicity studies are required for Phase 2 studies (4-6 week toxicity study in two species).
- Toxicity studies are required in a phase 3 trial (4-6 week toxicity study in two species). The studymust follow ethical guidelines (patient information, informed consent, protection of vulnerable population groups, etc.).
- Clinical trials must be coordinated with the scientific and ethical committees of the respectiveinstitutions.
- Clinical trials should be conducted only when a qualified Ayurvedic, Siddha or Unani physician isinvolved as a researcher.[12]

MARKET STANDARDIZATION

Standardization:-

Standardization of herbal medicine means confirming its identity and identifying its quality, purity and the nature of the degradable substance through various parameters such as morphological, microscopic, physical, chemical and biological observations.andquot;[1]

Standardization of Herbal Medicines Crude Medicines

- passport data of crude herbal medicines (crude medicines). Correct
- taxonomic identification and authentication
- Study of medicinal part: root, stem, bark, leaves, flowers, fruits, nuts, gum, resins, etc.
- Collection information: plant location, stage and development/growth, time, pre-treatment storage, etc. Sensory
- examination of the raw drug: »Evaluation using the senses: touch, taste, smell
- Study of medicinal part: root, stem, bark, leaves, flowers, fruits, nuts, gum, resins, etc.
- Collection information: plant location, stage and development/growth, time, pre-treatment storage, etc. Sensory
- examination of the raw drug: »Evaluation using the senses: touch, taste, smell
- Microscopic and molecular studies
- Chemical composition (TLC, GLC, HPLC, DNA fingerprint)
- Biological activity of the whole plant
- Consumption duration of crude drugs.[4]

Standardization of the market of herbal medicines.

1) Volatile oil: eugenol

2) Glycoside: Digitoxin

3) Resin: Curamine.

1. Volatile Oil- Eugenol

- Species: Cinnamomum zeylancium Eugenia caryophyllus. TLC
- Mobile phase.
- Toluene: ethyl acetate(98:7)
- Detection: vanelin H2SO4 and Visible light
-

Observation pinkish red spot

- RF Value: 0.9
- Eugenol oil on treatment with KOH, produce Potassium eugenate crystals.

1. **Glycoside: Digitoxin**
   - Species: digitaliac lanata
   - TLC mobile phase:
   - Ethyl acetate: methanol: water (81:11:8)
   - Detection: Kedde regent & visible light
   - Observation: Grey to violate grey to colour spot.
   - Detection: SbCl3 & UV-365
   - Observation: Dark blue fluorescence
   - RF Value: 0.05 to 0.95
   - Keller-killiani test for Cardiac glycoside.

Resin: Curcumin

- Species: Curcuma longs
- Curcuma domestica
- TLC Mobile Phase
- Chloroform: Ethanol: Glacial acetic acid (95:5:1)
- Detection: UV-365 Observation: Yellow
- Rf value: 0.3 - bisdemethoxycurcumin
- 0.5-0.55 – desmethoxycurcumin
- 0.6 – curcumin.[9]

Example of Homoeopathic Mother Tinctures: Bacopa Monnieri

A homeopathic tincture of flowers is made from Arialos. This is covered in Homeopathic Pharmacopoeiaby M. Bhattacharyya and Company. It is used for nervous disorders, neuralgia, epilepsy, improves mentalfunctions, memory and concentration and shortens study time. It has also been used externally for healthy hair growth, cooling and headaches. Many studies have shown its effectiveness in Alzheimer's disease and significantly improves logical memory, learning skills, attention, short-term memory, decision-making and memory consolidation, and motor responsiveness in both children and adults.[1]

Application of Herbal Medicines

• Benefits and possible side effects of the same important herbs.

• Benefits: Used to treat colds, coughs, sinus infections and respiratory infections. Also used for digestive problems, heartburn, nausea, vomiting etc.

• Peppermint oil is applied to the skin for headaches, muscle, neuralgic pains, etc.

• Stomatitis: joint disease itchy allergic viral infection.(12)

Advantages Of Herbal Formulation:

Sl	[redacted]
1	[redacted]
2	
3	
4	

5	[redacted]
6	
7	

PHYTOSOMAL HERBAL PRODUCT

Side Effect:

- Alovera – hepatotoxicity abdominal spams pain, allergic reaction, cramps and kidney damageTurmeric -
- risk of bleeding, potentive the effect of warfarin therapy
- Fennel- homiophage, pneumonia.
- Thyme - it can cause digestive system to upset, in some people applying the oil.

CONCLUSION:

- IT is even undergoing a transformation of traditional medicine.
- May be approved by FDA under regulatory procedure.
- Herbal supplements can benefit consumers. Results
- take time, but their effects are long-lasting.
- Compared to allopathic reactions of herbal medicines, they are very few.All
- reactions caused by herbal medicines can be treated in less time.
- Because they are derived from plants, their production costs are lower.
- Herbal medicines are used to treat serious diseases such as diabetes and high blood pressure. [6]It is
- also used to treat burns, nerve point headache viral infections etc.
- High dosage can cause serious side effects and toxicity.[4]

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