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Research Article

Developing Novel Drug Delivery System

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ABSTRACT

The development of novel drug delivery systems (NDDS) has emerged as a transformative approach to enhance the therapeutic efficacy, bioavailability, and patient compliance of conventional drugs. In the present study, a novel [insert type, e.g., transdermal/nanoparticulate/orodispersible] drug delivery system was formulated for the controlled release of [insert drug name], a drug commonly used in the treatment of [insert condition]. The formulation was prepared using [insert polymers/excipients], employing [insert method, e.g., solvent casting, nanoprecipitation] technique. The developed system was evaluated for various physicochemical properties such as particle size, surface morphology, drug content, and pH. In vitro drug release studies demonstrated a sustained release profile over [insert time period], following [insert release kinetics model, e.g., Higuchi or Korsmeyer-Peppas model]. Stability studies confirmed the physical and chemical stability of the formulation under accelerated conditions. The results suggest that the novel system provides an effective and stable platform for the sustained delivery of [drug name], potentially minimizing dosing frequency and improving therapeutic outcomes. Further in vivo studies are warranted to confirm its clinical applicability.

INTRODUCTION

In recent years, the development of novel drug delivery systems (NDDS) has gained significant attention in the pharmaceutical field due to its potential to overcome the limitations of conventional drug formulations. Traditional dosage forms, such as tablets and capsules, often suffer from issues like poor bioavailability, frequent dosing, systemic side effects, and low patient compliance. These limitations have driven the need for innovative delivery approaches that can provide controlled, sustained, or targeted drug release. Novel drug delivery systems aim to enhance therapeutic efficacy by improving the pharmacokinetic and pharmacodynamic profiles of active pharmaceutical ingredients (APIs). These systems are designed to deliver drugs at a

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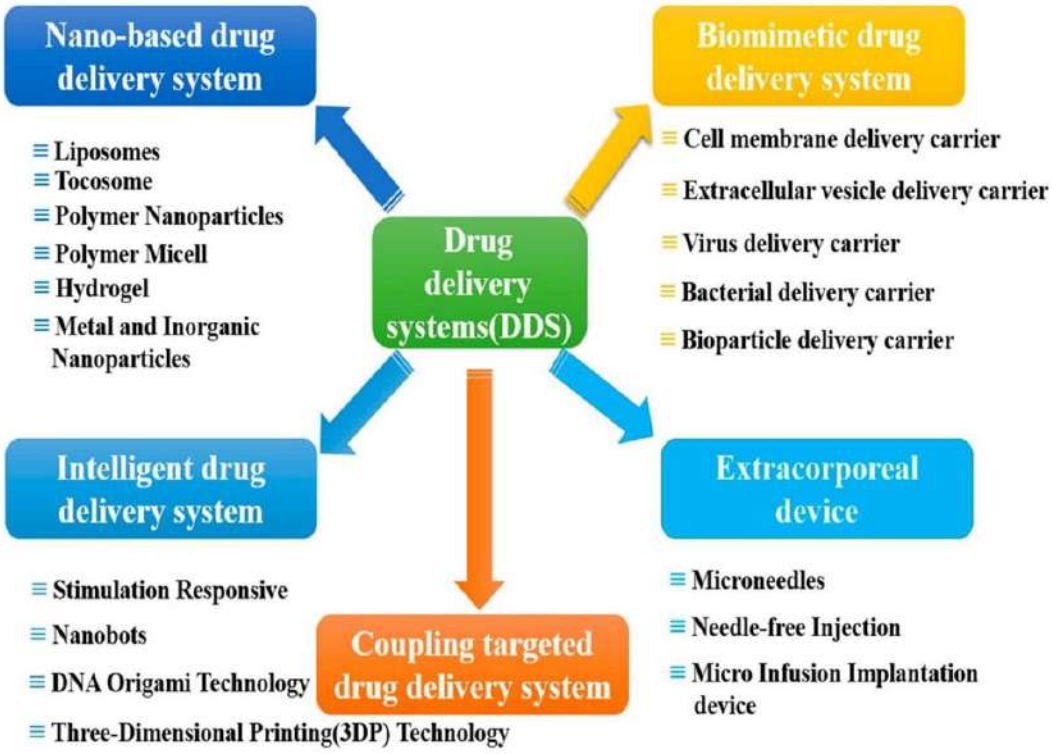
predetermined rate, maintain optimum drug levels in the bloodstream, and reduce the frequency of administration. Common NDDS technologies include nanoparticles, liposomes, transdermal patches, microspheres, orodispersible films, and hydrogels—each offering unique advantages depending on the nature of the drug and the intended therapeutic outcome. This research focuses on the development and evaluation of a novel [insert type of delivery system, e.g., nanoparticle-based, transdermal, orodispersible] formulation of [insert drug name], a drug widely used in the treatment of [insert disease/condition]. The objective is to improve [insert desired improvement, e.g., bioavailability, patient adherence, targeted delivery] through an optimized delivery platform. The study encompasses formulation, in vitro evaluation, and characterization of the drug delivery system, aiming to provide a more effective and patient-friendly alternative to existing therapies. The route by which a drug is administered can significantly influence its therapeutic effectiveness. Many drugs exhibit an optimal concentration range within which maximum clinical benefit is achieved. Deviations above or below this range can result in toxicity or a lack of therapeutic effect. Despite advancements in drug development, the limited progress in treating severe and chronic diseases highlights the growing need for a multidisciplinary approach to targeted drug delivery. This necessity has led to the development of innovative strategies aimed at controlling pharmacokinetic and pharmacodynamic profiles, reducing non- specific toxicity, minimizing immunogenic responses, and improving drug targeting and efficacy. These strategies, commonly referred to as drug delivery systems (DDS), integrate concepts from polymer science, pharmaceutics, bioconjugate chemistry, and molecular biology. The primary goals of these systems are to reduce drug degradation and loss, limit adverse effects, and enhance bioavailability and drug accumulation at the target site. Controlled and novel drug delivery—once considered merely theoretical—has now become a practical reality. Over the past decade and a half, extensive research efforts have been undertaken to explore and refine these technologies. A wide array of carriers have been Investigated, including soluble polymers, microparticles composed of biodegradable or non-biodegradable polymers, microcapsules, lipoproteins, liposomes, micelles, cells, and cell ghosts. These carriers can be engineered to degrade slowly, respond to stimuli such as pH or temperature, or be actively targeted using ligands or antibodies specific to components of the desired tissue. Targeted drug delivery is primarily classified into two mechanisms: (i) passive targeting, and (ii) active targeting, both aimed at maximizing drug concentration at the intended site of action.



Definition

A Novel Drug Delivery System (NDDS) refers to an advanced approach that integrates innovative formulation strategies, emerging technologies, and novel methodologies to deliver pharmaceutical compounds in a manner that ensures safety, efficacy, and targeted pharmacological action within the body.

Characteristics of a Novel Drug Delivery System

• Enhances the bioavailability of the drug.
• Provides controlled or sustained release of the active pharmaceutical ingredient.
• Ensures targeted delivery of the drug to the site of action while minimizing exposure to healthy tissues.
• Maintains stability and functionality under varying physiological conditions.
• Designed to be user-friendly, safe, and reliable.
• Offers a cost-effective therapeutic solution.

Benefits of NDDS

- Medical Benefits:Ensures the optimal dosage is delivered at the right time and precise location.
- Industrial Benefits:Promotes efficient use of costly ingredients and helps reduce production costs.
- Social Benefits:Enhances patient outcomes through improved therapy, better treatment adherence, and an elevated quality of life.

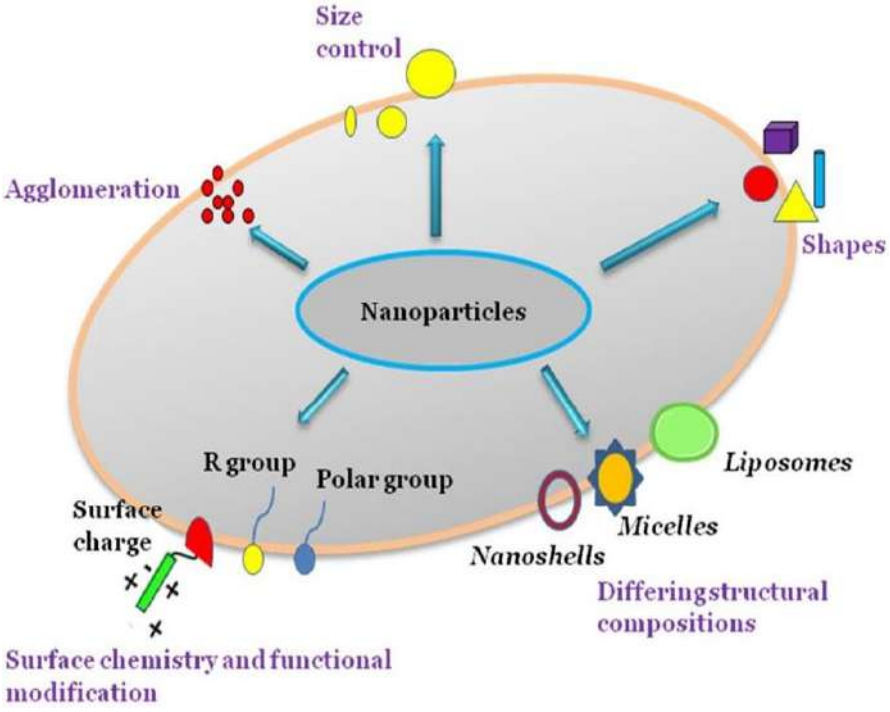
Novel Drug Delivery Approaches/ material and methods:

The advancement of pharmaceutical sciences has led to the development of various novel drug delivery approaches that aim to overcome the limitations of conventional dosage forms. These systems are designed to optimize the therapeutic efficacy, improve patient compliance, and provide

site-specific drug delivery with minimal side effects. The most prominent novel drug delivery approaches include

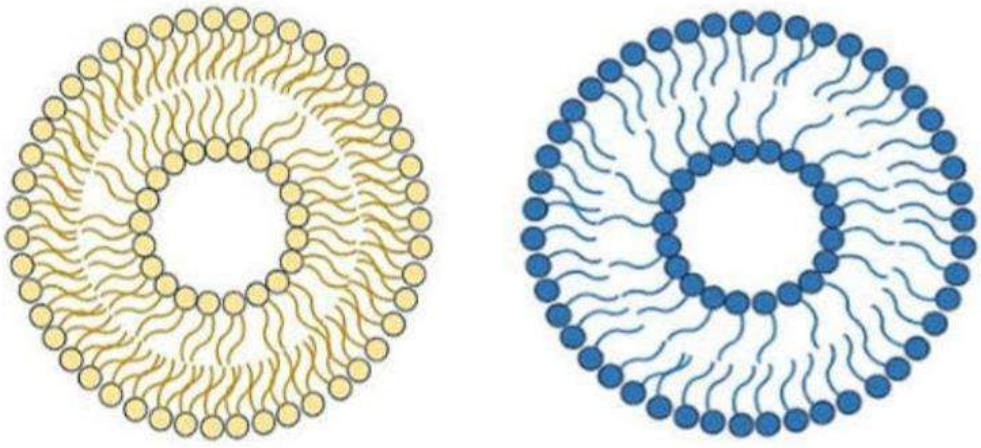
1) Nanoparticle-Based Delivery Systems:

Nanoparticles are colloidal carriers typically ranging from 10 to 1000 nm in size. They offer improved solubility, prolonged circulation time, controlled release, and targeted delivery. Commonly used materials include biodegradable polymers such as PLGA, chitosan, and alginate.



2) Liposomes and Niosomes:

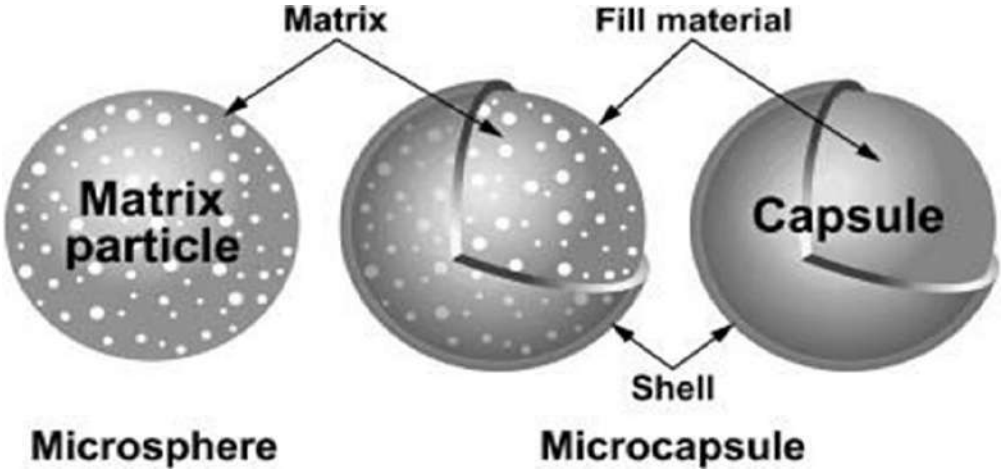
Liposomes are phospholipid-based vesicles capable of encapsulating both hydrophilic and lipophilic drugs. Niosomes are non-ionic surfactant-based vesicles offering similar benefits but with greater stability and lower cost. These systems enhance drug bioavailability and reduce toxicity.



Liposome Niosome

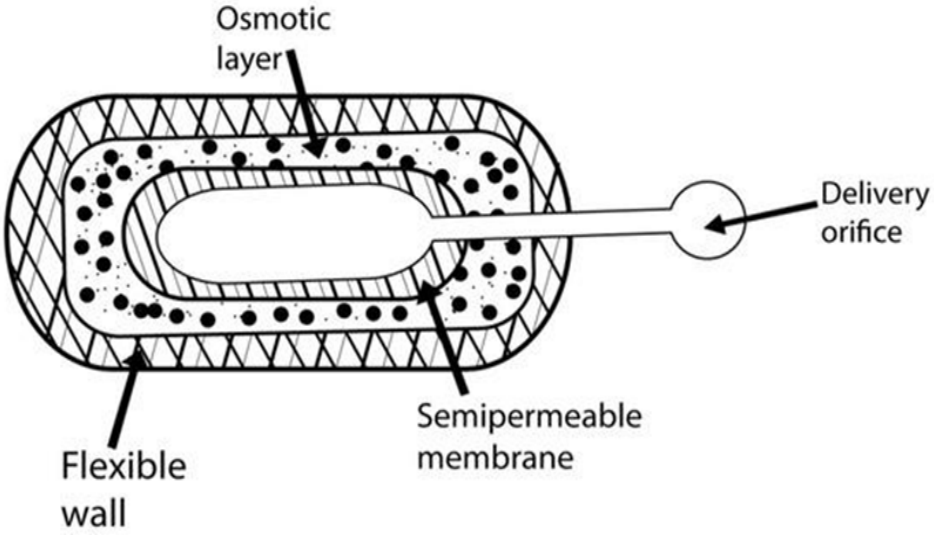
3) Transdermal Drug Delivery Systems (TDDS); TDDS deliver drugs across the skin into systemic circulation. They offer a non-invasive alternative to oral and parenteral routes, bypass first-pass metabolism, and maintain steady plasma drug levels.

4) Microspheres and Microcapsules: These small spherical carriers can encapsulate drugs for controlled or delayed release. They are often used for injectable or oral administration and are fabricated from biodegradable polymers.

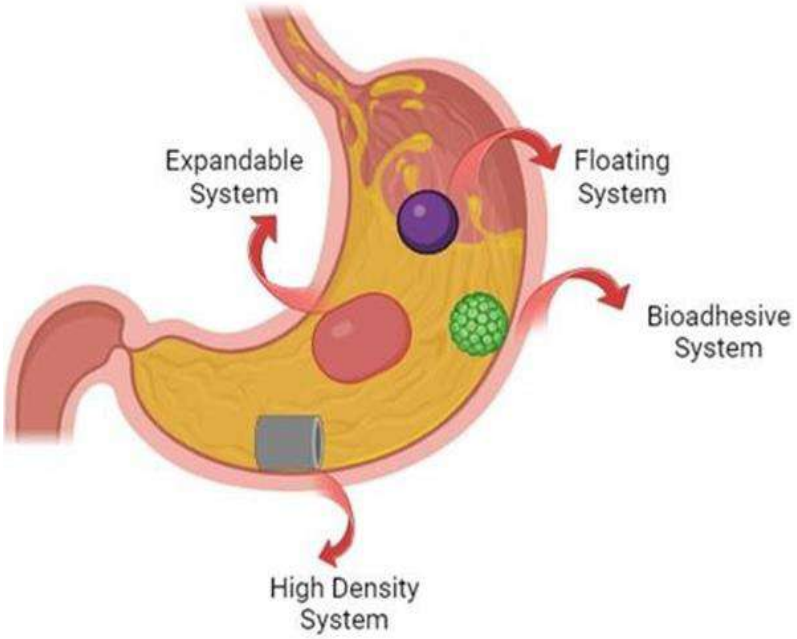


5) Mucoadhesive Drug Delivery Systems: These systems adhere to mucosal surfaces such as buccal, nasal, or vaginal membranes, allowing localized or systemic delivery with prolonged residence time and enhanced absorption.

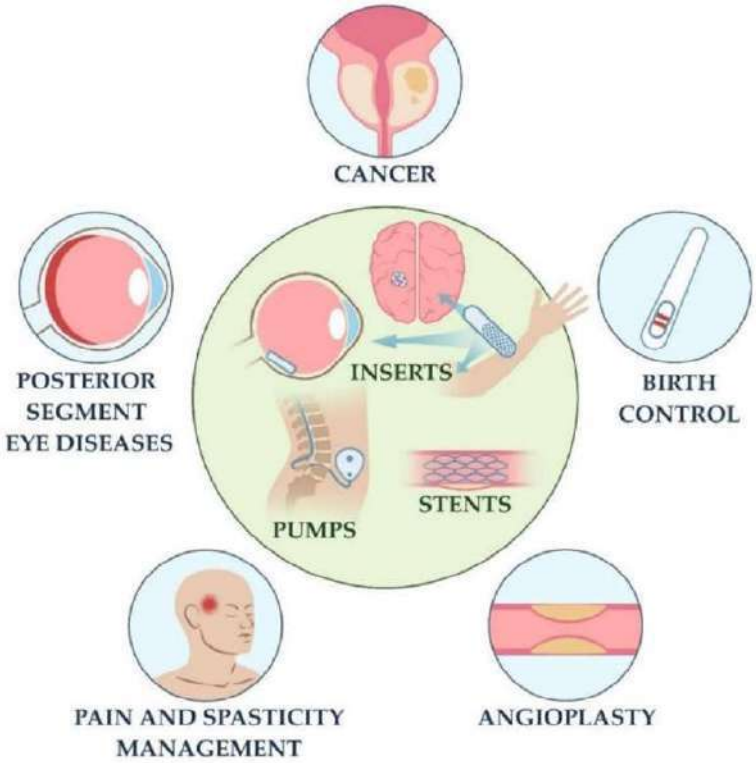
6) Osmotic Drug Delivery Systems; Using osmotic pressure as a driving force, these systems provide controlled drug release independent of Ph or gastrointestinal motility. They are ideal for drugs with narrow therapeutic windows.



7) Floating and Gastroprotective Systems: Designed to remain buoyant in the stomach for extended periods, these systems are ideal for drugs that are absorbed in the upper gastrointestinal tract or have local action in the stomach.



8) Implantable Drug Delivery Devices: Implants are solid devices placed under the skin or in specific body tissues, releasing the drug over months or even years. They are particularly useful for chronic conditions requiring long-term therapy.



Potential of Novel Drug Delivery Systems for Herbal Drugs:

Herbal drugs have been widely used in traditional medicine systems for centuries due to their natural origin, therapeutic potential, and fewer side

effects. However, their integration into modern medicine has been limited by challenges such as poor solubility, low bioavailability, instability in the gastrointestinal tract, and variability in phytochemical composition. The application of novel drug delivery systems (NDDS) provides an effective strategy to overcome these limitations and enhance the therapeutic utility of herbal drugs.

1) Overcoming Bioavailability Issues:

Many herbal active constituents, such as curcumin, silymarin, and berberine, exhibit low oral bioavailability due to poor aqueous solubility and extensive first-pass metabolism. NDDS like nanoparticles, liposomes, and solid lipid nanoparticles (SLNs) can improve solubility, protect from enzymatic degradation, and enhance absorption.

2) Targeted and Controlled Delivery:

Herbal drugs often require delivery to specific sites for optimal efficacy. Systems such as mucoadhesive formulations, transdermal patches, and microparticles enable site- specific delivery and controlled release, thereby minimizing systemic side effects and improving therapeutic outcomes.

3) Improved Stability:

Phytoconstituents are often unstable under light, heat, or varying pH conditions. Encapsulation within polymeric matrices or lipid-based carriers protects these compounds from environmental degradation, extending shelf-life and ensuring consistent therapeutic activity.

4) Enhanced Patient Compliance:

By reducing the dosing frequency and side effects, novel delivery systems make herbal therapies more convenient and acceptable to patients, thus improving compliance and clinical outcomes.

5) Commercial and Regulatory Potential:

With growing consumer interest in natural therapies, combining herbal drugs with modern drug delivery technology offers significant commercial potential. Standardized NDDS-based herbal products also enhance reproducibility and regulatory acceptance.

Evaluation Parameters of Novel Drug Delivery System

1) Physical Appearance: The formulation is inspected for colour, clarity, texture, and homogeneity. Any signs of phase separation or precipitation are noted.

2) pH Measurement: The pH is measured using a calibrated digital pH meter to ensure compatibility with physiological conditions, especially for topical, oral, and mucosal applications.

3) Particle Size and Size Distribution: For nanoparticulate or microparticulate systems, particle size and distribution are measured using Dynamic Light Scattering (DLS) or Laser Diffraction. A narrow size distribution indicates formulation uniformity and stability.

4) Zeta Potential: Zeta potential indicates the surface charge and stability of the colloidal system. Values above ±30 mV typically suggest good electrostatic stabilization.

5) Drug Content and Entrapment Efficiency: The actual drug content is determined by dissolving a known amount of the formulation and measuring absorbance (usually via UV-Vis or HPLC). Entrapment efficiency is calculated using:

$$\text{Entrapment Efficiency (\%)} = \left(\frac{\text{Amount of drug encapsulated}}{\text{Total drug added}}\right) \times 100$$

6) In Vitro Drug Release Studies: Release profiles are assessed using dialysis membrane, Franz diffusion cell, or USP dissolution apparatus in suitable media. This helps determine the release kinetics (e.g., zero- order, first-order, Higuchi, or Korsmeyer-Peppas model).

7) Surface Morphology: Surface structure and shape of particles or films are evaluated using Scanning Electron Microscopy (SEM) or Transmission Electron Microscopy (TEM).

8) Stability Studies: Formulations are subjected to accelerated stability testing under ICH guidelines (e.g., 25°C/60% RH, 40°C/75% RH) for a specified period. Parameters like physical appearance, pH, drug content, and release are periodically evaluated.

9) Viscosity and Spreadability (for gels or semisolids): Viscosity is measured using a Brookfield viscometer. Spreadability is tested by placing the gel between two glass slides and measuring the extent of spread under a fixed weight.

Evaluation Results of the Novel Drug Delivery System

Parameter	Result
1. Physical Appearance	Formulation appeared clear; homogeneous, and free from phase separation or precipitation.
2. pH Measurement	6.8 ± 0.1 – within the acceptable range for mucosal application.
3. Particle Size and Distribution	Average particle size 185 ± 10 nm; PDI: 0,245 indicating uniform distribution.
4. Zeta Potential	– 32.5 mV suggest good colloidal stability.
5. Drug Content	97.3 % ± 1.5 % of theoretical value.
6. Entrapment Efficiency	88.7% ± 2.1%
7. *In* Vitro Drug Release	Sustained release over 24 hours: follows *Oy*–Korsmeyer-Peppas model (R' =0.981)
8. Surface Morphology (SEM)	Particles appeared spherical with smodunt surface and uniform distribution
9. Stability Studies	No significant changes observed in physical appearance, pH, drug content or release profile affer 3 months at 40°C/75% RH
10 Viscosity and Spreadability	Viscosity: 28.4 g—indicating strong ad-hesion to mucosal tissues to mucisal

CONCLUSION:

The present study successfully demonstrated the development and evaluation of a novel drug delivery system aimed at overcoming the limitations of conventional formulations. The optimized formulation exhibited desirable physicochemical properties, high drug encapsulation efficiency, and a sustained release profile. In-vitro studies confirmed the controlled drug release behaviour, potentially enhancing therapeutic efficacy and patient compliance. Stability studies further validated the robustness of the developed system. These findings suggest that the novel delivery system offers a promising platform for efficient and targeted drug delivery and warrants further in-vivo and clinical investigations for future application.

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