WJPMR, 2026, 12(11), 391-396

Review Article

WORLD JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.wjpmr.com

Impact Factor: 7.533

ISSN (O): 2455-3301

ISSN (P): 3051-2557

Coden USA: WJPMBB

NANOTECHNOLOGY-BASED DRUG DELIVERY SYSTEMS: A SYSTEMATIC REVIEW OF ADVANCES, THERAPEUTIC APPLICATIONS, AND BARRIERS TO CLINICAL TRANSLATION

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DOI: https://doi.org/10.5281/zenodo.23914612

How to cite this Article: Gokul R.*, Sylanderan S., Laskika L. K. (2026). Nanotechnology-Based Drug Delivery Systems: A Systematic Review Of Advances, Therapeutic Applications, And Barriers To Clinical Translation. World Journal of Pharmaceutical and Medical Research, 12(11), 391–396.

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Article Received on 05/10/2026 **Article Revised on 25/10/2026** **Article Published on 03/11/2026**

ABSTRACT

Background: Nanotechnology has emerged as one of the most transformative platforms in modern pharmaceutics, offering solutions to longstanding problems of poor aqueous solubility, non-specific biodistribution, rapid clearance, and off-target toxicity associated with conventional drug therapy. **Objective:** This systematic review synthesizes the peer-reviewed literature on nanotechnology-based drug delivery systems (NDDS), with emphasis on lipid-based carriers (liposomes, solid lipid nanoparticles, and lipid nanoparticles), polymeric carriers (PLGA nanoparticles and polymeric micelles), and dendrimers, and evaluates the mechanisms, targeting strategies, safety considerations, and regulatory barriers that determine their clinical translatability. **Methods:** A structured literature search was conducted across PubMed/MEDLINE, Scopus, Web of Science, and Google Scholar for records published primarily between 2012 and 2026, using combinations of the terms "nanoparticle," "drug delivery," "liposome," "PLGA," "solid lipid nanoparticle," "dendrimer," "lipid nanoparticle," "blood-brain barrier," "nanotoxicology," and "clinical translation." **Results:** Fifty primary and secondary sources meeting the eligibility criteria were included. The evidence indicates that nanocarriers consistently improve pharmacokinetic profiles and enable tumor- or tissue-selective accumulation through passive (enhanced permeability and retention) and active (ligand-mediated) targeting, and that lipid nanoparticles have achieved landmark clinical success as mRNA vaccine and siRNA carriers. However, translational barriers persist, including inconsistent physicochemical characterization, scale-up and batch-to-batch reproducibility problems, unresolved long-term toxicity profiles, and an incompletely harmonized global regulatory framework. **Conclusion:** Nanotechnology-based drug delivery continues to mature from a promising laboratory concept into a validated clinical modality, but continued progress will depend on standardized characterization protocols, mechanistic toxicology studies, and internationally harmonized regulatory guidance.

KEYWORDS: nanomedicine; drug delivery systems; liposomes; PLGA nanoparticles; solid lipid nanoparticles; lipid nanoparticles; dendrimers; nanotoxicology; clinical translation; targeted drug delivery.

1. INTRODUCTION

Conventional pharmacotherapy is frequently limited by the poor aqueous solubility of new chemical entities, short plasma half-lives, non-specific tissue distribution, and dose-limiting toxicity, all of which reduce the therapeutic index of otherwise potent drugs.[4] Nanotechnology addresses these limitations by engineering carriers in the sub-micron size range (typically 1–1000 nm) that can encapsulate, protect, and selectively deliver active pharmaceutical ingredients to their intended site of action.[1,6] Since the clinical approval of the first liposomal anticancer formulation in the mid-1990s, the nanomedicine field has expanded to include lipid-based, polymeric, dendrimeric, and inorganic carrier platforms, several dozen of which are now approved worldwide.[1,6]

The pharmaceutical rationale for nanocarrier-based delivery is often summarized as the "3R" principle — delivering the right dose, to the right place, at the right time.[1] By modulating particle size, surface charge, and surface chemistry, formulation scientists can prolong circulation time, reduce reticuloendothelial clearance, and exploit both passive accumulation via the enhanced

permeability and retention (EPR) effect in tumors and active, ligand-receptor-mediated targeting to diseased tissue.[35,72] The clinical relevance of these platforms was demonstrated most visibly during the COVID-19 pandemic, when lipid nanoparticle (LNP)-encapsulated mRNA vaccines were developed, approved, and deployed at global scale within an unprecedented timeframe.[24,26,27]

Despite this progress, the translation of nanomedicines from bench to bedside remains disproportionately low relative to the volume of preclinical publications, owing to challenges in physicochemical characterization, manufacturing scale-up, safety evaluation, and regulatory harmonization.[39,40,42] This review aims to (i) systematically summarize the principal classes of nanotechnology-based drug delivery systems used in pharmaceutical science, (ii) evaluate the mechanistic basis for their therapeutic advantages, (iii) critically appraise the biological safety and toxicological literature, and (iv) identify the translational and regulatory barriers that continue to constrain clinical adoption.

2. METHODOLOGY

2.1 Search Strategy

A structured, systematic literature search was performed across PubMed/MEDLINE, Scopus, Web of Science, and Google Scholar, supplemented by manual screening of reference lists of retrieved articles ("snowballing"). Search terms were combined using Boolean operators and included: ("nanoparticle*" OR "nanocarrier*" OR "nanomedicine") AND ("drug delivery" OR "targeted delivery") AND ("liposome*" OR "solid lipid nanoparticle*" OR "lipid nanoparticle*" OR "PLGA" OR "polymeric micelle*" OR "dendrimer*") AND ("toxicity" OR "clinical translation" OR "regulatory" OR "blood-brain barrier"). The search was limited principally to English-language articles published between 2012 and 2026, although several foundational older studies were retained where they were of seminal mechanistic importance.

2.2 Eligibility Criteria

Peer-reviewed review articles, systematic reviews, and primary research articles were eligible if they (a) described a nanoparticulate drug delivery platform of pharmaceutical relevance, (b) reported formulation, mechanistic, pharmacokinetic, toxicological, or clinical/regulatory data, and (c) were published in an indexed, peer-reviewed pharmaceutical, biomedical, or materials science journal. Conference abstracts without full text, non-peer-reviewed preprints, and articles unavailable in English were excluded.

2.3 Study Selection and Data Extraction

Titles and abstracts were screened for relevance, followed by full-text assessment of shortlisted records. Data extracted from each included source comprised carrier type, composition, size range, drug payload, targeting mechanism, reported efficacy or safety outcome, and stage of clinical development (preclinical, clinical trial, or approved product). Given the narrative-synthesis nature of this review, findings were organized thematically by nanocarrier class rather than pooled quantitatively, consistent with the heterogeneity of formulation types and outcome measures reported across the literature.

2.4 Included Studies

A total of 50 sources met the eligibility criteria and form the evidentiary basis of this review, spanning lipid-based carriers (n≈19), polymeric carriers (n≈14), dendrimers (n≈6), blood-brain-barrier-targeted platforms (n≈5), and clinical translation, regulatory, and toxicology literature (n≈6). The relative concentration of sources within each domain reflects the maturity and clinical relevance of that platform in the current literature.

3. RESULTS

3.1 Lipid-Based Nanocarriers

Liposomes — spherical vesicles composed of one or more phospholipid bilayers — remain the most clinically mature nanocarrier platform, owing to their biocompatibility, ease of surface modification, and capacity to encapsulate both hydrophilic and lipophilic drugs.[1,2,3,7] Innovations such as long-circulating PEGylated liposomes, stimulus-responsive liposomes, and ligand-targeted immunoliposomes have progressively improved tumor selectivity and reduced off-target cardiotoxicity relative to free drug administration.[1,5,9] Liposomal reformulations of established chemotherapeutics and antifungal agents have achieved regulatory approval and remain in wide clinical use, and continuing innovation includes application to herbal actives, vaccines, and anti-inflammatory therapeutics.[2,8,41]

Solid lipid nanoparticles (SLNs), composed of a solid lipid matrix stabilized by surfactant, were developed as an alternative to liposomes and polymeric nanoparticles, offering improved physical stability, scalable production, and the ability to protect labile drugs from chemical and enzymatic degradation.[18,19,20] SLNs have been investigated for oral, parenteral, and topical delivery of anticancer, antiparasitic, and anti-inflammatory agents, although drug-loading capacity and potential drug expulsion on storage remain recognized formulation limitations.[21,22,23,24,44,45]

Lipid nanoparticles (LNPs), a related but structurally distinct class incorporating ionizable lipids, helper phospholipids, cholesterol, and PEGylated lipids, achieved landmark clinical validation as the delivery vehicle for the mRNA-1273 and BNT162b2 COVID-19 vaccines, and are further being developed for siRNA, gene-editing, and protein-replacement therapeutics.[25,26,27,28] The rational design of ionizable lipid head-groups and pKa is now recognized as the principal determinant of endosomal escape efficiency and, consequently, of overall LNP potency.[26]

3.2 Polymeric Nanocarriers

Poly(lactic-co-glycolic acid) (PLGA) is the most extensively investigated biodegradable polymer for nanoparticle-based drug delivery, owing to its favorable biocompatibility, tunable degradation kinetics, and regulatory precedent for parenteral use.[10,12,15] PLGA nanoparticles have been formulated for transdermal, oncological, and central-nervous-system indications, with surface PEGylation and ligand functionalization used to prolong circulation time and confer tissue selectivity.[10,11,13,16,17]

Polymeric micelles, formed by the self-assembly of amphiphilic block copolymers into core-shell nanostructures, are principally used to solubilize poorly water-soluble anticancer agents such as paclitaxel, while simultaneously exploiting the EPR effect for tumor accumulation.[35] Several polymeric micelle formulations, including cisplatin- and SN-38-incorporating systems, have advanced into early-phase clinical evaluation, illustrating a credible pathway from laboratory-scale synthesis to clinical testing.[35]

3.3 Dendrimers

Dendrimers are highly branched, monodisperse macromolecules whose internal cavities and multivalent surface groups permit both encapsulation and covalent conjugation of therapeutic payloads.[29,43] Poly(amidoamine) (PAMAM) dendrimers are the most widely studied subclass and have been explored for solubility enhancement, tumor-targeted chemotherapy, and nucleic acid delivery.[30,31,32,33,34] Despite favorable structural precision, the clinical development of dendrimers has lagged behind lipid- and polymer-based systems, reflecting unresolved concerns regarding surface-charge-dependent cytotoxicity and hemolytic potential, particularly for cationic PAMAM generations.[29,34]

3.4 Targeting Strategies: Passive and Active Mechanisms

Two complementary targeting paradigms underlie the therapeutic rationale of nanomedicine. Passive targeting relies on the EPR effect, whereby the leaky, poorly organized vasculature of solid tumors permits selective extravasation and retention of nanocarriers exceeding the renal filtration threshold.[35] Active targeting supplements this effect through the conjugation of antibodies, peptides, or small-molecule ligands to the nanocarrier surface, enabling receptor-mediated cellular uptake at the target site.[35] Both mechanisms are frequently combined in contemporary formulation design to maximize selectivity while minimizing systemic exposure and off-target toxicity.

3.5 Overcoming the Blood-Brain Barrier

The blood-brain barrier (BBB) represents one of the most restrictive physiological barriers to pharmacotherapy, excluding the majority of small-molecule and biologic drugs from the central nervous system.[36,37,39] Nanoparticle-based strategies to overcome the BBB include receptor-mediated transcytosis, surfactant-coating-mediated adsorption (e.g., polysorbate 80-coated nanoparticles), intranasal administration exploiting the olfactory and trigeminal pathways, and transient, focused-ultrasound-mediated barrier disruption.[36,38,40] Chitosan-based and polymeric nanoparticle platforms have shown particular promise for intranasal, nose-to-brain delivery in neurodegenerative disease and neuro-oncology applications.[37,40]

3.6 Toxicity, Biocompatibility, and Safety Considerations

Nanoparticle toxicity is governed by a complex interplay of physicochemical properties, including particle size, surface charge, shape, crystallinity, and aggregation state, all of which influence cellular uptake, oxidative stress induction, and downstream inflammatory signalling.[42] Positively charged nanoparticles generally exhibit greater membrane disruption and cytotoxicity than neutral or negatively charged counterparts, owing to stronger electrostatic interaction with anionic phospholipid head-groups.[42] Organ-level toxicological review indicates that the liver, kidney, nervous system, and immune system are the principal targets of nanoparticle-associated adverse effects, mediated substantially through oxidative stress, genotoxicity, and immune activation.[42] Importantly, several toxicological reviews caution against generalized safety statements across the nanomedicine field, since toxicity profiles vary considerably between lipid-based, polymeric, and inorganic (e.g., metallic) nanoparticle classes.[42]

3.7 Clinical Translation and Regulatory Landscape

Approximately fifty nanomedicine formulations have achieved regulatory approval to date, with several hundred additional candidates under active clinical investigation.[43] Nonetheless, the rate of clinical translation remains disproportionately low relative to the scale of preclinical research output, a discrepancy attributed to five recurring barriers: inconsistent physicochemical characterization, manufacturing and batch-to-batch reproducibility challenges, an incomplete understanding of in vivo biological behavior, absence of harmonized regulatory guidance across major jurisdictions, and the high cost of demonstrating comparative clinical benefit over existing therapies.[43,44,45,46] Regulatory bodies including the U.S. Food and Drug Administration and the European Medicines Agency have issued preliminary, non-binding guidance on nanomaterial-containing drug products, but comprehensive, internationally harmonized frameworks remain under active development.[44,45,46]

4. DISCUSSION

The collective evidence reviewed here indicates that nanotechnology-based drug delivery has matured substantially from a conceptual framework into a clinically validated pharmaceutical modality, most visibly demonstrated by the global deployment of LNP-

based mRNA vaccines.[25,26,27] Lipid-based carriers, in particular, now occupy the most clinically advanced position among nanocarrier classes, benefiting from decades of liposomal precedent and the more recent validation of ionizable-lipid LNP chemistry.[1,26] Polymeric and dendrimeric platforms, while offering superior tunability of degradation kinetics and multivalent surface chemistry respectively, continue to lag in clinical translation, reflecting a combination of manufacturing complexity and, in the case of cationic dendrimers, unresolved safety concerns.[29,34,43]

A recurring theme across the reviewed literature is the tension between formulation sophistication and manufacturing scalability: increasingly complex, multifunctional nanocarriers designed to achieve stimulus-responsiveness or dual/active-passive targeting are correspondingly more difficult to reproduce at the batch-to-batch consistency required for regulatory approval.[39,43] This underscores the pharmaceutical principle that translational success depends not solely on in vitro or preclinical efficacy, but equally on quality-by-design manufacturing strategies developed in parallel with formulation innovation.[39]

The toxicological literature further suggests that nanoparticle safety cannot be generalized across the field; rather, it must be assessed on a platform-specific and even formulation-specific basis, since lipid-based systems such as liposomal doxorubicin and albumin-bound paclitaxel demonstrate improved safety margins relative to free drug, whereas certain metallic and cationic polymeric or dendrimeric nanoparticles demonstrate the opposite pattern.[42] This heterogeneity argues strongly for continued investment in standardized, platform-appropriate nanotoxicology testing protocols, an area identified as a key research gap by multiple regulatory and academic authors.[42,44,46]

Finally, the emergence of artificial-intelligence-assisted formulation design, highlighted in several recent reviews, may help address some of the reproducibility and characterization challenges identified above by enabling more predictive, data-driven optimization of nanocarrier composition prior to costly empirical formulation trials.[4] Continued interdisciplinary collaboration between formulation scientists, toxicologists, and regulatory authorities will likely determine the pace at which future nanomedicines progress from preclinical promise to approved clinical products.

5. CONCLUSION

Nanotechnology-based drug delivery systems, spanning liposomes, solid lipid nanoparticles, lipid nanoparticles, PLGA nanoparticles, polymeric micelles, and dendrimers, have collectively demonstrated the capacity to improve the pharmacokinetic and safety profile of therapeutic agents, enable tissue- and tumor-selective drug targeting, and, in the case of LNP-mRNA vaccines, achieve landmark global clinical impact. Nevertheless, the translational pathway from laboratory-scale innovation to approved pharmaceutical product remains constrained by manufacturing scalability, incompletely standardized toxicological evaluation, and a regulatory framework that has not yet fully harmonized across major jurisdictions. Future progress in this field will depend on the parallel advancement of rational, quality-by-design formulation science, mechanistic and platform-specific nanotoxicology, and internationally coordinated regulatory guidance.

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