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REVIEW ARTICLE

Novel drug delivery systems-A review

Raghavendra Kumar Gunda, J.N. Suresh Kumar, Jampana Lakshmi, Jada Vydhurya, Jarapala Saikiran Naik, Jonnalagadda Lalitha Varshini and Katta Reshma

Department of Pharmaceutics, Narasaraopeta Institute of Pharmaceutical Sciences (Autonomous), Narasaraopet, Palnadu (Dt), Andhra Pradesh, India

ABSTRACT

Objective: In pharmaceutics, Novel Drug Delivery Systems (NDDS) have become cutting-edge methods for enhancing the therapeutic efficacy, bioavailability, stability, and safety of medications while lowering dosage frequency and systemic side effects. Poor solubility, limited bioavailability, quick drug elimination, and nonspecific drug distribution can all be linked to conventional drug administration methods. By delivering medications in a regulated, sustained, or targeted manner and keeping drug concentrations within the therapeutic range, NDDS are intended to get around these restrictions.

Major drug-delivery technologies: The main innovative drug delivery strategies, such as transdermal, sustained-release, controlled-release, targeted, and carrier-based drug delivery systems, are summarized in this review. The mechanisms and potential benefits of a variety of carrier systems, including liposomes, phytosomes, nanoparticles, microspheres, niosomes, transferosomes, ethosomes, dendrimers, monoclonal antibodies, emulsions, and hydrogels, are covered. Important drug-release mechanisms, such as diffusion, dissolution, erosion, swelling, osmotic, ion-exchange, pH-responsive, ligand-mediated, and stimuli-responsive mechanisms, are also included in the review.

Key Findings: Additionally covered are evaluation characteristics such stability studies, in vitro drug release, zeta potential, particle size, and drug entrapment efficiency. Applications of NDDS in cancer, transdermal therapy, pulmonary and neurodegenerative diseases, cardiovascular disorders, and diabetes management are highlighted. Recent developments in advanced biomaterials and nanotechnology show promise for improving drug targeting, therapeutic results, and patient compliance.

Future Perspectives: In contemporary pharmaceutical practice, NDDS offer potential approaches for effective and efficient drug administration with fewer side effects, enhanced therapeutic performance, and better overall clinical results.

KEYWORDS

Innovative method of medication distribution; Controlled drug delivery; Therapeutic efficacy; Targeted medication delivery; Nanotechnology and bioavailability

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Introduction

Limitations of conventional drug delivery

Conventional drug delivery systems, including oral, parenteral, topical, and conventional dosage forms, remain fundamental to modern pharmacotherapy; however, they are associated with several limitations that can compromise therapeutic efficacy and patient outcomes. Following conventional administration, many drugs undergo variable absorption, enzymatic or chemical degradation, first-pass metabolism, and rapid systemic elimination, which can result in low or inconsistent bioavailability. These limitations are particularly important for drugs with poor aqueous solubility, limited permeability, narrow therapeutic windows, or inadequate stability in physiological environments.

The delivery of biological and highly sensitive therapeutics presents additional challenges. Proteins, peptides, nucleic acids, and other macromolecules may undergo degradation, aggregation, or rapid clearance following conventional administration. Moreover, biological barriers such as the gastrointestinal tract, blood–brain barrier, cellular membranes, and skin can substantially restrict drug transport to specific tissues or intracellular targets. Consequently, conventional approaches may be inadequate for achieving efficient delivery of certain therapeutic molecules.

Need for advanced/novel delivery systems

These limitations have stimulated the development of advanced drug delivery technologies capable of improving drug solubility, stability, bioavailability, pharmacokinetic profiles, and site-specific delivery. Nanoparticles, liposomes, polymeric systems, micelles, dendrimers, stimuli-responsive carriers, microneedles, extracellular vesicles, and other emerging platforms have therefore attracted considerable attention as strategies for achieving controlled, targeted, and personalized drug delivery. Nevertheless, these advanced systems also present challenges related to formulation complexity, toxicity, manufacturing reproducibility, scalability, cost, and regulatory approval. A critical evaluation of both their therapeutic advantages and limitations is therefore essential for assessing their potential for clinical translation.

Conventional delivery limitations → need for advanced systems → novel technologies → critical/comparative evaluation → advances and future perspectives.

The creation of new pharmaceutical formulations with better properties including decreased particle size, increased permeability, and targeted administration to certain locations is referred to as a novel drug delivery system. Technologies called drug delivery systems are made to move medicinal substances throughout the body in order to produce the intended therapeutic impact [1]. Numerous strategies have been used to improve

***Correspondence:** Mr Raghavendra Kumar Gunda, Department of Pharmaceutics, Narasaraopeta Institute of Pharmaceutical Sciences (Autonomous), Narasaraopet, Palnadu (Dt), Andhra Pradesh, India. e-mail: raghav.gunda@gmail.com

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gastrointestinal permeability and medication solubility [2].

The technique of encasing tiny liquid or solid droplets or particles in a continuous layer of polymeric material is known as microencapsulation. During the final decades of the 20th century, a sustainable attempt was made to transition from continuous but essentially uncontrolled release systems to more dependable dosage forms like tablets and capsules (example: waxes and other polymeric matrices).

Evolution of drug-delivery technologies

By using revolutionary technologies like nanoparticles, liposomes, micro-needle patches or implantable devices. These advancements do not improve therapy results but also patient satisfaction and compliance [3].

Innovative methods and instruments developed to increase the therapeutic efficacy of drugs are collectively referred to as novel drug delivery systems. The goal of an appropriate drug delivery system is to administer an efficient therapeutic dose at specific locations at the appropriate times and intervals until the intended recovery is attained. High permeability and a high drug loading capacity are caused by the size of nanoparticles and their high surface area to volume ratio [4]. Conventional delivery methods to advanced technologies marks a significant shift in how drug is administered, and treatment outcomes are optimized. Additionally, because the drug molecules are entrenched in pockets of the phytosomal assembly, it has higher absorption and bioavailability and is better protected from the gastrointestinal environment. Novel drug delivery systems are ones that a more rational approach to developing the ideal drug delivery system by offering novel insight into the pharmacokinetics and pharmacodynamics of the drug [5].

Against this background, the present review provides a comprehensive and critical overview of novel drug delivery systems (NDDS) developed to overcome the physicochemical, biopharmaceutical, and biological limitations of conventional approaches. It examines the principles, formulation strategies, release mechanisms, and therapeutic applications of major advanced platforms, including nanoparticles, liposomes, polymeric carriers, micelles, dendrimers, lipid-based systems, hydrogels, transdermal and microneedle technologies, targeted delivery systems, and stimuli-responsive carriers.

Objectives

- In novel drug delivery system improves bioavailability
- To examine the role of biodegradable polymers and sustained / controlled release system in improving therapeutic outcomes
- In novel drug delivery system recent advances in nano technology based and targeted drug delivery approaches are seen [6].
- It maintains consistent drug levels in the body for prolonged periods
- Reduces dosing frequency and enhances treatment adherences
- To use smaller particles sizes carriers for better absorption and distribution
- To reduce first pass metabolism of drugs.
- Protects drugs from degradation during storage and after administration
- To minimize side effects and toxicity
- To enhance the drug absorption through biological membranes.

Classification of NDDS

Transdermal drug delivery system

The introduction of a medicinal material through unbroken skin for a systemic impact is known as transdermal medication delivery [7]. The transdermal drug delivery technique demonstrates the skin's relative accessibility. Drug molecules' biological characteristics, such as skin irritation and inadequate bioavailability, and their physical characteristics, such as molecular size and polarity [8].

Transdermal Drug Delivery System are categorized into:

Microencapsulation

In order to improve therapeutic efficacy by delivering controlled doses to target tissues with the least amount of toxicity and adverse effects, microencapsulation materials, including medications, were developed. One such technique for long-term medication delivery is the use of microspheres, which are composed of synthetic polymers or biodegradable proteins. The goal of bioencapsulation, a subset of microencapsulation, is to increase performance and shelf life by encasing biologically active molecules [9].

Sonophoresis

By creating cavitation, which produces areas of high permeability, ultrasound in the 20–100 kHz range can improve skin permeability for transdermal medication delivery. Medication can be administered either during or after a quick ultrasound procedure. A regulated and reversible skin breach is made possible by adjustable parameters like frequency, intensity, and application time. Low-frequency ultrasound (55 kHz) is used by devices like Sono prep to rapidly increase permeability and speed up the absorption of local anesthetics. Furthermore, studies have looked into using tiny ultrasound transducers to enhance the skin's ability to distribute insulin [10].

Osmotic Pump

The osmotic pump system has a reservoir-like design, but it

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also includes an osmotic agent that draws water from the environment through a semipermeable membrane that is impervious to drugs but receptive to water. In an osmotic system, the release of medication is controlled by osmotic pressure rather than hydrodynamic factors or physiological characteristics of the gastrointestinal tract, such as pH. Osmotic pumps or delivery devices typically consist of a core that holds a medication and an osmogene. These have a semi-permeable lining that gradually delivers one or more drugs as a suspension or solution. When attempting to create delivery orifices, a tablet core with a semi-permeable membrane is compressed using a laser beam or a mechanical drill. Mixtures like mannitol + sucrose, dextrose + fructose, sucrose + fructose, and dextrose + sucrose can also be considered osmogenes or osmotic agents.

Mechanism

The mechanism of transdermal drug delivery centres on how a drug crosses the skin's barrier to reach systemic circulation. The outermost skin layer, the stratum corneum, forms the main barrier, following a "brick and mortar" model dead corneocytes embedded in intercellular lipids made of ceramides, cholesterol, and fatty acids. Since the corneocytes are largely impermeable, drugs must take a long, which is why the stratum corneum acts as such an effective, predominantly lipophilic barrier.

A drug reaching the skin has three possible entry routes: through hair follicles, via sweat ducts, or directly across the stratum corneum. The follicular and sweat gland routes cover only a tiny fraction of skin surface area, so they contribute little under normal conditions except for ions, large polar molecules, or when penetration enhancers are used. Within the stratum corneum, drugs travel via either the intracellular route (between cells) or the transcellular route (across the lipid-rich regions), with the transcellular route being dominant for polar drugs.

Several factors affect this mechanism, including the drug's partition coefficient, pH dependent ionization, and concentration; the vehicle's composition and its ability to hydrate the skin and the skin's own physiological state (age, hydration, temperature, enzymatic activity, and injury).

Finally, penetration enhancers work by disrupting the stratum corneum's lipid organization altering the polar lipid head groups, increasing the free water content between lipid layers, or loosening the packing of lipid tails thereby increasing drug flux, which follows Fick's first law of diffusion (flux depends on the diffusion coefficient and concentration gradient across the membrane) [11].

Sustained drug delivery system

The purpose of sustained release systems is to deliver the medication gradually and continuously over an extended length of time. The rate at which the medication is released is regulated and predefined. These systems aid in maintaining consistent blood drug levels. Additionally, they increase patient convenience and lessen the frequency of administration. Drug side effects and dose variations can be reduced with controlled release. The characteristics of the medication, the kind of administration method, the state of the illness, and the length of treatment all influence SRDDS design. The most popular sustained-release dose formulations are the Matrix tablets. Pharmaceutical preparations that release a medicine at a set rate to minimize side effects while maintaining a constant drug concentration for a preset period of time [Figure 1].

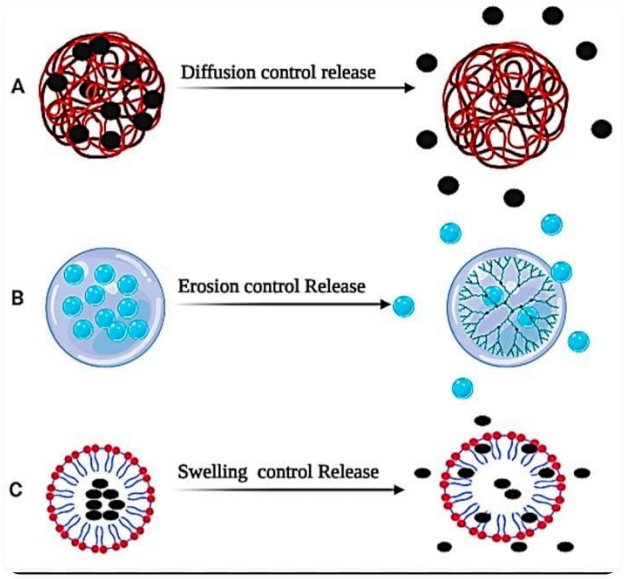


Figure 1. Sustained release drug delivery system.

Mechanism

Controlling the rate at which the drug is released from the dosage form is the fundamental idea behind a sustained or controlled drug delivery system, which ensures that the medicine is available in the body for an extended amount of time. This lessens variations in plasma drug concentration, keeps drug concentration within the therapeutic range, lowers dosage frequency, and increases patient compliance. Controlled drug delivery methods based on the drug release mechanism into systems based on dissolution, diffusion, water penetration, chemistry, and nanoparticles.

Dissolution-controlled mechanism: This method involves coating or encasing the medication in a polymeric membrane or matrix that dissolves gradually. The polymer eventually degrades and serves as a barrier. The medicine can be released when the polymer degrades. Since dissolution is the rate-limiting stage, the polymer's and dosage form's dissolution properties mostly determine the release rate. These systems could be monolithic/matrix systems or reservoir systems.

Diffusion-controlled mechanism: The medication is integrated into a polymeric membrane or matrix in diffusion-controlled devices, where it is released through diffusion. The medication travels from an area within the system with a greater concentration to an area outside the system with a lower concentration. The characteristics of the polymer and the drug's passage through it regulate the release. According to the article, Fick's first law of diffusion control these systems.

Fick's first law:

$$J = D\frac{dc}{dt}$$

where, J = drug flux; D = diffusion coefficient.

Osmotic Pressure-Controlled Mechanism: Water passing over a semipermeable membrane is necessary for this mechanism to function. Water enters the delivery system because of an osmotic concentration difference. The resulting osmotic pressure provides the driving force for controlled drug release. The basic components include the drug or osmogene, semipermeable membrane and delivery orifice.

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Water enters through the membrane, producing pressure inside the system, and this pressure helps push the drug out through the delivery orifice.

Swelling-Controlled Mechanism: Drug is dissolved or disseminated in a hydrophilic polymer in swelling-controlled systems. The polymer is initially in a glassy, hard, and rigid form. When it encounters water, water penetrates the polymer matrix, causing the polymer to swell. The drug then slowly diffuses through the swollen polymer matrix [12].

Controlled release drug delivery system

Controlled and sustained release drug delivery systems are designed to provide controlled and prolonged release of the drug in the body. They help maintain relatively constant plasma drug levels for an extended period, thereby improving therapeutic efficacy. These systems reduce the frequency of dosing, making the treatment more convenient and improving patient compliance, especially in long-term therapy. By avoiding sudden fluctuations in drug concentration, they minimize dose-related adverse effects and enhance the overall safety of the medication. Controlled release formulations also improve drug utilization and, in some cases, reduce the total amount of drug required while maintaining the desired therapeutic effect.

Mechanism

• Diffusion-controlled release: Drug molecules move from a region of high concentration to low concentration through a polymer membrane or matrix. The polymer acts as a barrier and controls the rate of drug release.

• Ion-exchange release: The drug forms a complex with an ion-exchange resin and is released gradually when exchanged with ions present in the gastrointestinal fluids.

• Dissolution-controlled release: The drug is released as the solid drug or coating slowly dissolves in the surrounding fluid, and the dissolution rate determines the release rate.

• Swelling-controlled release: The polymer absorbs water, swells, and forms a gel layer through which the drug diffuses slowly.

• Erosion-controlled release: The polymer matrix gradually erodes or degrades, leading to controlled release of the entrapped drug [13].

Targeted drug delivery system

The goal of the targeted drug delivery system (TDDS) is to deliver a medication precisely to the target cells, sick tissue, organ, or site of action. The primary goal is to minimize exposure to healthy tissues while increasing the drug's concentration at the target site. This lowers systemic toxicity and adverse effects, increases therapeutic efficacy, and may lower the necessary dosage. In the treatment of illnesses like cancer, where selective drug delivery to tumor tissues might enhance therapeutic results, targeted drug delivery is especially crucial.

Types of targeting

"Passive targeting and active targeting" are the two fundamental components of targeted drug delivery. The physiological features of sick tissues determine passive targeting. For instance, tumors may have poor lymphatic drainage and leaky blood arteries, creating the Enhanced Permeability and Retention (EPR) effect, which permits the accumulation of nanocarriers like liposomes and nanoparticles at the site of disease. Attaching particular ligands to the surface of drug carriers is known as active targeting. Through receptor–ligand interaction and cellular absorption, these ligands identify overexpressed receptors on target cells and enable targeted drug delivery.

Three levels of active targeting are possible: first-order targeting, in which the drug is directed to a particular organ or tissue; second-order targeting, in which specific cell types are targeted; and third-order targeting, in which the drug is delivered to specific intracellular organelles such as the nucleus or mitochondria [Figure 2].

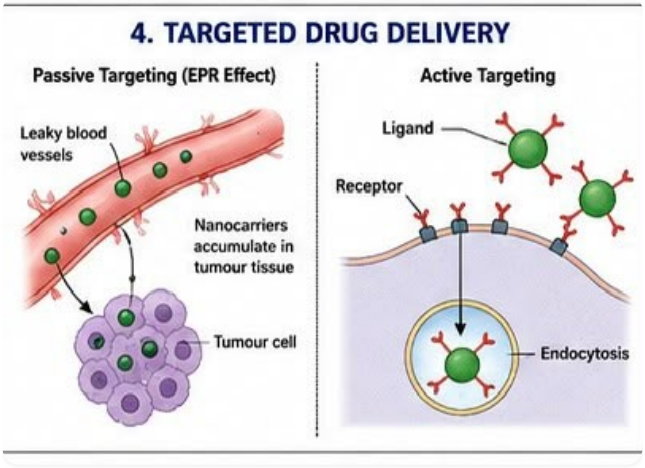


Figure 2. Targeted drug delivery system.

Mechanism

The physiological distinctions between healthy and sick tissues are how passive targeting operates. Because of the Enhanced Permeability and Retention (EPR) effect, nanocarriers including liposomes and nanoparticles preferentially concentrate in sick tissues, particularly tumors. Tumours have leaky blood vessels and poor lymphatic drainage, allowing the carriers to accumulate at the tumour site and increase the local drug concentration while reducing exposure to healthy tissues.

Active targeting works through a ligand–receptor interaction. The drug carrier's surface is coated with certain ligands. These ligands identify and attach to highly expressed receptors on the target cells. The drug-loaded carrier then undergoes receptor mediated endocytosis, resulting in increased intracellular drug concentration and improved therapeutic effect [14].

Carrier based drug delivery system

Different drug carrier systems have been created to reduce drug loss and degradation, avoid negative side effects, and maximize the percentage of drug deposited at the desired site. By conjugating them with antibodies against particular elements of the target site, for instance, carriers can be made to be slowly degradable, stimuli-reactive (such as pH or temperature-sensitive), and even targeted.

The physicochemical characteristics of the medication and the illness being treated determine which carrier is best. Carrier selection is influenced by a number of variables, including the drug's chemical makeup, stability, and partition coefficient as well as the kind of absorption enhancer employed. The functional groups on the drug molecule are also important. For example, an azo bond can be formed

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between the drug and a benzene group using aniline or nitro groups. Release characteristics and overall effectiveness can be further influenced by carriers that contain additives such polymers (used as matrices, hydrogels, or coating agents).

Types that involved in carrier-based drug delivery system are:

Phytosomes

Phytosomes are novel drug delivery systems used mainly for herbal and plant derived constituents. In phytosomes, herbal constituents are associated with phosphatidylcholine molecules, which helps in improving their absorption. They are particularly useful for herbal compounds having poor water solubility. Phytosomes can improve the bioavailability and penetration of herbal phytoconstituents. The chemical bonds formed between phosphatidylcholine molecules provide good stability. They can also improve the percutaneous absorption of herbal constituents. Therefore, phytosomes are useful for improving the delivery and effectiveness of herbal drugs [Figure 3].

Advantages of Phytosomes:

- They improve the bioavailability of herbal constituents.
- They improve the absorption of poorly soluble herbal compounds.
- They provide better stability to the incorporated phytoconstituents.
- They improve the percutaneous absorption of herbal constituents.
- They help in improving the solubility and penetration of suitable drugs.

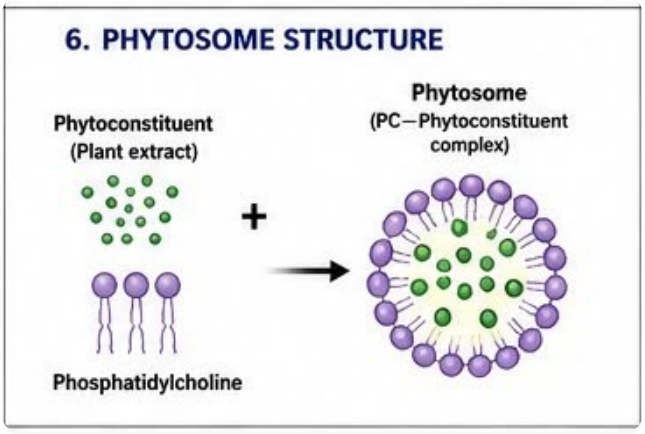


Figure 3. Phytosomes.

Mechanism:

1. Complex Formation:
2. Bonding Mechanism:
3. Vesicle Structure and Dual Compatibility:
4. Enhanced Stability and Reduced Leakage:
5. Gradual Release Mechanism:
6. Evasion of Immune Recognition:
7. Protection from Degradation:

Liposomes

Liposomes are small, spherical vesicles with an aqueous core surrounded by layers of lipid or phospholipid. They are frequently employed in innovative drug delivery systems as carriers. Liposomes can encapsulate both hydrophilic and lipophilic drug molecules because of their special phospholipid structure. Hydrophilic drugs can be present in the aqueous core, while lipophilic drugs can be associated with the lipid bilayer. They are widely used for delivering drugs and have important applications in cancer treatment and infectious diseases. In cancer therapy, liposomes can help deliver drugs while reducing exposure of healthy cells to toxicity [Figure 4].

Advantages of Liposomes:

- They have high biocompatibility.
- They are relatively easy to prepare.
- They can carry hydrophilic, amphiphilic and lipophilic compounds.
- Their pharmacokinetic properties can be modified by changing the chemical composition of the bilayer.
- They can encapsulate drugs having different solubility characteristics.
- They are useful as carriers for targeted drug delivery.
- They can help reduce toxicity associated with some drug treatments.

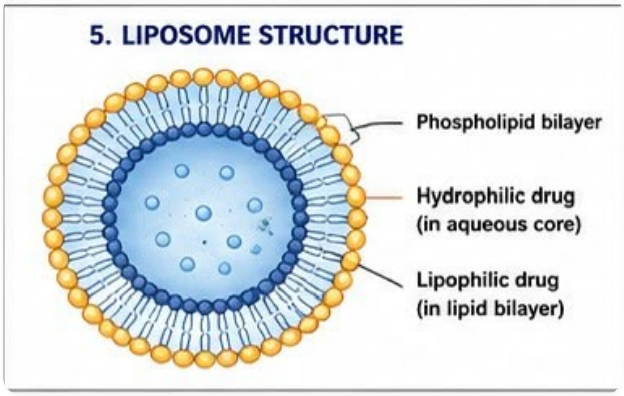


Figure 4. Structure and composition of liposomes.

Mechanism: Liposomes are tiny lipoidal vesicles with a hydrophobic membrane enclosing an aqueous solution. The liposome functions as a drug carrier by fusing with other bilayers, such as the cell membrane, to transport drug molecules to the intended location. Polar drug molecules can be contained in the liposomal core due to its polar nature, but amphiphilic and lipophilic molecules are solubilized inside the phospholipid bilayer itself based on their attraction for phospholipids. Liposomes can consist of many, few, or just a single phospholipid bilayer. During cancer treatment, they encapsulate cytotoxic drugs, which shields healthy cells from toxicity and prevents excessive drug concentration in vulnerable organs like the kidneys and liver, thereby reducing side effects such as nausea and hair loss. Clinically approved liposomal drugs mentioned include liposomal daunorubicin, doxorubicin, amphotericin B, and cytarabine [15].

Nanoparticles

Nanoparticles are very small particles generally having a size of about 10–200 nm. They may be solid and can be either amorphous or crystalline. A drug can be encapsulated or adsorbed by nanoparticles, shielding it from enzymatic and chemical deterioration. They can be helpful for targeted and

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regulated drug distribution due to their small size. As possible medication delivery systems, biodegradable polymeric nanoparticles have garnered a lot of interest. They can be used for delivering drugs, genes, proteins, peptides and enzymes to organs or tissues. Their applications are also important in the delivery of genetic material [Figure 5].

Advantages of nanoparticles:

- They protect the drug from chemical and enzymatic degradation.
- They can provide controlled drug delivery.
- They can help in targeted delivery to tissues or organs.
- They can be used for delivery of drugs as well as proteins, peptides, genes and enzymes.
- Biodegradable nanoparticles can provide controlled release of drugs.

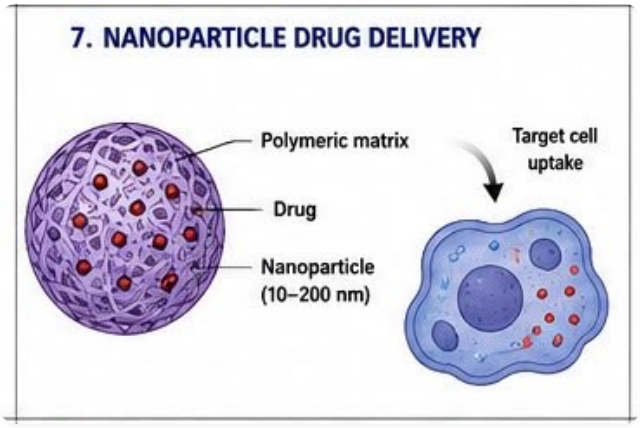


Figure 5. Drug delivery from polymeric nanoparticles to target specific cells.

Mechanism: Nanoparticles are solid particle either amorphous or crystalline ranging in size from about 10 to 200 nm and include forms such as nanospheres and nanocapsules. Their mechanism of drug release is based on controlled diffusion or erosion the drug is released from the core, travels across the polymer matrix or membrane, and the membrane itself acts as a barrier controlling the release rate. Because of this, the solubility and diffusivity of the drug within the polymer membrane become the key determining factors for how the drug is released. Drug loading onto nanoparticles can occur either by adsorption onto the nanoparticle surface (surface-bound) or by entrapment within the nanoparticle matrix (core bound), with the drug added either during polymerization or afterward to a solution of preformed nanoparticles. Nanoparticles protect the drug against chemical and enzymatic degradation and are especially valued for controlled release, tissue/organ targeting, gene therapy (as DNA carriers), and oral delivery of proteins, peptides, and genes. One article adds that improved permeability and the enhanced permeability and retention (EPR) effect arising from leaky, discontinuous tumour vasculature and poor lymphatic drainage allow nanoparticles to preferentially accumulate in tumour tissue, aiding passive targeting.

Emulsions

An emulsion is a biphasic system where tiny droplets of one phase are scattered across another phase. The droplets may have a diameter ranging approximately from 0.1 to 100 µm. In an emulsion, one phase is generally water or an aqueous phase, while the other phase is liquid oil or a non-aqueous phase. Depending on the system, different types of emulsions such as microemulsions, nano emulsions and sub-microemulsions can be prepared. Microemulsions are clear, thermodynamically stable systems, frequently used with a co-surfactant.

Advantages of emulsion-based formulations:

- Because the medication is packed in the inner phase and makes direct contact with bodily tissues more difficult, they can release the drug for an extended period of time.
- They can provide prolonged contact with the body and other tissues.
- Lipophilic medications added to oil-in-water emulsions may become more concentrated in organs like the liver, spleen, and kidney after being phagocytosed by macrophages
- Herbal formulations incorporated into emulsions can improve their stability.
- They can improve the penetration of drugs into skin and mucous membranes.
- Emulsions can therefore be useful for improving the delivery of suitable herbal and other drug substances.

Mechanism:

1. Core Mechanism
2. Formation Process
3. Structural Mechanism (Droplet Architecture)
4. Stabilization Mechanism
5. Degradation Mechanism
6. Stability Classification [16].

Microspheres

Microspheres are tiny, free-moving particles made of synthetic polymers or proteins. They should preferably have a particle size of less than 200 µm and are typically biodegradable. Microspheres can be prepared using both natural and synthetic materials. They fall into two general categories: natural polymers and synthetic polymers.

Synthetic Polymers:

- Poly methyl methacrylate (PMMA)
- Glycidyl methacrylate
- Epoxy polymers
- Lactides, glycosides and their copolymers
- Poly alkyl cyanoacrylates
- Polyanhydrides

Natural Polymers:

Natural materials used for microspheres include proteins and carbohydrates.

Proteins:

- Albumin
- Gelatin
- Collagen

Carbohydrates:

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- Agarose
- Carrageenan
- Chitosan
- Starch

Mechanism: Microspheres as small, typically spherical particles ranging in diameter from about 1 μm to 1000 μm (1 mm), sometimes referred to as micro-particles. They can be prepared from a variety of natural materials (albumin, gelatin, starch, chitosan, collagen) and synthetic polymers (both biodegradable types like lactides/glycosides and poly alkyl cyanoacrylates, and non-biodegradable types like PMMA and epoxy polymers), and can also be made of glass or ceramic. Drug release from microspheres occurs from the formulation into the surrounding environment, allowing the drug to be protected and released over an extended period; the release profile depends on the density and porosity of the sphere (solid versus hollow) and the degradation behaviour of the chosen polymer. Because they can be tailored for specific release profiles, microspheres allow site-specific or even organ-targeted drug release and are used for drug encapsulation, protection of drug function, and prolonged outer-phase release.

Applications: Albumin microspheres can act as carriers for drugs or proteins for site specific or local delivery. They have also been used for targeted drug delivery to tumour cells. Gelatin microspheres can act as carriers for drugs or biological response modifiers. Starch microspheres are carbohydrate-based systems and contain a large number of free hydroxyl groups, through which active ingredients can be incorporated or attached to the surface. Chitosan is a modified product of chitin and becomes positively charged when its amino groups are protonated. These properties make natural polymers useful materials for microsphere-based drug delivery.

Niosomes

Niosomes are tiny lamellar structures made by combining a non-ionic surfactant with cholesterol, a material that induces charge, and then hydrating the mixture with water. They can store therapeutic compounds with varying solubilities since they can have both hydrophobic and hydrophilic moieties. Niosomes can encapsulate drugs and help in their controlled delivery. They have the ability to lower systemic toxicity by encapsulating treatment drugs and reducing the harmful effects of such drugs on the body. Due to their structure, they can entrap different types of medicines [Figure 6].

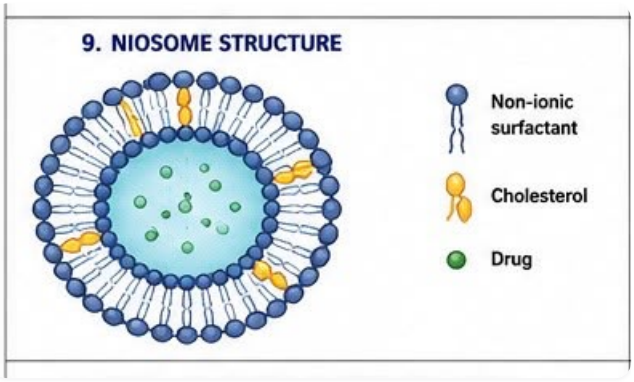


Figure 6. Structure of niosomes.

Mechanism:

1. Formation
2. Forces Maintaining Vesicle Structure
3. Drug Accommodation
4. Therapeutic Action Mechanism
5. Bioavailability Enhancement Mechanism
6. Cellular Uptake Mechanism [17].

Transferosomes

Transferosomes are highly deformable vesicular drug delivery systems. The term is derived from the idea of transferring substances across the body. They are synthetic vesicles that resemble cell vesicles and contain phospholipids along with surfactants. They generally contain about 10–25% surfactant and 3–10% ethanol. Their surfactants act as edge activators and help the vesicles deform and squeeze through the pores of the stratum corneum. Transferosomes can bend and pass through very small pores without appreciable loss. Their high deformability makes them suitable for penetrating the skin. They can act as carriers for both low and high molecular weight medicines. Because of their ability to penetrate the skin, transferosomes are particularly useful for transdermal drug delivery.

Mechanism: Transferosomes are ultra-deformable, phospholipid-based vesicular systems engineered to overcome the barrier properties of the stratum corneum. Their mechanism is rooted in their unique bilayer architecture a combination of phospholipids and edge activators (surfactants) granting exceptional flexibility. This ultra-elastic nature allows them to traverse narrow intercellular spaces in the skin, far smaller than their own size, without causing structural damage.

Transferosomes are drawn into deeper skin layers by the natural transdermal hydration gradient. As water is lost through the skin, osmotic pressure acts as a driving force, propelling the vesicles through the stratum corneum into the viable epidermis and dermis. Edge activators further enhance this by temporarily disrupting lipid packing, allowing the vesicles to deform and squeeze through tight junctions. Once inside deeper skin layers or systemic circulation, transferosomes gradually release their drug payload, ensuring sustained and controlled release.

This enhanced permeation significantly improves drug bioavailability, especially for poorly absorbed molecules with methylphenidate, clindamycin, and tacrolimus formulations achieving higher therapeutic levels than traditional gels or creams. Permeation enhancers like hyaluronic acid or chitosan further amplify skin penetration while maintaining skin integrity.

Transferosomes also enable targeted, localized delivery demonstrated in cutaneous leishmaniasis, dermatitis, and hypertrophic scars reducing systemic exposure and side effects [18].

Ethosomes

Ethosomes are modified liposomal systems developed by incorporating a relatively high concentration of alcohol, mainly ethanol, into the vesicles. They contain phospholipids, alcohol and water. The presence of ethanol makes the vesicles more flexible and improves their ability to penetrate the skin. They can be a few microns or a few nanometers in size. Ethosomes can swiftly enter the skin and have a greater transdermal flow.

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They improve the ability of medicines to pass through the skin during transdermal drug delivery. Ethosomes have applications in medical, veterinary and cosmetic industries. They are therefore useful for delivering suitable drugs through the skin.

Advantages:

- Ethosomes enhance transdermal penetration of drugs.
- They improve the ability of drugs to pass through the skin.
- They can be used for delivering different types of drugs.
- They are useful for topical and transdermal drug delivery.

Mechanism:

The effect of ethanol:

Damage to skin lipids: High quantities of ethanol (20–45%) in ethosomes modify the way lipids are distributed in the stratum corneum (the outermost protective layer of skin). Ethanol lowers the transition temperature and makes the lipids more fluid by interacting with the polar head groups of the lipid bilayers. This makes the skin barrier less stiff, more porous, and less dense.

Better penetration: Ethanol acts as a strong penetration enhancer. It increases drug solubility within ethosomal vesicles and boosts thermodynamic activity, which creates a concentration gradient that drives the drug deeper into the skin. Ethanol also breaks down the stratum corneum barrier, making it easier for the vesicles and their contents to pass through.

Working of ethosomes:

Vesicles that bend and change shape easily: When ethanol penetrates the ethosomes, the phospholipid bilayer becomes less stiff and more flexible. This flexibility allows ethosomes to bend and squeeze through the tiny intercellular gaps between skin cells something many conventional vesicles cannot achieve.

Release of drugs and fusion of vesicles: Within or beyond the stratum corneum, ethosome vesicles may fuse with the skin's lipid matrix. This fusion enables the carried drug to be released directly into the epidermis, and possibly the dermis, or in some formulations, into the systemic circulation. Essentially, ethosomes act as storage containers releasing drugs in a controlled and sustained manner at the target site.

Penetration between and inside cells: Confocal microscopy and molecular studies show that ethosomes predominantly use the intercellular lipid pathway to move across corneocytes without damaging the cells. Some vesicles may rupture and release their contents as they penetrate deeper, while others remain intact, retaining the drug beneath the skin for a longer duration.

Thermodynamic and molecular perspective: Ethosomes treatment lowers the melting point (Tm) and enthalpy of skin lipids, indicating that they become more fluid and less ordered. Unlike harsh chemical penetration enhancers that severely damage or delaminate the skin, ethosomes produce small, reversible changes that permit drug passage while preserving the overall integrity of the skin barrier a finding supported by electron microscopy [19].

Dendrimers

Dendrimers are synthetic particles that possess a specific, well-defined diameter, and they belong to the polymeric system category of drug carriers discussed in the article. Structurally, dendrimers are made up of successive layers of polymer branches that encircle a central core, giving them a highly ordered, tree-like architecture. One of the most useful features of dendrimers is that the medication may bind to them at a number of different locations on their surface, which allows for a relatively high drug-loading capacity compared to simpler carrier systems. Because of this versatility, dendrimers are employed not only in drug delivery but also in medical imaging and gene transfection.

Mechanism: Dendrimers, particularly PAMAM (Poly amidoamine)-type dendrimers, begins with the drug either being encapsulated within the branched internal structure of the dendrimer or conjugated directly onto its surface. Once the dendrimer-drug complex is administered, it circulates systemically throughout the body. It then reaches the target cells through either passive targeting, which relies on the enhanced permeability and retention (EPR) effect caused by leaky tumour vasculature, or active targeting, in which specific ligands attached to the dendrimer surface bind to receptors on the target cells.

Dendrimer is internalized by the target cell, it is able to escape the endosome, following which the drug is released intracellularly. This allows the therapy to be site-specific while significantly reducing toxicity to healthy tissues. Finally, the dendrimer itself is eliminated from the body either through renal excretion or through biodegradation, making it a relatively safe and controllable carrier system.

Monoclonal antibodies

Monoclonal antibodies fall under the biological carrier category described in the article. They represent a single type of identical immunoglobulin, all directed against one particular epitope, or antigenic determinant. This uniformity arises because they are produced by clones of a single parent B-cell, typically through what is known as a hybridoma cell line. A hybridoma cell line itself is created by fusing one B-lymphocyte with one myeloma cell, although some myeloma cells are naturally capable of producing a single type of monoclonal antibody on their own.

Mechanism: Monoclonal antibodies begin with their ability to bind with high specificity to unique antigens present on pathogens, toxins, or diseased cells. Because of this antigen specific binding, monoclonal antibodies are able to detect and neutralize their target they are widely used in assays where they help measure targets, kill microbes, or clump and precipitate antigens. When used in drug delivery systems, this same antigen-binding mechanism is exploited for active targeting: the monoclonal antibody is conjugated onto the surface of a nanoparticle or other carrier, and once the drug-loaded complex circulates in the body, the antibody portion selectively binds to receptors that are overexpressed on the target diseased cells, such as tumour cells. This receptor-specific binding directs the entire carrier system precisely to the disease site, allowing the drug to accumulate selectively at the target while minimizing exposure to healthy tissue.

Applications: Monoclonal antibodies have revolutionized the laboratory diagnosis of various diseases. They are employed both as diagnostic reagents for biochemical analysis and as tools for diagnostic imaging of diseases. Beyond their diagnostic role, monoclonal antibodies are also extremely valuable in active targeting strategies for drug delivery, where they are conjugated onto nanoparticles or other carriers to

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guide the entire drug-loaded system specifically toward receptor-overexpressing diseased cells [20].

Hydrogels

One of the most extensively researched and adaptable classes of innovative drug delivery technologies is hydrogels. Large volumes of water or biological fluids can be absorbed and retained by these three-dimensional, hydrophilic polymeric networks without compromising their structural integrity. Their network topology, which is made up of homopolymers or copolymers made impenetrable by chemical or physical crosslinks such chain entanglements or crystallites, gives them their special ability to hold water.

Hydrogels can be classified in several ways. Based on the method of preparation, they may be categorized as homopolymer hydrogels, co-polymeric hydrogels, or interpenetrating networks. They are categorized as temperature-sensitive hydrogels, pH-sensitive hydrogels, or dual pH-thermal sensitive systems according to how responsive they are to stimuli. They may also be classified according to their mechanism of drug release, namely diffusion-controlled or swelling-controlled systems.

Mechanism: The drug-release mechanism of hydrogels is fundamentally governed by their ability to swell upon contact with water or biological fluids. Because hydrogels exhibit thermodynamic compatibility with water, the polymeric network absorbs fluid and expands as this swelling occurs, the mesh size of the polymer network increases, which in turn increases its permeability and creates channels through which the entrapped drug can diffuse outward. This forms the basis of the swelling-controlled release mechanism.

Hydrogels can also function within reservoir-based controlled-release systems, where the drug is enclosed by the hydrogel material, and release occurs at a rate governed by diffusion of the drug through the swollen polymer matrix rather than by the swelling process itself. This is referred to as diffusion-controlled release [Figure 7].

A particularly notable feature of hydrogels is their ability to act as enviro intelligent or stimuli-responsive systems. In these systems, the degree of swelling and consequently the rate of drug release can be modulated in response to specific external or physiological triggers such as pH, temperature, ionic strength, electric field, or the concentration of particular analytes. For example, a pH-sensitive hydrogel may remain compact and release minimal drug in the acidic environment of the stomach but swell and release the drug once it reaches the higher pH of the intestine. Similarly, temperature sensitive hydrogels may undergo a sharp change in swelling behaviour at body temperature, triggering drug release at the target site [20].

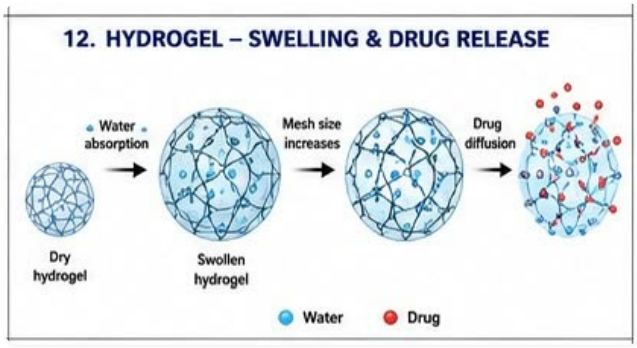


Figure 7. Schematic representation of drug release and water absorption in hydrogels.

Advantages

1. Improved drug efficiency and efficacy.
2. Decreased development of drug resistance.
3. Enhanced bioavailability of some medications.
4. Potential for personalized and combination therapy.
5. A decrease in overall drug uses when compared to traditional therapy.
6. Decrease in systemic or local drug toxicity.

Disadvantages

1. Rapid clearance of drug carriers from circulation.
2. Inadequate accumulation in target tissues or tumours.
3. Challenges in ensuring stability and reproducibility of the delivery system.
4. Not all medications can be formulated into a dosage form [21].

Evaluation parameters of NDDS

Particle size analysis

A scanning electron microscope was used to measure the nanoparticles' size, which varied according to the polymer load and ranged from 350 to 600 nm.

Drug entrapment efficiency

The prepared nanoparticle suspensions were centrifuged for 30 minutes at 2000 rpm. After gathering the supernatant, the particles were cleaned with water and put through another centrifugation cycle. The UV-Visible Spectrophotometer was used to measure the amount of free drug in the supernatant.

Zeta potential

Using a zeta sizer (Malvern Instruments), the electrophoretic mobility in a micro electrophoresis flow cell was used to calculate the zeta potential of the drug-loaded chitosan nanoparticles [14,15].

In vitro drug release using dialysis tube

The dialysis membrane method was used to conduct the in vitro drug release investigation. The produced drug-loaded nanoparticles were submerged in a receptor compartment with 250 mL of phosphate buffer (pH 6.8) after being put in a dialysis tube with 10 mL of phosphate buffer (pH 7.4). A magnetic stirrer was used to continually agitate the receptor media, and the temperature was kept at 37 ± 1°C. Five milliliters of the sample were removed at prearranged intervals and replaced with an equivalent volume of brand-new buffer. The study was conducted for a whole day, and the cumulative percentage of medication released was calculated using spectrophotometric analysis of the collected samples.

Accelerated stability study

The samples were kept in environmental simulation chambers for consistent climate settings after the nanoparticles were placed in borosilicate glass vials. The stability study's storage settings and the times at which the samples were examined in accordance with International Conference on Harmonization (ICH) criteria [22].

Preparation methods of NDDS

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Diffusion-controlled release

This method regulates drug release through diffusion, where drug molecules move from an area of higher concentration to one of lower concentration. A core tablet is prepared first, and it is then coated with insoluble polymers. Tablet powder is mixed together with an insoluble polymer, and this mixture is compressed into a tablet.

Dissolution-controlled release

This method relies on the slow dissolution of the drug or its carrier matrix in bodily fluids, after which the drug becomes bioavailable for absorption. Reservoir Dissolution Control: Drug granules are prepared, then coated with different concentrations of a slowly soluble polymer, and the coated granules are packed into a capsule. Matrix Dissolution Control: Tablet powder is mixed with a slowly soluble polymer, and this mixture is compressed into a tablet.

Erosion-controlled release

Drug release occurs as the polymeric carrier erodes or breaks down. This is especially important in biodegradable systems, where the matrix breaks down gradually due to external factors like pH or enzymatic activity. It occurs through bulk erosion, where the whole polymer matrix degrades uniformly, or surface erosion, where the system deteriorates layer by layer from the outside inward, with drug release rate directly correlated to the erosion rate.

Osmotically controlled release

Drug release is governed by osmotic pressure, created when water passes through a semi-permeable membrane into the drug delivery device. This pressure forces the drug solution through a tiny opening at a predetermined pace, producing a steady, zero-order release regardless of surrounding conditions.

Swelling-controlled release

This method uses hydrophilic polymers that draw in water, causing the matrix to swell. The swelling increases the polymer's permeability or creates channels that allow the drug to diffuse out. Hydrogels are commonly used for this type of release since their swelling kinetics can be precisely controlled.

Release Sensitive to pH

Drug release is triggered by changes in the surrounding pH environment. These systems use polymers that either dissolve or swell depending on the pH. For example, a drug intended for intestinal release can be enclosed in a polymer that remains solid in the stomach's acidic environment but dissolves in the intestine's basic pH..

Targeted release (Ligand-Mediated)

Drugs are delivered to specific tissues or cells using targeting ligands such as small molecules, peptides, or antibodies that bind to particular receptors on target cells. Once the delivery system binds to the target site, the drug is released through endocytosis or other triggered mechanisms.

Stimuli-responsive release

This method releases the drug in response to external stimuli such as light, magnetic fields, temperature, or ultrasound. Temperature-responsive systems release the drug when the polymer matrix expands or contracts due to temperature changes; light-responsive systems release the drug through a chemical or physical change triggered by specific light wavelengths; and magnetically triggered systems contain magnetic nanoparticles activated by an external magnetic field.

Ion-exchange controlled release:

In this method, the drug-loaded polymer exchanges ions with surrounding biological fluids. Controlled drug release occurs when counter-ions present in the bodily fluid displace the drug that is bound to an ion-exchange resin.

Release triggered by ultrasound

Ultrasound waves cause mechanical vibrations or heating, which leads to the breakdown of the drug carrier or increased permeability of the matrix. This facilitates drug release in response to ultrasonic exposure, allowing targeting of particular tissues or regions [23].

Applications

Cancer therapy: In cancer, targeted delivery of drug is essential because it maximizes drug concentration at tumor areas while reducing harm to healthy cells. Gene therapy modifies or replaces cancer cells' faulty genes Suicide gene therapy, gene editing, gene substitution, and immunotherapy augmentation are among methods.

Transdermal drug delivery: Transdermal patches present a novel, non-invasive insulin delivery option. They can do away with the requirement for numerous daily injections and are made to deliver regulated insulin release over a period of time.

Pulmonary diseases: TDDS, which uses inhaled nanoparticles or gene carriers, provides localized treatment with better efficacy and fewer adverse effects for conditions like asthma, COPD, and cystic fibrosis.

Neurodegenerative diseases: Nerve cells gradually deteriorate in neurodegenerative diseases. The efficacy of treatment for conditions like Parkinson's and Alzheimer's is improved by targeted transport across the blood-brain barrier (BBB) using ligands, nanocarriers, or gene therapy.

Cardiovascular diseases: By delivering medications straight to the damaged cardiac regions, TDDS can maximize effectiveness while reducing systemic exposure. Methods include liposomes, micelles for controlled release, and nanoparticles for drug encapsulating.

Recent advances in novel drug delivery systems

In recent years, significant progress in Novel Drug Delivery Systems (NDDS) has been driven largely by the integration of nanotechnology and advanced biomaterials. These developments aim to overcome the limitations associated with conventional drug therapy, such as poor solubility, low bioavailability, rapid systemic clearance, and nonspecific drug distribution. Nanotechnology-based delivery platforms have enabled the design of sophisticated carrier systems capable of improving drug stability, enhancing tissue targeting, and optimizing therapeutic performance, particularly in the treatment of complex diseases such as cancer.

Various nanocarrier platforms including nanoparticles, dendrimers, polymeric micelles, liposomes, polymer drug conjugates, exosomes, and polymerases have been extensively investigated for their ability to improve drug delivery efficiency while reducing systemic toxicity and adverse effects.

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These advanced systems offer controlled drug release, improved pharmacokinetics, and enhanced cellular uptake, thereby increasing therapeutic effect [Figure 8].

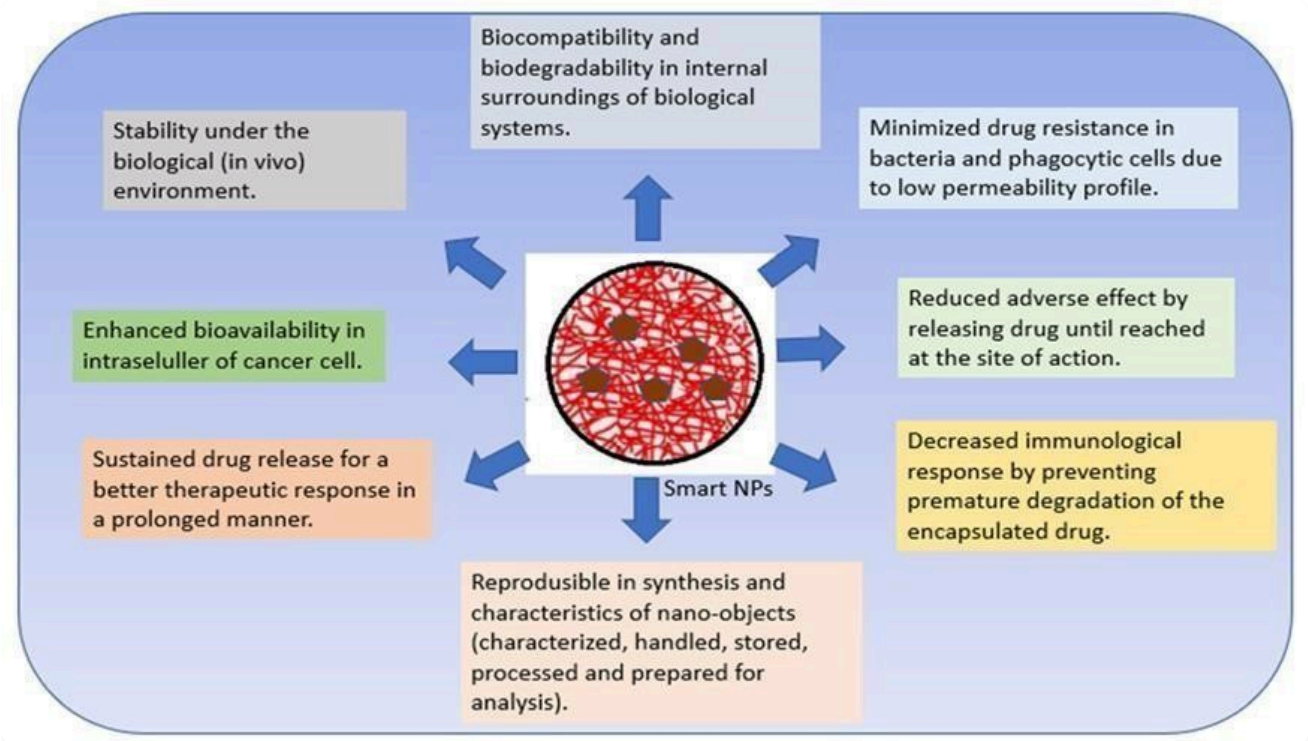


Figure 8. Recent advances of novel drug delivery system.

Novel drug delivery system for diabetes management

Recent developments in drug delivery systems, such as oral, inhalable, and transdermal techniques, as well as the use of nanotechnology and glucose responsive smart systems in diabetes treatment, are given in this article.

Oral insulin delivery systems

Because it is non-invasive and can mimic the physiological pathway of endogenous insulin secretion, oral insulin administration is regarded as the "holy grail" of diabetes treatment. The main problems with oral insulin are low intestinal epithelium permeability and its breakdown by digestive enzymes in the gastrointestinal tract.

Systems for transdermal drug delivery

Transdermal patches present a novel, non-invasive insulin delivery option.

They can do away with the requirement for numerous daily injections and are made to deliver regulated insulin release over an extended period of time. Microneedle Patches: These devices use tiny needles to gently pierce the skin and administer insulin or other diabetic drugs. One such example that is being developed is the microneedle patch from Zosen Pharma. Benefits: The ease of use of these patches increases patient adherence, and they may lead to more reliable glucose control. Challenges Concerns about skin irritation, variations in absorption rates according to skin type, and the necessity of additional research on long-term use still need to be addressed.

Recent advances in niosomes

Recent innovations in niosomal drug delivery systems have primarily focused on improving vesicle stability, enhancing site-specific targeting, and achieving precise control over drug release kinetics. Advances in surface engineering techniques have enabled the modification of niosomes with targeting ligands such as peptides, antibodies, and other biomolecules. These modifications facilitate receptor-mediated uptake and improve drug accumulation at diseased tissues while minimizing unwanted systemic exposure.

The application of modern pharmaceutical design strategies, including Quality by Design (QbD) and Design of Experiments (DoE) methodologies, has further enhanced the development of niosomal formulations. These approaches allow systematic optimization of formulation parameters, thereby improving reproducibility, scalability, and drug bioavailability. Such developments highlight the increasing relevance of niosomes in contemporary drug delivery research.

Recent advances in liposomes

Recent progress in liposomal drug delivery systems has largely centred on the development of long circulating and targeted formulations designed to improve therapeutic selectivity. Nano-enabled liposomal carriers have become highly valuable in cancer therapy because they address several limitations associated with traditional chemotherapeutic regimens, including poor aqueous solubility, rapid systemic elimination, and lack of site-specific delivery.

Liposomes have received substantial research attention due to their excellent biocompatibility, reduced toxicity, high drug-loading capability, and ability to enhance drug bioavailability. Contemporary research is focused on developing stealth

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liposomes and actively targeted liposomal formulations that can evade immune clearance while selectively delivering drugs to tumour tissues.

Recent advances in microspheres

Microsphere-based drug delivery systems have emerged as promising approaches for achieving controlled, sustained, and targeted drug delivery. These spherical carriers can encapsulate therapeutic agents within biodegradable polymeric matrices and release the drug gradually over an extended period.

Recent developments have focused on improving drug encapsulation, targeted delivery, controlled release, and therapeutic efficacy. Microspheres can be administered through oral, injectable, and inhalational routes, providing flexibility in drug delivery. In cancer therapy, PLGA-based microspheres have shown potential for localized delivery of anticancer drugs to tumour sites, which may reduce systemic toxicity and improve treatment effectiveness.

Future prospects of NDDS

Personalized medicine

Personalized medicine is one of the most promising future applications of NDDS. It focuses on tailoring drug therapy according to an individual's genetic makeup, age, disease condition, and physiological characteristics. NDDS helps in delivering the right drug at the right dose and at the right time. This approach improves therapeutic efficacy and reduces adverse effects. Advanced delivery systems can adjust drug release based on patient specific requirements. Personalized medicine is expected to play a major role in the treatment of cancer, diabetes, and cardiovascular diseases. It will improve treatment outcomes and enhance patient quality of life

Targeted drug delivery

Targeted drug delivery aims to deliver drugs directly to the site of action while minimizing exposure to healthy tissues. NDDS uses carriers such as nanoparticles, liposomes, and monoclonal antibodies for site-specific delivery. This approach reduces systemic toxicity and improves drug effectiveness. It is particularly beneficial in cancer therapy where anticancer drugs can be directed specifically to tumour cells. Targeted delivery also reduces the required dose and frequency of administration. It increases patient safety and therapeutic success. Future developments are expected to make targeted therapy more precise and efficient.

Nanotechnology

Nanotechnology has revolutionized the field of NDDS by enabling the development of nanosized drug carriers. Nanoparticles improve drug solubility, stability, and bioavailability. They can cross biological barriers and reach specific target sites more effectively. Liposomes, dendrimers, nano sponges, and polymeric nanoparticles are widely used nanocarriers. These systems help in controlled and sustained drug release.

Nanotechnology also plays an important role in cancer diagnosis and treatment. Future advancements will further improve drug targeting and therapeutic outcomes.

Stimuli-responsive (Smart) drug delivery systems

Smart drug delivery systems release drugs in response to specific physiological stimuli such as pH, temperature, enzymes, light, or magnetic fields. These systems provide controlled and precise drug release only when needed. This minimizes drug wastage and reduces side effects. Smart systems improve therapeutic efficiency and patient compliance. They are especially useful in the treatment of cancer and chronic diseases. Researchers are developing more advanced responsive materials for better performance. Such systems represent a significant advancement in modern drug delivery technology.

Gene therapy and RNA-based drug delivery

NDDS plays a vital role in the delivery of genes, DNA, RNA, and siRNA to target cells. These therapies can correct genetic defects or suppress disease-causing genes. Gene delivery systems protect genetic material from degradation before reaching the target site. They offer promising treatment options for inherited disorders, cancer, and viral infections. RNA interference technology has shown great potential in controlling disease progression. NDDS improves the efficiency and safety of gene therapy. Future research is expected to expand its clinical applications significantly.

Non-invasive drug delivery systems

Future NDDS focuses on developing non-invasive routes of drug administration. Transdermal patches, nasal sprays, pulmonary delivery systems, and buccal formulations eliminate the need for injections. These methods improve patient comfort and acceptance. They also reduce the risk of infection associated with invasive procedures. Non-invasive systems can provide controlled and sustained drug release. Such delivery methods are especially beneficial for paediatric and geriatric patients. Continuous advancements will make drug administration more convenient and effective.

Biodegradable and biocompatible drug carriers

Biodegradable and biocompatible materials are increasingly used in NDDS to enhance safety and efficacy. These carriers degrade naturally into non-toxic products after releasing the drug. They eliminate the need for surgical removal of delivery devices. Common materials include biodegradable polymers, hydrogels, and natural biomaterials. These systems provide sustained and controlled drug release. They also reduce long-term toxicity and adverse reactions. Future research will focus on developing more efficient and environmentally friendly carrier systems.

Advanced monitoring and feedback systems

Modern NDDS is being integrated with biosensors and digital technologies for real-time monitoring of therapy. These systems can measure drug levels and physiological parameters continuously. Feedback mechanisms help adjust drug release according to patient needs. This improves treatment accuracy and safety. Such technologies are particularly useful in chronic disease management. They enable healthcare professionals to monitor treatment effectiveness remotely. Future smart healthcare systems will heavily rely on these advanced drug delivery platforms.

Future scope and opportunities in India

India has emerged as a major hub for pharmaceutical research and manufacturing. Increasing investments in NDDS research are driving innovation in drug delivery technologies. The growing burden of chronic diseases creates a demand for advanced therapeutic systems. Government initiatives and collaborations between academia and industry are supporting

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development in this field. India has significant potential in the production and export of novel drug delivery products. The country is also witnessing growth in patents and clinical research activities. NDDS offers vast opportunities for researchers, pharmacists, and pharmaceutical industries in the future.

Controlled and sustained release drug delivery

Among the most significant developments in NDDS are controlled and sustained release systems. For prolonged periods, these systems keep the medication concentration within the therapeutic range. They increase patient compliance and decrease the frequency of doses. Sustained release formulations help in the effective management of chronic diseases such as hypertension, diabetes, and asthma. They minimize fluctuations in plasma drug concentration and reduce side effects. Such systems improve therapeutic efficiency and patient convenience. Future developments will focus on achieving more precise and predictable drug release profiles [Table 1].

Table 1. Comparative evaluation of novel drug delivery technologies.

Novel drug delivery system	Key features/mechanism	Major advantages	Major limitations/challenges	Representative therapeutic applications	Translational potential
Polymeric nanoparticles	Drugs are encapsulated, entrapped, or adsorbed within biodegradable or biocompatible polymeric matrices	Controlled/sustained release; protection of drugs from degradation; possibility of surface functionalization and targeting	Formulation complexity; potential toxicity depending on polymer; stability and scale-up challenges	Cancer therapy, antimicrobial therapy, CNS drug delivery, protein/peptide delivery	**High**, provided reproducibility, safety, and scalable manufacturing are established
Lipid nanoparticles (LNPs)	Lipid-based nanocarriers encapsulate and protect therapeutic molecules and facilitate cellular uptake	High capacity for nucleic acids; improved intracellular delivery; biocompatibility; clinically validated platform	Physical/chemical instability; formulation optimization; potential immunogenicity; storage requirements	mRNA delivery, vaccines, gene therapy, anticancer therapeutics	**High,** particularly for nucleic-acid therapeutics
Liposomes	Phospholipid bilayer vesicles capable of carrying hydrophilic and lipophilic drugs	Improved drug solubility and stability; reduced systemic toxicity for some drugs; versatile drug loading	Drug leakage; oxidation; relatively complex manufacturing; stability concerns	Cancer, antimicrobial therapy, vaccines, targeted therapy	**High**, with several formulations already clinically established
Polymeric micelles	Amphiphilic polymers self-assemble into micelles with a hydrophobic core and hydrophilic shell	Particularly useful for poorly water-soluble drugs; improved solubility; relatively small particle size	Limited drug-loading capacity for some drugs; dilution-induced instability; premature drug release	Anticancer and poorly soluble drug delivery	**Moderate–High**, depending on formulation stability and clinical evidence
Dendrimers	Highly branched, nanoscale polymers with multiple surface functional groups	Precise molecular architecture; high surface functionality; potential for drug conjugation and targeting	Complex synthesis; possible cytotoxicity; relatively high production cost	Targeted drug delivery, gene delivery, imaging	**Moderate**, with safety and manufacturing remaining important considerations
Niosomes	Non-ionic surfactant-based vesicles that encapsulate therapeutic agents	Improved drug stability; ability to carry hydrophilic and lipophilic compounds; potentially lower cost than some lipid systems	Physical instability; aggregation; drug leakage; limited clinical translation	Topical, transdermal, anticancer, and antimicrobial delivery	**Moderate**, requiring further standardization and clinical validation
Transfersomes/Ethosomes	Highly deformable or ethanol-containing vesicular systems designed primarily for enhanced skin penetration	Improved transdermal delivery; non-invasive administration; useful for molecules with poor skin permeability	Formulation sensitivity; physical instability; limited systemic applications	Transdermal delivery of analgesics, anti-inflammatory agents, hormones, and other drugs	**Moderate**, particularly for localized/transdermal therapy
Dendritic/targeted nanocarriers	Surface ligands or antibodies facilitate preferential interaction with specific cells or receptors	Potential for site-specific delivery; reduced off-target exposure; improved therapeutic index	Target heterogeneity; ligand stability; complex manufacturing; biological barriers	Cancer, inflammatory diseases, CNS and receptor-targeted therapies	**Moderate–High**, but clinical efficacy depends strongly on target biology
Stimuli-responsive systems	Drug release is triggered by pH, temperature, enzymes, redox conditions, light, or other stimuli	On-demand or site-specific release; potential reduction of systemic exposure	Complex formulation; unpredictable physiological conditions; challenges in reproducibility and scale-up	Cancer, localized therapy, intracellular delivery	**Emerging**, requiring extensive in vivo and clinical validation
Microneedle systems	Microscopic projections create temporary pathways across the skin for drug delivery	Minimally invasive; improved transdermal delivery; potential for self-administration; improved patient compliance	Limited drug-loading capacity; fabrication challenges; skin variability	Vaccines, peptides, proteins, hormones, and transdermal therapeutics	**Moderate–High**, particularly for vaccines and selected systemic therapies

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Table 1 (continued)

Novel drug delivery system	Key features/mechanism	Major advantages	Major limitations/challenges	Representative therapeutic applications	Translational potential
Exosome/extracellular-vesicle delivery	Naturally derived vesicles transport proteins, lipids, nucleic acids, or incorporated therapeutic molecules	Potential biocompatibility; intrinsic cellular communication properties; potential biological targeting	Isolation and purification; batch variability; characterization; loading efficiency; regulatory challenges	RNA delivery, regenerative medicine, cancer and CNS research	**Emerging**, with major manufacturing and regulatory barriers
Implantable/long-acting systems	Drug reservoirs or biodegradable matrices provide prolonged drug release at predetermined rates	Reduced dosing frequency; sustained therapeutic concentrations; improved adherence	Invasive placement for some systems; dose adjustment can be difficult; manufacturing complexity	Hormone therapy, cancer therapy, chronic diseases	**High** for suitable long-term therapies
In situ drug delivery systems	Formulation undergoes gelation or structural transformation after administration	Prolonged local retention; controlled release; reduced dosing frequency	Premature gelation, formulation stability, administration-related issues	Ocular, injectable, periodontal, and localized therapies	**Moderate–High**, depending on route and formulation

Conclusion

Novel drug delivery technologies have substantially expanded the possibilities for improving drug solubility, stability, bioavailability, controlled release, and site-specific delivery. However, the advantages of individual platforms vary according to the therapeutic agent, delivery route, target tissue, formulation characteristics, and intended clinical application. Although nanocarriers, liposomes, polymeric systems, stimuli-responsive platforms, microneedles, and biological delivery systems have demonstrated considerable potential, important challenges remain concerning reproducibility, toxicity, stability, scale-up, manufacturing, regulatory approval, and clinical translation.

The current evidence therefore supports continued development of these technologies while emphasizing the need for standardized evaluation and clinically relevant validation. Future research should integrate formulation science with pharmacokinetic, toxicological, mechanistic, and clinical investigations. Greater attention to scalable manufacturing, quality control, personalized delivery approaches, and regulatory requirements will be essential for translating cutting-edge drug delivery technologies from experimental platforms into reliable therapeutic products.

Data Availability

This manuscript is a review article. No new experimental data were created or examined in this study. All the data mentioned can be found in the references that are cited in the manuscript.

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Conflict of Interest

The Authors declare no conflict of Interests.

Authors Contribution

Raghavendra Kumar Gunda: Conceptualisation, writing (original draft), writing (review and editing), project administration, and corresponding author.

J.N. Suresh Kumar : Writing (review and editing), Supervision.

Jampana Lakshmi : Literature collection.

Jada Vydhurya : Literature collection.

Jarapala Saikiran Naik : Literature collection.

Jonnalagadda Lalitha Varshini : Literature collection, writing (review and editing).

Katta Reshma: Literature collection.

All authors have read and approved the final version of the manuscript.

Ethics Declaration

This article provides an overview of existing literature. It does not include data from human participants, animal studies, clinical trials, or any materials that would require ethical review by an institutional committee. There was no need for ethics committee approval for this work.

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