

## The Role of Nanoparticles in Overcoming the Challenges of Biotherapeutic Stability and Bioavailability

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### DESCRIPTION

Biotherapeutics, including monoclonal antibodies, peptides, and nucleic acids, have transformed the landscape of modern medicine by providing highly specific and potent treatments for a variety of diseases. Despite their promise, these biomolecules face significant challenges in clinical applications due to their inherent instability, susceptibility to enzymatic degradation, and limited bioavailability. Nanoparticles (NPs), due to their unique physicochemical properties, have emerged as a revolutionary solution to address these challenges and to optimize the delivery and efficacy of biotherapeutics. Biotherapeutics are inherently fragile molecules that are subject to denaturation, aggregation, and degradation during storage and systemic circulation. For example, proteins and peptides can lose their secondary and tertiary structure due to environmental factors such as temperature, pH, and agitation. In addition, nucleic acids such as siRNA (small interfering Ribonucleic Acid) and mRNA (messenger RNA) are highly susceptible to enzymatic degradation by nuclease, which limits its therapeutic potential. Nanoparticles provide a robust platform to improve biotherapeutic stability.

The encapsulation of biomolecules in nanoparticles can protect from external environmental stressors. Lipid-based nanoparticles, such as liposomes, create a biocompatible environment that preserves the structural integrity of the encapsulated proteins. Similarly, polymeric nanoparticles, formulated from materials such as Poly Lactic-co-Glycolic Acid (PLGA), offers controlled release properties, which guarantee prolonged stability and sustained therapeutic action. Bioavailability is a key factor determining the clinical success of biotherapeutic products. Many biomolecules exhibit low oral bioavailability due to enzymatic degradation in the gastrointestinal tract and low permeability across intestinal barriers. Even when administered parenterally, rapid clearance by the Reticuloendothelial System (RES) and renal filtration can limit systemic bioavailability. Nanoparticles can significantly improve bioavailability by improving the pharmacokinetics and biodistribution of biotherapeutics. Surface modification of

nanoparticles with Polyethylene Glycol (PEG), a process known as PEGylation, can reduce opsonization and RES clearance, thereby extending systemic circulation. Additionally, nanoparticles can facilitate targeted delivery by coupling specific ligands to overexpressed receptors in diseased tissues. For example, transferrin-conjugated nanoparticles have been shown to improve the delivery of therapeutic agents across the Blood-Brain Barrier (BBB), a major challenge in the treatment of neurodegenerative diseases.

One of the main advantages of nanoparticle-based systems is their ability to provide controlled and targeted drug release. Controlled release minimizes the risk of toxicity at the maximum dose while maintaining therapeutic drug levels for a long period. Polymeric nanoparticles, dendrimers, and hydrogels are examples of nanocarriers that allow programmable drug release in response to stimuli such as pH, temperature, or enzymatic activity. Targeted delivery also improves therapeutic efficacy and minimizes off-target effects. For example, nanoparticles functionalized with antibodies or aptamers can selectively bind to specific tumour antigens, thereby delivering chemotherapeutic agents directly to cancer cells while sparing healthy tissues. This approach has been successfully used in the development of Antibody-Drug Conjugates (ADCs) and ligand-targeted nanoparticles. The clinical translation of nanoparticle-based biotherapeutic delivery systems is exemplified by Lipid Nanoparticles (LNPs) used in mRNA vaccines, such as those developed for COVID-19. These LNPs protect the fragile mRNA cargo from degradation and facilitate its efficient delivery to host cells, where they trigger an immune response. Similarly, nanoparticle formulations of siRNA, such as Patisiran, have shown remarkable success in the treatment of hereditary transthyretin-mediated amyloidosis by effectively silencing the genes that cause the disease.

Although nanoparticles have tremendous potential, some challenges remain to be addressed in their development and clinical implementation. Scalability and reproducibility of nanoparticle formulations, potential immunogenicity, and regulatory hurdles are critical areas that need to be addressed.

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Advances in nanotechnology, combined with interdisciplinary research, are expected to overcome these limitations and pave the way for next-generation biotherapeutics. Nanoparticles have emerged as a transformative tool to address the challenges of stability and bioavailability of biotherapeutics. By providing

protection, controlled release, and targeted delivery, they have the potential to improve the efficacy and safety of new treatments. Continued innovation in this field will undoubtedly open up new horizons in the treatment of complex diseases, cementing the role of nanotechnology in the future of medicine.