

Ayurvedic Dosage Forms: Pressing Priorities and Challenges therein with Respect to Solid and Semisolid Oral Dosage Forms

ABSTRACT

Continuous improvements in elevating traditional dosage forms to increase therapeutic efficacy, to enable patient-centric approaches, and to improve patient compliance are becoming more rational with advancements in technology and an advanced vision to address the existing concerns. Oral dosage forms are well known and still the preferred choice of drug administration methods due to their convenience and cost-effectiveness. Hence, newer areas are explored to modify the preexisting traditional as well as present-day dosage forms to encounter the changing market needs. Search engines and databases were screened thoroughly for all the related published matter. The data were properly assessed, analyzed, and then presented in the paper. Many emerging dosage forms have potential to provide as an alternate to the present drug forms. These have multiple added benefits like better palatability, increased stability, enhanced absorption, and improved bioavailability in a presentable and attractive form. Evolution of traditional dosage forms is the absolute necessity keeping its multidimensional benefits in view. Patient-centric approach along with the fundamentals of Ayurveda pharmaceutics should be the guiding tool in developing new dosage forms.

Key words: New herbal dosage forms, novel drug form, oral dosage form, *Panchavidha Kashaya Kalpana*

Introduction

In *Samhita* period also modifications in five primitive and fundamental dosage forms were done as per the need. These changes were primarily done in view of patient and severity of disease. Various evidence have been found in the literature with respect to changing the form of drug to be administered. Acharya *Charaka* states that a *Vaidya* (physician) with the virtue of *Yukti* can apply innumerable permutations and combinations to increase the potency of the raw drug.^[1] A single drug can be used in multiple forms when used with

various other drugs. Further, it is said that the desired efficacy (either increased or decreased) of the drug can be altered by applying appropriate *Samyoga* (addition of ingredients), *Vishlesha* (elimination of ingredients), *Kaala* (appropriate time of administration), and *Samskara* (processing).^[2] Ancient seers have highlighted the patient-centric dosage modification in a verse stating that drugs of antagonistic properties are to be added to impart the desirable taste, odor, and color of the medicine, thereby easing the patient compliance.^[3] The severity of the disease was also considered when deciding

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the route of administration. Changes/modifications in the preexisting dosage forms can be done but always keeping the fundamentals intact, i.e., safety and efficacy of the remodeled drug should not be compromised.

Certain key factors like improvement of pharmaceutical technologies, introduction of new diseases, aggressive competition, and increasing complexity of new therapeutic entities entering the developmental pipeline have led to introduction of novel dosage forms in Ayurveda sector. Developing the ideal dosage form for pharmaceutical products has long been a priority for the companies. Improper development of a dosage form can lead to potentially lower adherence toward medication by the patients resulting in heavy financial errors for the pharmaceutical companies. Optimum adherence of a treatment regimen can be ensured by keeping the dosage form patient-centric. As said, "change is the need of hour," one should be well aware of the changing trends in the society. By 2030, one in six people will be over the age of 60 years, hence will accordingly develop the rise of new dosage form more acceptable to that age group.^[4] This study focuses at the changing trends observed in the herbal dosage forms along with the future prospects in the concerned area. The main objective of this paper is to explore the changes occurring in the dosage forms and the probable future prospects.

Methodology

Classical textbook including *Charaka Samhita*, *Ashtanga Hrudya*, and *Sharangdhar Samhita* were studied rigorously for the literary aspect. Data were accessed, reviewed, and screened from published research work with the help of search engines such as Google, Google Scholar, and Research Gate by searching keywords such as Ayurvedic Novel Dosage Forms and New Drug Dosage forms. Databases such as PubMed, NCBI, and NLM were also searched to obtain data from the related publications.

Results

Changes in dosage forms have been observed in the recent times. Many pharmacies with the aid of research and development have successfully introduced many novel dosage forms in the market, thereby turning the scenario of Ayurvedic pharmaceutical industry. Acceptance of new modified dosage forms such as tablets (coated, fast dissolving, and effervescent), capsules, granules, lozenges, candy, and gummies in place of traditional dosage forms such as *Vati*, *Churna*, and *Avaleha* has been observed. New dosage forms are comparatively more stable due to increased shelf-life when compared with traditional dosage forms.

Discussion

Recently, changes occurring in the dosage forms can be observed both in medicine and in cosmetics category. Based on the physical property, different preparations can be categorized into solid, semisolid, and liquid dosage forms.

From traditional to existing

1. *Vati*: *Vati*, *Vatak*, or *Gutika* is considered the secondary preparation in Ayurvedic pharmaceutics resulting from the primary *Kalka Kalpana*.^[5] This evolution from *Kalka* to *Vati* happened back in the *Samhita Kaala* only to overcome the disadvantages often encountered with the use of *Kalka*. Unlike previous times, when *Vaidyas* used to prepare medicine with the purpose of treating their patient only, today, Ayurvedic medicines are being manufactured at large scale for marketing purpose. Furthermore, owing to their lesser shelf-life and various manufacturing and dispensing difficulties on a large scale, the advancements were made in existing primary *Kalpanas*.^[6] With the advancements in technology and growing competition in market, some new herbal dosage forms were introduced which are following:
 - a) Coated tablets: The uniform deposition of a layer of material on a solid dosage form is termed as coating process. This is done as the last step in the formulation of tablet. It protects the tablet from humidity and temperature variabilities. It has many added benefits such as product distinction, masks undesirable taste and odor, and prevents accidental contact with the drug substance.^[7] Multiple coating options are present according to the need basis, for example, gold-coated *Navratna Rasa*, silver-coated *Divya Rasayana*, and enteric-coated *Lashun* tablets. Enteric-coated tablets help the tablets to move through the stomach without getting destroyed and get absorbed in the intestine, thereby delivering the right amount of active pharmaceutical ingredients in the system
 - b) Fast dissolving tablets: These tablets are gaining popularity owing to their quicker dissolution or disintegration in the saliva without the use of water.^[8] In pediatric, geriatric, and psychiatric patients, administration of oral dosage form is a challenge.^[9] It is a common notion that Ayurvedic medicines tend to have long disintegrating and dissolution time as compared to modern pills and tablets specially medicines prepared from *Guggulu*. Furthermore, medicines containing *Guggulu* when administered orally in the form of solid dosage form pass through fecal matter without getting absorbed

in the entire gastrointestinal tract.^[10] Applying principle of fast dissolving tablets to ancient treatment will be quite fruitful and will help overcome the above-said issues. Quick dissolving tablets of *Triphala* extract, *Shilajit* extract, etc., are options available in the market

c) Effervescent tablets: Effervescent tablets are prepared by compressing active ingredients along with sodium bicarbonate and organic acids.^[11] These liberate carbon dioxide gas when dissolved in a liquid media. These tablets can be easily dissolved in any liquid media as water or fruit juices making it pleasant in taste than regular tablets and pills, which is the primary cause of their popularity.^[12] Ayurveda pharma industry is also exploring this area and has introduced some market options as *Ashwagandha* effervescent tablet, *Panchamrita Triphala* effervescent tablet, Liver detox effervescent tablets etc.

2. *Churna*: This is considered a secondary preparation originating from *Kalka Kalpana*. Properly sieved fine powder of herbs is generally termed as *Churna*. Both internal applicability and external applicability of *Churna* are explained in classical texts. However, this dosage form has various limitations as powders are more prone to deterioration when it comes in contact with moisture. Powders are often disliked by patients due to its bulk dose and poor palatability owing to bitter and unpleasant taste. Definite dose determination has always been a concern related to powders.^[13] To past these hurdles, following dosage forms are popular presently:

a) Capsules: These constitute solid dosage forms in which active ingredient of a drug is enclosed within a shell. Shell is usually made up of gelatin. Based on this, capsules are primarily of two types: hard gelatin and soft gelatin. It overcomes the unwanted odor and masks the unpleasant taste. These are dose-specific and easy to handle in manufacturing units. Furthermore, it provides attractive appearance to the medicine.^[14] In market, capsules for different disorders are available like for immunity booster- Ayukarma Giloy Capsules, for piles- Pilogest Capsule, for sexual wellness- Ayukarma Testobuild Capsule and other as Zandu Shallaki Capsules, Himalaya Haridra Capsules etc.

3. *Avaleha*: It is a secondary preparation of Ayurvedic pharmaceutics processed from *Kvatha Kalpana*. Due to presence of high sugar content in these preparations, these are often palatable but has certain disadvantages also. Maintaining the dose accuracy is difficult with this semisolid preparation. If it is not prepared or stored properly, it may lead to microbial growth. It is comparably difficult to carry than other solid dosage forms.^[15] To overcome these difficulties, dose modification was done, and in present times, we have the following evolutions of *Avaleha Kalpana*

a) Granules: These can be somewhat compared to *Khanda Kalpana* described in classics. Ancient seers also tried to modify the form of drug to prevail over existing problems. Furthermore, the shelf-life of granules is also more as compared to *Avaleha*. In market, granules specifically intended for respiratory care are available e.g., Zeal granules, Cough & Flu granules, Baidyanath Madhumehari granules, Baidyanath Shatavari granules, etc.

b) Lozenges: These are well accepted as a novel method of delivering drugs exhibiting local and systemic effect in the oral cavity. Due to their longer retention time in the oral cavity, it increases bioavailability, bypasses first metabolism, and reduces gastric irritation experienced due to intake of other oral medications. It is also easy to prepare with minimum equipment usage and increases patient compliance due to its good palatability.^[16] Herbal lozenges present in the market include Koflet, Honitus, and Kuka Cough lozenges

c) Candy: Hard-boiled candies are usually prepared by a mixture of sugar, glucose-syrup, active ingredient, and water mixture. Moisture content in these candies is about 1%-3% enhancing their stability.^[17] Nowadays, in herbal category, sugar-free Amla candies, Turm Candy, cough candy, etc., are a quite popular choice

d) Gummies: Gummies and jellies are gel-like structures containing active ingredient along with sugar in the form of sucrose syrup or glucose in combination with gelling agents and other required excipients. This dosage form is more popular in the pediatric and teen groups.^[18] This is a growing area in fast-moving consumer goods category. Ayurveda pharma companies are coming up with healthy gummy options like *Ashwgandha* gummies, *Triphala* gummies, and *Chyawanprash* gummies.

Growing market

Mouth dissolving films

Oral route is considered the most common and convenient drug route. Permeability of the skin is about 4–4000 times more than that of the skin, but is lesser than intestine. Therefore, it can be preferably used for drugs having poor dermal absorption.^[19] It enhances the patient compliance specifically related to pediatric and geriatric patients, provides faster action as compared to other conventional means, and has many other added benefits. A few researches are ongoing

to develop, standardize, and introduce this dosage form in the market. A pharmaceutical study conducted revealed that the mouth dissolving film prepared from the extract of *Uncaria tomentosa* showed 99.9% drug release in about 30 min.^[20] In an another study, single and multilayer oral films are prepared with active herbal ingredients takes about 1 to 1.15 minutes for dissolution in oral cavity after hydration.^[21]

Future prospects

However, upgradations in Ayurvedic pharmaceutical sector are observed over the past few years, yet there is tremendous scope in updating the existing dosage forms. It has always been a priority for drug companies to develop the ideal dosage form for pharmaceutical products. Development of poor dosage forms can result into huge financial burden for pharmaceutical companies.^[22] Furthermore, the trend of the form of drug is changing every few years. This owes to the changes in the demographic pattern, which could vary from country to country. For example, in a report published in the 2011 Census of India, demographic data revealed that the youth population in the age group of 15–24 years was expected to increase from 23.3 crores in 2011 to 25.1 crores in 2021 and then continue to decrease to 22.9 crores in 2036, and similarly, these data will further change along with the time lag.^[23] Hence, these factors are also very important and are a major driving force in market when it comes to introduction of a new dosage form. Furthermore, emergence of new diseases has provided another outlook in reference to existing dosage forms. The development process should always be “patient-centric” to ensure the optimum adherence to the treatment regimen. There are certain areas which are yet unexplored or in the pipeline and can be further reached out to enhance the traditional dosage system:

- a) Floating capsules: These are oral dosage forms intended to prolong the resistance period of dosage form within the gastrointestinal tract. These are manufactured in such a way that their density is lesser than the gastric fluid when it comes in contact of gastric fluid, thereby floating over the gastric juices and hence slowly releasing the drug into the system. Due to its prolonged stay in the gastric cavity, it enhances the drug reaching its absorption site in solution.^[24] This dosage form is favorable for drugs having poor solubility and low stability in intestinal fluids. Due to its slow-release rate, it also minimizes the risk of gastric mucosa irritation. It will be a good option to adopt in certain disease conditions where intestinal motility is increased like in diarrhea, leading to early intestinal emptying and resulting in poor absorption.^[25] Research work related to developing floating tablets of *Yashtimadhu* aqueous extract has been carried out.^[26] Another such attempt containing *Amla*, ginger, fenugreek,

and *Isabgol* has been made to formulate and establish the manufacturing process of herbal floating tablets.^[27] Formulations of *Guggulu* can be explored for this dosage form as it takes longer time to disintegrate. Hence, allowing its presence in gastric fluid for a longer time will enhance the more absorption of the drug

- b) Multilayer tablets: Multilayer tablet is a delivery system that aims to deliver two or more drugs at different rates or simultaneously release two or more drugs with desired release rate.^[28,29] Even if two drugs are incompatible, they can be incorporated together in multilayer tablets. These have greater advantage as compared to immediate release tablets having same active ingredient.^[30,31] This type of medicaments has controlled-release system which optimizes the treatment regimen and provides better patient convenience and compatibility.^[32] Looking from the Ayurvedic perspective, concept of *Bhavna* can be modified with the introduction of this dosage form in the herbal pharma sector
- c) Herbal nanomedicine: These have gained considerable amount of attention in a very short span. These are becoming popular owing to their lesser dose administration, better drug absorption, target-specific activity, increased bioavailability, and reduced adverse events.^[33] Nanoparticles are colloidal systems having particle size varying between 10 nm and 100 nm. *Bhasmas* in Ayurveda are one such dosage form which are considered to be an ancient form of nanomedicine. Many research studies are conducted in multiple institutes with an attempt to prepare nanoparticles using herbs and comparing their therapeutic effect with their corresponding *Bhasmas*.^[34]

Challenges

Vigorous Research and Development is the key to achieve positive results in this direction. However, micro, small, and medium enterprises cannot afford such hefty expenses. Clinical and toxicological studies will also be required before launching the product in public domain, which again is both time-taking and financially upscale. In the present times, evolution of traditional dosage forms is much required, but keeping the fundamentals of Ayurveda intact as well as maintaining the quality and therapeutic efficacy of the drug is a challenging point. No regulatory guidelines regarding the quality parameters have been laid down for these new dosage forms, which is a matter of concern.

Conclusion

The industry has witnessed a remarkable evolution in drug dosage forms, driven by a convergence of scientific

breakthroughs, patient-centric approaches, and regulatory incentives. As we stand at the intersection of innovation and health care, it has become exciting to delve into the trends that are shaping the future of drug delivery. However, this change should always lie on the foundation of traditional principles that were established thousands of years back to attain desirable health benefits and for the betterment of society.

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Conflicts of interest

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