

## **POLYMERIC NANOPARTICLES IN CANCER THERAPY: A COMPREHENSIVE REVIEW OF TARGETED DRUG DELIVERY SYSTEMS, MECHANISMS, AND CLINICAL TRANSLATION**

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### **ABSTRACT**

Cancer treatment is still hindered by systemic toxicity, multidrug resistance, and inadequate specificity for tumors. Polymeric nanoparticles (PNPs) have gained recognition as sophisticated drug delivery systems that can overcome these issues due to their biodegradability, compatibility with biological systems, and capability to encapsulate various therapeutic agents. Their nanoscale size allows for passive targeting through the enhanced permeability and retention (EPR) effect, while attaching ligands such as folate, transferrin, and antibodies enables active targeting specific to tumors. This review discusses the main categories of polymeric carriers, including poly(lactic-co-glycolic acid) (PLGA), polyhydroxyalkanoates (PHAs), cyclodextrins, and smart polymers that respond to pH, redox, or enzymatic changes. These systems facilitate controlled drug release, shield drugs from early degradation, and increase their concentration at

tumor locations. Their applications encompass chemotherapy, gene therapy, and immunotherapy. and theragnostic strategies that combine therapy with imaging. Although there is substantial preclinical evidence, the clinical application of polymeric nanoparticles (PNPs) is still limited by challenges such as large-scale production, variations in tumor microenvironments, and regulatory hurdles. Nevertheless, advancements in polymer design, biomimetic functionalization, and the integration of artificial intelligence provide hope for

addressing these issues. In summary, polymeric nanoparticles represent a groundbreaking approach in precision oncology, facilitating safer, more efficient, and personalized cancer treatment.

**KEYWORDS:** Polymeric nanoparticles, targeted drug delivery, cancer therapy, PLGA, smart polymers, clinical application.

## INTRODUCTION

Cancer remains a leading cause of morbidity and mortality worldwide, and conventional therapies surgery, radiotherapy and systemic chemotherapy — are often constrained by poor tumor specificity, dose-limiting systemic toxicity, and the emergence of multidrug resistance. Polymeric nanoparticles (PNPs) have emerged as a versatile platform to address these limitations by combining controllable physicochemical properties with biocompatible, biodegradable polymer matrices that can encapsulate small molecules, biologics and nucleic acids. PNPs exploit two main targeting paradigms. Passive targeting leverages the enhanced permeability and retention (EPR) effect of many solid tumors, allowing nanoscale carriers (typically ~10–200 nm) to accumulate in tumor interstitium, whereas surface functionalization is used for active targeting — e.g. G. peptides, transferrin ligands, folate, or antibodies—to encourage cancer cells' receptor-mediated uptake. In addition to hybrid and biomimetic formulations designed for controlled release and enhanced stability, advances in polymer chemistry have produced extensively researched carriers like poly(lactic-co-glycolic acid) (PLGA), polyhydroxyalkanoates (PHAs), polyethylenimine/dendrimers, cyclodextrin-based systems. The creation of "smart" or stimuli-responsive PNPs, which release payloads in response to tumor-specific cues, is a primary area of current research. G. enzymes, redox gradients, acidic pH, etc.) or outside stimuli (e.g. G. magnetic fields, heat, and light). The goal of these clever designs is to minimize off-target exposure while increasing on-target drug concentration. Simultaneously, PNP techniques are going beyond chemotherapy to allow for immunomodulation (vaccine) and gene delivery (siRNA/miRNA/DNA).

Despite compelling preclinical results demonstrating improved pharmacokinetics, reduced systemic toxicity and the potential to overcome drug-resistance mechanisms, clinical translation of PNPs has been slower than anticipated. Key barriers include reproducible large-scale manufacturing, batch-to-batch physicochemical consistency, incomplete understanding of biodistribution and long-term safety, regulatory complexity, and heterogeneity of the tumor microenvironment that limits universal EPR applicability. Emerging solutions combine

rational polymer design, biomimetic surface coatings, advanced manufacturing methods, and data-driven optimization (including AI-assisted design) to accelerate clinical adoption. This review synthesizes foundational concepts, polymer classes and formulation strategies, cellular and microenvironmental targeting mechanisms, recent preclinical and clinical developments, and translational challenges for polymeric nanoparticles in oncology — with the goal of mapping a realistic path from bench to bedside for precision.<sup>[1,2,3]</sup>

### Types of polymers<sup>[4-8]</sup>

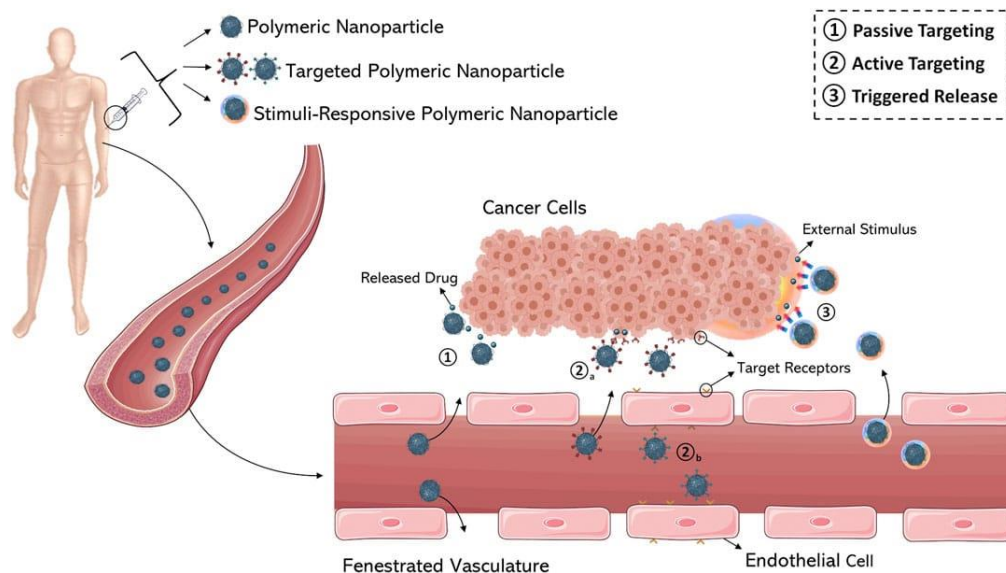
Type of Polymer	Definition / Advantages / Applications / Translation
PLGA (poly (lactic-co-glycolic acid)) nanoparticles	Definition & advantages — FDA-approved biodegradable co-polymer used for drug-loaded nanospheres and nanocapsules. Offers controlled/sustained release, tunable degradation, and surface modification (PEGylation). Preparation & functionalization — Methods: single/double emulsion solvent evaporation, nanoprecipitation, spray-drying. Functionalization: PEGylation, ligand conjugation, siRNA loading. Examples — Platform in multiple clinical trials; backbone for many investigational PNPs.
Polyhydroxyalkanoates (PHAs)	Definition & advantages — Bacterially produced biodegradable polyesters (e.g., PHB, PHBV) with good biocompatibility and hydrophobic domains for encapsulating hydrophobic drugs. Applications — Used in folate, EGF, and integrin-targeted systems for drugs like paclitaxel and doxorubicin. Less clinically advanced than PLGA.
Cyclodextrin-based polymeric nanoparticles	Definition & advantages — Cyclodextrins form inclusion complexes with hydrophobic drugs; polymeric CD systems enhance solubility and stability of anticancer agents.
Polymeric micelles (amphiphilic block copolymers)	Definition & advantages — Self-assembled core-shell structures from amphiphilic block copolymers (PEG-PLA, PEG-PLGA). Solubilize poorly water-soluble drugs and reduce excipient toxicity. Examples — Genexol-PM (paclitaxel micelle) and NK105 are clinically advanced.
Dendrimers	Definition & advantages — Highly branched macromolecules with multiple surface functional groups for drug conjugation or targeting. High payload and multivalency. Applications — Used for hydrophobic drugs, nucleic acid delivery, and targeting. Biodegradable variants like polylysine and PAMAM derivatives are being optimized.
Polymersomes (polymeric vesicles)	Definition & uses — Bilayer polymer vesicles analogous to liposomes but more robust. Can encapsulate both hydrophilic and hydrophobic cargos for controlled release and imaging co-loading.
Nanogels / crosslinked polymeric networks	Definition & advantages — Nanoscale hydrogel particles enabling high loading of hydrophilic drugs, proteins, and nucleic acids. Responsive to pH/redox/enzymes for triggered release; suitable for intracellular delivery.
Polymeric drug-	Definition & advantages — Drugs covalently linked to polymers

conjugates / prodrugs	(e.g., PEGylation, HPMA copolymers) for altered pharmacokinetics, reduced toxicity, and controlled/triggered release. Several clinical candidates exist.
Stimuli-responsive (“smart”) polymeric nanoparticles	Definition & rationale — Respond to internal (pH, redox, enzymes) or external (light, heat, ultrasound, magnetic field) stimuli for site-specific release and reduced systemic toxicity. Examples — pH-sensitive, redox-cleavable, enzyme-cleavable, thermo/photo-responsive systems are in preclinical development.
Hybrid / topologically heterogeneous polymeric nanoparticles	Definition & advantages — Lipid-polymer hybrids, core-shell, or Janus particles combining polymer stability with lipid biocompatibility. Improve circulation, targeting, and multifunctionality.
Biomimetic / cell-membrane coated polymeric NPs	Definition & translational potential — Polymer cores coated with natural cell membranes (RBC, platelet, cancer cells) for immune evasion, prolonged circulation, and homologous targeting. Promising preclinical reports.

### Key references

**Mechanism:-** The therapeutic benefits of nanoparticles in cancer therapy are primarily realized through their capacity to target tumor tissues with greater precision compared to traditional drug formulations. There are two main mechanisms at play: passive targeting and active targeting. In passive targeting, nanoparticles take advantage of the structural and functional irregularities present in the tumor vasculature. Tumor tissues are marked by permeable blood vessels featuring large openings (100–800 nm) and inadequate lymphatic drainage. This condition enables appropriately sized nanoparticles to escape from the bloodstream into the tumor interstitial space, resulting in their accumulation. This occurrence is referred to as the Enhanced Permeability and Retention (EPR) effect. The increased permeability is attributed to the abnormal blood vessel structure, while the enhanced retention is a consequence of ineffective lymphatic drainage. This passive targeting mechanism is fundamental to nanoparticle-mediated drug delivery in solid tumors. Recent research has suggested that the extravasation of nanoparticles may also involve active vesicle-mediated transport (transcytosis), indicating that passive targeting alone does not completely account for the accumulation of nanoparticles within tumors. In active targeting, the surfaces of nanoparticles are modified with specific ligands such as antibodies, peptides, or other molecules. These ligands attach to overexpressed receptors on tumor cells or the tumor endothelium, facilitating preferential accumulation and internalization of nanoparticles in cancerous tissues. This process enhances drug localization, improves therapeutic effectiveness, and minimizes systemic toxicity. Once nanoparticles arrive at the tumor site, they are taken up by tumor cells via endocytosis, enabling controlled and sustained drug

release directly within the cancerous tissue. Furthermore, stimuli-responsive nanoparticles can release drugs in reaction to internal or external stimuli such as pH, temperature, or enzymes, ensuring targeted action. The tumor microenvironment is crucial in this mechanism.



**Figure 1: Digramatic representation of various drug targeting approaches (1–3). (1) Passive targeting of nanocarriers through fenestrated vasculature of tumor.<sup>[9]</sup>**

## FACTORS AFFECTING

**1. Nanoparticle size — distribution and optimal ranges:** Size controls circulation half-life, renal clearance, extravasation through tumor vasculature (EPR), tumor penetration, and cellular uptake. Small NPs (<10 nm) are rapidly cleared renally; large NPs (>200 nm) are more likely taken up by the mononuclear phagocyte system (MPS) or get trapped in liver/spleen. Intermediate sizes (≈20–150 nm) often balance long circulation and tumor accumulation, but optimum depends on tumor vasculature.

**2. Particle shape and aspect ratio:** Shape influences margination in blood, cellular uptake pathways, circulation time, and phagocytosis. Non-spherical particles can evade clearance differently and show distinct tumor uptake/penetration patterns.

**3. Surface charge (zeta potential) and hydrophobicity:** Cationic surfaces increase cellular uptake but also serum protein binding, toxicity, and rapid clearance; strongly negative or highly hydrophobic surfaces promote opsonization. Slightly negative or near-neutral hydrophilic surfaces can prolong circulation.

**4. Surface chemistry:** PEG reduces protein adsorption (opsonization), extends blood half-life, and reduces rapid clearance by phagocytes. However, anti-PEG antibodies and the “accelerated blood clearance” phenomenon can limit repeated dosing. Alternatives (zwitterionic polymers, polysaccharides) are being explored.

**5. Protein corona formation (biomolecule adsorption):** The corona changes identity, targeting, cellular recognition, clearance, and biodistribution. Corona composition is patient- and disease-dependent and can mask targeting ligands or alternatively mediate uptake into undesired organs.

**6. Polymer composition, degradability, and mechanical properties:** Polymer chemistry affects drug compatibility, release profile, degradation rate (thus drug exposure), immunogenicity and toxicity of degradation products. Biodegradability helps avoid long-term accumulation.

**7. Drug loading and release kinetics (encapsulation vs conjugation):** Loading influences dose, release rate, burst release risk, and stability. Controlled/sustained release helps increase tumor exposure while reducing systemic toxicity; stimuli-responsive release (pH, enzymes, redox) can enhance tumor selectivity.

**8. Targeting strategies: passive vs active targeting:** Active ligands can increase cellular uptake by specific cells but rarely dramatically increase whole-tumor accumulation because first-order delivery is dominated by circulation and vascular extravasation; ligand density, orientation, and shielding by corona matter. The EPR effect itself is highly variable between tumor types and patients.

**9. Tumor microenvironment (TME) barriers:** High IFP and dense ECM limit NP penetration; hypoxia and acidity change NP stability and drug activity. These factors cause heterogeneous distribution within tumors and limit efficacy despite tumor accumulation at the periphery.

**10. Cellular internalization pathways and endosomal escape:** For cytosolic or nuclear-acting drugs (siRNA, some proteins), endosomal escape is essential; otherwise payloads are degraded in lysosomes. Polymer chemistry (proton sponge effect, pH-responsive linkages) and membrane-disruptive motifs are used to promote escape.



**11. Immune system interactions and toxicity:** Immune recognition can clear NPs and cause adverse events; toxicity from polymers, solvents, or accumulation can limit doses and translation.

**12. Pharmacokinetics/pharmacodynamics (PK/PD) and modeling:** PK/PD for nanomedicines is complex (carrier + payload). Accurate models help predict dose, schedule, and therapeutic window and are critical for translation.

**13. Manufacturing, scale-up, reproducibility, and stability:** Clinical translation requires GMP-compatible, reproducible processes that produce stable formulations with controlled CQAs (critical quality attributes). Regulatory scrutiny often focuses on these aspects.

**14. Patient and tumor heterogeneity (biomarker-driven selection):** Heterogeneity explains variable clinical responses: some patients/tumor types show strong EPR and respond; others do not. Companion diagnostics and patient selection improve trial outcomes.<sup>[10-21]</sup>

## ADVANTAGES & DISADVANTAGE

### Advantages of Polymeric Nanoparticles (PNPs) in Cancer Therapy

#### 1. Size & PDI

- Optimal size (10–200 nm) enhances tumor uptake via the EPR effect.
- Tunable size allows targeting of specific tumors and biological barriers.

#### 2. Surface Charge & Chemistry

- PEGylation extends circulation time by reducing immune recognition.
- Functional ligands enable targeted delivery and receptor-mediated uptake.

#### 3. Drug Loading & Encapsulation

- Effective for encapsulating hydrophobic drugs, improving solubility/stability.
- Allows co-delivery of multiple therapeutic agents for synergistic or theranostic applications.

#### 4. Stability & Aggregation Resistance

- Stabilizers and lyophilization enhance shelf-life.
- Surface modifications (e.g., PEG) reduce aggregation in serum.

**5. Targeting Performance**

- Passive (EPR) and active (ligand-based) targeting improve tumor localization and cellular uptake.

**6. Pharmacokinetics & Biodistribution**

- Prolonged circulation and reduced accumulation in non-target tissues.
- Customizable surface features to modulate organ distribution.

**7. Safety & Biocompatibility**

- Biodegradable polymers (PLGA, PLA, etc.) have low systemic toxicity.
- Encapsulation reduces side effects of toxic anticancer drugs.

**8. Tumor Penetration**

- Small and deformable particles penetrate tumor interstitium more effectively.
- Designs can be tailored for microenvironment-responsive delivery.

**9. Manufacturing & Translation Potential**

- Scalable manufacturing platforms exist for certain polymers (e.g., PLGA).
- Some clinical success in related nanomedicines (e.g., Abraxane, Doxil).

**10. Clinical Readiness**

- Clinical experience and regulatory precedents guide design.
- PNPs offer versatility for combination therapies and personalized medicine.

**Disadvantages / Limitations of PNPs****1. Size & PDI**

- Broad PDI reduces reproducibility and increases clearance by RES.
- Very small particles (<10 nm) are cleared renally; large particles (>200–300 nm) are phagocytosed.

**2. Surface Charge & Chemistry**

- Positive charge increases toxicity and protein binding.
- PEG can provoke anti-PEG antibodies, reducing effectiveness with repeated dosing.
- Ligand addition increases formulation complexity and off-target risk.



**3. Drug Loading & Release**

- Burst release in circulation can reduce efficacy and increase toxicity.
- Stimuli-responsive release may fail in the heterogeneous tumor environment.
- Complex chemistries hinder scale-up and regulatory approval.

**4. Stability & Aggregation**

- Aggregation in storage or upon dilution affects biodistribution and efficacy.
- Surfactants/stabilizers may introduce toxicity or immune reactions.

**5. Targeting Performance**

- EPR effect is variable across tumor types, patients, and tumor regions.
- Active targeting does not always improve overall tumor accumulation.
- Receptors may also be expressed on normal cells → off-target effects.

**6. PK & Biodistribution**

- High liver and spleen uptake due to RES limits tumor availability.
- Variability in protein corona formation affects consistency between individuals and species.

**7. Safety & Immunotoxicity**

- Some polymers or degradation products may accumulate long-term.
- Risks include complement activation, infusion reactions, and immune sensitization (e.g., anti-PEG antibodies).
- Long-term nanotoxicology is not fully understood.

**8. Tumor Penetration Challenges**

- Dense stroma, high interstitial pressure, and poor vascularization hinder access.
- Intra-tumoral heterogeneity limits uniform drug delivery.

**9. Manufacturing & Regulatory Complexity**

- Difficult to scale up while maintaining consistent particle properties.
- Multi-functional formulations raise analytical and regulatory hurdles.
- High cost and limited long-term safety data slow approvals.

**10. Clinical Translation Limitations**

- Few PNP-based drugs have reached market despite strong preclinical data.

- Variable tumor biology and patient-specific PK make clinical outcomes unpredictable.<sup>[22-31]</sup>

## FUTURE PERSPECTIVE

Future prospects for polymeric nanoparticle (PNP) therapeutics focus on establishing globally accepted regulatory standards (e.g., ISO or pharmacopeial monographs), developing automated, PAT-integrated manufacturing platforms for consistent GMP-scale production, and leveraging digital twins that integrate process data with *in vivo* behavior to streamline scale-up and regulatory bridging. Advances in AI and organ-on-chip models will enhance prediction of PNP behavior in humans, reducing reliance on animal models. The field is also moving toward open data practices, validated *in vitro*–*in vivo* translation metrics, and standardized characterization methods, all of which will be critical for accelerating clinical translation and ensuring safety, efficacy, and reproducibility of next-generation PNP-based cancer therapies.<sup>[32-46]</sup>

## CONCLUSION

Polymeric nanoparticles (PNPs) signify a groundbreaking development in cancer treatment, facilitating accurate drug delivery through adjustable size, surface chemistry, and stimuli-responsive release mechanisms. Their capacity to encapsulate a variety of therapeutics—including chemotherapeutics, nucleic acids, and imaging agents—improves treatment effectiveness while reducing systemic toxicity. Both passive targeting via the EPR effect and active targeting through ligands contribute to enhanced tumor accumulation and cellular uptake. Nevertheless, challenges persist in addressing tumor microenvironmental barriers, ensuring batch-to-batch reproducibility, and scaling up for clinical applications. The diversity of tumor biology and variability in patient responses further complicate the translation of these therapies. However, continuous innovations—such as AI-driven nanoparticle design, biomimetic coatings, and advanced manufacturing techniques—present promising solutions. With the growing clarity in regulations and the incorporation of standardized quality controls, PNPs are set to assume a pivotal role in the future of personalized oncology, facilitating safer, more effective, and targeted cancer therapies.<sup>[47-52]</sup>

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