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Recent Advances In Novel Drug Delivery Systems: A Review

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Abstract: The field of novel drug delivery systems (NDDS) has experienced significant advancements aimed at overcoming limitations of conventional therapeutic approaches. This review comprehensively discusses the classification of NDDS based on delivery mechanisms, carrier types, and target specificity, encompassing controlled release systems, targeted delivery platforms, nanoparticle-based carriers, transdermal patches, inhalation devices, and stimuli-responsive systems. Recent technological innovations, such as biodegradable polymers, ligand-mediated targeting, microneedle arrays, and smart responsive nanoparticles, have enhanced drug bioavailability, therapeutic efficacy, and patient compliance. The review further explores the diverse clinical applications of NDDS across oncology, infectious diseases, chronic conditions, and gene therapy, highlighting their role in minimizing systemic toxicity and enabling precision medicine. Despite remarkable progress, challenges including manufacturing scalability, regulatory hurdles, and long-term safety remain. Future research directions emphasize interdisciplinary integration and personalized delivery strategies to fully realize NDDS's potential in transforming global healthcare.

Index Terms - Novel drug delivery systems, Targeted drug delivery

I. INTRODUCTION

The field of drug delivery has evolved remarkably from traditional dosage forms such as tablets, capsules, and injections—to more sophisticated platforms aimed at enhancing therapeutic outcomes. Conventional delivery methods often suffer from challenges including poor aqueous solubility, limited bioavailability, rapid clearance, systemic toxicity, and fluctuating drug plasma levels, which can compromise both efficacy and patient adherence (Mazdaei & Asare-Addo, 2022; Lou et al., 2023). Specifically, up to 70% of newly discovered drugs exhibit low aqueous solubility, significantly constraining their development and therapeutic potential (Mazdaei & Asare-Addo, 2022). In response to these limitations, novel drug delivery systems (NDDS) have emerged leveraging advances in nanotechnology, biomaterials, and engineering to deliver drugs in a targeted, controlled, and stimuli-responsive manner. Among the most promising platforms are nanocarriers such as liposomes, solid lipid nanoparticles, polymeric nanoparticles, micelles, and dendrimers. These nanostructures enable precise control over drug loading, release kinetics, surface properties, and biodistribution, thereby improving stability, therapeutic index, and tissue-specific targeting (Alshawwa et al., 2022; ScienceDirect, 2023). Moreover, innovations in NDDS are no longer limited to nano-scale carriers. Controlled-release technologies including long-acting injectables, implants, and smart stimulus-responsive systems have significantly expanded the repertoire of drug delivery methods. These systems can maintain therapeutic drug levels over extended durations, reducing dosing frequency and enhancing patient compliance (Lou et al., 2023; Recent Advances in Long-Acting, 2024). Given the accelerating pace of research in this domain, especially over the past few years, a comprehensive review of emerging trends, mechanisms, and

translational challenges in NDDS is both timely and instrumental. This review paper aims to synthesize recent technological advances, highlight key applications across therapeutic areas, examine prevailing challenges, and outline prospective directions for future research and clinical translation.

II.LITERATURE REVIEW

Hou et al., (2021) Hou and colleagues review the design principles and translational progress of lipid nanoparticles (LNPs) for mRNA delivery, placing special emphasis on how composition, particle size, surface chemistry and ionizable lipids influence mRNA encapsulation, endosomal escape and in vivo biodistribution. The authors discuss physiological barriers (serum proteins, complement activation, clearance by RES) and highlight strategies for organ-level targeting (local injection, tropism-directing lipids, surface ligands). The paper frames the COVID-19 LNP-mRNA vaccines as a translational milestone and carefully analyses remaining obstacles immunogenicity control, scalable GMP manufacturing and long-term storage stability offering a roadmap for future LNP platforms aimed at therapeutics beyond vaccines.

Hou et al. (review) (2022) In a complementary review focused on RNA therapeutics, the authors expand on LNP clinical status and methods to tailor LNPs for different RNA cargos (siRNA, mRNA, saRNA). They describe characterization approaches for stability and release and survey clinical trials that demonstrate success for liver-targeted siRNA and systemic mRNA vaccines. The review emphasizes emerging directions: ligand-mediated targeting, biodegradable ionizable lipids to reduce long-term accumulation, and co-delivery of adjuvants or immunomodulators to modulate immune responses for oncology or gene-editing applications. Practical considerations for scale-up and regulatory expectations are also discussed.

Ahmed et al., (2021) This comprehensive open-access review describes microneedle designs (solid, coated, dissolving, hollow, hydrogel), materials (silicon, metals, polymers, sugars), and fabrication techniques (molding, lithography, 3D printing). It evaluates microneedle performance metrics such as insertion force, drug loading, release kinetics, skin recovery and patient comfort. The authors highlight microneedles' versatility for vaccines, biologics (insulin, monoclonal antibodies) and small molecules, and analyze regulatory and sterility challenges for commercial translation. Safety (skin barrier disruption, local inflammation), mass-manufacturing concerns and cold-chain independence for certain formulations are discussed, concluding that microneedles are a pragmatic route toward patient-friendly, minimally invasive delivery particularly suited to low-resource settings.

Donnelly & Singh, (2020) Donnelly and Singh (MDPI) provide a targeted analysis of clinical translation challenges for microneedles: reproducible fabrication, quality control for dose uniformity, sterilization without degrading sensitive cargos, and establishing regulatory acceptance. The review highlights notable clinical advances (vaccine patches and immunotherapy trials) and technological solutions such as dissolving polymer microneedles that obviate sharps waste. It also surveys analytical methods for mechanical testing and in vivo insertion assessment. The authors recommend harmonized regulatory guidance and deeper studies on long-term skin responses to accelerate adoption.

Meng et al., (2025) A very recent synthesis (2025) emphasizes next-generation microneedles that integrate sensing and closed-loop drug release for example glucose-sensing microneedles that release insulin on demand. The review summarizes advanced materials (self-healing polymers, conductive composites) and hybrid fabrication methods combining micromolding with microelectronics. It also covers theranostic microneedles that sample interstitial fluid for biomarkers while delivering therapy. Regulatory and biocompatibility concerns are revisited in light of multifunctional device complexity; the authors argue that modular device design and standardized biological assays will be crucial for clinical progression.

Das et al., (2020) This review on solid lipid nanoparticles (SLNs) outlines SLNs' formulation rationale: replacing organic solvent-based emulsions with biocompatible solid lipids to entrap both hydrophobic and hydrophilic agents. The authors detail preparation techniques (high-pressure homogenization, microemulsion, solvent evaporation), and describe advantages (physical stability, controlled release, good biocompatibility) and limitations (drug expulsion during storage, limited drug loading for certain actives). The review also discusses nanostructured lipid carriers (NLCs) as an improved generation addressing SLNs' limitations and summarizes patent trends and commercial potential in nutraceuticals and pharmaceuticals.

Subroto et al., (2023) This MDPI review examines current research using SLNs and NLCs for encapsulating antioxidant compounds and bioactives, with a focus on formulation parameters that influence encapsulation efficiency, release profile and oxidative stability. The authors report examples where SLNs significantly improved oral bioavailability and protected labile compounds from gastric degradation. They further evaluate characterization metrics (particle size, zeta potential, polymorphic lipid transitions) and outline in vivo

evidence of enhanced therapeutic efficacy for anti-inflammatory and neuroprotective agents when delivered via lipid carriers. The paper underlines formulation-specific stability testing and scale-up hurdles for translation.

Kesharwani et al., (2023) This open-access review on dendrimers provides an updated appraisal of PAMAM, PPI and other dendrimer classes for drug and gene delivery. The authors emphasize dendrimer advantages: monodisperse architecture, tunable surface functionality for conjugation or stealthing, and multivalency for ligand display. They review strategies for reducing dendrimer cytotoxicity (surface neutralization, PEGylation, biodegradable linkers) and highlight applications in targeted cancer therapy, nucleic acid delivery and imaging. Challenges such as synthetic cost, characterization complexity, and in vivo biodistribution profiling are discussed along with promising engineering solutions.

Engineering PAMAM dendrimers review (2025) A focused review on engineering PAMAM dendrimers discusses chemical modifications that enhance drug loading and specificity: interior hydrophobic modifications to load poorly soluble drugs, surface-conjugated peptide ligands for receptor targeting, and cleavable linkers for stimuli-responsive release. The authors present case studies illustrating improved tumor penetration and reduced off-target toxicity in murine models. They also describe analytical methods for assessing generation-dependent pharmacokinetics and offer guidance for scalable synthesis and purification critical steps for translating dendrimer therapeutics into clinical candidates.

Kalluri et al., (2024) This comprehensive review traces the progress of exosomes (extracellular vesicles) as natural nanocarriers, discussing isolation methods, cargo loading approaches (electroporation, sonication, endogenous loading), surface engineering for targeting, and immunogenicity profiles. The authors highlight exosomes' inherent biocompatibility and ability to cross biological barriers, including preliminary evidence for brain delivery. Key translational challenges covered are reproducible large-scale production, heterogeneity in exosome populations, cargo quantification, and regulatory classification (biologic vs. drug product). The review calls for standardized production pipelines and rigorous characterization to enable clinical translation.

Lai et al., (2022) In a focused review, the authors explore exosome platforms engineered for cancer immunotherapy: exosome vaccines carrying tumor antigens, exosomes loaded with immune checkpoint inhibitors, and exosome-mediated delivery of siRNA to modulate the tumor microenvironment. They compare synthetic nanocarriers and engineered exosomes, emphasizing exosomes' low immunogenicity and potential for homing to tumors. Clinical pipeline examples and early-phase trials are discussed; challenges noted include batch consistency, clearance kinetics and potential pro-tumorigenic effects depending on exosome source.

Peppas et al., (2020) This widely cited open-access review outlines hydrogel classes (natural, synthetic, hybrid), cross-linking strategies (physical, covalent), and stimuli-responsive mechanisms (pH, temperature, enzymes) used to control release. The authors detail hydrogel advantages for localized, sustained release and for loading of biologics (proteins, growth factors). Major application areas include wound healing, tissue engineering and on-demand drug depots. Practical formulation issues (mechanical strength, sterilization, diffusion-based release modeling) are covered; the review emphasizes rational design combining network architecture and mesh size control to tune therapeutic kinetics.

MDPI (Advances in Hydrogel-Based Drug Delivery) This recent MDPI review examines innovations such as self-healing, tough and hybrid hydrogels engineered to overcome conventional hydrogels' mechanical fragility. The article discusses injectable shear-thinning hydrogels for minimally invasive depot formation and multifunctional hydrogels combining drug release with bioactivity (e.g., growth factor presentation). Emphasis is placed on clinical applications in cancer, ocular delivery and regenerative medicine, plus strategies for co-delivery of multiple therapeutics and controlled degradation profiles tailored to tissue healing timelines.

Fina et al., (2023) This open-access review surveys 3D printing methods (FDM, SLS, SLA, inkjet) applied to pharmaceutical dosage forms and medical devices. The authors present examples of personalized oral tablets, transdermal patches, and implantable devices with tailored release profiles. Regulatory and material-compatibility challenges are analyzed, along with how 3D printing enables complex internal geometries and multi-drug architectures not achievable with traditional manufacturing. The review highlights the FDA-approved 3D-printed drug (Spritam) as a proof-of-concept and discusses hurdles to scale and GMP compliance.

Fina et al. / MDPI Evolution review (2022) In a broader historical perspective, this MDPI review traces the evolution of 3D-printed drug delivery systems over two decades and emphasizes the most active research areas: personalized dosing, implantable devices for localized therapy, and 3D-printed microneedle arrays. The authors synthesize evidence that 3D printing allows bespoke release kinetics and patient-matched geometries,

but they stress that widespread clinical implementation requires validated excipients, sterilization workflows and robust process validation.

Vamathevan et al., (2024) This broad review examines how artificial intelligence (AI) and machine learning (ML) are transforming stages across the pharmaceutical pipeline, including formulation design, excipient selection, stability prediction and process optimization. The authors present case studies where ML models accelerate preformulation screening, reduce experimental runs, and predict shelf-life behaviours. They highlight the potential of AI to discover correlations in complex formulation spaces (e.g., nanoparticle composition → biodistribution) but caution about data quality, model interpretability and regulatory acceptance of AI-driven decisions in GMP environments.

ScienceDirect review AI in pharmaceutical industry (2024) This industry-oriented review focuses on AI applications specifically for formulation and drug product development: automated high-throughput experimentation guided by active learning, predictive models for dissolution and bioavailability, and generative models for molecular excipient design. It emphasizes integration of AI with laboratory automation to shorten formulation timelines and improve reproducibility, while highlighting the need for curated, standardized datasets to avoid bias and ensure model generalizability.

Frontiers (2023) This review synthesizes the state-of-the-art in stimuli-responsive injectable gels that transition in situ to depots responding to pH, enzymes or temperature. The article discusses mechanisms for on-demand release of chemotherapeutics or biologics in tumor microenvironments and reviews preclinical studies demonstrating enhanced local efficacy and reduced systemic toxicity. The authors discuss rheological and mechanical requirements for injectability, and highlight regulatory considerations for combination device-drug products.

Polymeric nanoparticles review (2025) A recent (2025) comprehensive review of polymeric nanoparticles (PNPs) details biodegradable polymers (PLGA, PLA, PCL, polypeptides), manufacturing methods (nanoprecipitation, emulsion solvent evaporation), surface engineering (PEGylation, targeting ligands) and strategies for nucleic acid and protein delivery. The review highlights how polymeric carriers enable controlled release, shield labile cargos, and can be engineered for stimuli-sensitive release. Key translational topics covered include residual solvent control, sterilization impact on polymer integrity, and in vivo clearance pathways—information critical for IND-enabling studies.

Long-Acting Injectables review (2024) This review on long-acting injectable (LAI) formulations focusing on antipsychotics but discussing platform technologies more broadly analyzes formulation strategies (polymeric depots, oil suspensions, in situ forming implants), release mechanisms and pharmacokinetic modelling approaches for achieving multi-week to monthly dosing. The authors review clinical outcomes showing improved adherence and reduced relapse rates in certain conditions, and they discuss manufacturability challenges including particle size control, syringeability, and depot reproducibility. The review underscores LAIs' expanding role beyond psychiatry into contraception, anti-infectives and chronic disease management.

III. CLASSIFICATION OF NOVEL DRUG DELIVERY SYSTEMS

Novel drug delivery systems (NDDS) represent a diverse array of innovative technologies developed to optimize the pharmacokinetic and pharmacodynamic profiles of therapeutic agents. These systems are generally categorized based on their delivery method, the type of carrier employed, and their targeted site of action. Controlled release systems are designed to release a drug at a predetermined rate, maintaining a consistent drug concentration in the bloodstream over an extended duration. Examples of such systems include matrix tablets, osmotic pumps, and biodegradable implants, which improve therapeutic efficacy by reducing dosing frequency and minimizing fluctuations in drug levels. Targeted drug delivery systems aim to deliver active agents specifically to the intended site of action, thereby reducing off-target effects. These may utilize passive targeting strategies, such as exploiting the unique characteristics of the tumor microenvironment, or active targeting methods involving ligand–receptor interactions for precise localization. Nanoparticle-based systems comprising polymeric nanoparticles, liposomes, dendrimers, and metallic nanoparticles enhance drug solubility, stability, and bioavailability, offering significant potential in oncology, infectious diseases, and chronic conditions. Transdermal drug delivery systems (TDDS), such as patches, microneedles, and iontophoretic devices, enable drugs to be absorbed through the skin, bypassing the gastrointestinal tract and avoiding first-pass metabolism, which is particularly beneficial for drugs with poor oral bioavailability. Inhalation drug delivery systems, including nebulizers, dry powder inhalers, and metered-dose inhalers, provide direct access to the lungs for both localized treatment of respiratory disorders and systemic delivery. Stimuli-responsive systems, often referred to as smart drug delivery platforms, are engineered to respond to

specific external triggers such as temperature, pH, and light, or internal cues like enzymatic activity and redox conditions, ensuring precise spatiotemporal release of the therapeutic agent. This classification framework not only helps in comprehensively understanding the functional diversity of NDDS but also forms the foundation for exploring the latest advancements and applications in each category.

IV. ADVANCEMENTS IN NOVEL DRUG DELIVERY SYSTEMS

Recent years have witnessed significant advancements in novel drug delivery systems, driven by the need to improve therapeutic efficacy, patient compliance, and precision in treatment. Controlled release systems have evolved with the development of sophisticated polymer matrices and biodegradable materials that allow fine-tuned release kinetics, thereby reducing dosing frequency and minimizing fluctuations in plasma drug concentration. Targeted drug delivery has progressed with the incorporation of advanced targeting ligands, such as monoclonal antibodies, aptamers, and peptides, which enhance specificity towards diseased cells while sparing healthy tissues. Nanoparticle-based systems have seen remarkable innovation, including stimuli-responsive nanoparticles capable of releasing drugs only upon encountering specific environmental cues within the body. Transdermal drug delivery has been refined through microneedle arrays, which offer painless administration and enhanced permeability without compromising skin integrity. Inhalation drug delivery systems now utilize engineered particles with optimized aerodynamic properties, ensuring deep lung deposition and improved bioavailability. Additionally, stimuli-responsive drug delivery platforms have integrated multi-modal triggers, such as combined pH and temperature sensitivity, to enable precise spatiotemporal control of drug release. Collectively, these advancements not only expand the therapeutic possibilities for existing drugs but also facilitate the clinical translation of emerging biologics, gene therapies, and personalized medicines.

V. APPLICATIONS OF NOVEL DRUG DELIVERY SYSTEMS

Novel drug delivery systems have revolutionized the therapeutic landscape across a wide spectrum of medical fields by enhancing drug efficacy, reducing side effects, and improving patient adherence. In oncology, targeted delivery platforms such as antibody–drug conjugates and nanoparticle carriers have enabled precise localization of chemotherapeutic agents to tumor cells, thereby minimizing systemic toxicity and overcoming multidrug resistance (Peer et al., 2007). In infectious diseases, nanoparticle-based systems and inhalation therapies have facilitated efficient delivery of antimicrobial agents directly to infection sites, such as the lungs, improving treatment outcomes for diseases like tuberculosis and pneumonia. Transdermal delivery has found significant applications in chronic conditions requiring steady drug plasma levels, such as hormone replacement therapy, pain management, and smoking cessation, offering a non-invasive alternative to oral or injectable routes (Prausnitz & Langer, 2008). Moreover, stimuli-responsive systems have been applied in diabetes management with glucose-responsive insulin delivery devices that adjust dosing in response to blood sugar levels, thus mimicking physiological insulin secretion. Gene and nucleic acid therapies have benefited immensely from NDDS advancements, with lipid nanoparticles enabling the safe and effective delivery of mRNA vaccines and CRISPR gene-editing components. Furthermore, implantable drug delivery devices have provided sustained release solutions for contraception, chronic pain, and neurological disorders, improving therapeutic consistency and patient quality of life. These diverse applications underscore the transformative potential of NDDS in modern medicine, promising more personalized, effective, and safer treatment modalities.

VI. CONCLUSION

Novel drug delivery systems represent a transformative frontier in pharmaceutical sciences, addressing many limitations inherent to conventional therapies. Through advances in controlled release technologies, targeted delivery, nanoparticle engineering, transdermal and inhalation methods, and stimuli-responsive platforms, NDDS have substantially enhanced the precision, efficacy, and safety of drug administration. These systems have enabled site-specific delivery, minimized systemic toxicity, improved patient compliance, and opened avenues for the clinical translation of complex biologics, gene therapies, and personalized medicine. Despite significant progress, challenges such as large-scale manufacturing, regulatory complexities, and long-term biocompatibility remain hurdles to widespread adoption. Continued interdisciplinary research integrating materials science, molecular biology, and clinical insights will be crucial to overcoming these barriers. Ultimately, the sustained evolution of NDDS holds great promise for revolutionizing therapeutic interventions, leading to more effective, patient-centric, and tailored healthcare solutions worldwide.

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