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UNIT PROCESSES AND OPERATIONS OF AYURVEDIC SOLID DOSAGE FORMS

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ABSTRACT

Ayurveda, the oldest system of Indian medicine, uses a variety of solid dosage forms such as vati, guti, churna, bhasma and many more for therapeutic purposes. The preparation of such ayurvedic solid dosage forms start with the selection and processing of raw materials such as herbs, minerals and metallic compounds. A series of unit operations portraying integral roles in the preparation of ayurvedic solid dosage forms including purification (Shodhana), size reduction (Churna nirmana), blending (mishrana), binding, granulation, drying, compression and packaging. In addition to these, various traditional processes such as samskara (therapeutic processing) and bhavana (trituration) are also used in the preparation of ayurvedic solid dosage forms. All these unit processes and operations are employed to achieve the desired consistency and potency in the dosage forms. Although traditional methods have stood the test of time, ensuring consistency and scaling up production remain significant challenges. To address this, recent advancements in the manufacturing process have introduced modern techniques such as ultrasound assisted extraction and microwave drying, in order to improve the quality and efficiency of Ayurvedic solid dosage forms.

This chapter aims to provide comprehensive information on various unit processes and operations involved in the preparation of ayurvedic solid dosage forms, integrating both classical methods and contemporary pharmaceutical practices.Bringing together traditional Ayurvedic wisdom and modern scientific methods can help make these herbal medicines safer, more effective, and more widely accepted around the world.

Keywords: Ayurveda; Solid dosage forms; Unit process; Unit operations; Formulation

1. INTRODUCTION

Ayurvedic system of medicine is one the oldest system of Indian system[1] and it encompasses a wide range of solid dosage forms that has been delivering herbal therapeutics safely and effectively over millenia[2]. Classic Ayurvedic texts present in Charaka Samhita and Sushruta Samhita[3] encompasses a range of Ayurvedic solid dosage forms starting from simple powders (Churna) to various elaborative preparations like Bhasma (calcined herbal-mineral ash) and many others. These Ayurvedic dosage forms deliver herbal constituents with full therapeutic efficacy and also aligns with the concept of Ayurveda known as Dravya (substance), Guna (quality), and Kriya (action). This concept of Ayurveda also guides in the selection and processing of raw materials[4].

The evolution in the manufacturing technology of Ayurvedic dosage forms has influenced both traditional Ayurvedic manufacturing knowledge and modern pharmaceutical engineering methods[5]. In olden times, when there were limited resources classic unit operations were used for manufacturing of Ayurvedic Solid Dosage Forms. These classic unit operations such as use of mortar and pestle for grinding, sun and shade drying for the removal of moisture, and hand granulation using natural binders for the preparation of vati were used to optimize bioavailability of the dosage form and also ensuring stability. In modern times, practices such as milling using various type of mills such as ball mill, pebble mill etc., tray drying and fluidised bed drying for removing moisture and granulation using high-shear granulation equipments offer more advantages as compared to traditional methods because these methods allow large scale production in a reproducible manner. The combination of ancient wisdom with modern techniques has paved the way for enhancing global safety and efficacy of the Ayurvedic dosage forms.

With time, technology has evolved, and so the unit operations and processes involved in the manufacturing of Ayurvedic Solid dosage forms. Conventional purification methods used for the purification of raw materials include Shodhana and Marana, while in modern setting, it has been upgraded with HPTLC and gas chromatography[6]. Conventional methods used to remove the impurities from the substance while modern setting technologies allow robust criteria for purity and potency.

Likewise, packaging technology has also evolved, in ancient times, earthen pots and cloth wrapping used to be a common practice for packing the manufactured Ayurvedic Solid dosage forms but in modern settings, these earthen pots and cloth wrapping has been replaced with blister/strip packing and moisture barrier container. It not just provides preservative efficacy but also plays an important role in extending the shelf life of the solid dosage forms.

Despite all the advancement in Ayurvedic solid dosage form manufacturing, major issues or challenges lies in the standardization and regulatory compliance. Ayurvedic scholars, formulation scientists and regulatory bodies are required to put collaborative efforts to produce such a

robust quality control framework that can help in sustainable manufacturing practices. This chapter provides a comprehensive overview of various unit operations and processes involved in the manufacturing of Ayurvedic Solid dosage forms. It provides information about the classification of Ayurvedic solid dosage forms, how raw materials are selected and processed, name and details of various unit operations involved in traditional and modern manufacturing of Ayurvedic solid dosage forms, along with quality control, package, storage and future perspectives.

2. CLASSIFICATION OF AYURVEDIC SOLID DOSAGE FORMS

Ayurvedic solid dosage forms are one of India's oldest dosage form used since time immemorial. Ayurvedic solid dosage forms can be mainly divided into two categories: primary forms and specialized forms. Primary forms of Ayurvedic solid dosage forms include churna, vati, varti etc. while specialized forms of Ayurvedic solid dosage forms include bhasma, pishti, guggulu, khanda and many more[7].

Primary forms

Primary forms of Ayurvedic solid dosage forms are the preparations that are the easiest to prepare and are conventional type of dosage form. Common examples of primary Ayurvedic solid dosage forms include churna, gutika, vati, varti and many more.

Churna

Churna is one of the oldest solid dosage forms used since many centuries and is one of the most basic dosage form present in the history of dosage form and Ayurveda. It is a powder like preparation commonly prepared by simple grinding of one or more plant parts. These are very commonly used even now is because of the reason that they produce the highest bioavailability and are the easiest to administer amongst all dosage forms. These are simply mixed with water, honey or any other suitable liquid diluent to easily administer and also to improve palatability. Common examples of Churna from Ayurveda are Triphala churna used for improving digestive problems, sitopaladi churni for any kind of respiratory disorders. Another example of therapeutically important churna related to Ayurveda is Trikatu churna for improving metabolic balance[8,9].

Vati/Gutika

Vati/Gutika are another important solid dosage form of Ayurveda used till now, but in modern world it has taken the form of tablet which is formed using modern compression machineries. In Ayurveda, vati/gutika were used to be prepared simply using hand rolling by using suitable binding agents. Binding agents used in the preparation of Vati/gutika, according to Ayurveda, includes use of jaggery, honey or any kind of decoction which holds the powdered material together and then can be simply compressed or rolled with hands to form Vati/Gutika. These are more advantageous as compared to Churna because these dosage forms ensure

accuracy of the dose, palatability and stability[10].

Classic examples of Vati/Gutika are Hing Vati used mainly in the case of indigestion and to promote flatulence, another common example is Chyawanprash vati used for the purpose of increasing immunity. Brahma vati is commonly used to promote memory and cognitive enhancement.

Varti

These are another kind of solid dosage form, which are prepared by directly by molding or by coating herbal paste on to the core. These are modern equivalent of suppositories and chiefly used for rectal or vaginal administration. These mainly promote local action and less side effects. Common examples of Varti include Aragvadi Varti commonly used for anal fissures. Yoni Varti is another common example of varti used for uterine inflammation.

Specialized forms

Specialized dosage forms are those solid dosage forms of Ayurvedic system of medicine, which are generally prepared by some specialized technology, other than those specified for primary dosage forms. Common examples of specialized Ayurvedic dosage forms include bhasma, pishti, guggulu, khanda etc[11,12].

Bhasma

It is one of the most commonly prepared specialized Ayurvedic solid dosage forms, it is basically ash like solid dosage form prepared using repeated calcination of metals, minerals and other substances. These are nano sized in nature which increases its absorption and thus rapid action. Bhasma has been found to possess rejuvenative properties. Examples of bhasma as Ayurvedic solid dosage form include Swarna bhasma, mainly used for prolonging immunity and for vitality. Another important bhasma preparation used in Ayurveda is Makaradhwaja for cognition related conditions.

Pishti

Pishti is one of the unusual preparation of Ayurveda. Pishti, is basically prepared by triturating bhasma with herbal decoction and finally yielding such preparation which is rich in minerals and all such elements. Common examples of Pishti include Suvarna Pishti used as a cardiotonic for boosting cardiovascular health, Pravala pishti is commonly used for gastrointestinal relief when there is acidity or ulcer kind of situation in the stomach, and Mukta pishti is anti-inflammatory in nature used for joint pain and inflammation[13].

Guggulu

Guggulu is a resinous substance mainly a resinous kind of exudate form Commiphora mukul, after collecting this resinous substance from the plants, it is processed into tablets or powders for ease of administration. Guggulu have guggulusterones present inside them which makes them an efficient agent for lipid-lowering, analgesic and anti-inflammatory action. Common conditions in which guggula has been used or is used include arthritis, hyperlipidemia and various kind of skin disorders.

Khanda

Khanda is one of the different kind of solid dosage form present in Ayurveda. It can be said its modern equivalent is candy. In this solid dosage form, mixture of herbs/minerals is mixed with sugar-based confections in a palatable matrix. This system helps in increasing the palatability and thus increased patient compliance[14,15]. These solid dosage forms are present in Ayurveda since forever and have been used for their therapeutic properties. Nowadays, their manufacturing has taken a step forward with their modern equivalents.

Table 1: Ayurvedic solid dosage forms along with their modern equivalents, preparation methods and shelf-life

Ayurvedic dosage form	Description of the dosage form	Modern Equivalent	Preparation methods	Shelf life (years)
Churna	Fine herbal powder	Powder/granules	Size reduction/Mixing/Direct consumption	2-3
Kalka	Paste	Paste/wet mass	Wet grinding with liquids	0.5-1
Satva/Ghana	Extract	Extract/concentrate	Extraction/concentration	3-5
Vati	Tablets made from herbal powder	Tablet	Compression with binding agents	3-5
Gutika	Pills made from herbal powder	Pill	Hand rolling with binding agents	3-5
Guggulu	Resin-based pills	Resin-based tablets	Hand rolling	Up to 5 years
Bhasma	Ash obtained through incineration	Calcined powder	Calcination at hight temperature	10-20
Pishti	Fine powder prepared by grinding without heat using liquids)	Triturated powder	Trituration with liquids	5-10
Modaka	Spherical herbal confections	Lozenges	Molding with sweetening agents	1-2
Khanda	Sugar-based herbal preparation with	Confection	Mixing with sugar/jaggery	1-2

	multiple ingredients			
Avaleha/Lehyam	Herbal jam like semisolids	Pastes, gels	Trituration	2-3
Rasayana	Rejuvenative preparation	Nutraceutical supplements	Blending of polyherbs	3-4

3. SELECTION OF RAW MATERIAL AND ITS PREPARATION

This is one of the first and the most important step in the preparation of Ayurvedic solid dosage form as selection of raw material and how it is collected and further processes influence the final attributes of solid dosage form. Selection of raw material and its preparation is also associated with consistency and safety of the final product.

Collection guidelines

Any kind of raw material including plants and minerals must be procured according to their collection protocol guidelines, so that maximum phytochemical content can be obtained from them and their are minimal chances of contamination. According to Ayurveda, specific Ritu (seasons) and Laghima (times of day) have been recommended in order to ensure the procurement of maximum active constituents[16]. Example of this approach includes collection of roots should be done in the morning in monsoon to ensure maximum alkaloid content. Botanicals collected must be identified and verified by a specialized person known as Vaidya or botanist to ensure the quality of the raw material.

Seasonal considerations

Seasons have a profound effect on the concentration of secondary metabolites in the botanicals. Common example of this approach include collection of leaves in the autumn season ensure maximum essential oils and phenolic content while if roots are harvested in pre-winter season shows high content of alkaloid. Manufacturers of Ayurvedic solid dosage forms should ensure that these guidelines have been followed in order to get maximum phytochemicals from botanicals and also to ensure batch-to-batch consistency[17].

Quality parameters

For the acceptance of raw materials, certain criteria have been set. The main acceptance criteria for raw materials include a set of organoleptic, physicochemical and chemical tests. Organoleptic evaluation is referred to as the color, odor, taste and texture of the plant material, physicochemical screening involves checking various parameters such as moisture content, extraction value, ash value etc. These values must be in compliance with Ayurvedic

Pharmacopoeial monograph. One of the most important quality parameter for botanicals include phytochemical screening, in which various chemical reagents are used to check the presence or absence of particular phytochemical and these markers and compounds should also comply with reference standards.

Purification process

Purification process in Ayurvedic terms is known as Shodhana, it is one of the most important and firsthand step in the preparation of Ayurvedic solid dosage forms. This step eliminates impurities from the raw material and helps in detoxification. Shodhana helps in removing any kind of unnecessary minerals and heavy metals from the raw material. It consists of various methods: Dhalana (melting), Swedana (steaming), Bhavana (trituration with herbal decoctions) in order to ensure the removal of unnecessary substances from the raw material. Example of this purification process in Ayurveda is purification of Shankha bhasma, which undergo incineration with Nirgundi leaf juice in order to ensure the removal of toxicity and also to reduce heavy metal concentration[18,19].

Storage requirements

Storage is one important factor in the processing of raw material for the manufacturing of Ayurvedic solid dosage form, after collection and purification of raw materials, they should be stored in temperature and humidity prescribed in the guidelines. Ideally, raw materials should be stored in airtight, light-resistant containers at temperature below 25^0 C and humidity below 60% in order to ensure the stability of the raw materials[20].

Storage requirements differ according to the raw materials as well, some raw materials requires cool temperature to ensure maximum phytochemical constituents while some raw materials may require warm temperature to show so. Examples of storage requirements in Ayurveda include storage of raw materials for trikatu in cool storage conditions to prevent them from rancidity and minerals after purification stage are kept in desiccated containers to prevent any kind of moisture absorption.

Adulteration challenges and detection of adulteration

Adulteration- whether intentional or unintentional, can cause significant harm to the product characteristics and to humans as well and also pose quality and safety risk to the raw material. One of the most common example of adulteration includes substitution of high value herbs with cheaper analogues. Several methods such as macroscopical and microscopical methods have been developed to identify the adulteration in raw materials, advanced techniques for detection of adulteration include FTIR spectroscopy and DNA barcoding, but these methods are highly advanced, not very commonly available for everyone to avail, hence not that beneficial to detect common adulteration practices. One of the best method to control and mitigate risks of adulteration is supply-chain audits and traceability systems[21].

Manufacturers of Ayurvedic solid dosage form should adhere to these guidelines- from collection to identification of adulteration to uphold the highest standards of quality, safety, and efficacy of the final product in compliance with the regulatory guidelines.

4. UNIT OPERATIONS INVOLVED IN SOLID DOSAGE FORMS

Unit operation can be defined as the single step involved in the preparation of any kind of dosage form, and hence preparation of any kind of dosage form i.e, solid, liquid or semi-solid involves many unit operations to be carried out, before any final product is formed. Various unit operations involved in the preparation of Ayurvedic solid dosage forms include size reduction, mixing, blending, granulation, drying and compression etc. These unit operations involved in the preparation of Ayurvedic solid dosage forms have been discussed below:

Size reduction

Size reduction is one of the first step in preparation of any kind of solid dosage form. It involves grinding of the plant materials to make fine powder[22].

Traditional methods

Traditional methods for size reduction include grinding with the help of mortar and pestle or stone grinders to pulverize herbs. These methods can yield coarse to moderately fine powder.

Modern methods

Modern equivalent technology for size reduction include use of ball mill, pin mill, hammer mill, pebble mill, and jet mills etc. All these mills operates on different aspects and helps in procurement of fine powders from herbs.

Particle size considerations

Proper particle size distribution in case of powders is important to ensure uniform blending and ideal dissolution rates. Particle size of powders has direct influence on surface area, dissolution, bioavailability and flow properties for granulation process[23].

Mixing and blending

Mixing and blending as the name suggests, is the unit operation in which one material is mixed with another material using a spoon or spatula in order to get uniform powder blend.

Traditional methods

In classic Ayurveda, mixing and blending of powders or substances was used to be done manually stone or wooden slabs, and were visualized normally to ensure homogeneity.

Modern methods

Modern methods for mixing and blending of powder include use of ribbon blender, planetary mixers, V-cone blenders and many other such equipments to ensure homogeneity. These equipments are so sophisticated in nature, that mixing intensities, blend time can be easily adjusted to ensure batch to batch consistency[24].

Homogeneity considerations

Homogeneity is an important parameter to be considered, as homogeneity allows the proper flow of powder material for further processing.

Granulation

After size reduction, mixing and blending, next important step in the preparation of Ayurvedic solid dosage forms is granulation. Granulation as its name suggests, is the process of converting powder to small round or flat granules so that they can be further compressed to take the form of guti or modern equivalent tablets[25].

Traditional methods

Traditional methods for wet granulation used to be done by mixing powder with liquid such as honey and ghee and kneading was done to form dough like structure, and then granules were used to be formed from that dough.

Modern methods

Modern methods for granulation process include high shear and fluidised bed granulators to control the concentration of binders and control moisture content and particle size.

Binding agents: traditional vs modern

With the evolution of modern technology, binding agents have also been used in advanced forms. In traditional methods, honey and ghee were mainly used as binding agents while in modern practice they have been replaced with polyvinyl pyrrolidone and hydroxypropyl methyl cellulose, which offers defined viscosity and robustness for various experimental conditions.

Drying

Drying is the process or unit operation which is basically used to remove moisture from anything. It is a crucial unit operation because it decides, the moisture content in the substance and allows for microbial contamination chances.

Traditional methods

Traditional methods for drying include drying in the sun or in the shade depending on the characteristics of the materials used and attributes desired in the final product[26].

Modern methods

In modern setting, drying involves the use of specially designed dryers, such as tray dryers, fluidised bed dryers, and vacuum dryers which allows control on temperature and air flow and help in achieving stability and optimal flow.

Moisture content optimization

Moisture content optimization is crucial in case of drying, because moisture content decides the stability and chances of microbial contamination due to moisture in the final product.

Compression

Compression means the unit operation in which solid dosage form takes it final shape.

Traditional methods

In traditional Ayurveda setting, compression was used to be carried out using hand rolling because no sophisticated equipments were available at that time. Wooden molds or methods such as rudimentary process were also used.

Modern methods

In advanced modern setting, hand rolling or wooden molds has been replaced with advanced compression machinery specifically designed for ideal compression. Single rotary press is one of such machinery that allows die to set and can adjust compression force as well.

Coating and Finishing

One of the last unit operations in the preparation of Ayurvedic solid dosage form is coating and finishing. As the name suggests, coating is defined as the unit operation which involves coating of the prepared dosage form with some coating agent to provide fine texture, taste and to prevent from atmospheric conditions.

Traditional methods

In traditional setting, coating was done using agents such as oil, ghee or sugar syrups to impart desired properties to the dosage form.

Modern methods

In modern setting, traditional approaches have been replaced with methods such as sugar coating, film coating which even allows uniform spraying, temperature and humidity control and help in ensuring uniform thickness coating.

Table 2 describes the various unit operations involved in the preparation of Ayurvedic solid dosage forms along with their traditional and modern equivalents.

Table 2: Unit operations involved in the preparation of Ayurvedic solid dosage forms along with their modern equivalents

Operation stage	Traditional method	Modern method
Pulverization/Size reduction	Hand grinding with stone/mortar	Mechanical milling
Mixing/Blending	Manual mixing	Planetary mixers
Granulation	Wet pasting and rolling into balls	High-shear granulation
Drying	Sun and shade drying	Tray dryer/Fluidised bed dryer
Tableting	Handrolling, carving and pressing	Tablet press machinery
Coating	Oil/ghee application	Film coating/sugar coating
Packaging	Cloth wrapping or packaging using jars	Blister packing/ strip packing/Bottle packing

CONCLUSION

The field of Ayurvedic Solid Dosage form development has evolved by witnessing a remarkable synergy from the traditional knowledge and modern engineering technologies. Traditional methods used for the preparation of solid dosage forms like Churna and Vati included grinding with the help of mortar and pestle, drying in the sun or shade etc., these methods were easily adaptable, but they could not produce reproducible results which often leads to variable product quality and therapeutic efficacy. In contrast to these traditional methods, modern technology offers scalability, reproducibility and standardization. These new technologies ensure homogenous mixing, proper particle size distribution and various other such benefits. This also helps in meeting regulatory and quality standards laid by the regulatory bodies. Another pivotal alignment of traditional Ayurvedic system lies with the use of their equivalent modern technologies. From the quality control perspective also, the system has evolved a lot, in earlier times, only organoleptic and physicochemical assessments were there but now those have been updated by modern analytical techniques. Various analytical techniques such as HPTLC, Gas chromatography and many more provide comprehensive framework for standardized batch release.

Revolution has also impacted the packaging technology as well, earlier there used to be packaging with the help of cloth, but now packaging of the solid dosage forms has been replaced by blister packing, strip packing etc which reduces the degradation pathways as encountered in the former and also aligns with the Pharmacopoeial and International Standards. Despite all these advancements, various challenges that persists are adulteration and seasonal variability. Regulatory bodies are continuously working in this direction, so that it can align with the official standards. Holistic integration should be adopted to promote the future of Ayurvedic Solid Dosage Forms. This holistic integration include using process intensification, digitalization of the unit operations and processes and use of sustainability principles.

In summary, the merge of age old Ayurveda with modern technology promises new era of safe and standardized herbal therapeutics

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