

A REVIEW ON HERBAL TABLET FORMULATION: TECHNIQUES, EXCIPIENTS AND THEIR IMPACT ON CHRONIC DISEASE MANAGEMENT

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ABSTRACT

Medicinal herbalism, being an extremely ancient practice dating thousands of years back and centuries in the making, remains a lifeline in medicine during this modern era and age with its depictions of remedies that are made from plant parts like leaves, flowers, stems, roots, and seeds. The active phytochemicals in herbal remedies include phytochemicals like alkaloids, flavonoids, saponins, and terpenoids that cause therapeutic activity. This research is focused on preparation, development, and characterization of herbal tablets as solid dosage forms developed from powder herbal compression with fillers-excipients' for the management of other diseases or as a food supplement. Preformulation deals with identification of physicochemical property of drug, i.e., organoleptic properties, purity, size, and shape, which are of prime importance towards maintaining quality and therapeutic performance of final tablet. Formulation is an operation process of consecution such as weighing, mixing, granulating, drying, and size reduction to achieve uniform mixture state with an aim to compress into tablet. Excipients like lubricants and binders are very important in the provision of tablets stability and effective release of active ingredients. Ashoka tablet preparation is also given as an example of tablet preparation in Ayurveda. It involves raw herbal material selection like Ashoka bark and Shatavari root processing, mixing, binding, and shaping into tablets. Quality control through rigorous regulation of parameters like weight variation, hardness, disintegration time, and chemical analysis provides efficacy and safety. Finally, production and manufacture of herbal tablets need pharmaceutical science expertise and the special nature of herbal products. This research emphasizes scientific evidence in formulating safe, effective, and standardized herbal medicine that bridges traditional medicine and modern pharmaceutical practice.

KEYWORDS: Herbalmedicine, Ayurveda tablet, Preformulation studies, Ashokatablets, Traditional medicine, Stability studies, Quality evaluation.

Herbal Medicine

The use of herbal medicine is the oldest type of healthcare which has been employed for decades in developing and developed nations. The foundation of contemporary medicinal drugs like aspirin, morphine, digitoxin and quinine were synthesized following scientific verification of herbal medicine.^[1] The World Health Organization (WHO) has defined herbal medicine as a practice which consists of herbs, herbal materials, herbal preparations and finished herbal products as active ingredients containing parts of plants or other plant materials or mixtures.^[2] These herbs are obtained from parts of plants like leaves, stems, flowers, roots and seeds. Herbal drugs have active ingredients in the form of phytochemicals including various classes like saponins, flavonoids, glycosides, tannins, alkaloids and terpenoid.^[3] Herbal formulations: Herbal formulation shall refer to a dosage form one or more herbs that are processed herbs in predefined quantities to convey predefined nutritional, cosmetic values, and/or other values intended for application to diagnose, treatment, alleviate diseases of human beings or animals.^[4]

Herbal Tablets

Herbal tablets are solid dosage form made up of herbal extract, granule is blended with excipients such as starch, tragacanth and compressed to form a defined size and shape.

Advantages

- Herbal tablets have low risk of side effect.
- The cost of herbal medicines are very low compared to pharmaceutical drugs
- Effective treatment for chronic medical conditions.
- Herbal tablets are used as herbal supplements.

Disadvantages

- When herbal tablets are consumed with pharmaceutical drugs, the two can interact with each other resulting in injuries to health.
- Herbal tablet lacks dosage standard.
- Since herbal tablets are not regulated, consumers run the risk of buying inferior quality herbs.^[5]

PREFORMULATION STUDIES

Preformulation is defined as branch of pharmaceutical science that utilizes biopharmaceutical principles in the determination of physicochemical properties of drug.

Organoleptic Properties

This includes the physical properties that can be examined merely by sense organs such as color, odour, taste and touch. Color is closely related with the composition of every material; mostly the extracts are dark brown or black in color. Some compound have specific odour. In case of herbo-mineral drugs, presence of metallic particles in bhasma gives specific metallic taste.^[6]

Purity

This is another important aspect for pre formulation studies. For every compound, depending on its dose and toxicity, the limit of impurity is defined. Until and unless the purity of the drug is assured other studies like stability, degradation and toxicity cannot be performed. Various parameters which are considered to find the purity of the drug substance are

pesticide residue, TLC, HPLC, UV absorption, IR spectra., Ayurveda purification methods may result in depletion of percent purity but according to therapeutic point of view, these purification methods removes some toxins and make the metals- minerals suitable for further processing.

Particle Size and shape

It is more important when bhasma of metals and minerals are used as drug. Thebhasmaave a particle size ranging from micron to Nano meters. The smaller the particle size, easy would be the dispersion, solubility and assimilation in the body.

Weighing

Each ingredient in the tablet formula is weighed and accurately dispensed as per dose. This is one of the critical steps in any type of formulation process and should be done under technical supervision.

Every pharmaceutical manufacturing plant features an area in which raw materials are weighed and transferred to clean containers. Weighing is the entry point to manufacturing and a transition point for materials coming from the warehouse and entering process areas. So it is need careful attention to design layout and operation of weighing area.

Manufacturing Processes in Herbal Tablet Production

Blending: Blending is defined as process that tends to result in randomization of dissimilar articles within a system. The diverse characteristics of particles, such as size, shape, volume of surface area, density, porosity, flow and charge, contribute to the solid blending. Blending of Herbal Powders: There are four methods of blending powders in herbal industry.^[7]

1. Trituration
2. Spatulation
3. Sifting
4. Tumbling

Blending Equipment

Tumbling mixers: (e.g., v-cone blender, double cone blender, cubic mixer, drum blender).

Diffusion mixers: (e.g., For berg blenders, horizontal double arm mixers. Vertical high-intensity mixer.)

Granulation

Granulation is a particle design process where by small particles are brought together to form physically strong agglomerates.

Reasons to granulate

- Improve flow
- Density materials
- Improve content uniformity
- Improve compression characteristics

Types of granulation

The principal methods of granulating herbal drugs may be classified into three main categories.

Wet Processes

High shear mixer granulator or, Fluid Bed Granulation, Spray Drying, Pan Granulation & Extrusion and Pelletizing.

Dry Processes: Roller Compaction & Slugging

Other Processes: Humidification, Pilling & Melt Pillarization

Drying

Drying is defined as the removal of small amount of water or other liquid form a material by the application of heat. Drying is most common method of medicinal plants preservation and, due to high investment and energy costs, drying is also a large expense in medicinal plant production .conventionally, low drying temperature between 30 and50°C are recommended to protect sensitive active ingredients. Influence of drying on microbial count of row drug is discussed, because the represents a major problem for medicinal plant growers. Furthermore, different types of dryers are described, suitable specific plant organs like leaves, flower, root or seeds.

Types of dryers

Static Bed Dryer (eg: Tray dryer and Freeze dryer)

Moving Bed Dryer: (eg: Drum dry)

Size Reduction

Size reduction is a process of reducing large solid unit massage (vegetable or chemical substances) into small unitmassescoarseparticlesorfineparticles.Sizereductionprocessisalso termed as comminution or diminution or pulverization. Normally precipitation or mechanical process.

Size Separation

Size separation is a unit operation that involves the separation of a mixture of various sizes of particles into two or more portions by means of screening surfaces. Size separation is also known as sieving, sifting, classify or screening. This technique is based on the physical differences between the particles such as size, shape and density.

Sieves: Sieves are the simplest and sieving is the most frequently used method for size separation.

HERBAL TABLET FORMULATION

Herbal tablets are made by compression a formulation containing a drug or drugs with excipients on stamping machines called presses.

- Herbal tablet compression reclassified as
- Single Punch
- Multiple Punch

HERBAL TABLET COATING

Coating is a process by which an essentially dry, outer layer of coating material is applied to the surface of a dosage form to achieve specific benefits. When coating composition is applied to a batch of tablets in a coating pan, the Tablet surfaces become covered with a tacky polymeric film. Tablets coating mask the taste, odour, or colour of the drug. Tablets coating control their lease of the drug from the tablet.

QUALITY CONTROL

Finished product controls (FPC) are performed after a product is manufactured. These checks are related to qualitative and quantitative characteristics, test procedures, and acceptance limits of the product, with which the finished product should comply throughout its valid shelf-life.

The following standards or quality control tests are carried out on finished tablets

1. Diameter size and shape,
2. Weight variation,
3. Thickness,
4. Hardness,
5. Friability.
6. Content uniformity
7. Disintegration test
8. Dissolution test

Herbal Tablet Packing

Packaging is enclosing or protecting products for distribution, storage, sale and use. Packaging may also be defined as the collection of different components (e.g. bottle, vial, closurecap, ampoule, blisteretc.) Which surround the pharmaceutical product from the time of production until its use.

EXAMPLE OF HERBAL TABLET-Ashokathi tablet

Description of Ashokathi tablets

Name: Ashokathi tablets (also known as Ashoka rista or Ashoka tablets)

Family: Fabaceae

Appearance: Typically round or oval in shape, with a smooth or slightly rough surface. Color ranges from light brown to dark brown or tan.

Size: Varies depending on the manufacturer, but usually around 1-2cm in diameter and 0.5-1cm in thickness.

Texture: Firm, dense, and slightly brittle.

Odor: Characteristic herbal aroma, slightly bitter and earthy.

Taste: Bitter, astringent, and slightly sweet.

Ingredients: Ashokabark, Lodhrabark, Shatvariroot, Dashamoolaroots, Guduchistem, Yashtimadhu root, and Nagakesara flowers.

Dosage: Typically 1-2 tablets, 2-3 times a day, with water or as directed by an Ayurvedic practitioner.

Shelf Life: 2-3 years from the date of manufacture, if stored properly in a cool, dry place.

Storage: Store in an air tight container, away from direct sunlight and moisture.

Caution: Consult an ayurveda practitioner or qualified health care professional before taking Ashokathi tablets, especially if you have any underlying health conditions or allergies.

Formulation of Ashokathi tablets**Ingredients**

1. Ashoka (Saracaasoca)-200mg
2. Lodhra (Symplocosracemosa) -150mg
3. Shatavari (Asparagusracemosus)- 100mg
4. Dashamoola (ablendof10roots) -100mg
5. Guduchi (Tinosporacordifolia)-50mg
6. Yashtimadhu (Glycyrrhizaglabra)-50mg
7. Nagakesara (Mesuaferrea) -25mg

Excipients

1. Ghrita (clarified butter) or honey – as binding agent
2. Guggulu (Commiphora wightii) - as preservative

Preparation method for Ashokathi tablets**Step 1**

- Ingredient Collection and Processing
- CollectfreshAshokabark,Lodhrabark,Shatavariroot,Dashamoolaroots,Guduchi stem,
- Yashtimadhu root, and Nagakesara flowers.
- Dry the ingredients in shade or using a machine.
- Grind the dried ingredients into fine powders.

Step 2: Powder Mixing

- Mix the powders in the specified proportions (as mentioned earlier).
- Blend well to ensure uniformity.

Step 3: Binding Agent Preparation

- Prepare ghrita (clarified butter) by heating butter separate the butterfat.
- Alternatively, use honey as the binding agent.

Step 4: Tablet Formation

- Add the binding agent to the powder mixture and blend until a uniform dough forms.
- Shape the dough into tablets or pills using a tablet press or manual mold.
- Dry the tablets in a controlled environment.

Step 5: Quality Control

- Check the tablets for uniformity, texture, and appearance
- Store the tablets in air tight containers to maintain freshness.

EVALUATION OF ASHOKATHI TABLETS**1. Organoleptic Evaluation**

- ❖ Color, shape, size, texture, and odor
- ❖ Uniformity and consistency

2. Physical Evaluation

- ❖ Weight variation
- ❖ Hardness and friability
- ❖ Disintegration time

3. Chemical Evaluation

- ❖ Ash value (inorganic content)
- ❖ Extractive values (soluble and insoluble content)
- ❖ Moisture content
- ❖ Heavy metal analysis (lead, mercury, arsenic, cadmium)

4. Pharmacological Evaluation

- ❖ Uterinotonic activity
- ❖ Anti-inflammatory activity
- ❖ Antimicrobial activity

5. Clinical Evaluation

- ❖ Efficacy in menstrual disorders, uterine health, and related symptoms
- ❖ Safety and tolerability
- ❖ Adverse effect profile

CONCLUSION

Herbal tablets are mainly like Ashoka tablets, which offer a natural remedy for treating various health ailments especially in the field of Ayurvedic practice. Subject to proper formulation such as the choice of therapeutic herbs and excipients, these tablets can form potential therapeutic agents with minimal side effects and relatively safety. However, if left unregulated and non-standard, the risk remains, and quality control procedures have to be exercised to ensure safety, efficacy, and consistency

Preformulation and process of manufacturing such as blending, granulation, and quality analysis are important to prepare high-quality herbal tablets. Ongoing research, coupled with stringent testing for purity, safety, and stability, is essential to ensure the efficacy and dependability of such products in contemporary healthcare.

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