

Novel Drug Delivery System

Shirsath Kamlesh S, Rathod Sujit S, Shekade Umesh N, Palve Ranjit G, Langhe Kiran S

Sahakar Maharshi Kisanrao Varal Patil College of Pharmacy, Nighoj

Assistant Professor, Sahakar Maharshi Kisanrao Varal Patil College of Pharmacy, Nighoj

Abstract: *Novel drug delivery systems (NDDS) are advanced technologies designed to improve the therapeutic efficacy, safety, and patient compliance of conventional drugs. These systems aim to deliver drugs in a controlled, targeted, and sustained manner, overcoming limitations such as poor solubility, rapid metabolism, and systemic side effects. NDDS encompass a variety of strategies, including nanoparticles, liposomes, micelles, hydrogels, dendrimers, and polymeric carriers, each offering unique advantages in terms of bioavailability, site-specific targeting, and controlled release. The integration of smart materials and stimuli-responsive mechanisms further enables precision therapy, minimizing off-target effects and enhancing treatment outcomes. Ongoing research focuses on optimizing formulation stability, reducing toxicity, and enabling personalized medicine approaches. The development and implementation of novel drug delivery systems hold significant potential to revolutionize the treatment of chronic diseases, cancer, neurological disorders, and infectious diseases.*

Keywords: Novel drug delivery system, controlled release, targeted therapy, nanoparticles, liposomes, polymeric carriers, bioavailability, stimuli-responsive delivery, precision medicine

I. INTRODUCTION

The field of drug delivery has undergone remarkable evolution over the past few decades, driven by the need for more effective, targeted, and patient-friendly therapies. Traditional drug administration methods, such as oral or intravenous routes, often face challenges including poor bioavailability, rapid metabolism, and systemic side effects. To overcome these limitations, **Novel Drug Delivery Systems (NDDS)** have been developed, integrating advanced technologies to optimize the therapeutic effects of drugs while minimizing adverse reactions.[1]

NDDS encompass a variety of strategies, including controlled-release formulations, targeted delivery, and nanotechnology-based carriers, which allow precise modulation of drug release and distribution within the body. These systems not only enhance the efficacy and safety of drugs but also improve patient compliance by reducing dosing frequency and simplifying administration. Furthermore, NDDS open new possibilities for the delivery of drugs that are otherwise unstable, poorly soluble, or rapidly metabolized.

With continuous research and innovation, novel drug delivery systems are transforming pharmaceutical therapy, offering tailored solutions for complex diseases such as cancer, diabetes, and neurological disorders. The development of these systems represents a significant shift from conventional therapy towards more personalized and efficient treatment approaches.[2]

The effectiveness of a drug is not solely determined by its chemical properties, but also by the way it is delivered to the body. Conventional drug delivery methods, such as oral tablets, injections, or topical formulations, often face significant limitations, including poor solubility, rapid degradation, nonspecific distribution, and suboptimal therapeutic levels. These challenges can result in reduced efficacy, increased side effects, and poor patient compliance.

Novel Drug Delivery Systems (NDDS) have emerged as a promising solution to address these challenges by enhancing the precision, efficiency, and safety of drug therapy. These systems are designed to deliver the active pharmaceutical ingredient in a controlled manner, targeting specific tissues or cells, and often utilizing advanced technologies such as nanoparticles, liposomes, microspheres, hydrogels, and biodegradable polymers. By controlling the release rate and distribution of drugs, NDDS can maintain therapeutic concentrations over extended periods, minimize toxicity, and improve the overall patient experience.[3]



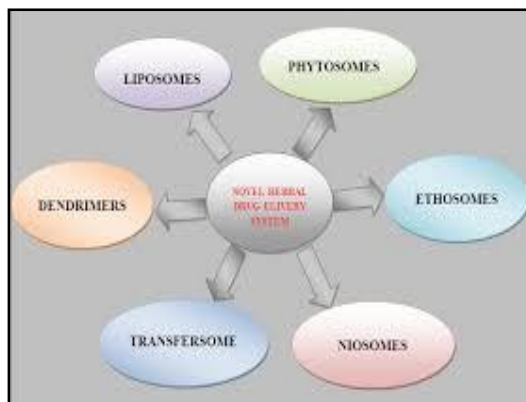


Fig 1. Novel

Definition:

A **Novel Drug Delivery System (NDDS)** refers to an advanced method or technology designed to deliver drugs in a controlled, targeted, and efficient manner, aiming to improve therapeutic outcomes while minimizing side effects. Unlike conventional drug delivery methods, NDDS focuses on optimizing the rate, time, and site of drug release in the body, often using innovative carriers such as nanoparticles, liposomes, microspheres, hydrogels, or biodegradable polymers. These systems enhance drug stability, bioavailability, and patient compliance, and enable delivery of drugs that are otherwise poorly soluble, unstable, or rapidly metabolized.[5]

Objectives of Novel Drug Delivery Systems

Enhance Therapeutic Efficacy:

NDDS aim to improve the effectiveness of drugs by maintaining optimal therapeutic concentrations at the target site for a desired duration.

Controlled and Sustained Release:

One key objective is to regulate the rate and duration of drug release, reducing the frequency of dosing and avoiding fluctuations in drug levels.[7]

Targeted Drug Delivery

NDDS are designed to deliver drugs specifically to the diseased site (e.g., tumor cells or infected tissues), minimizing exposure to healthy tissues and reducing side effects.

Improve Bioavailability:

Many drugs have poor solubility or are rapidly metabolized; NDDS enhance absorption and stability, ensuring more of the active drug reaches systemic circulation.

Reduce Toxicity and Side Effects:

By delivering drugs precisely and in controlled amounts, NDDS help minimize systemic toxicity and adverse reactions associated with conventional therapy.[11]

Patient Compliance and Convenience:

Sustained or controlled-release formulations reduce dosing frequency, simplify administration, and improve adherence, especially for chronic conditions.

Enable Delivery of Difficult Drugs:

NDDS facilitate the use of drugs that are unstable, poorly soluble, or rapidly degraded, expanding the range of therapeutically viable compounds.

Innovative Routes of Administration:

NDDS support alternative delivery methods such as transdermal, nasal, pulmonary, or ocular routes, offering non-invasive options for patients.



Detailed Advantages of Novel Drug Delivery Systems

Improved Therapeutic Effectiveness:

NDDS are designed to deliver the drug directly to the site of action, ensuring that a higher proportion of the administered dose reaches the target tissue. For example, in cancer therapy, liposomal formulations of anticancer drugs can accumulate preferentially in tumor tissues, increasing the drug's effectiveness while sparing normal cells. This targeted approach enhances the overall therapeutic outcome compared to conventional formulations.[13]

Controlled and Sustained Drug Release:

Many NDDS are formulated to release drugs slowly over time. This controlled release prevents the peaks and troughs of drug concentration that often occur with traditional dosing. For instance, biodegradable polymeric microspheres can release an anti-inflammatory drug over several days or weeks, maintaining a constant therapeutic level without repeated administration. This is particularly beneficial for chronic diseases like diabetes or arthritis.

Reduced Side Effects and Toxicity:

By targeting drugs specifically to diseased tissues, NDDS minimize the exposure of healthy tissues to potent drugs, which reduces systemic toxicity. For example, nanoparticle-based chemotherapy delivers drugs directly to tumors, lowering the toxic effects on healthy organs like the liver and kidneys. This leads to safer treatment options and improved patient tolerance.

Enhanced Bioavailability:

Some drugs have poor solubility, are unstable in the gastrointestinal tract, or are rapidly metabolized by the liver, leading to low bioavailability. NDDS, such as solid lipid nanoparticles or self-emulsifying drug delivery systems, protect these drugs and improve absorption. This means more of the active drug reaches systemic circulation, enhancing efficacy without increasing the dose.[17]

Patient Convenience and Compliance:

Sustained-release and controlled-release formulations reduce the frequency of dosing. Instead of taking a drug multiple times a day, patients may need it only once daily or even less frequently. For example, transdermal patches for pain management or hormonal therapy allow continuous drug delivery, improving adherence, especially in elderly patients or those with chronic conditions.

Ability to Deliver Difficult Drugs:

Some drugs are unstable in the body, poorly soluble, or rapidly metabolized. NDDS can encapsulate or modify these drugs to protect them until they reach their target. For example, insulin cannot be given orally in its conventional form because it is broken down in the digestive tract, but NDDS like nanoparticles or liposomes offer potential oral or non-invasive delivery routes.

Versatile Routes of Administration:

NDDS enable alternative routes beyond oral or intravenous delivery. Drugs can be administered transdermally (through the skin), nasally, pulmonary (inhaled), or ocularly (eye drops), offering flexibility and convenience. For example, nasal sprays using nanocarriers can deliver drugs directly to the brain, bypassing the blood-brain barrier—a feat not possible with standard oral delivery.

Potential for Personalized Therapy:

NDDS allow customization of drug release profiles and targeting strategies according to patient-specific factors such as age, metabolism, or disease stage. For example, controlled-release implants in oncology can provide localized chemotherapy at a rate adjusted for tumor growth, tailoring treatment to individual patient needs.[19]

Types of Novel Drug Delivery Systems

Novel Drug Delivery Systems can be classified based on their design, mechanism of action, or route of administration. Here are the major types:

1. Nanoparticle-Based Drug Delivery Systems

Description: Nanoparticles are tiny particles (1–100 nm) that can carry drugs either within their core or attached to their surface.

Examples: Solid lipid nanoparticles, polymeric nanoparticles, dendrimers, and gold nanoparticles.



Advantages: Improve solubility, protect drugs from degradation, allow targeted delivery, and can cross biological barriers (like the blood-brain barrier).

Applications: Cancer therapy, targeted gene delivery, vaccines.[23]

2. Liposomes and Niosomes

Description: Spherical vesicles made of phospholipid bilayers (liposomes) or non-ionic surfactants (niosomes) that encapsulate drugs.

Advantages: Reduce toxicity, improve bioavailability, enable controlled release, and allow targeted delivery.

Applications: Chemotherapy drugs, antifungal agents, vaccines.

3. Microspheres and Microcapsules

Description: Small spherical particles (microspheres) or capsules (microcapsules) made of biodegradable polymers, which can entrap drugs.

Advantages: Provide sustained and controlled release, protect drugs from degradation, reduce dosing frequency.

Applications: Hormone therapy, vaccines, anti-inflammatory drugs.

4. Hydrogels

Description: Three-dimensional, water-absorbing polymer networks capable of carrying drugs.

Advantages: Can be designed for controlled release, biocompatible, and suitable for local drug delivery.

Applications: Wound healing, ocular delivery, tissue engineering, transdermal patches.[25]

5. Transdermal Drug Delivery Systems (TDDS)

Description: Patches or gels that allow drugs to be absorbed through the skin into systemic circulation.

Advantages: Avoid first-pass metabolism, provide sustained release, and improve patient compliance.

Applications: Pain management, hormonal therapy, cardiovascular drugs.

6. Targeted Drug Delivery Systems

Description: Systems designed to deliver drugs specifically to target cells or tissues using ligands, antibodies, or magnetic guidance.

Advantages: Increase drug concentration at diseased sites, minimize side effects, and improve therapeutic efficiency.

Applications: Cancer therapy, targeted antibiotic therapy.[24]

7. Gene and Nucleic Acid Delivery Systems

Description: Vehicles designed to deliver genetic material such as DNA, RNA, or siRNA into cells.

Advantages: Enable treatment of genetic disorders, cancers, or viral infections by modifying gene expression.

Applications: Gene therapy, mRNA vaccines.

8. Inhalation and Pulmonary Delivery Systems

Description: Aerosols or dry powder formulations that deliver drugs directly to the lungs.

Advantages: Rapid onset, high local concentration, reduced systemic exposure.

Applications: Asthma, chronic obstructive pulmonary disease (COPD), pulmonary infections.

9. Ocular Drug Delivery Systems

Description: Specialized systems for delivering drugs to the eye, including implants, gels, and nanoparticles.

Advantages: Overcome barriers like poor corneal penetration, provide sustained release, reduce dosing frequency.

Applications: Glaucoma, macular degeneration, ocular infections.



10. Oral Controlled-Release Systems

Description: Tablets, capsules, or pellets designed to release drugs at a controlled rate in the gastrointestinal tract.

Advantages: Maintain consistent drug levels, reduce side effects, and improve patient compliance.

Applications: Chronic diseases like diabetes, hypertension, and cardiovascular disorders.[22]

Routes of Administration in Novel Drug Delivery Systems

Novel Drug Delivery Systems utilize various routes of administration to improve drug efficacy, bioavailability, and patient compliance. Each route is chosen based on the drug's properties, target site, and therapeutic goal.

1. Oral Route

Description: Drugs are administered through the mouth in forms like tablets, capsules, or nanoparticles.

Advantages: Convenient, non-invasive, suitable for self-administration.

NDDS Examples: Controlled-release tablets, enteric-coated capsules, nanoemulsions, polymeric nanoparticles.

Applications: Chronic diseases such as diabetes, hypertension, and cardiovascular disorders.[21]

2. Parenteral Route (Injection)

Description: Drugs are delivered directly into the bloodstream or tissues via intravenous (IV), intramuscular (IM), or subcutaneous (SC) injection.

Advantages: Rapid onset of action, bypasses first-pass metabolism, suitable for drugs unstable in the gastrointestinal tract.

NDDS Examples: Liposomes, polymeric nanoparticles, microspheres.

Applications: Cancer therapy, vaccines, hormones, biologics.

3. Transdermal Route

Description: Drugs are delivered through the skin using patches, gels, or creams.

Advantages: Non-invasive, sustained drug release, avoids first-pass metabolism, improves patient compliance.

NDDS Examples: Transdermal patches with nanoparticles or microneedles.

Applications: Pain management, hormonal therapy, cardiovascular drugs.[20]

4. Pulmonary (Inhalation) Route

Description: Drugs are inhaled into the lungs as aerosols, dry powders, or sprays.

Advantages: Rapid onset, high local drug concentration, minimal systemic side effects.

NDDS Examples: Liposomal or nanoparticle-based inhalers, dry powder formulations.

Applications: Asthma, chronic obstructive pulmonary disease (COPD), pulmonary infections.

5. Nasal Route

Description: Drugs are delivered through the nasal cavity for local or systemic effects.

Advantages: Rapid absorption, bypasses first-pass metabolism, can target the brain.

NDDS Examples: Nanoemulsions, nanoparticles, mucoadhesive gels.

Applications: Brain-targeted therapies, migraine treatment, vaccines.

6. Ocular Route

Description: Drugs are delivered to the eye using drops, gels, inserts, or implants.

Advantages: Provides localized therapy, reduces systemic exposure, can achieve sustained release.

NDDS Examples: Liposomal eye drops, ocular implants, hydrogels.

Applications: Glaucoma, macular degeneration, ocular infections.[18]

7. Rectal and Vaginal Routes

Description: Drugs are delivered via suppositories, gels, or inserts for local or systemic action.

Advantages: Useful when oral administration is not possible, bypasses partial first-pass metabolism.

NDDS Examples: Polymeric nanoparticles, mucoadhesive gels.

Applications: Hormonal therapy, local infections, anti-inflammatory drugs.

8. Implantable and Injectable Depot Systems

Description: Biodegradable implants or depots are placed subcutaneously or intramuscularly for long-term drug release.



Advantages: Sustained drug release over weeks or months, reduces frequent dosing, ensures compliance.

NDDS Examples: Biodegradable polymer implants, microspheres.

Applications: Contraceptives, hormone therapy, chronic disease management.[16]

Applications of Novel Drug Delivery Systems

Novel Drug Delivery Systems are designed to improve drug efficacy, reduce side effects, and target specific sites in the body. Their versatility allows applications across multiple therapeutic areas:

1. Cancer Therapy

Application: NDDS are widely used in oncology to deliver chemotherapeutic drugs specifically to tumor cells.

Example: Liposomal doxorubicin or nanoparticle-based paclitaxel accumulates preferentially in tumors, reducing toxicity to healthy tissues.

Advantage: Enhances therapeutic efficacy while minimizing side effects like cardiotoxicity or hair loss.

2. Cardiovascular Diseases

Application: Controlled-release systems and transdermal patches deliver drugs for conditions such as hypertension and angina.

Example: Nitrates or beta-blockers formulated in sustained-release tablets or transdermal patches.

Advantage: Maintains stable drug levels, reduces dosing frequency, and improves patient compliance.[15]

3. Diabetes Management

Application: NDDS are used for insulin and oral hypoglycemic drugs to improve bioavailability and reduce injection frequency.

Example: Biodegradable nanoparticles for oral insulin delivery or sustained-release insulin implants.

Advantage: Improves glycemic control and reduces patient discomfort from frequent injections.

4. Neurological Disorders

Application: Targeted NDDS can cross the blood-brain barrier to deliver drugs for diseases like Alzheimer's, Parkinson's, and epilepsy.

Example: Liposomes, nanoparticles, or intranasal delivery systems carrying dopamine or neuroprotective agents.

Advantage: Enables precise brain targeting, overcoming limitations of conventional oral or injectable drugs.[14]

5. Infectious Diseases

Application: NDDS enhance the delivery of antibiotics, antivirals, and antifungals to infected tissues.

Example: Liposomal amphotericin B for fungal infections or nanoparticle-encapsulated antiviral drugs.

Advantage: Increases drug concentration at the infection site, reducing resistance and side effects.

6. Vaccines and Gene Therapy

Application: NDDS are used to deliver antigens or genetic material efficiently to immune cells or target tissues.

Example: mRNA vaccines encapsulated in lipid nanoparticles, or plasmid DNA delivered via nanoparticles.

Advantage: Enhances immune response, improves stability, and allows controlled release.

7. Ocular Disorders

Application: NDDS deliver drugs to treat eye conditions like glaucoma, macular degeneration, and infections.

Example: Liposomal eye drops, hydrogels, or biodegradable ocular implants.

Advantage: Provides sustained local drug release, reduces systemic side effects, and improves patient compliance.

8. Hormone Replacement Therapy and Contraception

Application: NDDS are used to deliver hormones in a controlled manner for therapeutic or contraceptive purposes.

Example: Transdermal patches, biodegradable implants, or microspheres for estrogen, progesterone, or testosterone.

Advantage: Ensures stable hormone levels, reduces dosing frequency, and enhances compliance.[12]

9. Pain Management

Application: NDDS deliver analgesics locally or systemically to control acute or chronic pain.

Example: Transdermal patches with opioids or non-steroidal anti-inflammatory drugs (NSAIDs), microspheres for sustained release.

Advantage: Provides consistent pain relief, reduces systemic toxicity, and improves quality of life.



Limitations and Challenges of Novel Drug Delivery Systems

While Novel Drug Delivery Systems offer numerous advantages, their development and use face several limitations and challenges:

1. High Development and Manufacturing Costs

Explanation: NDDS often involve advanced materials, sophisticated fabrication techniques, and extensive quality control, making production expensive.

Impact: Limits accessibility, especially in low-resource settings, and increases the cost of therapy for patients.[10]

2. Complex Formulation and Stability Issues

Explanation: Many NDDS, such as nanoparticles, liposomes, or hydrogels, require precise formulation to maintain stability, prevent drug degradation, and ensure controlled release.

Impact: Improper formulation can lead to drug leakage, aggregation, or reduced efficacy during storage.

3. Limited Drug Loading Capacity

Explanation: Some carriers, especially nanoscale systems, can only encapsulate small amounts of drug.

Impact: High-dose drugs may be difficult to deliver effectively using NDDS, limiting their use for certain therapies.

4. Potential Toxicity and Immunogenicity

Explanation: Materials used in NDDS, such as polymers, surfactants, or metals, can sometimes cause toxic effects or trigger immune responses.

Impact: Safety concerns may restrict clinical use and require extensive preclinical testing.[9]

5. Regulatory and Approval Challenges

Explanation: NDDS often involve novel materials and delivery mechanisms, which may lack standardized regulatory guidelines.

Impact: Lengthy approval processes and high regulatory scrutiny can delay clinical translation.

6. Scale-Up and Manufacturing Challenges

Explanation: Techniques that work at the laboratory scale may not be easily scalable for industrial production without compromising quality or uniformity.

Impact: Limits mass production and commercial availability of NDDS.[8]

7. Drug Release Variability

Explanation: Biological factors like pH, enzymes, and blood flow can affect the release and distribution of drugs from NDDS in the body.

Impact: Can lead to inconsistent therapeutic effects across different patients.

8. Storage and Shelf-Life Limitations

Explanation: Many NDDS require specific storage conditions (e.g., low temperature) to maintain stability.

Impact: Increases logistical challenges and may reduce accessibility in regions without advanced storage facilities.[6]

9. Patient-Specific Variability

Explanation: Factors such as age, metabolism, disease state, and genetics can influence how NDDS perform in individual patients.

Impact: Personalized adjustments may be needed, complicating treatment protocols.[4]

II. CONCLUSION

Novel Drug Delivery Systems (NDDS) represent a significant advancement in modern pharmaceutical science, offering innovative approaches to improve drug efficacy, safety, and patient compliance. By enabling controlled, sustained, and targeted delivery of therapeutic agents, NDDS overcome many limitations of conventional drug delivery, such as poor bioavailability, rapid metabolism, and systemic side effects. These systems have found wide applications across multiple medical fields, including oncology, cardiology, neurology, infectious diseases, ophthalmology, and hormonal therapy. Techniques such as nanoparticles, liposomes, microspheres, hydrogels, and transdermal patches demonstrate the versatility and potential of NDDS to transform treatment strategies, making therapy more precise and personalized. However, despite their advantages, NDDS face several challenges, including high production costs, formulation complexity, potential toxicity, regulatory hurdles, and patient-specific variability. Continued research and technological



innovation are essential to address these limitations, optimize formulations, and make these advanced systems more accessible and practical for clinical use.

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