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ROLE OF PHARMACOVIGILANCE IN ENSURING SAFETY AND EFFICACY OF AYURVEDIC NOVEL DOSAGE FORMS: A REVIEW

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ABSTRACT

The unprecedented global expansion of Ayurveda has led to medicines produced as international commodities, yet they are valued for their perceived 'traditional virtues. Ayurvedic dosage forms were designed by ancient scholars of Ayurveda focusing on disease condition, strength of the patient, tolerance, digestive capacity, bowel habits, diet patterns, pathology of the disease and so on. However, in the modern era, the focus is on effective and palatable drug dosage form to enhance the solubility, bioavailability, pharmacological activity, stability, and increase the compliance. Hence, unique challenges are posed by novel dosage forms in pharmacovigilance. This study aims to (1) understand the safety and efficacy of novel dosage forms in comparison with traditional Ayurvedic formulations, dosage and to be aware of side effects if any from new dosage forms (2) to expand the horizons of pharmacovigilance to accommodate future innovations and the role of regulatory agencies in ensuring safety and efficacy. An in-depth review was conducted on various Novel oral dosage forms which includes granules (effervescent and rapid release granules), tablets (fast dissolving, Oral disintegrating, multilayered tablet), gummies, capsule in capsule, chews, latte and topical dosage form like toothpaste, hair dye, sprays, emulsions, patches etc. for any possible side effects. The review discusses how the bioavailability of novel dosage forms like orally disintegrating tablets, may differ from conventional oral formulations and explores how Ayurvedic medicine is adapting to these innovations, emphasizing the critical role of pharmacovigilance in ensuring their continued safety and therapeutic efficacy.

Keywords: Pharmacovigilance, novel drug dosage forms, Ayurveda, bioavailability

INTRODUCTION

Ayurveda, traditionally known as the "Science of Life," has seen a significant resurgence in recognition and relevance in recent years. It is marching to become global holistic healthcare system and is expected to cater worldwide needs due to surge in demand for natural products with minimal side effects. India has emerged as a rapidly growing player in the Ayush market, contributing approximately 2.8% to the global share.[1] As we stand at the crossroads of innovation and healthcare, exploring the evolving trends in drug delivery has become both essential and exciting. Ayurvedic dosage forms were designed by ancient scholars of Ayurveda focusing on disease condition, strength of the patient, tolerance, digestive capacity, bowel habits, diet patterns, pathology of the disease and so on.[2] At the confluence of innovation and healthcare, exploring the emerging trends in drug delivery has become both timely and compelling.

Ayurveda has recommended more than 100 dosage forms as mentioned in ancient Ayurvedic texts Charaka Samhita (12thBC) 128 dosage forms Sushruta Samhita (10thBC) 129 dosage forms Ashtanga Hridaya (6thAD) 90 dosage forms Chakradutta (9thAD) 90 dosage forms Sharangadhara (14thAD) 75 dosage forms Bhaishajya Ratnavali (18thAD) 98 dosage forms which includes even Pathya Kalpanas (wholesome dietary preparations).[3] Classical Ayurvedic formulations include dosage forms like Swarasa (extracted juice), Kalka (grounded paste of medicine), Kwatha (herbal decoction), Churna (fine powder of drug) etc. At present, the majority of proprietary Ayurvedic medicines are formulated using modern dosage forms such as tablets, capsules, gels, and syrups, with the principles of contemporary pharmaceutics guiding their development.

Hitherto overlooked aspect of pharmacovigilance is the lack of therapeutic efficacy representing a significant failure of a product to achieve its intended pharmacological effect. This includes instances such as treatment failure, poor patient response, or the absence of expected therapeutic outcomes despite appropriate use.[4] This paper intends to focus on those aspects related to novel drug dosage forms in Ayurveda.

Wisdom In Designing Ayurvedic Formulation

A single herbal drug, when subjected to different extraction methods, can exhibit dramatically different therapeutic effects. Example, Guduchi (*Tinospora cordifolia*) in 6 different dosage forms has six different and specific medicinal effects. Fresh juice of Guduchi with honey is indicated in Prameha (diabetes) due to its Rasayana (immunomodulatory) activity, decoction with Pippali (*Piper longum*) powder is effective in inflammation due to its 'Pachana' (process of digestion and metabolism) action, cold infusion of guduchi in fever. Here, all three liquid forms of guduchi (juice, decoction and cold infusion) target the rasa dhatu (plasma).[5] Ghrita (medicated ghee extract) of guduchi alleviates the vitiated Pitta Dosha, initiates healing of ulcer due to its Rasayana property, hence it is indicated in acid peptic disease.[6] Guduchi given in the form of a rectal enema (in medicated milk), is used for bone diseases such as Osteoporosis. The medicated milk extract of Guduchi alleviates the vitiated Vata Dosha, strengthens bones due to its Rasayana properties.[7] Arishta (alocholic form) of Guduchi known as Amrutharishta is indicated

in diseases of respiratory system caused by imbalances in Kapha Dosha as Arishta has Agnideepana activity (penetrates quickly and aids quicker absorption as well as assimilation) and can alleviate the vitiated Kaphadosha.[8] The aqueous extracts of Guduchi such as juice, decoction, and cold infusion are known to be effective in managing inflammation and fever. In contrast, three other distinct formulations of Guduchi exhibit varied Rasayana properties, making them suitable for diabetes, ulcers, and osteoporosis, respectively. This suggests that the Rasayana potential of Guduchi can be directed toward specific body tissues by altering the solvents and extraction methods used on the source herb, *Tinospora cordifolia*.

The new drug delivery system is a modern pharmaceutical approach aimed at developing innovative methods and dosage forms for targeted drug delivery. Bhaishajya Kalpana (Pharmaceutics) of Ayurveda has incorporated new drug delivery system based on two concepts (a) Adjunct route: by suggesting various Anupanas (Adjunct/after drinks) which helps in better absorption. For instance, the same drug Guduchi is indicated in different diseases with different Anupanas like Guduchi with ginger in Amavata (Rheumatoid arthritis), in Vatarakta (Gouty arthritis) with Eranda taila (castor oil), In Jwara (fever) with Triphala, in Kamala (Jaundice) with madhu.

(b) Formulation Design: The design of dosage forms in Ayurveda often considers targeted therapeutic outcomes. Ghrita-based formulations serve as an effective medium for transporting lipophilic active compounds to specific organs like the brain, facilitating the crossing of the blood brain barrier and supporting cognitive enhancement. This reflects a traditional approach to Ayurvedic drug delivery, guided by foresight and vision.

EMERGENCE OF NOVEL DOSAGE FORMS IN AYURVEDA

Challenges such as seasonal unavailability of fresh raw materials, the need for larger doses, issues with palatability, and limited shelf life have led to the development of modified formulations like pills, confections, fermented biomedical preparations, oleaginous products, syrups, and granules. Introduction of modern dosage forms (e.g., capsules, tablets, transdermal patches, nanoparticles) are witnessed now. Pharmaceutical companies are making significant investments in research and development to drive innovation and improve their product portfolios. By integrating cutting-edge technology with traditional knowledge, Indian pharmaceutical companies are ensuring that their products meet global standards, thereby boosting consumer confidence and expanding their market reach.

Benefits of Novel Dosage Forms in Enhancing the Bioavailability and Stability of Ayurvedic Formulations

Earlier, Pottalikalpa was used as lifesaving drug by virtue of its quick absorption through sublingual capillary bed of buccal mucosa, now orally disintegrating tablets are used. Chousashta Pippali is fortification process designed to enhance the efficacy of Pippali. Innovative dosage forms such as the capsule-in-capsule system represent a unique multi-release drug delivery platform, designed specifically for the targeted delivery of prebiotics, probiotics, and herbal ingredients to support gut health. Additionally, rapid-release, mouth-dissolving formulations provide quick relief for common conditions like acidity, indigestion, nausea, cramps, and immunity-related concerns, offering convenient and fast-acting solutions. Effervescent tablets, tailored to modern wellness demands, ensure high patient compliance and effectively support daily health and well-being. Spray-dried powders effectively address practical needs such as extended shelf life, ease of portability, and convenient, hassle-free consumption particularly benefiting patient compliance without compromising the therapeutic efficacy described in classical texts. The dosage of spray-dried powders is standardized to reflect the properties of classical Kashaya, based on both organoleptic and analytical parameters.

Examples of Novel Ayurvedic Dosage Forms

Gels- Retention time of gels is higher than the other dosage forms like creams and ointments. It acts as a protective layer on the site of application and easy to wash after application. Gels provide excellent spreadability and cooling effect due to solvent evaporation. A transdermal patch is a medicated adhesive applied to the skin, designed to deliver drugs into the bloodstream through transdermal absorption. The primary objective of this dosage form is to maximize drug flux across the skin while minimizing drug retention and metabolism within the skin layers.

Kashaya (herbal decoction) in Ayurveda has paved way to spray dried powder, Ex: Kashaya chewable tablets, Kashayam tablets and Syrup. Ksheerapaka (medicines are boiled with milk) has gained modern popularity in the form of herbal lattes, notably turmeric based golden latte, Ghrita and Taila are available in the form of capsules, Taila is available as ointment, cream, jelly, patches, liniment, emulsion, and aerosol. Avipattikara churna is modified into Churna tablets, internal consumption of oil-based medicines like Ksheerabala are changed to capsule form as modified as Ksheerabala (101) capsules, Dhanwantara taila capsules, Gandha taila soft get capsules etc. Rasaoushadis (mineral drugs) like Parpati (thin, flake-like preparation, often involving mercury and sulfur), Bhasmas (purified calcinations) preparations are made into nano form and dispensed like Swarna bhasma capsule, Sankha bhasma capsule, Bhallataka parpati capsules. Churnas are available as granules too.

Sitopaladi churna, Triphala churna are modified into suspension forms, Mahanarayana taila liniment, Murivenna ointment, Nalpamaradi Taila emulsion, Eladi taila emulsion, Shatadhouta ghrita ointment, Jatyadi taila ointment, Manahshiladi lepa ointment, Dadimavaleha syrup are some of the examples[9]. Upanaha and Lepana kalpanas are modified into transdermal patches through obtaining the extract of the particular drug. Few medications like Phalavarti, Panchavalkala varti are most commonly used herbal suppositories in clinical practice. Ashwagandha (*Withania somnifera*) mouth dissolving strips, turmeric extract in different flavors as mouth dissolving strips are available in the market. Gummies are trending in sugarless forms with better compliance.

IMPORTANCE OF MONITORING THE SAFETY OF AYURVEDIC MEDICINES, ESPECIALLY NOVEL DOSAGE FORMS

Though novel dosage forms are catering to the global community with increased compliance, there is a need to look into the subtle aspects like evaluating the therapeutic efficacy and ensuring adherence to basic principles of Ayurveda. For instance, Haarita Samhita has mentioned total 7 types of Kwatha, viz. based on the extent of boiling; it acts in the following ways. Pachana $1/2^{th}$, Deepana, $1/10^{th}$, Shodhana $1/12^{th}$, Shamana $1/8^{th}$, Tarpana and Kledana $1/4^{th}$, Shoshana $1/16^{th}$ which may not be available in spray dried Kashaya forms or Kashayam tablets as it will not be fully transparent to physicians about the methods used by pharma industry. In clinical practice, converting Avipattikara churna into tablet form may not provide the same therapeutic effect as the traditional Churna (powder) dose of 3-5 grams taken at once. Some of these dosage forms have shown significant limitations, including the need for higher doses, reduced therapeutic efficacy,

potential toxicity, and the risk of adverse side effects in certain cases.[10] Ex- Gelatin causes burping bloating and digestive discomfort. General caution says "Effervescent tablets may contribute to elevated blood pressure due to the sodium content present in their excipients. Individuals with kidney stones are advised to follow a low-sodium diet, as the salt generated upon ingestion of effervescent tablets can potentially aggravate their condition."[11] Caution is also advised for individuals with hypertension, as the increased sodium intake may worsen their symptoms. For oral disintegrating tablet (ODT) and lyophilized formulations, the drug dose should typically be below 400 mg for poorly soluble drugs and under 60 mg for soluble drugs. ODTs may exhibit varying degrees of pregastric absorption, which can influence their pharmacokinetic profiles. Literature reports have documented cases where the pharmacokinetic parameters and bioavailability of a drug administered via ODTs differ significantly from those of the same drug given in conventional oral dosage forms, indicating a lack of bioequivalence. It is possible that these differences may, in part, be attributed to the drug molecule, formulation, or a combination of both. If notably elevated plasma concentrations and systemic exposure are observed, pregastric absorption resulting in the bypass of first-pass metabolism may be a contributing factor. This phenomenon can have significant implications for the drug's safety and efficacy, warranting thorough evaluation in the marketing application of an ODT. For example, drugs that generate toxic metabolites through hepatic or gastric first-pass metabolism may exhibit improved safety profiles when delivered via ODTs. Additionally, drugs with substantial absorption in the oral cavity or other pregastric regions of the gastrointestinal tract may benefit from enhanced bioavailability through this route. Therapeutic failure may sometimes mask underlying problems related to novel dosage forms, leading to misattribution of inefficacy instead of recognizing formulation-related shortcomings.

Current Practices and Challenges in Pharmacovigilance for Ayurvedic Products

New drug delivery has been developed to overcome the limitations like difficulties in consuming crude form of Ayurvedic medicines and less stability. New dosage forms were adopted to increase the bioavailability of the drugs and also to provide the effect of herbs directly on the site of action. So, today modification becomes indispensable in an Ayurvedic pharmaceutical industry and therefore done to make different formulations.

Ayurvedic Formulations As 'Crude Extracts'

A recent review on Bael (*Aegle marmelos*) highlights that its purified compounds exhibit anti-cancer, antidiabetic, and cardioprotective properties, while the crude extract demonstrates antimicrobial and anti-ulcer effects.[12] In another study, Deocaris *et al.* compared the effects of the crude leaf extract of Ashwagandha with its purified withanolides. The purified withanolides were found to alter the expression of a large number of genes associated with cell growth and survival. In contrast, the crude leaf extract modulated the expression of a few key 'hub' genes with high connectivity within the gene network that regulates the growth and proliferation of cancer cells.[13] The concept of developing standardized Ayurvedic formulations as crude extracts, under stringent quality control measures, is increasingly being recognized at both scientific and commercial levels. For instance, standardized crude extracts of Ginger and Guggulu (*Commiphora mukul*) are formulated to contain fixed concentrations of gingerols [14] and boswellic acids, respectively.[15] The growing interest and recognition of Ayurvedic crude extracts is also evident in the ICMR's regulations concerning Ayurvedic drugs. The latest ICMR ethical guidelines for biomedical research on human participants explicitly state that purification of Ayurveda-Siddha-Unani medicines to single chemical constituents is not necessary, as such purification may lead to the loss or degradation of the original drug's synergistic effects or properties.[16]

According to the Drugs and Cosmetics (6th Amendment) Rules, 2010, hydro-alcoholic extracts prepared using methods other than those described in the Ayurvedic classical texts (as listed in Schedule 1 of the Drugs and Cosmetics Act, 1940) must be supported by proof of safety and efficacy for licensing. In contrast, aqueous or hydro-alcoholic extracts prepared using traditional methods outlined in the classics do not require such proof. However, if these traditionally prepared extracts are intended for a new indication, evidence of effectiveness will be required. A recent study compared the bioactivity of Ashwagandha root extracts prepared using two different extraction methods. The results indicated that the maceration method, using water as the solvent, was more effective than the hot continuous percolation process. Hydro-alcoholic and aqueous extracts obtained through maceration yielded higher extract percentages and demonstrated superior antistress activity. The authors concluded that the traditional maceration method (using a 1:8 ratio of root to water) may be the most effective approach for extracting Ashwagandha roots.[17]

A comparative study evaluated nine different extraction methods for Brahmi *(Bacopa monnieri)*, a medicinal plant widely used in Ayurveda as a brain tonic to enhance memory and support mental health. The cognition-enhancing effects of Brahmi are attributed to its tetracyclic triterpenoid saponins. Various solvents such as water, methanol, and hexane were used under differing temperatures and pressures, with some methods employing a Soxhlet apparatus. HPLC analysis revealed that the extract with the highest total saponin content was obtained through percolation with ethanol, following prior soaking of the plant material in water.[18] This study underscores the critical influence of extraction techniques on the efficacy of herbal preparations—an aspect often overlooked by the pharmaceutical industry and not widely recognized by clinician.

INTEGRATION OF PHARMACOVIGILANCE WITH NOVEL DOSAGE FORMS

Therapeutic Drug Monitoring (TDM) can be utilized not only to confirm the cause of an adverse drug event (ADE) after it has occurred but also as a proactive measure to prevent such events. In this way, TDM has the potential to transform pharmacovigilance from a system focused primarily on monitoring and documenting ADEs into a safety-oriented tool that supports the prevention of ADEs in drug therapy.[19]

Patient treatments often involve the use of two drugs with synergistic therapeutic effects, prompting drug developers to innovate with fixed-dose combinations. One such innovation is the use of multi-layer tablets, which allow for the incorporation of multiple delivery mechanisms. These tablets can deliver ingredients at different rates or through distinct mechanisms for example, one layer may provide an initial loading dose, while another delivers a sustained-release dose of the same drug, or each layer may contain different sustained-release compounds. Various formulation strategies are employed to achieve these controlled-release profiles in multi-layer tablets.

However, drug interactions or reduced drug efficacy may occur in certain situations. For instance, Aloe vera, an ingredient in the Ayurvedic formulation Kumaryasava has a purgative effect that can reduce intestinal transit time. As a result, if a patient concurrently takes a multilayered tablet for another condition, the

medication may be expelled before it is fully absorbed, compromising its effectiveness. This highlights the importance of Therapeutic Drug Monitoring (TDM), which aims to maintain drug concentrations within a defined 'therapeutic range'- the window between the minimum effective concentration and the minimum toxic concentration to ensure optimal efficacy while minimizing toxicity.

Lieu et al. conducted a comparative study between levodopa the standard treatment for Parkinson's disease and a water extract of Kapikacchu *(Mucuna pruriens)*, a plant widely used in Ayurveda for the same condition. Both treatments demonstrated long-term reductions in neurological symptoms. However, animals treated with the *Mucuna pruriens* extract did not exhibit the adverse effects commonly associated with levodopa.[20] This suggests that, in some cases, a synergistic therapeutic effect may be achieved with traditional plant-based formulations, potentially offering comparable efficacy with improved safety profiles.

REGULATORY PERSPECTIVES

According to the Indian Council of Medical Research (ICMR) guidelines, When an extract of a plant or a compound isolated from the plant, or any compound formulation containing plants, metals, minerals, or animal products is to be clinically evaluated for a therapeutic effect not originally described in traditional texts, or if the method of preparation differs from classical methods, it must be considered a new substance or new chemical entity (NCE). In such cases, the same type of acute, sub-acute, and chronic toxicity data required for synthetic products must be generated before approval for clinical evaluation[21] (ICMR, 2006). This important regulatory requirement must be clearly communicated to all relevant stakeholders.

RESEARCH AND DEVELOPMENT ON NOVEL DOSAGE FORMS IN AYURVEDA

Studies that conduct qualitative and quantitative comparisons between Ayurvedic and modern quality control parameters are particularly valuable. One such study offers a compelling comparison between Guduchi Ghana (solid extract) prepared using the classical Ayurvedic method and that produced using a Soxhlet apparatus. The findings revealed that while the classical Guduchi Ghana contained 50% less water- and alcohol-soluble compounds compared to the Soxhlet-extracted version, its total solid content was nearly double. This difference was attributed to higher starch content in the classical preparation, likely due to the prolonged boiling step in the Ghanasara extraction process, which solubilizes starch from Guduchi. In contrast, such solubilization would not occur with gentler aqueous extraction methods like infusions or decoctions.[22]

This type of research is essential for understanding the chemical and biochemical distinctions between herbal extracts obtained through traditional and modern techniques. It provides deeper insight into the complex transformations occurring within crude extracts and underscores the need to reexamine traditional Ayurvedic pharmaceutics methods in light of contemporary scientific approaches and reexamine and draw valuable insights for developing innovative extraction methods tailored to drugs derived from Ayurvedic source herbs. Strengthening consumer awareness will foster the appropriate use of Ayurvedic medicines, ensuring optimal therapeutic efficacy.[23]

CONCLUSION

The importance of integrating traditional Ayurvedic knowledge with modern pharmacovigilance and novel drug delivery systems for improved patient outcomes is emphasized. As we stand at the crossroads of innovation and healthcare, exploring the emerging trends shaping the future of drug delivery is both timely and compelling. As the old adage suggests, even a poison can become a remedy when used wisely, while the misuse of an elixir can prove harmful underscoring the critical importance of precision and context in therapeutic interventions. Creating a common framework and guidelines for the quality, safety, and efficacy of Ayurveda products and services, and for the ethical and responsible use of technology in Ayurveda is the need of the hour. Collaboration can also help to overcome the challenges and barriers that Ayurveda faces. Ayurveda and technology can create a synergistic and mutually beneficial relationship that can enhance the health and wellbeing of individuals, communities. This paper is an attempt to understand how Ayurvedic medicine is adapting to modern drug delivery systems and the role of pharmacovigilance in ensuring their safety and efficacy.

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