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ROLE OF RESEARCH AND DEVELOPMENT IN NOVEL DRUG DELIVERY SYSTEM–A REVIEW

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ABSTRACT

The rising demand for improved therapeutic outcomes and decreased side effects in the pharmaceutical sector has spurred a new wave of innovation and research in novel drug delivery systems. These systems aim to overcome the limitations of traditional drug administration methods, such as short half-life, poor targeting, low solubility, and bioavailability. As the fields of pharmacy, materials science, and biomedicine advance and intersect, the focus on developing efficient and safe drug delivery systems, including biopharmaceutical formulations, has grown significantly both nationally and internationally. This article provides an overview of the latest advancements in drug delivery systems, categorized into four key areas: carrier-based and coupling-based targeted drug delivery systems, intelligent drug delivery systems, and drug delivery devices, according to their primary objectives and methodologies. Furthermore, it critically examines the technological barriers, current research challenges, and future trends in the application of novel drug delivery systems.

Keywords: *Novel drug delivery systems, carrier-based, coupling-based, solubility.*

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INTRODUCTION

Research and Development (R & D) in Novel Drug Delivery Systems (NDDS) is the scientific and economic backbone of modern pharmaceutical advancement. Its role spans from enhancing basic drug solubility to the intricate engineering of biomimetic carriers that can bypass biological barriers like the blood-brain barrier. Strategically, R&D allows pharmaceutical companies to extend product lifecycles, introduce fresh ideas into regulated markets, and sustain revenue growth amid intense global competition [1].

A Novel Drug Delivery System (NDDS) refers to the development of new pharmaceutical formulations that offer improved characteristics, such as reduced particle size, enhanced permeability, and targeted delivery to specific sites. These systems can significantly improve the efficacy of bio-therapeutic agents, offering advantages over conventional dosage forms. Various design strategies exist for NDDS, and they have demonstrated effective clinical applications in treating a range of conditions [1,2].

The way a drug is delivered plays a crucial role in its effectiveness. Many drugs work best within a specific concentration range and exceeding or falling below this range can either cause toxicity or fail to provide any therapeutic benefit. However, the slow progress in treating severe diseases has highlighted the need for a more multidisciplinary approach to deliver treatments directly to tissue targets. This has led to the development of new methods for controlling the pharmacokinetics, pharmacodynamics, toxicity, immunogenicity, and overall effectiveness of drugs. These approaches, known as drug delivery systems (DDS), combine expertise from fields like polymer science, pharmaceutics, bio-conjugate chemistry, and molecular biology. Current drug delivery and targeting systems aim to reduce degradation, minimize side

effects, and improve drug bioavailability, ensuring that more of the drug reaches the desired site [3,4].

The concept of controlled and novel drug delivery, once considered a distant possibility, is now a reality thanks to significant research and advancements made in the past decade and a half. Traditional drug formulations often face issues like low bioavailability, instability, the first-pass effect, plasma fluctuations, and rapid drug release. Novel Drug Delivery Systems (NDDS) help address these challenges, improving performance, patient compliance, and shelf life. Nanoparticles, with sizes between 10 and 100 nm, are gaining attention for their environmental impact and potential in drug delivery. They can encapsulate or adsorb active agents and improve the pharmacodynamics and pharmacokinetics of drugs, enhancing targeted delivery to tissues. Nanoparticles also increase drug stability and retention at the target site, benefiting from solubilization and enzyme action [5,6].

Novel Drug Delivery Systems (NDDS) are advanced methods improving drug efficacy, involving types like Controlled Release (osmotic pumps, microspheres), Targeted Delivery (liposomes, nanoparticles), and Site-Specific systems (gastroretentive, mucoadhesive), plus methods like Transdermal Patches and Inhalations, all designed to control release, enhance absorption, or direct drugs to specific body areas, often using nanotechnology [7,8].

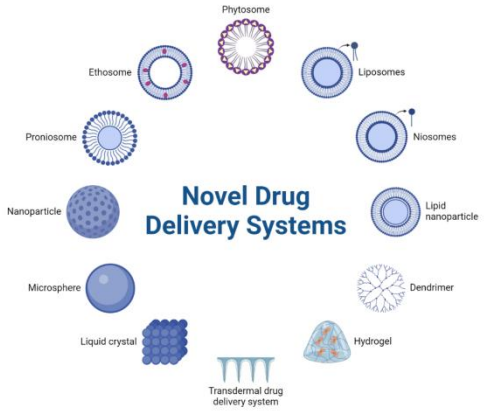

Figure 01: Types of NDDS

HERE ARE KEY CATEGORIES AND EXAMPLES OF NDDS

1. Controlled Release Systems

- **Osmotic Pump:** Uses osmotic pressure for precise, sustained drug release (e.g., Alza pumps).
- **Matrix & Reservoir Systems:** Drugs embedded in polymers that control release via diffusion or erosion.
- **Implants:** Biodegradable or non-biodegradable devices for long-term delivery.

2. Targeted Delivery Systems

- **Liposomes/Niosomes:** Vesicular carriers that encapsulate drugs for better delivery.
- **Nanoparticles/Nanoshells:** Tiny carriers for improved solubility and targeting, especially for cancer.
- **Dendrimers:** Branched macromolecules for precise drug attachment and release.

3. Site-Specific & Mucosal Systems

- **Gastroretentive:** Stays in the stomach longer for better absorption (e.g., floating systems).
- **Mucoadhesive:** Sticks to mucosal surfaces (like nose, gums, intestines) for sustained local action.
- **Colon-Targeted:** Delivers drugs to the colon, often for local treatment.

4. Other Prominent Types

- **Transdermal:** Patches delivering drugs through the skin (e.g., nicotine, pain relief).
- **Nasopulmonary:** Inhalers for lung delivery (e.g., asthma medications).
- **Microencapsulation:** Tiny capsules (microcapsules, microspheres) protecting or controlling release.

These systems improve effectiveness by maintaining drug levels in the therapeutic window, reducing side effects, and making difficult-to-deliver drugs (like proteins) usable [9-12].

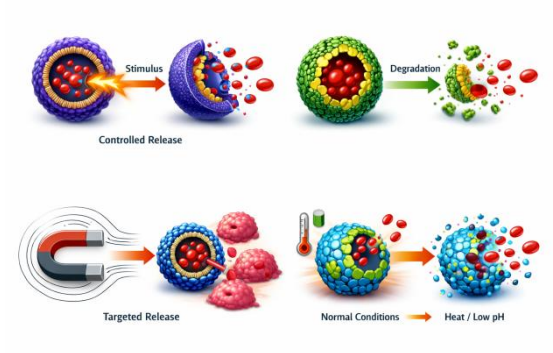

Figure 02: Drug release

CORE ROLES OF R&D IN NDDS

The primary function of R&D in NDDS is to design systems that maximize therapeutic efficacy while minimizing adverse effects. Key roles include:

- **Enhancing Bioavailability and Stability:** R&D identifies nanocarriers (e.g., liposomes, nanoparticles, niosomes) that protect drugs from enzymatic degradation and improve their solubility, ensuring more drug reaches the circulation.
- **Site-Specific Targeting:** Researchers develop passive and active targeting mechanisms to direct medications precisely to diseased tissues (e.g., tumors), reducing systemic exposure and interactions with healthy organs.
- **Overcoming Biological Barriers:** Research aims on ruling out challenging barriers, such as the blood-brain barrier (BBB), using specialized technologies like PEGylated nanoparticles.

- **Controlling Release Rates:** R&D involves engineering matrix-based systems and responsive materials (sensitive to temperature or ultrasound) to provide sustained or programmed drug release profiles.
- **Extending Product Life Cycles:** Pharmaceutical companies use R&D to transform existing drugs into new delivery systems, reviving older molecules and creating additional revenue streams.
- **Nanotechnology Synergy:** Nano-bio-technology R&D enables tumour-specific identification and precise delivery through nano-bio-sensors.
- **Advanced Manufacturing:** The intersection of pharmacy and materials science has introduced 3D printing (3DP) technology for creating customized dosage forms.
- **Artificial Intelligence (AI):** AI is now being utilized to predict chemical interactions, binding affinities, and molecular pathways, significantly accelerating lead drug selection and formulation optimization.
- **Herbal Drug Integration:** Researchers are applying NDDS technologies to herbal medicines (phytomedicines) to increase their therapeutic value through carriers like phytosomes and nanoparticles [13-15].

MARKET AND ECONOMIC IMPACT

The global NDDS market reflects the heavy investment and high value of successful R&D:

- ✓ **Market Growth:** The industry size was valued at $145.1 billion in 2025 and is projected to grow to $240.65 billion by 2035.
- ✓ **Competitive Advantage:** Intense global competition drives companies to allocate substantial resources to R&D to differentiate their products and protect intellectual property.
- ✓ **Investment Shifts:** Major players, including Johnson & Johnson, Pfizer, and Novartis, leverage advanced R&D pipelines to dominate specialized segments like oncology and neurodegenerative disorders.
- ✓ Core Strategic Roles of R&D in NDDS
- ✓ **R&D activities provide multi-faceted benefits across the pharmaceutical value chain:**
- ✓ **Optimizing Bioavailability and Stability:** Scientists identify compounds and carrier structures to protect sensitive molecules (like proteins and mRNA) from degradation and ensure effective concentration at target sites.
- ✓ **Targeted and Precise Delivery:** R&D enables "active" targeting by modifying nanocarriers with ligands to bind specific cell receptors, such as tumour markers. Systems are also designed to cross complex barriers like the blood-brain barrier (BBB).
- ✓ **Controlled and Sustained Release:** Research into polymers and matrix systems allows for drugs to be released at a predetermined rate, reducing dosing frequency and improving patient adherence.
- ✓ **Product Lifecycle Management:** NDDS development can give "new life" to existing medication molecules by improving their effectiveness or creating new dosage forms (e.g., long-acting versions), maintaining market presence as older patents expire.
- ✓ **Meeting Regulatory Standards:** R&D is essential for ensuring products meet strict standards from the WHO, FDA, and EMA, validating everything from safety and efficacy to manufacturing stability and sterility [4,16-18].

REGULATORY ASPECTS AND R&D CHALLENGES IN NOVEL DRUG DELIVERY SYSTEMS (NDDS)

Novel Drug Delivery Systems (NDDS) involve complex formulations and advanced technologies that require stringent regulatory evaluation to ensure safety, efficacy, and quality. Depending on their design and intended use, NDDS may be regulated as new drug products, reformulated drugs, or drug–device combination products. Regulatory authorities such as the US Food and Drug Administration (USFDA), European Medicines Agency (EMA), and Central Drugs Standard Control Organization (CDSCO) play a critical role in the approval and commercialization of NDDS.

Compliance with Good Manufacturing Practices (GMP) is mandatory to ensure consistent product quality and safety. The application of Quality by Design (QbD) principles has gained importance in NDDS development, enabling systematic identification and control of critical quality attributes and process parameters. NDDS often modify the pharmacokinetic and biodistribution profiles of drugs, necessitating extensive preclinical evaluation, including/controller toxicity, biocompatibility, and biodistribution studies, especially for nano-based delivery systems. A major regulatory challenge associated with NDDS is the lack of harmonized global guidelines and standardized analytical methods for characterization, which complicates regulatory approval.

Despite technological advancements, several R&D challenges limit the successful development of NDDS. Selection of suitable polymers, lipids, and carriers, along with achieving optimal drug loading and formulation stability, remains a major formulation challenge. Manufacturing and scale-up of NDDS from laboratory to industrial scale are difficult due to reproducibility issues, process variability, and high production costs. Safety concerns such as nanotoxicity, immunogenicity, and long-term tissue accumulation further complicate NDDS development. Additionally, poor correlation between preclinical studies and clinical outcomes contributes to high failure rates

during clinical trials. Economic constraints, intellectual property issues, and limited market acceptance also pose significant barriers to the commercialization of NDDS [18-20].

RECENT ADVANCES IN NOVEL DRUG DELIVERY SYSTEMS THROUGH R&D

Recent advances in research and development (R&D) have significantly transformed Novel Drug Delivery Systems (NDDS), enabling improved therapeutic efficacy, safety, and patient compliance. Innovations in materials science, nanotechnology, biotechnology, and digital tools have led to the development of sophisticated delivery platforms capable of controlled, targeted, and stimuli-responsive drug release.

Nanotechnology-based drug delivery systems represent one of the most prominent advances in NDDS. Lipid nanoparticles, polymeric nanoparticles, solid lipid nanoparticles, dendrimers, and polymeric micelles have been extensively investigated to enhance drug solubility, stability, and bioavailability while minimizing systemic toxicity. These nanocarriers allow efficient encapsulation of both hydrophilic and lipophilic drugs and have demonstrated improved pharmacokinetic and biodistribution profiles, particularly in cancer and infectious disease therapy.

Another significant advancement is the development of targeted drug delivery systems, which utilize ligands such as antibodies, peptides, and sugars to achieve site-specific drug delivery. Active targeting strategies have improved drug accumulation at disease sites while reducing off-target effects, thereby enhancing therapeutic outcomes. Passive targeting approaches, particularly the enhanced permeability and retention (EPR) effect, have also been widely explored in tumor-targeted NDDS.

Stimuli-responsive or smart drug delivery systems have emerged as a major focus of R&D in NDDS. These systems respond to internal stimuli such as pH, enzymes, redox conditions, or external stimuli such as temperature, light, ultrasound, and magnetic fields, enabling controlled and on-demand drug release [30]. Such smart systems offer precise spatial and temporal control over drug delivery, making them highly suitable for chronic and site-specific diseases.

Advances in transdermal, mucoadhesive, and implantable drug delivery systems have further expanded the scope of NDDS. Research has led to improved transdermal patches, microneedle-based systems, and bio-adhesive formulations that enhance drug permeation, prolong residence time, and improve patient compliance. These systems are particularly beneficial for long-term therapy and non-invasive drug administration.

Recent R&D efforts have also emphasized the integration of Quality by Design (QbD), computational modeling, and artificial intelligence (AI) in NDDS development. These tools enable rational formulation design, prediction of drug–carrier interactions, and optimization of critical formulation parameters, thereby reducing development time and cost. Additionally, advances in biodegradable and biocompatible materials have addressed safety concerns associated with long-term drug exposure.

Overall, continuous R&D has driven the evolution of NDDS from conventional carriers to advanced, patient-centric delivery platforms. These innovations are expected to play a crucial role in personalized medicine and future pharmaceutical development [20-22].

CONCLUSION

It concludes that Research and Development (R&D) plays a pivotal and transformative role in field of Novel Drug Delivery. The primary goal of R&D in this area is to overcome the limitations of conventional drug administration methods, thereby maximizing therapeutic efficacy, minimizing side effects, and significantly improving patient outcomes and compliance. The shift of focus towards NDDS from new chemical entity discovery allows pharmaceutical companies to enhance performance of existing drugs, thereby extending product life cycles and gaining a competitive edge through enhancing therapeutic efficacy and safety, improving patient compliance, overcoming the limitations of conventional delivery, innovation and technological advancements and strategic economic importance. Ultimately Research and Development plays an important role in NDDS by bridging the gap between drug discovery and commercial manufacturing leading to more stable, efficacious, and patient centric products.

CONFLICTS OF INTEREST

The authors have declared that no competing interests exist.

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ETHICAL APPROVAL

Not applicable

ETHICAL STATEMENT

The present study did not involve any experiments on humans or animals. Hence, ethical approval was not required.

AUTHOR CONTRIBUTION

All authors contributed equally.

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