REVIEW PAPER

Biomimetic Nanoparticles for Targeted Drug Delivery: Current Advances, Cell Membrane-Coated Nanocarriers, and Future Clinical Perspectives

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Abstract

Targeted drug delivery has been driven as a promising new generation of drug delivery platforms and biomimetic nanoparticles are created by combining the structural properties of synthetic nanocarriers with the biological properties of the natural cell-derived components. These systems are more biocompatible than conventional nanoparticles, and have longer circulation, immune evasion properties and improved targeting efficiency, which overcome many of the limitations of conventional drug delivery systems. One of the most promising biomimetic approaches is the use of nanoparticles that are coated with the membrane of cells. These nanoparticles retain the membrane proteins and surface properties of the source cells and retain the versatility of engineered nanoparticle cores. This review presents a detailed insight into design, classification, formulation and physicochemical properties of biomimetic nanoparticles, especially the cell membrane-coated nanocarriers. It critically evaluates the mechanisms in targeted delivery of drugs such as immune escape, homotypic targeting, receptor mediated interaction and controlled drug delivery. Recent therapeutic applications in cancer, inflammatory disorders, infectious diseases, cardiovascular and neurological diseases, gene delivery, regenerative medicine and Theranostics are also discussed. Moreover, the review discusses the key issues of large-scale manufacturing, quality control, regulatory approval, biosafety and clinical translation. New areas of development such as hybrid membrane engineering, stimuli-responsive systems, artificial intelligence driven by new nanoparticle design and the creation of personalised nanomedicine are emphasized as future innovative directions. In conclusion, biomimetic nanoparticles are a revolutionary way to achieve precision medicine, and their applications are poised to enhance the effectiveness of treatment while minimizing systemic toxicity. As research in related fields continues to advance, scaling up manufacturing processes and evaluating them in the clinic should speed their progress into clinical reality.

Keywords

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1. Introduction

The use of conventional drug delivery systems (tablets, capsule, injection or topical formulation) is linked to certain drawbacks, including low aqueous solubility, reduced bioavailability, fast systemic clearance, non-specific tissue distribution, frequent administration and dose dependency toxicity. Such deficiencies are especially notable for the treatment of complex diseases, such as cancer, neurodegenerative, autoimmune and chronic inflammatory diseases, in which selective and controlled delivery of a drug is vital to attain the best therapeutic outcome. For this reason, research has been focused on creating new and complex drug delivery systems that are able to cross biological barriers and improve targeting over time [1].

The advent of nanotechnology has transformed the way drugs are delivered to tissues or cells, with the development of nanosized particles that are able to carry therapeutic agents, protect them and deliver them to specific tissues and/or cells. Nanoparticles are generally smaller than 100 nm and generally between 10 and 200 nm have unique physicochemical properties as high surface-area-to-volume ratio, tunable surface characteristics, high drug-loading capacity, controlled drug release and are capable of accommodating both hydrophilic and lipophilic therapeutic agents [2]. Various nanocarriers like liposomes, polymeric

nanoparticles, solid lipid nanoparticles, dendrimers, micelles, mesoporous silica nanoparticles and metallic nanoparticles have been shown to exhibit marked enhancement in drug stability, pharmacokinetics and therapeutic activity. The clinical approval of a number of nanoformulations further reflects the advances of nanomedicine in contemporary medicine [3]. Although significant strides have been made, the use of conventional synthetic nanoparticles in clinical applications is still limited by certain biological issues. After systemic injection, nanoparticles easily bind to plasma proteins, creating a protein corona and triggering their fast elimination by the mononuclear phagocyte system (MPS), such as liver and spleen macrophages. In addition, synthetic nanocarriers can induce immune responses, have poor tissue penetration, have poor cellular uptake, and lack targeting specificity. The biological barriers such as vascular endothelial cells, extracellular matrix and cell membranes further complicate the delivery of therapeutic agents to diseased tissues efficiently [4].

Biomimetic nanotechnology has become an innovative, and therefore very promising, approach to targeted drug delivery, that is able to overcome these limitations. Biomimetic nanoparticles consist of synthetic nanoparticle cores coupled with natural biological structures and components, such as cell membrane, extracellular vesicles, membrane proteins, peptides and other biomolecules. These hybrid nanocarriers have been designed to mimic the structure and function of living cells, which results in better biocompatibility, longer circulation in the blood, better immune tolerance, better interactions with cells and targeted drug delivery.

In particular, cell membrane-coated nanoparticles have been the subject of much interest as they retain the biological features of their cell source and possess the engineered nanoparticle core versatility. In this method, the plasma membranes were isolated from various cell types and coated on synthetic nanoparticles leaving essential membrane proteins, receptors, phospholipids and surface antigens [5]. This makes these nanoparticles ideal candidates for developing novel therapeutics with enhanced biological functions derived from their parental cells. The biological activity of the nanocarriers is greatly influenced by source of the membrane. The expression of the CD47 proteins on red blood cell membrane-coated nanoparticles are responsible for their prolonged circulation and immune evasion, as it is a natural 'self-recognition' signal that prevents their clearance by macrophages [6]. These platelet membrane coated nanoparticles could target damaged blood vessels and circulating tumour cells selectively and be therefore useful for the treatment of cancer and cardiovascular diseases. Similarly, The membranes of leukocytes and macrophages confer inflammation targeting properties to the tumor-targeting nanoparticles, and the membrane of cancer cells imparts homotypic targeting properties to the tumor-targeting nanoparticles, which enhances selective accumulation in the tumour. Inherent tissue-homing properties of stem cell membrane-coated nanoparticles make them especially interesting for regenerative medicine and tissue repair [7].

A typical biomimetic nanoparticle consists of three essential components: a synthetic nanoparticle core, a biological membrane coating and a therapeutic payload. The core of the nanoparticles could also be a polymer, lipids, silica, metallic, magnetic nanoparticles or hybrid nanoparticles, ensuring structural integrity and efficient drug loading. The biological membrane coating makes it immune compatible, prolonging the circulation time and provides targeting capability, and the enclosed payload can be small molecule drugs, proteins, peptides, nucleic acids, vaccines or imaging agents [8]. The fabrication of biomimetic nanoparticles has been significantly enhanced by the remarkable progress in membrane isolation, extrusion, sonication, microfluidic engineering, and membrane fusion technologies that have yielded nanocarriers that retain the biological functionality, reproducible physicochemical characteristics and enhanced therapeutic potential of their natural counterparts [9].

Biomimetic nanoparticles have been studied in a wide range of therapeutic applications due to their unique biological properties. In cancer therapy, these nanocarriers increase the association with tumors by prolonged circulation, the enhanced permeability and retention (EPR) effect, receptor-mediated targeting and the homotypic cellular interactions. In inflammatory and infectious diseases, immune cell membrane-coated nanoparticles selectively accumulate at inflamed tissues, thereby improving therapeutic efficacy whilst reducing systemic toxicity. However, biomimetic nanoparticles have also shown the potential to cross difficult biological barriers such as the blood-brain barrier, which could provide valuable treatment avenues for neurological disorders. Furthermore, such nanocarriers are becoming the focus of many studies for gene delivery, mRNA- and siRNA-based therapeutics, vaccine development, immunotherapy, tissue engineering and precision medicine [10].

Although biomimetic nanoparticles hold great therapeutic promise, a number of challenges need to be overcome for these nanoparticles to be translated into routine clinical practice. These include standardisation of biological membrane

sources, preservation of membrane integrity during fabrication, batch to batch reproducibility, scalability of the manufacturing processes, long-term storage stability and the development of a robust quality control system. Further, careful study of long-term safety and immunogenicity, and regulatory pathways and cost-efficient large-scale manufacturing are key to successful clinical translation [11].

The current advancement of artificial intelligence, machine learning, CRISPR based genome editing, hybrid membrane engineering, microfluidic technologies and personalised medicine is driving the development of next generation biomimetic nanocarriers [12]. Such innovations, which span multiple disciplines, allow the rational design of nanoparticles with more precise targeting, better therapeutic responses, and customized treatments for different patients.

This review gives an all-inclusive and current overview of biomimetic nanoparticles for targeted drug delivery, especially focusing on cell membrane-coated nanocarriers. It evaluates their design principles, their classification, fabrication strategies, characterisation techniques, targeted drug delivery mechanisms and therapeutic applications in various disease conditions critically. Moreover, the review highlights the major benefits and existing challenges, regulatory issues, and the new technology breakthroughs that will influence the future of biomimetic nanomedicine. Biomimetic nanoparticles are one of the most promising platforms for targeted drug delivery and precision medicine that can revolutionize future therapeutic strategies and enhance clinical outcomes.

1.2 Novelty of the Review

While there are many review articles that have investigated biomimetic nanoparticles and nanocarrier-based drug delivery systems, the majority have concentrated on either individual therapeutic applications or the principles of biomimetic nanotechnology, in general, rather than the use of individual membrane sources. Current comprehensive reviews that combine nanoparticle design, engineering approaches, targeted drug delivery mechanisms, all the array of cell membrane-coated nanocarriers, therapeutic applications, and the challenges that lie in their translation into the clinic and the latest technology developments in the field are scarce.

This review aims to provide an extensive and modern overview of biomimetic nanoparticles, especially that of cell membrane-coated nanocarriers, as advanced platforms for targeted drug delivery. It systematically reviews biomimetic nanoparticles designed and engineered, various membrane sources and functions, and mechanisms of immune evasion and active targeting, along with the recent developments in fabrication technologies, and their therapeutic applications in a wide spectrum of diseases.

Along with summarizing knowledge, this review identifies the new developments that are influencing the future of the field such as hybrid membrane engineering, stimuli-responsive biomimetic nanocarriers, artificial intelligence-assisted nanoparticle design, theranostic platforms, CRISPR-based gene delivery and personalized biomimetic nanomedicine. It also features a critical analysis of the important issues that surround large scale manufacturing, quality assurance, regulatory aspects and clinical translation, and highlights important research priorities.

This review provides a comprehensive analysis of biomimetic nanotechnology by combining recent scientific innovations with the considerations for clinical application. It is designed to be an excellent resource for pharmaceutical scientists, biomedical researchers, clinicians and postgraduate students involved in the design and development of advanced drug delivery systems, nanomedicine and precision medicine.

2. Biomimetic Nanoparticles: Concept and Fundamentals

2.1 Definition of Biomimetic Nanoparticles

Biomimetic nanoparticles are defined as nanoparticles that mimic a natural entity in their shape and structure. Biomimetic nanoparticles (BNPs) are the advanced nanocarrier based drug delivery systems, which are designed by combining synthetic nanocarriers with biologically derived components that have similar structural and functional features to living cells or naturally occurring biological entities [13]. Compared to conventional nanoparticles, which are made of synthetic polymers, biomimetic nanoparticles consist of biological membranes, proteins, peptides or extracellular vesicles and other natural materials to help them interact more effectively with the physiological environment. This biomimetic strategy increases biocompatibility, evades the immune system, extends systemic circulating half-life, increases target specificity and decreases off-target toxicity [14].

Biomimicry in nanomedicine is based on the incredible ability of cells to function within the body to carry, transport and communicate

biomolecules efficiently. The use of these inherent biological properties brings some limitations of conventional nanocarriers to biomimetic nanoparticles, such as fast clearance by the mononuclear phagocyte system (MPS), corona protein formation, short circulation time and poor accumulation at disease sites. As a result, biomimetic nanotechnology has become a promising approach toward precision drug delivery and personalized medicine.

2.2 Principles of Biomimicry in Drug Delivery

The biomimetic nanoparticles therapeutic performance has been attributed to its ability to mimic the structural and functional properties of the native-cells, which allows them to interact with the biological systems in a manner that mimics the native cells' biological functions [15]. Biomimetic nanoparticles can actively engage in biological interactions as a result of their ability to preserve membrane proteins, phospholipids, receptors and adhesion molecules, compared to conventional nanoparticles that are only passive drug carriers [16].

Immune evasion is one of the basic principles of biomimetic drug delivery. Membrane proteins, such as CD47, which are found on red blood cell membranes, are known to convey a natural 'don't eat me' signal to macrophages, thus minimizing phagocytosis by the mononuclear phagocyte system and prolonging the systemic circulation. A second principle is selective target recognition which is mediated through membrane-bound receptors and adhesion molecules that facilitate interactions with diseased tissues via receptor–ligand interactions, homotypic recognition and inflammatory chemotaxis. Such systems allow to target the drugs preferentially to the target while allowing to spare healthy tissues [17].

The biological membrane coating of biomimetic nanoparticles also exhibits excellent biocompatibility, as the coating is very close to the composition of the native cell membranes. In concert with membrane-associated proteins and glycoproteins, the phospholipid bilayer also minimizes immune activation, prevents clearance by complement and enhances the blood and tissue-compatibility of cells [18]. Moreover, the biological membrane helps to secure a prolonged circulation time and a higher bioavailability for the nanoparticle, in order to avoid its rapid renal elimination, as well as enzymatic degradation and pre-dissolution of the drug.

Another feature is the ability of biomimetic nanoparticles to communicate with cells. Membrane proteins can be retained in their biological activity, enabling cell-to-cell interactions, such as intracellular signalling, adhesion and receptor-mediated endocytosis, resulting in improved therapeutic efficacy and cellular uptake. Moreover, the core of the nanoparticles can be tailored for controlled delivery of the drug via sustained, localized or stimuli-mediated release pathways triggered by shifts in pH, temperature, enzyme activity, reactive oxygen species or in response to external physical stimuli. These biological and physicochemical properties collectively enhance the pharmacokinetic characteristics, enhance therapeutic efficacy, minimize systemic toxicity and support the clinical potential of biomimetic nanoparticle-based drug delivery systems [19].

2.3 Evolution of Biomimetic Nanotechnology

In the last 30 years, nanotechnology has come a long way and made tremendous progress in the field of drug delivery. The first generation of nanocarriers has mainly been designed for enhanced drug solubility and ensuring the stability of fragile therapeutic molecules. Liposomes, polymeric nanoparticles, dendrimers and solid lipid nanoparticles were important steps in the development of nanomedicine and had shown better pharmacokinetic characteristics than the conventional dosage forms [20].

Nevertheless, the clinical use of synthetic nanoparticles was limited by problems of immune clearance, non-specific biodistribution and limited targeting efficiency. Researchers have developed surface modification strategies, including polyethylene glycol (PEG) coating, for extension of circulation and reduced immune recognition, to improve the biological performance. PEGylation increased in vivo stability of the nanoparticles, however repeated administration was linked to increased blood clearance and in some instances immunogenic response [21].

The advent of biomimetic nanotechnology led to a major breakthrough in nano-technology engineering. To avoid the exclusive use of synthetic surface modifications, researchers have started to coat nanoparticle cores with the natural cell membrane while maintaining the membrane proteins, surface receptors, glycoproteins and lipids involved in recognition in the biological world [22]. The approach allowed the nanoparticles to inherit functional properties of their original cells, leading to increased immune compatibility, longer circulation time and increased targeting.

The biomimetic nanoparticles also have been advanced by recent advances in membrane isolation technology, micro fluidic fabrication, and membrane fusion technology and bioengineering. These advancements have enabled the creation of multifunctional hybrid nano-carriers that can deliver therapeutic agents, nucleic acids, proteins, and imaging agents simultaneously, creating new possibilities for targeted drug delivery and precision medicine.

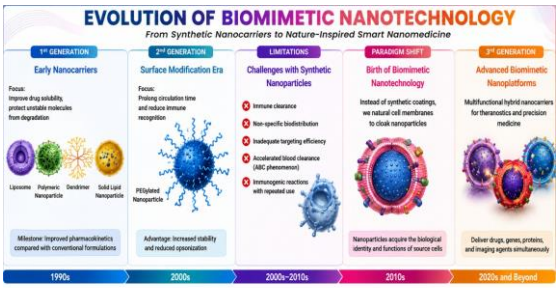

Figure no 1.1 : Evolution of Biomimetic Nanotechnology

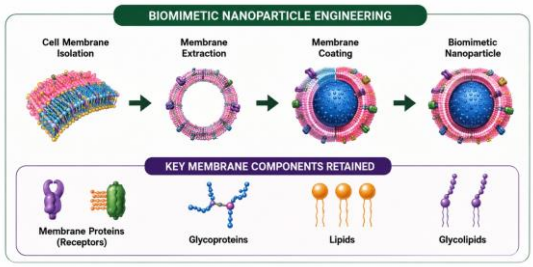

Figure no 1.2 : Biomimetic Nanoparticle Engineering

2.4 Classification of Biomimetic Nanoparticles

Based on the type of biological material used to develop the biological system-nanoparticle, biomimetic nanoparticles are classified [23,24,25].

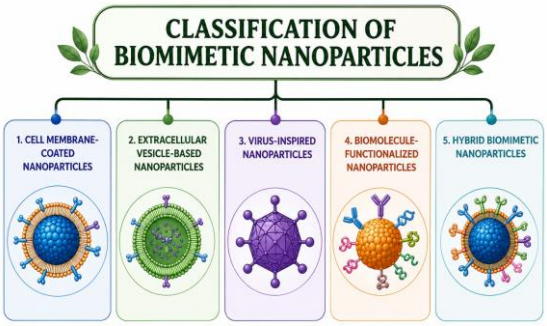

Figure no 1.3 : Classification of Biomimetic Nanoparticles

2.4.1 Cell Membrane-Coated Nanoparticles

The most widely studied biomimetic nanocarriers are cell membrane-coated nanoparticles. These are made up of synthetic nanoparticle cores surrounded by natural cell membranes, which contain all the key membrane proteins, receptors and phospholipids. This biomimetic design provides enhanced immune evasion, extended systemic circulation and targeting ability. Depending on the membrane source these nanoparticles can carry out special biological functions. Properties of membranes include immune escape, targeting to inflammation, targeting to blood vessels, targeting to tissues, and homotypic tumour recognition, among others, that are provided by membranes derived from red blood cells, platelets, macrophages, leukocytes, stem cells and cancer cells. Owing to these characteristics, cell membrane-coated nanoparticles have been widely investigated for the treatment of cancer, inflammatory disorders, cardiovascular diseases, neurological conditions and infectious diseases.

2.4.2 Extracellular Vesicle-Based Nanoparticles

Extracellular vesicles (EVs) and especially exosomes are naturally released nanoparticles which are a key part of intercellular communication. They are biocompatible, have low immunogenicity, long circulating times and are naturally targeting. Exosomes have the ability to execute an effective delivery of therapeutic agents, including small molecule drugs, proteins, nucleic acids and vaccines, and also have the capability to permeate biological barriers like the blood brain barrier. In spite of these benefits their wider use in clinical practice is limited by the difficulties with large-scale production, purification and standardisation.

2.4.3 Virus-Inspired Nanoparticles

Sometimes nanoparticles are designed to mimic viruses and their structure and functions in the absence of infectious genetic material. They have been found to be good vehicles for vaccine, gene therapy, intracellular drug delivery, and immunotherapy because they have efficient cellular uptake, receptor-mediated internalisation and efficient intracellular trafficking. These nanoparticles have the advantageous properties of viral systems but without the danger of viral replication.

2.4.4 Biomolecule-Functionalised Nanoparticles

The difference between biomolecule-functionalised nanoparticles and cells with complete cell

membranes is that biological ligands, such as antibodies, peptides, aptamers, carbohydrates and growth factors, are conjugated to the surface of the nanoparticles. These ligands selectively target disease-specific receptors, which can facilitate receptor-mediated cellular uptake and improve targeting specificity. Their capacity to deliver therapeutic agents with greater precision has been exploited in the field of targeted chemotherapy, molecular imaging, gene delivery and personalised medicine to name but a few, and has been explored widely.

2.4.5 Hybrid Biomimetic Nanoparticles

Biomimetic nanoparticles are nanoparticles that exploit the biological membrane of two or more types of cells in order to integrate multiple biological functions in a single nanocarrier. For instance, hybrid membranes made of red blood cells and platelets result in a long-lasting co-circulation and vascular targeting, while cancer cell-macrophage hybrid membranes are able to deliver homotypic tumour recognition and inflammation-targeting properties. These multifunctional nanocarriers combine complementary biological functions for improved targeting performance and therapeutic versatility, making them promising candidates for advanced targeted drug delivery and precision medicine.

Table no 1.1 : Classification of Biomimetic Nanoparticles

Type	Biological Source	Major Advantages	Therapeutic Applications
Cell membrane-coated nanoparticles	RBC, platelet, macrophage, stem cell, cancer cell	Immune evasion, long circulation	Cancer, inflammation, cardiovascular diseases
Extracellular vesicle-based nanoparticles	Exosomes, microvesicles	Natural targeting, high biocompatibility	Gene therapy, CNS disorders
Virus-inspired nanoparticles	Viral capsid mimics	Efficient cellular uptake	Vaccines, gene delivery
Biomolecule-functionalized nanoparticles	Antibodies, peptides, aptamers	Receptor-specific targeting	Targeted chemotherapy
Hybrid biomimetic nanoparticles	Multiple membrane sources	Multifunctional targeting	Precision medicine

2.5 General Characteristics and Advantages of Biomimetic Nanoparticles

General Characteristics

Biomimetic nanoparticles have the potential to become a very interesting platform for future drug delivery systems with a natural cell membrane bio-functionality which is combined with a synthetic nanocarrier structural versatility. The diameter of these nanoparticles is typically 50-250 nm, which is an appropriate size to cross biological barriers, to promote efficient cellular uptake, and to avoid rapid renal elimination[26]. The unique feature is that they are naturally-coated with a biological membrane that keeps the phospholipid bilayer intact along with membrane proteins, glycoproteins, receptors and adhesion molecules from the source cells. This membrane has the important role to maintain biological functions, including the ability to recognize cells, modulate immune response and communicate with other cells, and interact with cells of the same tissue type[27]. The synthetic core underneath the membrane is a stable and flexible carrier that can be loaded with a variety of therapeutic and diagnostic agents such as small molecule drugs, proteins, peptides, nucleic acids, vaccines, gene-editing systems and imaging probes.

The membrane coating also helps to achieve colloidal stability and minimise protein corona formation, which helps to prevent premature degradation of the nanoparticles and decrease the clearance rate by the mononuclear phagocyte system, leading to a prolonged circulation time and increased drug accumulation at the targeted sites[28]. In addition, recent progress on nanotechnology has allowed the design of stimuli-responsive biomimetic nanoparticles that selectively release their therapeutic content under certain internal or external stimuli, such as changes in pH, presence of specific enzymes, light, heat, ultrasound, or magnetic field, allowing more precise treatment and minimizing systemic toxicity[29].

Advantages of Biomimetic Nanoparticles [30,31,32]

- Excellent biocompatibility, because it contains natural cell membrane components.
- Low immunogenicity (less likely to cause an adverse immune response).
- Ability to evade the immune system efficiently, including by downregulating clearance by macrophages, e.g. through membrane proteins like CD47.
- Long-lasting systemic circulation, leading to enhanced pharmacokinetic behaviour.
- Improved targeting function by receptor mediated interaction, homotypic recognition and inflammatory chemotaxis.
- Minimised off-target toxicity by targeting the drug to diseased tissues and minimising exposure to healthy organs. Enhanced physicochemical stability such as decreased protein corona formation and increased protection from premature degradation.
- High drug-loading versatility for delivery of small molecules, proteins, peptides, nucleic acids, vaccines, gene editing systems and imaging agents regulated and stimuli responsive drug release; site specific drug delivery by changing pH, enzyme, ROS, temperature, light, ultrasound or magnetic field.
- Wide range of therapeutic applications such as cancer therapy, gene delivery, immunotherapy, regenerative medicine, infectious disease therapy and personalised medicine.
- Bridges synthetic nanotechnology with biological systems, providing a potential platform for next generation precision medicine and clinical translation.

3. Design and Engineering of Biomimetic Nanoparticles

Biomimetic nanoparticles therapeutic performance, physicochemical stability and potential for clinical application is critically dependent on the design and engineering. Biomimetic nanoparticles are nanoparticles that are engineered by combining synthetic elements with naturally occurring biological components, such as cell membranes or extracellular vesicles. With this blend, they are able to leverage the complementary benefits of synthetic nanotechnology and biological systems. The biological membrane, which is used to provide functions such as immune evasion, long blood circulation, enhanced biocompatibility and targeting towards a particular disease, forms a part of the structure, while the synthetic nanoparticle core provides structural integrity and high drug loading capacity with controlled drug release [33].

Biomimetic nanoparticles require optimization of several parameters including choice of the nanoparticle core, choice of biological membrane source, fabrication strategy and therapeutic payload. All of these factors have a bearing on the formulation's physicochemical properties, its interactions with biological systems, and its therapeutic activity. Recent innovations in nanotechnology, membrane engineering and microfluidic fabrication have led to the development of biomimetic nanoparticles that have been designed to become multifunctional nanocarriers with high clinical translation potential and high reproducibility[34].

3.1 Components of Biomimetic Nanoparticles

The components of biomimetic nanoparticles are discussed here. A biomimetic nanoparticle consists of three main components: the core of the nanoparticle, the coating biological membrane and the therapeutic payload. All of these together ensure structural stability, biological functions and efficient targeted drug delivery [8].

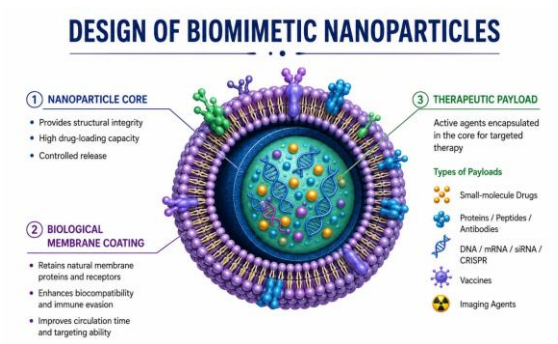

Figure no 1.4 : Design of Biomimetic Nanoparticles

3.1.1 Nanoparticle Core

The structural framework of the biomimetic nanocarrier is the core of the nanoparticles that act as a reservoir for the therapeutic agents. It is an integral factor in defining particle size, drug-loading capacity and release characteristics as well as overall formulation stability. The core materials that are used include biodegradable polymers (e.g. poly(lactic-co-glycolic acid) (PLGA), polylactic acid (PLA), polycaprolactone (PCL), and chitosan), lipid-based systems (e.g. solid lipid nanoparticles (SLNs) and nanostructured lipid carriers (NLCs)), mesoporous silica nanoparticles and metallic nanoparticles (e.g. gold and iron oxide). Polymeric and lipid-based cores are extensively used due to

their good biocompatibility, biodegradability and good controlled drug release. However, metallic nanoparticles have unique physicochemical properties which make them highly useful for diagnostic imaging, photothermal therapy and magnetically directed drug delivery [35].

3.1.2 Biological Membrane Coating

Biomimetic nanoparticles are uniquely characterized by the biological membrane that coats them, and imparts functions similar to the source cells. Natural cell membranes have phospholipid bilayers that hold membrane associated proteins, receptors, glycoproteins and can provide immune evasion, long blood circulation time, increased biocompatibility, and selective targeting. Depending on the source of the membrane, the biological properties of these nanocarriers are different. Red blood cell membranes serve to prolong circulation time by masking the cells from immune recognition; platelet membranes show preferential homing to sites of vascular injury; macrophage- and leukocyte-derived membranes promote homing to inflamed tissues; stem cell membranes provide tissue homing capability; bacterial membranes have been the focus of significant interest for vaccine delivery and immunotherapy [36].

3.1.3 Therapeutic Payload

The therapeutic payload is the active agent that is encapsulated or incorporated into the core of the nanoparticle. The biomimetic nanoparticles can deliver a wide variety of therapeutic and diagnostic molecules, such as small molecule drugs, proteins and peptides, monoclonal antibodies, DNA, mRNA, siRNA, gene-editing systems based on CRISPR, vaccines and imaging agents. The biological membrane ensures the integrity and stability of these payloads in circulation before drug release, while the engineered nanoparticle core allows targeted and/or stimuli-responsive drug release. This combination improves the therapeutic efficiency and widens the application of biomimetic nanoparticles in cancer therapy, gene delivery, immunology and precision medicine [10].

Figure no 1.5 :Fabrication strategy

Table no 1.2 : Comparison of Fabrication Techniques for Biomimetic Nanoparticles

Technique	Principle	Advantages	Limitations	Typical Applications
Extrusion	Mechanical membrane fusion	Uniform coating	Difficult scale-up	Cell membrane-coated nanoparticles
Sonication	Ultrasonic membrane fusion	Simple, rapid	Protein denaturation	Drug delivery
Microfluidics	Controlled fluid mixing	Highly reproducible	Expensive instrumentation	Clinical-scale manufacturing
Electroporation	Electrical membrane permeabilization	Efficient nucleic acid loading	Membrane damage	Gene delivery

3.2 Surface Functionalisation, Engineering and Design Considerations for Clinical Translation

While the natural cell membrane coating provides biomimetic nanoparticles with desirable biological characteristics, there are other surface engineering strategies to further tune their therapeutic performance and broaden their clinical use. Surface functionalisation refers to the process of attaching specific molecules to the surface of the nanoparticles, which enhances their targeting accuracy, imaging capability, circulation time, and drug release rate [37]. A range of targeting ligands—such as antibodies, peptides, aptamers, carbohydrates and small molecules—can be anchored to the surface of the membrane to selectively recognize diseased cells while minimizing the interaction between the membrane and healthy tissues. PEG is often used to enhance the colloidal stability and reduce non-specific protein adsorption and to increase the systemic circulation.

Another potential function for biomimetic nanoparticles is to be loaded with fluorescent dyes, magnetic nanoparticles, radioactive tracers and other imaging probes, allowing the combination of diagnosis and therapy to be performed in a single

platform, as is often termed, theranostics [38]. More importantly, the stimuli-responsive polymers allow for the ability to control the release of the drugs in response to a physiological or external stimulus such as pH, enzyme activity, reactive oxygen species, temperature, ultrasound, light and magnetic fields. The systems are responsive and cause local drug release, which enhances therapeutic effectiveness whilst minimizing systemic toxicity [39].

One key development in biomimetic nanotechnology has been the development of hybrid membrane engineering in which membranes from two or more cell types are fused together before coating the core of the nanoparticle. This strategy involves the integration of complementary biological properties in one nanocarrier, thus expanding its functionalities. Hybrid nanoparticles coated with red blood cell and platelet membranes, for instance, could have a very long circulation time, but targeted interaction at damaged blood vessels and circulating tumour cells. Similarly, hybrid membranes of cancer cells and macrophages possess both homotypic recognition of tumor cells and inflammatory targeting, while hybrid membranes of stem cells and leukocytes show both tissue homing and immune modulating properties. These multifunctional systems offer more targeting accuracy and therapeutic versatility, and are promising tools for precision medicine and personalised drug delivery [40].

Despite these developments, however, there are critical formulation design, manufacturing, quality control and regulatory considerations for successful clinical translation. The ideal biomimetic nanoparticle should exhibit stable, reproducible, and reproducible physicochemical properties, stability during storage, and scale-able manufacturing and production with biological activity. Critical quality attributes, such as particle size, polydispersity index, zeta potential, membrane protein retention, membrane coating integrity, drug encapsulation efficiency, sterility, endotoxin content, and long-term storage stability are crucial to monitor during product development as changes in these critical parameters may affect product safety and therapeutic activity.

Achievement of consistent product quality is increasingly important through the application of Quality-by-Design (QbD) principles and Process Analytical Technology (PAT). These systematic methods enable identification of critical process parameters, formulation optimization and ensure batch-to-batch consistency crucial for regulatory approval and commercial production. The recent advances in automated membrane isolation, continuous manufacturing platforms and microfluidic technologies have additionally enhanced production efficiency and scalability [39]. Simultaneously, the use of artificial intelligence and machine learning in the design of nanoparticles is growing to predict the formulation behaviour, optimise targeting and facilitate product development.

Analysing and successful design of biomimetic nanoparticles require the collaboration of pharmaceutical sciences, nanotechnology, materials and cell biology and biomedical engineering. As membrane engineering, fabrication technologies, quality assurance and scalable manufacturing continues to develop, biomimetic nanocarriers are likely to be more widely used in clinical settings in the future. Biomimetic nanoparticles are important platforms for future precision medicine and advanced therapeutic systems owing to their versatility of engineered nanoparticles and biological functions of natural cell membranes [41].

4. Cell Membrane-Coated Nanocarriers

One of the most widely studied advances in biomimetic nanotechnology are the cell membrane coated nanoparticles (CMNPs). They are made by surrounding synthetic nanoparticle cores with plasma membranes that have been removed from living cells, which would allow the nanocarriers to maintain the structure and drug loading capacity of the synthetic core, while retaining membrane-associated proteins, receptors, phospholipids, glycoproteins and adhesion molecules. For this reason, the circulation time, biocompatibility, immune recognition and targeting ability of CMNPs are improved relative to conventional nanoparticles [42].

One of the main drawbacks of conventional nanocarriers is their fast clearance from the bloodstream by the mononuclear phagocyte system (MPS) which renders them unavailable to tumor cells. To overcome this, the concept of coating the cell membrane was introduced. Due to the advances made in membrane isolation and membrane fusion techniques, membranes from a different kind of cell types have been employed to produce CMNPs with different biological functions and appropriate for different therapeutic applications [43]. These nanocarriers can selectively target tumours, inflamed tissues, damaged blood vessels or infected sites, depending on the type of membrane, and thus minimize “off-target” effects.

Red blood cell (RBC) membranes have been studied most extensively of the various membrane

sources available. Red blood cells travel in the circulation for about 120 days, and during this time they express a membrane protein called CD47 that sends out a natural 'don't eat me' signal to macrophages, thus decreasing clearance of the cells. The immune evasive property is inherited by the nanoparticles coated with RBC membranes so their circulation time is prolonged and their accumulation at the disease sites is enhanced due to the EPR effect. They are biocompatible and have low immunogenicity, which makes them a good carrier for anticancer drugs, anti-inflammatory drugs, antimicrobial therapy and imaging probes.

Platelet membrane-coated nanoparticles take advantage of the physiological functions of platelets during haemostasis, wound healing, inflammation and tumour metastasis. The platelet membrane includes adhesion molecules such as P-selectin, glycoprotein Ib (GPIb) and integrins that allow the platelet to specifically adhere to damaged blood vessels, inflammatory tissue and circulating tumour cells [44]. Their properties have resulted in their study in the context of targeted chemotherapy, cardiovascular disease, thrombosis, anti-bacterial therapy and prevention of tumour metastasis.

Macrophages coated with nanoparticles have the ability to move towards inflammation, infection and tumor formation because of their innate property. They have receptors and adhesion molecules that enable them to be located in the inflamed tissue and could be used as vehicles for chemotherapeutics, antibiotics, anti-inflammatory drugs and gene therapy. Moreover, the membrane of macrophages helps to control immune responses in the disease microenvironment [45].

Leukocyte membrane-coated nanoparticles also retain adhesion molecules including lymphocyte function-associated antigen-1 (LFA-1) and macrophage antigen-1 (Mac-1) which allow them to invade the vascular endothelium and to localize strongly at inflamed tissues. These features have enabled them to explore inflammatory diseases, auto-immune diseases, infectious diseases and some cancers. They are also capable of crossing biological barriers, which expands their possibilities for targeted drug delivery [46].

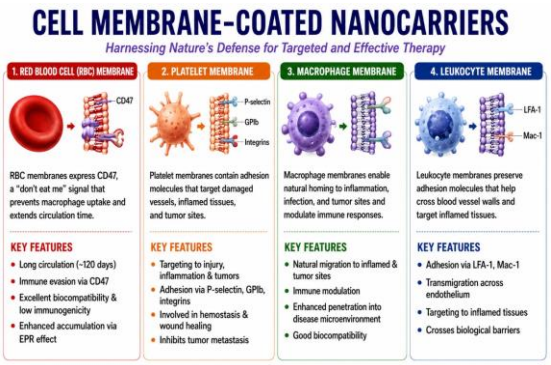

Figure no 1.6 : Cell Membrane-Coated Nanocarriers

4.1 Stem Cell-, Cancer Cell-, Bacterial- and Hybrid Membrane-Coated Nanoparticles

The attraction of stem cell membrane-coated nanoparticles is due to the fact that stem cells have a natural ability to move towards the site of inflammation, injury to tissues and the development of tumours. The tissue homing properties of the mesenchymal stem cells (MSCs), neural stem cells (NSCs) and induced pluripotent stem cells (iPSCs) are transferred onto the surface of these nanoparticles, thus enabling selective drug delivery. The nanocarriers have been studied in cancer treatment, regenerative medicine, neurological diseases, cardiovascular diseases and inflammatory pathologies. They also provide targeted delivery, can decrease systemic toxicity, and can facilitate tissue repair, and in some cases, can facilitate passage across biological barriers, such as the blood–brain barrier [47].

Homotypic targeting is the mechanism by which membrane proteins and adhesion molecules allow for the selective recognition of tumour cells derived from the same tissue, and is the basis of nanoparticles coated with a tumour cell membrane. This property allows drugs to be selectively localized in the primary and metastatic tumors, and to avoid the effects on healthy tissues. Additionally, the tumour-associated antigens allow for the development of therapeutic cancer vaccines, personalised medicine and cancer immunotherapy. Nanocarriers have been investigated for the delivery of various chemotherapeutic agents, nucleic acids and photothermal or photodynamic therapeutic agents [48].

Up to now, mainly the application of bacterial membrane-coated nanoparticles in vaccine delivery and immunotherapy has been studied. Pathogen-associated molecular patterns (PAMPs) are found in bacterial membranes and trigger innate and adaptive immune response and are therefore suitable as vaccine carriers and immune adjuvants.

Further, these systems have been shown to carry promise for targeted delivery of antibiotics and cancer immunotherapy via their ability to enhance antigen presentation and T-cell activation. However, other issues such as endotoxin-associated toxicity and membrane purification must be addressed prior to clinical application [49].

Hybrid membrane-coated nanoparticles are particles that contain membranes from two or more cell types, and thus have two complementary biological functions in one single nanocarrier. For instance, red blood cell–platelet hybrid membranes contain long-lasting circulation properties along with vascular targeting, while macrophage–cancer cell hybrid membranes encompass inflammation-targeting properties plus homotypic tumour recognition. In the same way, stem cell–leukocyte hybrid membranes are capable of tissue homing and migrating towards inflamed tissues. These multifunctional nanocarriers, which combine several biological functions, are capable of evading the immune system, have long blood circulation times, can be targeted to special cells and tissues, and are effective in cellular uptake, can be used for combination therapy and gene delivery, in immunotherapy and precision medicine [50].

5. Mechanisms of Targeted Drug Delivery

Biomimetic nanoparticles differ from traditional nanocarriers in that they can accomplish targeted drug delivery. Because biomimetic nanoparticles have been coated with natural cell membranes that possess membrane proteins, membrane receptors, adhesion molecules and signalling molecules, they are able to distribute naturally, rather than relying mainly on passive distribution like traditional nanoparticles. These biological components allow the nanocarriers to mimic the behaviour of living cells, helping them to evade the immune system, selectively target diseased tissues, cross biological barriers and deliver therapeutic agents more efficiently. Therefore, better levels of drugs can be delivered to the target site while reducing the levels in the general circulation.

Immune evasion is one of the main mechanisms involved in targeted delivery. The circulation time of conventional nanoparticles is short as they are rapidly recognised and removed by the macrophages of the mononuclear phagocyte system (MPS). Conversely, the proteins that are present in the natural 'don't eat me' signal, like CD47, are retained by the red blood cell membrane-coated nanoparticles that decreases phagocytosis by the macrophage. This allows for an extension of systemic circulation and enhances the probability of accumulation of nanoparticles at diseased tissues [51].

Another mechanism is receptor-mediated targeting, which is an interaction between the receptor and the ligand. Selective binding to target cells and tissues is achieved through the action of membrane-associated proteins and adhesion molecules. In this respect, for instance, platelet membrane-coated nanoparticles are more likely to come in contact with damaged blood vessels and tumour cells, while membrane-coated leukocytes and macrophages naturally target inflamed tissue. This made it possible to accumulate the drug in the damaged area, and minimize the side effects of the drug on healthy tissues.

In addition, cancer cell membrane-coated nanoparticles also have homotypic targeting characteristics, which is that membrane proteins of the tumour cells preferentially recognize the cancer cells of the same tissue of origin. This results in drug accumulation in the tumour and less harm to healthy tissues. Furthermore, membrane surface displaying of tumour associated antigens may trigger anti-tumour immune responses, which will make them useful in cancer immunotherapy [52]. The enhanced permeability and retention (EPR) effect is another advantage of biomimetic nanoparticles as they tend to accumulate in the tissues of tumours due to their high permeability and poor lymphatic drainage. Their long circulation allows for passive accumulation within tumour tissue, and active targeting mechanisms further enhance targeting within tumour tissue.

Another key mechanism of action is inflammation targeting. Leukocyte/macrophage membrane-coated nanoparticles have receptors that can recognise inflammatory signals, which enables them to accumulate specifically at inflammatory tissue. This property has been investigated in the treatment of inflammatory diseases, bacterial infections, atherosclerosis and inflammation-associated malignancies.

Some biomimetic nanoparticles have also been shown to cross biological barriers, such as the blood–brain barrier, which allows for the transport of drugs to the central nervous system. Therefore, stem cell-, leukocyte- and macrophage-membrane-coated nanoparticles are of interest for the treatment of neurological disorders such as brain tumours, Alzheimer's disease, Parkinson's disease and stroke [53].

The core of the nanoparticle may also be modified for a controlled or stimuli-responsive drug release, such as in a pH- or enzyme-responsive release,

triggered by reactive oxygen species, hypoxia, temperature or external stimuli like light and ultrasound. By the same time, the biomimetic membrane shields the encapsulated therapeutic agents from early degradation in circulation, maintaining their biological activity until they get to the target site.

After the site of localisation to the target tissue, the nanoparticles are phagocytosed, fused to the cell membrane or enter the cell via receptor-mediated endocytosis, allowing the therapeutic payload to be released into the cytoplasm. This type of delivery is especially beneficial for therapeutic proteins, nucleic acids, small interfering RNA (siRNA), messenger RNA (mRNA) and gene-editing systems, which require cellular delivery to achieve therapeutic effects.

Overall, the biomimetic nanoparticles combine various mechanisms such as immune evasion, receptor-mediated targeting, homotypic tumour recognition, EPR-mediated accumulation, inflammation targeting, biological barrier penetration, controlled drug release and efficient cellular internalisation to realize highly selective drug delivery. The complementary features render these biomimetic nanoparticles as advanced platforms for targeted drug delivery and precision medicine, thanks to their favourable pharmakinetics, higher therapeutic accuracy and lower systemic toxicity, which will ensure their development into advanced targeted delivery systems [54].

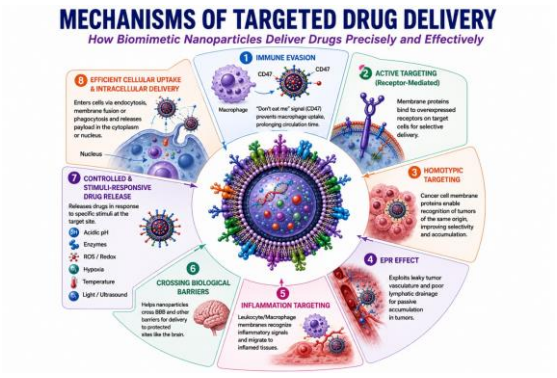

Figure no 1.6 : Mechanisms of Targeted Drug Delivery

6. Therapeutic Applications of Biomimetic Nanoparticles [55,56,57]

- **Cancer therapy:** Immune evasion, long blood circulation time, homotypic targeting, and recognition of the tumour microenvironment are all features exhibited by biomimetic nanoparticles that enable them to target the tumour tissue specifically for cancer therapy. They have also been explored for use in combination therapy, immunotherapy, and photothermal and photodynamic therapies, which help deliver higher doses of therapy while minimizing systemic side effects.
- **Inflammatory and autoimmune diseases:** Macrophages and leukocytes engulf nanoparticles by wrapping them in their membrane tend to accumulate at the site of inflammation and respond to inflammatory signals, thus being attracted to inflamed tissues by inflammatory and autoimmune diseases. The systems have been investigated for treating RA, IBD, psoriasis and asthma, as well as systemic exposure to anti-inflammatory drugs, and modulation of inflammatory cytokines.
- **Infectious diseases:** Bio-mimicking nanoparticles for targeted antimicrobial delivery, that carry the antibiotic directly to the site of infection and will shield the therapeutic agents from premature degradation. The ability of these bacteria to activate innate and adaptive immunity has also made them a focus of interest for use as vaccine carriers and as immune adjuvants.
- **Cardiovascular diseases:** When the platelets come into contact with microcirculations and/or blood clots, nanoparticles are coated with the platelet membrane, thereby targeting them to damaged blood vessels and blood clots, which can facilitate targeted delivery of thrombolytic and anti-inflammatory agents. Macrophage membrane coated nanoparticles are also being tested to help decrease inflammation of the coronary vessels that can cause atherosclerosis.
- **Neurological disorders:** Stem cell coated nanoparticles, macrophage coated nanoparticles and leukocyte coated nanoparticles have all shown the ability to cross the blood–brain barrier and deliver drugs to treat neurological disorders, such as brain tumours, Alzheimer's disease, Parkinson's disease and stroke.
- **Gene therapy and genome editing:** Biomimetic nanoparticles can protect and deliver nucleic acid therapeutics such as DNA, messenger RNA (mRNA), small interfering RNA (siRNA) and gene-editing systems to the cell in an enzymatically stable and efficient manner.
- **Vaccine delivery and immunotherapy:** Biomimetic nanoparticles are extensively explored as delivery systems in vaccine and immunotherapy, due to their

biocompatibility and innate immune properties, which facilitate antigen presentation and boost immune responses.

- **Regenerative medicine:** Natural tissue-homing and targeted delivery of regenerative therapeutics, along with tissue repair and regeneration characteristics, make the regenerative medicine application of stem cell membrane-coated nanoparticles a promising field.
- **Theranostics:** Theranostics biomimetic nanoparticles combine diagnostic imaging with therapeutic capabilities in a single unit, thus allowing the simultaneous detection of disease, delivery of therapeutic agents and monitoring the therapeutic response.
- **Precision medicine:** Biomimetic nanoparticles are potential candidates for next-generation personalised treatment strategies and precision medicine due to their ability to selectively target, control drug release, and carry multiple therapeutic payloads across the body.

7. Challenges and Limitations of Biomimetic Nanoparticles

Although significant advances have been made in biomimicry nanoparticle research, continued scientific, technical, and regulatory hurdles impede the translation of nanoparticles to clinical use. These nanocarriers have proven to have a number of benefits compared to traditional drug delivery systems; however, bringing these promising preclinical studies to market is not without its challenges. The major problems are the variability of membrane sources, scalability to manufacturing, quality assurance, long-term safety, regulatory approval and production costs.

The availability and standardisation of sources of biological membranes is one of the major problems. Biomimetic nanoparticles are made from various types of cells such as red blood cells, platelets, leukocytes, macrophages, stem cells and cancer cells membranes [58]. The quality and biological properties of these membranes can vary from donor to donor, depending on the cell type, the isolation processes and the storage procedures. These differences may affect the membrane protein composition, targeting and therapeutic outcome. Therefore, standardized and well-established methods for the isolation, purification and storage of membranes are vital for the consistency of products.

Scale production is also a factor to consider. Laboratory-scale methods like membrane extrusion, sonication and microfluidics are employed today to manufacture most biomimetic nanoparticles on a small scale. Although these techniques are appropriate for experimental studies, it is difficult to achieve uniform particle size, complete coating of the membranes and preservation of the biological activity during the production of large quantities of particles. The automated, continuous and scalable manufacturing processes will therefore be crucial to commercial production in the future[59].

Maintaining structural integrity and biological activity of the cell membrane during fabrication and storage is also a challenge. Membrane proteins and receptors play a significant role in many functions of biomimetic nanoparticles, such as immune evasion and targeting, but are known to be susceptible to alteration or damage during processing and extended storage [60]. It is therefore essential to carefully optimise manufacturing conditions and storage protocols to preserve the stability of the nanoparticles and biological activity.

The formulating of biomimetic nanoparticles is far more complex than conventional nanoparticles, as it involves both synthetic and biological materials, and thus quality control and physicochemical characterisation are more complex. The critical quality attributes consist of particle size, zeta potential, coating efficiency of the membrane, protein retention in the membrane, drug encapsulation efficiency, sterility, endotoxin content and storage stability[61]. To ensure batch-to-batch consistency and meet regulatory expectations, reliable analytical methods and well-designed quality assurance processes must be implemented. Biomimetic nanoparticles typically have a good biocompatibility profile, but this has not yet been completely determined for long-term use. The current evidence is largely from laboratory investigations and from preclinical studies in animals, and clinical evidence is still limited. Possible problems are immune response, long-term toxicity and build up in nontarget tissues and degradation products. Prior to the systems gaining wider clinical use, comprehensive toxicological studies and well-designed clinical trials are thus needed.

Other obstacles to clinical translation involve the lack of specific regulations for biomimetic nanomedicines [62] and the high production costs resulting from the complex membrane isolation process, the need for specialised production equipment and the need for extensive quality testing.

8. Future Perspectives and Emerging Trends

The biomimetic nanoparticles are an emerging field in nanomedicine, and ongoing research efforts are likely to broaden their potential applications in targeted drug delivery and precision therapeutics. Continued future innovations may include making the system more accurate and scalable in manufacture, enhanced clinical safety and better support for personalised treatment strategies. Advancements in nanotechnology, molecular biology, artificial intelligence (AI), and Biomedical Engineering are making it possible to create more and more advanced biomimetic nanocarriers with better therapeutic activity.

The field of personalised biomimetic nanomedicine is one of the most important new areas. Biological membranes are being researched as components from the patients' own red blood cells, immune cells and tumour cells to be used for the fabrication of patient-specific nanocarriers. These systems could achieve this by reducing immune elimination, enhancing the specificity of targeting and optimizing therapeutic results, especially in the field of cancer treatment and regenerative medicine. With the rapid progress of precision medicine, use of patient derived biomimetic nanoparticles will be a key part of personalized treatment regimens in the future.

Another emerging field is the design of nanoparticles with the help of AI. AI and machine learning algorithms can process vast amounts of data to forecast the behavior of nanoparticles, tweak formulation variables, and determine the best membrane sources for specific disease conditions. These computational strategies can be applied to speed up formulation development, enhance manufacturing reproducibility, lower development costs, and enable the translation of biomimetic nanoparticles from the preclinical to clinical environment [63].

Another direction of research is toward the development of hybrid membrane coated nanoparticles. These nanocarriers integrate complementary biological functions in a single nanocarrier by combining membranes from different cell types. These hybrid platforms allow for long circulation, immune evasion, inflammation targeting and binding to tumour cells simultaneously and are therefore especially well suited for the treatment of complex and multifactorial diseases.

The biomimetic nanoparticles are also likely to find more applications in genome editing and gene therapy. Their biological membrane coating preserves the sensitive genetic materials such as DNA, messenger RNA (mRNA), small interfering RNA (siRNA) and CRISPR-Cas gene-editing systems from enzymatic degradation and promotes cellular uptake. These properties make them good tools for their use as non viral vehicles for inherited disorders, cancer and other genetic diseases.

Another promising field of research is the development of theranostic biomimetic nanoparticles that have both diagnostic and therapeutic properties in one package. These multipurpose systems can not only be used to deliver therapeutic agents but can also carry imaging probes to allow for real-time monitoring of biodistribution, therapeutic response and disease progression. These user-friendly platforms facilitate targeted disease management and customised therapy [38].

Stimuli-responsive biomimetic nanoparticles are also targeted in future research as nanoparticles that release therapeutic molecules only when exposed to a particular physiological or external stimulus, such as enzymes, acidic pH, reactive oxygen species, temperature, light, ultrasound and magnetic fields. This control release mechanism will result in higher drug levels at the desired site and lower levels in healthy tissues, which will enhance the therapeutic index.

In the manufacturing context, membrane automated isolation, microfluidic process fabrication, continuous manufacturing processes, and Quality-by-Design (QbD) principles are anticipated to enable large scale manufacturing and product consistency. However, the successful clinical translation will rely on the development of standardised manufacturing procedures, thorough safety evaluation, established quality control procedures and integrated regulatory guidelines. Ongoing cooperation among researchers, clinicians, regulatory agencies and industry is necessary to facilitate the clinical translation of biomimetic nanoparticles into routine clinical care.

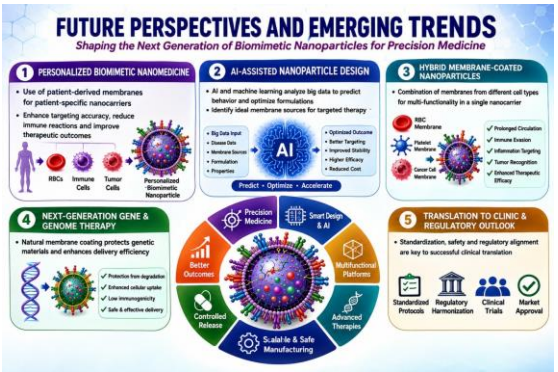

Figure no 1.7 : Future Perspectives and Emerging Trends

9. Conclusion

The biomimetic nanoparticles have proved to be one of the most advanced next-generation drug delivery systems, and have been developed to overcome many of the drawbacks of traditional nanocarriers. These are composed of synthetic nanoparticle cores with naturally derived biological membranes, providing high loading capacity, immune evasion, extended circulation, improved biocompatibility and targeted delivery to disease sites. All these properties contribute to an enhanced therapeutic efficacy and lower systemic toxicity, making biomimetic nanoparticles highly appealing for precision medicine. As mentioned in this review, the development of cell membrane-coated nanoparticles is the most thoroughly studied biomimetic platform as they have been able to retain the biological activity of the cells and retain the built-in functions of engineered nanocarriers.

However, recent developments in the design and creation of membranes, development of hybrid membranes, microfluidic technology, stimulous response drug delivery, theranostic systems, and artificial intelligence in the design of nanoparticles have been greatly contributing to the advancement of the field. The innovations have broadened the possible biomimetic nanoparticles' applications beyond conventional chemotherapy to gene delivery, immunotherapy, regenerative medicine, vaccine delivery, antimicrobial therapy, neurological disorders, and personalised medicine. Also, the integration of Quality by Design (QbD), Process Analytical Technology (PAT) and automated manufacturing technologies is anticipated to increase the formulation reproducibility and enable future industrial scale production.

Current Clinical Status

Although the laboratory-to-clinical translation of biomimetic nanoparticles is still in its infancy, the achievements in these fields are very promising. At present:

- Most biomimetic platforms of nanoparticles are still in the early stages of research, and efficacy has been established in cell culture and animal models.
- Multiple biomimetic approaches, including red blood cell membrane-coated, platelet membrane-coated and cancer cell membrane-coated nanoparticles, have yielded promising therapeutic results in experimental models of cancer.
- While complete cell membrane coatings of nanoparticles have yet to be approved, the rise to clinical success of lipid nanoparticle technologies has raised the confidence of the biologically inspired nanocarriers.
- Pharmaceutical scientists, clinicians, biomedical engineers and regulators are increasingly connecting up to speed up the process towards clinical evaluation.

Current Developments and Representative Examples

The biomimetic nanotechnology has undergone significant progress in a short period of time; some of the significant developments are:

- The red blood cell membrane-coated nanoparticles containing CD47 have been shown to circulate in blood for a long time and decreased clearance by macrophages in cancer drug delivery.
- The capacity of targeting circulating tumour cells and damaged vasculature with platelet membrane-coated nanoparticles has been demonstrated and is promising for the future of metastatic cancer and cardiovascular diseases.
- Membrane-coated nanoparticles, such as those with macrophages and leukocytes, have been shown to accumulate selectively in inflammatory tissues and are good candidates to be used in inflammatory bowel disease, rheumatoid arthritis, and infectious diseases.
- Homotypic targeting with nanoparticles coated with cancer cell membranes has been shown to have superior therapeutic activity in several experimental cancer models, and to have a superior ability to target tumours.
- Hybrid membrane-coated nanoparticles, which incorporate membranes of several cell types, are now appearing as multifunctional platforms that enable to simultaneously control long circulation time, immune evasion, and active targeting.

Existing Translational Evidence and Representative Case Studies

While biomimetic nanoparticles have yet to be incorporated into clinical usage, a large preclinical research effort has shown the nanoparticles' translational potential in a variety of disease models.

Nanoparticles coated with red blood cells (RBC) have been demonstrated in several studies to greatly extend the circulation time in the bloodstream, due to the presence of self-recognition signals, such as CD47, which prevent their clearance by macrophages. These biomimetic nanocarriers have proven to be more selective to the tumour and less harmful to the system when compared with conventional nanoformulations in experimental cancer models, making them promising as long-circulating drug delivery nanocarriers. The biomimetic nanotechnology has also been investigated recently in other fields that goes beyond drug delivery, such as neutralising blood group antibodies in order to enable incompatible blood transfusion in pre-clinical models, which highlights the growing clinical applications of RBC membrane technology.

Platelet membrane-coated nanoparticles have been shown to specifically bind to circulating tumour cells and damaged vascular endothelium via platelet-specific adhesion molecules. These systems have been used in experiments in mice to decrease metastatic spread and enhance the delivery of anti-cancer drugs to the site of metastases. The same platforms have also been used to demonstrate promising results in other disease models of thrombosis and vascular inflammation, suggesting a role in oncology and cardiovascular medicine.

Researchers have used macrophage and leukocyte coated nanoparticles have reported preferential accumulation in inflamed tissues and tumour microenvironments. Targeted delivery of anti-inflammatory agents, antibiotics and chemotherapeutic drugs have been enhanced in experimental models of rheumatoid arthritis, inflammatory bowel disease, bacterial infection and atherosclerosis by these biomimetic systems. The inflammatory tissue tropism is something intrinsic that makes them a good promise for future clinical development in immune-mediated diseases.

Likewise, in preclinical studies, homotypic tumour targeting has been consistently shown with cancer cell membrane coated nanoparticles. The nanocarriers preserve the tumour-associated membrane proteins and adhesion molecules, which directly target the tumour of the same cell origin, leading to higher drug concentrations in the tumour and enhanced therapeutic outcomes after chemotherapy, photothermal therapy and cancer immunotherapies.

Recently, hybrid membrane-coated nanoparticles that can simultaneously achieve prolonged circulation, immune evasion, and active targeting within a single construct have been developed. Initial experimental investigations show that introducing membranes from different cell types can offer complementary biological functions which can enhance therapeutic performance beyond that of a single-membrane system.

All these studies collectively demonstrate the promising proof-of-concept evidence for biomimetic nanocarriers to achieve better pharmacokinetic behaviour and targeting specificity, and lower off-target toxicity than conventional nanoparticles. However, the majority of the discoveries are limited to preclinical studies, which means the need for extensive clinical testing and validation to fully realize their therapeutic potential.

Future Clinical Perspectives

Several important points must be overcome in order to achieve successful clinical application of biomimetic nanoparticles:

- Standardization of membrane isolation, purification and storage methods.
- Scalable Good Manufacturing Practice (GMP) compliant manufacturing processes development.
- Harmonisation of regulatory guidelines specific to biomimetic nanomedicines.
- Comprehensive long-term safety, immunogenicity and biodistribution studies.
- Adoption of AI and machine learning to enhance the design of nanoparticles and tailor patient-specific formulations.
- The development of personalised biomimetic nanomedicine by using auto cells membrane to reduce immune incompatibility.
- Multifunctional theranostic nanoparticles for diagnostics, targeted treatments and real-time monitoring of treatments.
- Growth of biomimetic nanoparticles as non-viral gene delivery vehicles for gene editing with CRISPR/Cas, mRNA therapeutics and precision oncology.

Future Opportunities for Clinical Case Studies

Further clinical studies will probably concentrate on:

- Clinical trials for the safety and pharmacokinetics of cell membrane-coated nanoparticles (Phase I and Phase II trials).

- Comparative studies on efficacy of biomimetic nanoparticles with the nanoformulations in use.
- Personalised nanomedicine with own blood or tumour membranes.
- Combination therapies using a single biomimetic platform that combine chemotherapy, immunotherapy and gene therapy.
- Clinical evaluation of difficult-to-treat diseases like glioblastoma, pancreatic cancer, metastatic cancers, Alzheimer's and chronic inflammatory disorders.
- Long-term post-treatment follow up study of biodegradation, immune compatibility, repeated-dose safety.

Future Research Priorities

Biomimetic nanoparticles have made great strides in development, but there are several scientific and technological hurdles to overcome before such systems can be broadly translated to the clinic. Future research is also needed for enhancements in therapeutic performance as well as manufacturing, regulatory and clinical implementation.

1. Standardisation of membrane isolation and characterisation

2. Scalable and GMP-compliant manufacturing

3. Advanced quality control strategies

4. Hybrid and multifunctional membrane engineering

5. Personalised biomimetic nanomedicine

6. Artificial intelligence-driven formulation design

7. Gene delivery and genome editing

8. Long-term safety and biodistribution

9. Clinical translation and regulatory harmonisation

10. Integration with emerging therapeutic technologies

The future biomimetic nanoparticles will probably be multifunctional, with the combined functions of targeted drug delivery, diagnostic imaging, immunotherapy, gene therapy, and the real-time monitoring of therapeutic effects. They could be used in even more clinical scenarios when combined with wearable biosensors, digital health technologies and precision medicine approaches.

However, additional research work is needed in the future to use a multidisciplinary approach, incorporating pharmaceutical sciences, nanotechnology, materials engineering, computational biology, artificial intelligence and clinical medicine. The collaboration will be vital in making biomimetic nanoparticles commercially viable platforms for delivery of safe and effective therapeutic agents from experimental platforms.

To sum up, biomimetic nanoparticles are a revolutionary development in targeted drug delivery that merges the accuracy and efficiency of natural biological processes and the adaptability of nanotechnology. While there are still some technical, production and regulatory hurdles to be overcome, the relentless advances of nanotechnology, molecular biology, artificial intelligence and precision medicine are set to speed up their adoption in the clinical environment. As interdisciplinary efforts continue and rigorous clinical testing is performed, biomimetic nanoparticles are promising to be a major component of the future generation of therapeutics, providing safer and more effective treatment, and highly personalized, for a wide variety of diseases.

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