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Review Article

Novel Pharmaceutical Dosage Form Design Strategies for Enhanced Drug Delivery and Efficacy

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ABSTRACT

A crucial tactic for enhancing medication distribution, therapeutic efficacy, patient adherence, and safety is the development of novel dosage forms. Low water solubility, poor bioavailability, quick drug elimination, instability, non-specific distribution, and frequent dosing are only a few of the drawbacks of conventional dosage forms. To solve these problems and improve the pharmacokinetic and pharmacodynamic characteristics of drugs, new techniques for designing dosage forms have been created. Drug solubility, dissolution, stability, absorption, and targeted (site-specific) delivery can all be improved by novel technologies, including advanced nanoparticles, liposomes, polymeric micelles, solid lipid nanoparticles, nanostructured lipid carriers, amorphous solid dispersions, lipid-based formulations, gastro-retentive systems, mucoadhesive systems, transdermal systems, controlled-release systems, and stimuli-responsive drug delivery systems. While amorphous solid dispersions and nanocrystal technologies are essential for boosting the bioavailability of weakly water-soluble medicines, nanotechnology-based systems can be used for targeted and controlled drug administration Controlled-release devices can decrease side effects, lower the frequency of dose, and keep medication levels within the therapeutic range over extended periods of time. Despite their enormous promise, their clinical translation is still influenced by issues such formulation instability, toxicity, industrial scale-up, reproducibility, cost, and regulatory approval. The main approaches for creating innovative dosage forms and their potential to enhance medication distribution and therapeutic efficacy will be the main topics of this review.

Keywords*: Novel dosage forms; drug delivery; nanoparticles; controlled release; targeted delivery; bioavailability; solubility enhancement; nanotechnology.*

INTRODUCTION

Along with the pharmacological characteristics of the active pharmaceutical ingredient (API), the design of the dosage form is an essential component since drug development culminates in the final pharmaceutical product. This is because therapeutic efficacy is largely dependent on physicochemical properties and delivery to the biological target site. In order to guaranty consistent therapeutic effects, acceptable administration, stability, and accurate dosing, a dosage form combines the active substance with suitable excipients and technology. Although they are still often used, conventional dosage forms (tablets, capsules, injectables, syrups, and creams) may not be able to effectively address problems such low solubility, poor bioavailability, short biological half-life, drug degradation, and variations in plasma drug levels [1,5].

Current drug delivery system research aims to minimize toxicity while delivering the treatment at the appropriate concentration, to the exact place, and for the necessary amount of time. New delivery methods that enable better drug targeting, controlled release, enhanced absorption and stability, and optimum bioavailability have been developed in order to address these issues [5,6]. These techniques are especially helpful for medications with less-than-ideal physicochemical and/or biologic characteristics.

The drug's poor water solubility presents a major formulation development difficulty. Many medication candidates have low water solubility, which can result in sluggish dissolution and inconsistent gastrointestinal absorption. Particle size reduction, nanocrystal technology, amorphous solid dispersions, inclusion complexes, lipid-based formulations, polymeric micelles, liposomes, solid lipid nanoparticles, microemulsions, and self-emulsifying delivery systems are just a few of the pharmaceutical strategies that have been investigated [3, 4]. Increasing dissolution rates and, when appropriate, oral bioavailability can be achieved with these techniques.

For medications that are poorly soluble in water, amorphous solid dispersion (ASD) is a tried-and-true formulation technique. Compared to the drug's crystalline form, the drug in ASD systems is absorbed into a polymeric carrier in an amorphous state, which can give better apparent solubility and a faster dissolving rate. By choosing the right polymer and managing drug-polymer interactions, it is possible to maintain physical stability and avoid recrystallization [7, 8]. Additionally, new developments have connected ASD technology with modified-release techniques, creating chances to enhance solubility and accomplish controlled medication release at the same time [9].

Nanotechnology-based systems are another quickly emerging area in dosage forms. It is possible to alter drug distribution, solubility, and stability as well as to facilitate targeted or controlled delivery using nanoparticles, liposomes, polymeric micelles, nanocrystals, and lipid nanoparticles. They have the ability to deliver medications to biological areas that are challenging for traditional formulations to reach because of their small size and adjustable surface properties [1,5].

Similarly, controlled-release dosage forms have received a lot of attention because traditional formulations can result in abrupt changes (peaks and troughs) in plasma drug levels. By using mechanisms like diffusion, polymer erosion, swelling, and osmotic pressure, controlled-release systems can be created to release the active ingredient in a controlled way. In addition to improving therapeutic control and patient adherence to therapy, these systems aid in keeping drug levels within the therapeutic range for extended periods of time, which may lead to fewer doses [5,6].To improve therapeutic specificity, drug delivery devices that react to specific stimuli are also being investigated. While stimuli-responsive systems will release medications in reaction to particular environmental circumstances, such as pH, temperature, enzymes, and redox conditions, targeted systems may be directed at particular tissues, cells, or receptors. These techniques could reduce exposure to normal tissues and improve therapeutic efficacy [5,6]. Pharmaceutical technology, polymer science, nanotechnology, materials science, pharmacokinetics, and biotechnology are all included in the multidisciplinary subject of innovation in new dosage forms. Drug distribution could become more regulated, effective, and patient-focused with additional research and development. However, safety, stability, manufacturing viability, scalability, prices, and regulatory issues will be necessary to achieve clinical and commercial success [5,6].

Yes. An extended overview of the literature, written in an academic language and numbered using the Vancouver style, is presented below. Included is literature on lipid-based systems, nanoparticles, liposomes, amorphous solid dispersions, nanocrystals, targeted or stimulus-responsive systems, and controlled release.

LITERATURE REVIEW

Overview of Novel Pharmaceutical Dosage Forms

New pharmaceutical dosage forms have been created recently to improve the therapeutic action of active substances and solve problems with conventional forms. Potential issues with traditional dose forms include low bioavailability, quick elimination, variations in plasma drug levels, and a lack of drug localization at the therapeutic site. Therefore, regulating drug release, boosting solubility and dissolution, enhancing absorption, shielding the medication from deterioration, and attaining targeted administration are the main goals of contemporary dosage form design [1,2].

After reviewing several drug delivery methods, Tiwari et al. came to the conclusion that by altering drug release and boosting drug availability at the site of action, novel formulations could enhance therapeutic efficacy. The creation of systems that allow for targeted, continuous, and regulated medication delivery was emphasized by the authors [1].

The history of controlled drug delivery systems, from smart and nanoscale devices to sustained-release formulations, was discussed by Adepu and Ramakrishna. Additionally, they emphasized how regulated distribution reduces variations in plasma drug levels and enhances patient adherence to treatment, safety, and efficacy [2].

Nanoparticle-Based Drug Delivery Systems

These days, one of the most researched drug delivery strategies is the utilization of nanoparticles. These particles can be created from polymers, lipids, proteins, or inorganic materials, and they typically fall within the nanometer range. To suit the intended therapeutic use, they can be developed to display particular physicochemical characteristics, such as particle size, surface charge, shape, and surface chemistry.

In addition to encasing and shielding poorly soluble medications from premature breakdown, nanoparticles can increase their apparent solubility and rate of dissolution. To alter circulation time and promote interaction with particular cells or tissues, polymers and/or targeting ligands can be affixed to their surface. Their special qualities make them very appealing for cutting-edge medication delivery methods, such as antibacterial and cancer treatments, among other uses [1,3].

However, there are a number of issues with nanoparticle systems, including physical instability, aggregation, drug-carrying capacity restrictions, possible toxicity, manufacturing complexity, and the difficulties of generating vast amounts

consistently and uniformly. As a result, both therapeutic performance and manufacturing viability must be considered in formulation design.

Liposome-Based Drug Delivery
Phospholipid bilayers encasing an aqueous compartment make up the majority of liposomes, which are vesicular medicinal dosage forms. They can be used as a platform for different medicinal agents because of their amphiphilic character, which permits the integration of both hydrophilic and lipophilic medicines.

According to scientific research, liposomes can improve a drug's stability, alter its pharmacokinetic characteristics, and lessen the exposure of healthy tissues to specific therapeutic agents. By adding polymers, antibodies, peptides, or other ligands to their surfaces, liposomal systems' functional characteristics can be further enhanced[4].

Liposomes continue to be one of the most therapeutically proven nanocarrier technologies, as reported in recent papers. However, there are still some issues with drug leakage, batch reproducibility, production scale-up, physical and chemical stability, and the effectiveness of active targeting techniques [4].

Amorphous Solid Dispersions
The low aqueous solubility of oral medications is one of the main obstacles in their development. One of the most promising formulation techniques for improving the dissolution of molecules that are poorly soluble in water is the use of amorphous solid dispersions (ASDs).

According to Bhujbal et al.'s analysis of pharmaceutical production techniques used to create ASDs, these techniques can increase the solubility and bioavailability of medications that are poorly soluble in water. These systems involve the amorphous incorporation of the active pharmaceutical ingredient (API) into a polymer matrix. Because the amorphous form has a higher free energy than the comparable crystalline form, its dissolution behavior is improved [5].

In their comparison of ASD and nanocrystal technologies, Jermain et al. discovered that both have shown themselves to be effective solutions for the problem of low aqueous solubility. However, as recrystallization may reduce the solubility enhancement, the physical stability of the amorphous drug is an important consideration [6].

ASDs can be prepared using a variety of methods, including solvent evaporation, hot-melt extrusion, spray drying, and freeze-drying. The durability of the formulation depends critically on the selection of polymer and drug loading, as well as processing and storage conditions.

[5,7].

Nanocrystal Technology
The usage of drug nanocrystals is another significant technique for enhancing the solubility and bioavailability of medications that are poorly soluble in water. The surface area accessible for dissolving rises when the drug particle size is decreased. To stop particle aggregation, conventional stabilizers are needed.

According to Jermain et al., nanocrystal technology has been utilized to create commercially successful pharmaceutical products and is already well-established as a technique for poorly water-soluble chemicals [6]. Nanocrystals have a reasonably high drug loading in certain carrier-based systems where the drug makes up a significant portion of the particle. Nonetheless, formulation issues still include maintaining a tiny particle size, avoiding particle aggregation, regulating crystal development, and guaranteeing physical stability during storage.

Lipid-Based Drug Delivery Systems
The use of lipid-based drug delivery systems for the oral administration of lipophilic, weakly water-soluble medications has been the subject of a significant amount of research. Lipid solutions, lipid emulsions, self-emulsifying drug delivery systems (SEDDS), self-microemulsifying drug delivery systems (SMEDDS), self-nanoemulsifying drug delivery systems (SNEDDS), and other lipid formulations are examples of these systems.
Lipid-based systems can improve medication bioavailability by boosting solubility and encouraging gastrointestinal absorption, according to Rahman et al. They are helpful for substances that are frequently poorly soluble in water [8].

Lipid-based formulations can enhance medication solubilization in the colon and interact with gastrointestinal processes; intestinal lymphatic transport can also contribute to drug absorption, according to Porter et al [9].

Williams et al. then emphasized that lipid-based formulations can improve medication absorption by promoting lymphatic transport and, for some medicines, by boosting solubilization in the gastrointestinal system [10].

Self-Emulsifying Drug Delivery Systems
Oils, surfactants, and sometimes co-solvents or co-surfactants make up SEDDS, which are isotropic solutions. After oral administration, these systems spontaneously emulsify in the presence of gastrointestinal fluids.

The potential of SEDDS, SMEDDS, and SNEDDS to improve the oral bioavailability and dissolution of medications with low water solubility was reviewed by Cerpnjak et al. The solubilization and absorption of the active ingredient are

facilitated by the creation of tiny droplets, which increase the interfacial surface area between the drug formulation and gastrointestinal fluids [11].

It is essential to choose the right oil, co-surfactant, surfactant, medication concentration, and formulation ratio. Additionally, the medication is known to precipitate after dilution or digestion, which may have an impact on these formulations' *in vivo* behavior.

2Controlled-Release Dosage Forms

The purpose of controlled-release dosage forms is to release the active component into the bloodstream at a predetermined pace. Drug exposure that is either below or over the therapeutic range may result from conventional immediate-release medications, which can cause a sharp increase in plasma drug levels followed by a decrease.

Diffusion, polymer swelling, matrix erosion, osmotic pressure, ion exchange, or a mix of these processes can be used in controlled-release systems. Drug effect can be prolonged and dose frequency can be decreased thanks to these technologies [2].

The transition from conventional polymer-matrix controlled-release systems to sophisticated nanoscale and microscale controlled-release systems was emphasized by Adepu and Ramakrishna. Additionally, they investigated the administration of drugs using intelligent, stimulus-responsive materials [2].

Gastroretentive Drug Delivery Systems

Making ensuring the dose form stays in the stomach for a long time is the aim of gastro-retentive dosage forms. Drugs that need to be exposed to the upper gastrointestinal tract for an extended period of time or that are preferentially absorbed there may benefit from these systems.

There are numerous methods, including mucoadhesive systems, high-density systems, expandable systems, floating systems, and combinations of these. Because they increase absorption and therapeutic action by extending gastric residence time, gastro-retentive devices may be helpful for some medications.

However, the rate of gastric emptying is influenced by physiological factors, including meal consumption, recumbent posture, intestinal motility, and individual variability. As a result, attaining consistent stomach retention is quite difficult.

Mucoadhesive Drug Delivery Systems

Mucoadhesive dosage forms are designed to have characteristics that enable the formulation to stick to the body's mucosal surfaces and extend its residence time at the administration site. Mucoadhesion has the potential to improve drug absorption by allowing the formulation to cling securely to the biological membrane.

Numerous mucoadhesive methods have been investigated for oral, buccal, nasal, ophthalmic, vaginal, and gastrointestinal medication administration. Many studies have been conducted on the adhesion qualities of polymers, including carbomers, chitosan, cellulose derivatives, and polyacrylic acid derivatives.

Increased residence period, higher local medication concentration, and the possibility of lowering dosage frequency are other advantages. However, performance may be impacted by excessive adhesion, mucosal irritation, and variations in mucus production.

Targeted Drug Delivery Systems

Transporting the medicine to the biological target site at a higher concentration than to non-target tissues is the aim of targeted drug delivery. Targeting can be classified as either passive or active.
While active targeting is based on altering the system's surface with ligands like antibodies, peptides, carbohydrates, or receptor-specific compounds, passive targeting just depends on the delivery system's physicochemical characteristics and natural dispersion.
Since the goal of cancer treatment is to enhance medication concentration in tumor tissue while lowering the dose reaching healthy tissues, regulated and targeted delivery methods may be especially helpful **[2,4]**.

Stimuli-Responsive Drug Delivery

Systems for stimuli-responsive release are designed to react to particular physiological or environmental events. These include light, magnetic fields, pH, temperature, enzymes, redox conditions, and other environmental factors.

For instance, pH-responsive systems can be engineered to display unique drug-release properties in various biological compartments according to pH. In a similar vein, materials that respond to temperature change their physicochemical characteristics when they reach particular temperatures.

These technologies are a big stride in the direction of more intelligent delivery methods and away from passive drug delivery. However, obtaining consistent and stimulus-specific release in intricate physiological settings continues to be a significant research problem [2].

Lipid Nanoparticles for Advanced Drug Delivery

Because lipid nanoparticles may contain and stabilize therapeutic substances, their significance in modern pharmaceutical technology is increasing. Both more complicated therapeutic agents and poorly soluble medications can have their bioavailability increased by using lipid-based nanocarriers.

Lipid-based nanocarriers have shown promise in oral administration for the delivery of molecules with low mucosal permeability that would not otherwise be able to tolerate gastrointestinal breakdown. They can be altered to affect characteristics including release, cellular interaction, stability, and drug encapsulation.

Relationship Between Dosage-Form Design and Therapeutic Efficacy

Innovative dosage form design aims to improve therapeutic efficacy rather than only produce a technologically advanced form. Predictable drug release, excellent bioavailability, sufficient tissue distribution, and minimal toxicity are all ideally guarantyd by an optimal dose form.

Therefore, to create a successful formulation, aspects such drug characteristics, pharmacokinetics, target tissue, excipient compatibility, stability, and manufacturing feasibility must be taken into account. As pharmaceutical development advances toward increased complexity and individualization, these elements become crucial for integration.

CONCLUSION

New dosage form designs are the key to overcome conventional dosage form limitations and enhance therapeutic outcomes. Incorporating nanotechnology, targeted delivery, controlled-release systems, lipid-based formulations, transdermal platforms, and smart drug delivery, has improved drug solubility, stability, bioavailability, efficacy, and patient compliance. Other therapeutic innovations for patient-specific therapies include personalized medicine, AI, 3D printing, and stimuli-responsive formulations. Yet, formulation stability, manufacturing costs, scale up, regulatory requirements, safety and clinical translation are key challenges. Future research should encourage interdisciplinary teamwork to create safe, effective, cost-effective and scalable dosage forms. Future innovations will lead to more accurate, effective and patient-focused drug delivery, which will further enhance the treatment outcomes and quality of life.

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