Review

Formulation and Evaluation Techniques in Novel Drug Delivery Systems

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Posted Date: 26 March 2025

doi: 10.20944/preprints202503.1953.v1

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Formulation and Evaluation Techniques in Novel Drug Delivery Systems

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Abstract: New drug delivery systems (NDDS) have significantly changed the pharmaceutical products with maximization of drug stability, patient compliance, and bioavailability. The present review elaborates on the different forms of NDDS, i.e., vesicular carriers such as liposomes and proniosomes, effervescent and mouth-dissolving drug delivery systems, and mucoadhesive drug delivery systems. New drug formulation methods including drug carrier systems using biopolymers, selection of excipients, and issues related to stability are elaborately discussed. Testing methodologies are necessary for safety and efficiency of drug products. Analytical characterization, in vivo and in vitro testing, and pharmacology screening are necessary for formulation success. Combination of nanotechnology and polymer-carriers has also escalated the significance of NDDS for overcoming solubility and targeted delivery problems. However, regulatory and scalability issues require further work on sustainable and patient-centred drug products. Emerging trends in drug delivery emphasize predictive modelling through the help of AI, intelligent therapeutics, and personalized medicine. In spite of the challenges faced, NDDS is marching ahead with the potential to bring revolutionary changes in future drugs. This new review has a snapshot of the existing status, assessment modes, and future of novel drug delivery technologies, highlighting their biggest contribution to contemporary medicine.

Keywords: novel drug delivery systems; vesicular carriers; nanotechnology; mucoadhesive drug delivery; formulation strategies

1. Introduction

1.1. Overview of Novel Drug Delivery Systems

New drug delivery systems (NDDS) enhance drug stability, bioavailability, and targeted delivery, the advantages over conventional dosage forms [1]. Vesicular carriers like liposomes and proniosomes enhance drug delivery via biological membranes with controlled release and minimum toxicity [2]. Effervescent tablets and mouth-dissolving films enhance patient compliance, especially in patients with swallowing disorders, and also prevent first-pass metabolism for enhanced efficacy [3]. Drug carrier nanoparticles improve drug targeting with lower side effects and enhanced therapeutic response [4]. Application of NDDS helps towards the achievement of a paradigm shift towards personalized medicine, where therapy is tailored to the patient [5].

1.2. Need for Advanced Formulation and Evaluation Techniques

Sophisticated formulation methods must overcome constraints such as low solubility and too much degradation in traditional medicine [1]. Nanocarriers and polymers provide superior regulation of release and bioavailability of drugs [2]. Procedures of measurement such as HPLC and spectroscopy introduce accuracy and reproducibility to a formula [3]. In vivo and in vitro assays allow assessing the activity of drugs and compatibility with regulations [4]. With the introduction of NDDS, there has to be continuous innovation in formulation and analytical technology to ensure safety and efficacy [5].

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2. Types of Novel Drug Delivery Systems

2.1. Vesicular Drug Delivery: Liposomes, Proniosomes, and Glycerosomes

Vesicular drug delivery systems promote drug stability and delivery at target sites through entrapment of therapeutic agents in lipid vesicles. Phospholipid bilayer liposomes have improved solubility and half-life within the circulatory system and therefore are most suitable for site-specific and controlled delivery of drugs [6]. Proniosomes are a powder form in a dehydrated state, which reconstitutes into niosomes and are more controllable and stable compared to traditional vesicles [7]. Glycerosomes, a glycerol-supplemented liposome modification, enhance membrane fluidity and permeability and are used in dermal and transdermal products [8].

2.2. Effervescent and Mouth-Dissolving Drug Formulations

Effervescent tablets facilitate quick drug dissolution with acid-base interaction and carbon dioxide gas release, enhancing drug solubility and intestinal absorption [9].

Tablet formulation enhances patient compliance by avoidance of swallowing and a comfortable alternative to traditional tablets. Mouth dissolving films and tablets are disintegrated immediately in oral cavity without water, have rapid action and enhanced bioavailability in pediatric and geriatric patients [10]. Superdisintegrants used in them enhance faster dissolution, rapid drug release and therapeutic response [11].

Table 1. Advantages of Effervescent and Mouth-Dissolving Drug Formulations.

Formulation Type	Mechanism	Key Benefits	Reference
Effervescent Tablets	Acid-base reaction generates CO_2, enhancing solubility	Faster absorption, improved compliance	[9]
Mouth-Dissolving Tablets	Disintegrates rapidly in the oral cavity	No water needed, faster onset of action	[10]
Mouth-Dissolving Films	Thin film dissolves on the tongue	Convenient for pediatric/geriatric use	[10]
Superdisintegrant-Based Tablets	Swelling agents accelerate dissolution	Immediate drug release, better bioavailability	[11]

2.3. Mucoadhesive, Floating, and Herbal Drug Delivery Systems

Mucoadhesive drug delivery systems increase the contact time of the drug at the target site by sticking to mucous membranes and giving local therapy and extended release [6]. Floating drug delivery systems, especially for narrow window of absorption drugs, float over gastric fluids for a long period of time, enhancing bioavailability [7].

Plant-origin bioactives with herbal drug products form a natural drug delivery system with highest therapeutic action and minimum synthetic excipients and side effects [9]. They are a blend of ancient medicine and modern pharmacy science to provide enhanced efficacy and safety to the patient [10].

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Table 2. Mucoadhesive, Floating, and Herbal Drug Delivery Systems.

Delivery System	Mechanism	Key Benefits	Reference
Mucoadhesive Drug Delivery	Adheres to mucosal surfaces for prolonged retention	Enhanced localized treatment, sustained release	[6]
Floating Drug Delivery	Remains buoyant in gastric fluids	Improved bioavailability for drugs with narrow absorption windows	[7]
Herbal Drug Formulations	Incorporates plant-based bioactives	Natural therapeutic benefits, reduced synthetic excipients	[9]

3. Formulation Strategies in Novel Drug Delivery

3.1. Selection of Excipients and Polymers

Excipients and polymers selection in new drug delivery systems are the most significant parameters in regulating the drug stability, drug release rate, and bioavailability. Excipients like stabilizers, surfactants, and permeability enhancers enhance drug solubility and permeability and facilitate effective therapeutic action [12]. Natural polymers, synthetic polymers, and biopolymers are widely utilized in regulating drug release, mucoadhesion, and targeting. Biocompatibility and the ability to produce stable drug-polymer matrices are some of the characteristics for which they are also used as active ingredients of NDDS products [13].

Table 3. Selection of Excipients and Polymers in Drug Delivery Systems.

Category	Role in Drug Delivery	Key Benefits	Reference
Excipients	Enhance solubility, stability, and permeability of drugs	Improved bioavailability, controlled drug release	[12]
Stabilizers	Prevent drug degradation and improve formulation stability	Extended shelf life, enhanced formulation consistency	[12]
Surfactants	Enhance drug dispersion and absorption	Increased solubility, improved membrane permeability	[12]
Permeability Enhancers	Facilitate drug transport across biological barriers	Enhanced absorption, better therapeutic efficacy	[12]
Natural Polymers	Used for controlled release and mucoadhesion	Biocompatible, biodegradable, non-toxic	[13]
Synthetic Polymers	Regulate drug release kinetics and targeting	Precise drug delivery, stable drug-polymer interactions	[13]

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Biopolymers	Form stable drug-polymer matrices for sustained release	Long-term efficacy, minimal systemic side effects	[13]

3.2. Biopolymer-Based Drug Delivery Approaches

Biopolymer systems from natural sources such as chitosan, alginate, and gelatin produce renewable and biocompatible delivery modes for drug carriers. Such medications maximize the efficacy of drug entrapment, achieve controlled release behavior, and reduce toxicity issues, hence suitable for use in oral, transdermal, and injectable routes [12]. Traditional herbal therapies, such as those processed from plant-based bioactives, utilize biopolymers to provide solubilization and target delivery rather than addition of traditional medicine on top of the new drug preparation [14]. Donkey milk nutraceuticals also employ biopolymer stabilization processes for enhanced therapeutic activity and the preservation of nutrients [15].

3.3. Stability and Compatibility Considerations

The product should be stable to ensure the efficacy of the drug within its shelf life. pH sensitivity, water content, and excipient interaction with active pharmaceuticals should be investigated thoroughly in order to avoid degradation [12]. Herbal and flavonoid-based products, owing to their very common occurrence in NDDS, must be put through stability testing to validate that pharmacological activity as well as therapeutic efficacy are also retained [16]. Techniques such as differential scanning calorimetry (DSC) and Fourier-transform infrared spectroscopy (FTIR) based on compatibility studies aid identification of any likely interaction and support formulation design to enable better performance [13].

Table 4. Stability and Compatibility Considerations in Drug Delivery Systems.

Factor	Role in Drug Stability	Key Considerations	Reference
pH Sensitivity	Maintains drug integrity under varying physiological conditions	Prevents degradation and ensures stability	[12]
Water Content	Affects drug solubility and stability	Excess moisture may lead to hydrolysis or reduced efficacy	[12]
Excipient-Drug Interaction	Ensures compatibility between excipients and active drugs	Avoids unwanted reactions that may alter drug effectiveness	[12]
Herbal & Flavonoid Stability	Preserves pharmacological activity in NDDS formulations	Stability testing ensures therapeutic efficacy over time	[16]

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Differential Scanning Calorimetry (DSC)	Detects thermal stability and potential degradation pathways	Helps refine formulation for improved stability	[13]
Fourier-Transform Infrared Spectroscopy (FTIR)	Identifies potential drug-excipient interactions	Supports compatibility studies for optimized formulation	[13]

4. Evaluation Techniques for Drug Delivery Systems

4.1. Analytical and Characterization Methods

Accurate formulation testing of the drug requires highly sophisticated analytical and characterization techniques. Stability-indicating equipment like Reverse Phase-High Performance Liquid Chromatography (RP-HPLC) is typically employed to identify the purity of a drug, drug degradation, and formulation stability in terms of varying conditions [22]. Excipient compatibility and physicochemical property within the formulation is established by characterization testing like Fourier-transform infrared spectroscopy (FTIR), differential scanning calorimetry (DSC), and X-ray diffraction (XRD) [21].

4.2. In Vitro and In Vivo Evaluation Techniques

In vitro test procedures such as permeability testing and dissolution testing give information about drug release kinetic and bioavailability. The performance of the formulation depends considerably on the above tests prior to performing clinical trials [20]. In vivo tests measure the drug pharmacokinetic and pharmacodynamic profile and ascertain the safety and therapeutic activity [18]. In mucoadhesive and buoyancy preparations, gastric retention animal model experiments are conducted to determine the drug release through sustained process along with enhanced absorption [23].

4.3. Pharmacological Screening and Therapeutic Assessment

Pharmacological screening is found to be applicable to identify therapeutic importance and safety of newly developed preparations. For instance, drug delivery systems of flavonoids are experimented for anxiolytic potential as a treatment indication to support its therapeutic action against neurologic disturbances [18]. Drug efficacy comparison in diverse formulation forms, e.g., drug delivery protocols on carbon dots and herbal sunscreens, establish maximum treatment programs [19,21]. Compliance of drug formulations to regulatory tests by drug delivery system assays ensures drug formulations are non-toxic as well as be biocompatible before introducing them into the market [20].

5. Recent Trends and Future Perspectives

5.1. Emerging Technologies and Innovations in Drug Delivery

The drug delivery system is going through fast advancements in the pharmaceutical sector that will deliver the highest therapeutic efficacy and patient compliance. Mucoadhesive tablets of buccal type have proven to be an effective drug delivery device for sustained drug release, enhancing bioavailability and reducing the frequency of dosing [24]. New suspending agents are incorporated in drug suspensions now to enhance drug uniformity and stability and resolve solubility problems

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with water-insoluble drugs [25]. These innovations, along with nanotechnology and drug targeting systems, are also revolutionizing the future of drug design.

5.2. Challenges, Opportunities, and Future Scope

With widespread development being the norm, drug delivery systems also face regulatory hurdles, scale-up, and stability in formulation. The need for proper characterization and biocompatibility tests only makes it even more difficult to create saleable products [25]. But with increasing research on polymers-based drug delivery systems, mucoadhesive systems, and intelligent drug delivery systems, the field has massive potential for personalized medicine and rational regimen treatment [24]. Trends will encompass patient-specific formulation with artificial intelligence and predictive models to maximize drug release profile and therapeutic efficacy.

Conclusion

Emerging drug delivery systems transformed the pharmaceutical sector with enhanced drug bioavailability, patient compliance, and therapeutic performance.

A number of strategies including vesicular systems like liposomes and proniosomes, effervescent systems, and drug mucoadhesive carriers have been found to be effective drug delivery methods. Innovative formulation strategies through the utilization of suitable excipients and polymers are crucial in ensuring efficacy and stability. Apart from analytical characterization, in vitro and in vivo assays, and pharmacological screening methods, those methods should be used to ensure efficacy and safety of such systems. Future directions involve the use of nanotechnology, drug delivery systems using polymers, and artificial intelligence-based predictive modeling for tailoring drug formulations. Regulatory issues and formulation complexity are challenges, yet the industry holds huge opportunities for innovation. Smart therapeutics are the future of drug delivery as patient-specific medications with patient-specific needs and enhanced therapeutic efficacy. Increased R&D and innovation will drive new drug delivery technology to deliver improved health outcomes globally.

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