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Biocompatibility Evaluation of Nanomedicine Delivery Systems and Their Safety Research in Biomedical Engineering

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Abstract: Advances in nanotechnology and biomedical engineering have significantly enhanced the potential of drug delivery systems for nanomedicines, offering improved drug solubility, extended intracellular residence times, optimized targeting, and controlled release. However, the micron-sized particles and large surface areas of nanomaterials may raise safety concerns, including unpredictable distribution within the body, heightened immune responses, difficulties in degradation and metabolism, and long-term accumulation. This paper reviews the literature and conducts structural analysis to examine various material types, biocompatibility evaluation, and safety factors in nanomedicine drug delivery systems. The results indicate that assessing the safety of such systems requires consideration of aspects such as cytotoxicity, hematological compatibility, immunological compatibility, local tissue response, and in vivo safety. Additionally, factors such as particle size, morphology, surface charge, material composition, administration method, release pattern, and exposure duration also influence safety. Future research should focus on selecting biodegradable materials, modifying surfaces, controlling release processes, and developing standardized evaluation systems to improve the design of nanomedicine delivery systems and enhance safety, stability, and controllability in biomedical applications.

1. Introduction

Nanotechnology, Biomaterials Science and Biomedical Engineering have made progress recently. Nanopharmaceutical Delivery Systems have recently been used in research to study the following areas. Pharmacotherapy, Disease treatment and Tissue repair. Compared with older drugs Nanotube transport systems have small particle sizes and a large specific surface area. Area, easier surface modification, high drug-loading capacity, and controlled-release mechanisms.

This can solve the problems of low solubility of some drugs, insufficient in vivo stability, and limited targeting and high systemic toxicity [1]. Recently, scholars have been employing polymeric Nanoparticles, inorganic nanomaterials, hydrogels, local depot systems and composite Nanocarriers

for drug, protein, gene and other active substance delivery, and these are showing good results. Applications in antimicrobial and anti-inflammatory therapy, adjuvant treatment for periodontitis.

Tissue engineering and regenerative medicine [2-6]. Local Delivery Systems Can Increase Drug Concentrations at the lesion site and reduce systemic exposure. Hydrogels that respond to external stimuli. Stimuli are used to achieve controlled-release drugs at different temperatures, pH values, lights, and enzymes. Based on the above research, a local-release mechanism will be adopted. Antimicrobial, immunomodulatory and tissue-regenerative effects in the treatment of periodontitis and are also relevant to the research of oral diseases and tissue regeneration [7-9].

Nanopharmaceutical delivery systems improve the efficacy of treatment but are also problematic. Serious problems in safety evaluation. Nanomaterials have size effects and high surface activity and complex interfacial behaviour. The body changes the effect of the drug. distribution, metabolism, and excretion, and interact with cells, blood, the immune system, etc., and the microenvironment of tissues. Some nanoparticles may be damaged by the cell membrane. damage, oxidative stress, inflammatory response, hemolysis, bleeding disorder, complement activation, local irritation, and long-term accumulation [10-11]. For materials that may come into use.Magnetic nanoparticles are in contact with the blood vessels and therefore need to be considered. Hemocompatibility, such as hemolysis and blood clotting, and interactions with blood cells [12].

In particular, inorganic nanomaterials, despite their advantages, such as a relatively stable structure, high drug delivery capacity, and easy functionalization, may have limitations in clinical application due to degradation processes, low in vivo elimination efficiency, long-term persistence, and chronic toxicity [13].

Existing studies provide valuable information for evaluating the safety of nanopharmaceutical delivery systems. Zhou Yexiu et al. [2] noted that different inorganic nanomaterials differ in drug delivery methods and biosafety. Song Mozhe et al. [3] evaluated the biocompatibility of polylactide and collagen composite materials. Their results indicated that researchers should consider indicators such as cytotoxicity, hemolysis, pyrogenic reactions, acute and subacute toxicity, sensitization, and local irritation when determining the safety of a material. A study by Qiao Chunxia et al. [10] also indicated that hemolysis, coagulation, platelet reactions, and complement activation should be considered for materials that may come into direct or indirect contact with blood. Based on this, this paper analyzes the aspects of biocompatibility and safety evaluation of nanopharmaceutical delivery systems using a literature review and structure analysis. This book describes the most important material types and their application properties, summarizes evaluation criteria such as cytotoxicity, hematological compatibility, immune response, local tissue reaction, and in vivo safety, and discusses the impact of factors such as particle size, morphology, surface charge, material composition, delivery method, release pattern, and degradation products on safety. Finally, it outlines potential improvements such as the selection of biodegradable materials, surface modification, controlled release, topical application, and the development of standardized evaluation systems. Thus, it provides a reference for the safe use of nanopharmaceutical delivery systems in biomedical engineering.

2. Review of nanomedicine delivery systems

2.1 Basic properties of nanomedicine delivery systems

Nanopharmaceutical delivery systems are technologies that employ nanomaterials as carriers for delivering drugs, proteins, nucleic acids and other active substances to particular tissues, cells or lesions. The above systems are more convenient for people to use daily. Substances, as well as enhance their stability and distribution, improve in vivo efficacy, etc. Material Structure, Surface Modification, and Controlled Release. Generally speaking, Nanocarriers have small particle size,

large specific surface area and strong interfacial interaction. Capacity. Therefore, they are easier to interact with the cell membrane and other plasma proteins in tissues. Barriers and the microenvironment of lesions. Functionally speaking, the benefits of nanopharmaceutical delivery systems are mainly improved bioavailability of poorly soluble drugs, prolonged action, and increased accumulation at the site of action and reduced systemic toxicity. Nanocarriers can overcome the low solubility, instability, and limited targeting of some drugs through encapsulation or adsorption.

Chemical Bonding and Targeted Release. However, these advantages are also biosafety risks. Assessments. All of them are relevant to determining the size of the particles and their shapes. Degradation products and release patterns are affected by cell interaction, blood, and the immune system. system and tissues. Therefore, the research should also consider drug loading and the therapeutic effect of nanocarriers and their physicochemical properties and biological responses

2.2 Common types of nanomedicine delivery systems

Nanopharmaceutical delivery systems can generally be divided into polymeric nanocarriers, inorganic nanocarriers, hydrogel systems, and composite systems for topical applications. Polymeric nanocarriers are based on materials such as polylactic acid and polylactic-co-glycolic acid. Copolymers, chitosan, collagen, and polyethylene glycol. Good processability and other attributes. Biodegradability is required for the extended release of drugs and tissue repair in topical applications. application. Mesoporous silica, gold nanoparticles, and magnetic inorganic nanomaterials are examples. Nanoparticle and calcium-containing nanomaterials. Although these materials have a relatively stable structure, a large drug-loading area, and easily modifiable surfaces, researchers still need to assess biodegradability, long-term stability, and accumulation in organs. Hydrogel drug delivery systems are highly hydrophilic, soft in shape, and also have a three-dimensional network. They offer an environment suitable for drug release physiologically and tissue repair, and are thus suitable for topical drug delivery and wound healing, periodontal tissue regeneration, and injectable scaffolds. Composite topical drug delivery systems generally integrate nanoparticles, hydrogels, membrane materials, and fiber scaffolds. Simultaneously provide drug loading, local retention, sustained release, and tissue repair. Different types of drug delivery systems are designed for various purposes. So, in practice, researchers need to consider safety when choosing materials and sites for contact, delivery methods, and in vivo elimination pathways.

2.3 Applied value in Biomedical Engineering

The role of nanopharmaceutical delivery systems in biomedical engineering is primarily focused on pharmacotherapy, localized disease treatment, and tissue repair. Nanocarriers enable controlled drug distribution within the body through encapsulation, sustained release, and targeted delivery. This allows drugs to act more precisely while minimizing nonspecific side effects on healthy tissue. For drugs with significant toxic side effects or instability, these properties improve the manageability of the therapeutic process.

In cases of local inflammation, periodontitis, wound infections, and tissue regeneration, nanotransport systems can be combined with materials such as hydrogels, collagen, and polylactic acid to achieve localized retention and sustained release. These systems can prolong drug action at the site of injury, reduce the side effects of systemic administration, and provide material support for tissue repair and regenerative medicine. However, further research into material compatibility, biodistribution, metabolic clearance, and long-term safety is needed for broader application.

3. Biocompatibility Evaluation

Upon entering the body, a nanopharmaceutical system interacts in various ways with cells, blood components, the immune system, and the tissue microenvironment. Assessing its safety requires a comprehensive analysis from multiple perspectives and cannot be based on the results of a single test. Biocompatibility assessment primarily aims to determine whether the nanocarrier and its drug affect normal cells, blood flow, immune homeostasis, and tissue structure during administration. Based on existing research, the evaluation of nanopharmaceutical delivery systems primarily includes cytotoxicity, hematological compatibility, immunocompatibility, local tissue response, and in vivo safety. To clarify the relationship between these evaluation criteria, this study develops a model for assessing the biocompatibility and safety of nanopharmaceutical delivery systems

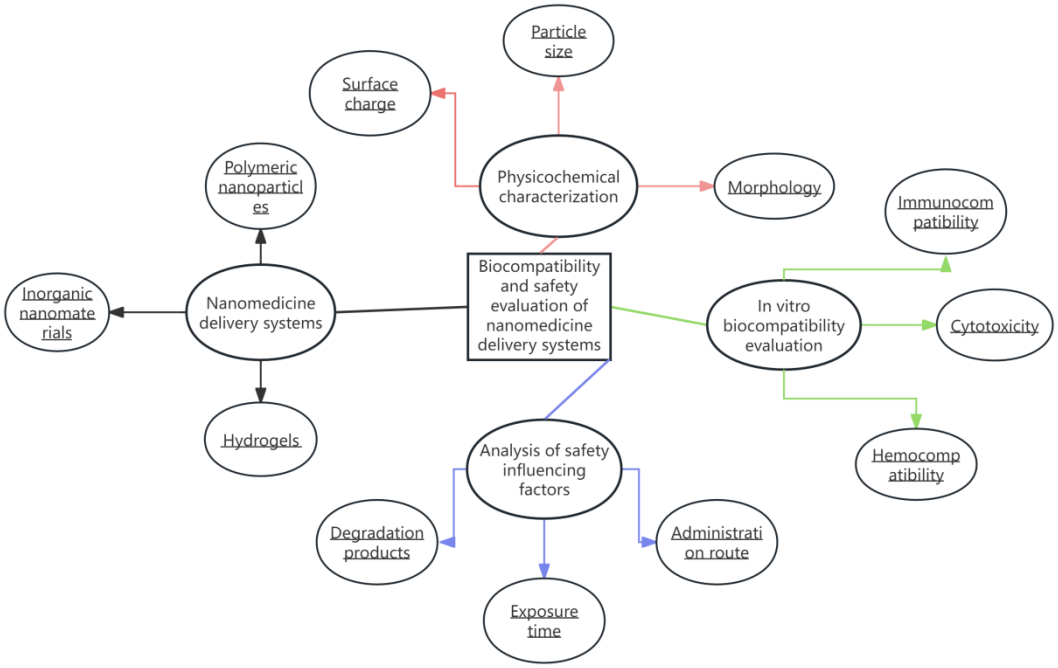

Figure 1. Flow chart for assessing the biocompatibility and safety of nanopharmaceutical delivery systems.

3.1 Aspects of biocompatibility assessment

The biocompatibility of nanopharmaceutical delivery systems can be assessed from four perspectives: cytotoxicity, hematological compatibility, immunocompatibility, and safety for local tissues and in vivo. Assessing cytotoxicity is fundamental and primarily determines whether the nanocarrier affects cell viability, cell membrane integrity, and metabolic function. Nanoparticles can alter cellular health through membrane adsorption, endocytosis, mitochondrial interference, or the generation of reactive oxygen species (ROS), potentially leading to decreased cell viability, increased oxidative stress, or apoptosis. Common detection methods include MTT assays, CCK-8 assays, LDH release assays, live/dead cell staining, and flow cytometry. During the evaluation process, researchers must simultaneously consider material concentration, processing time, cell type, and negative controls (without carriers) to avoid misinterpreting the therapeutic effect of the active ingredient as carrier toxicity.

Blood compatibility tests are for nanotransport systems that will be injected intravenously or may join the blood system. Nanoparticles in the blood will also interact with red blood cells., platelets, plasma proteins, and coagulation factors, may lead to hemolysis. Coagulation disorders,

platelet aggregation, or complement activation. Typical assessment criteria include the rate of hemolysis, blood coagulation function, platelet adhesion or aggregation, and the degree of complement activation. To quantify hemolysis, the rate of hemolysis can be calculated as follows:

$$\text{Hemolysis rate}(\%) = \frac{A_t - A_n}{A_p - A_n} \times 100\%$$

Where At is the absorbance of the test sample, An is the absorbance of the negative control, and Ap

is the absorbance of the positive control. Test for cross-contamination of nanomaterials with strong surface activity urgently needs to be carried out. Charging, high protein adsorption capacity, or extended circulation time. Immunocompatibility Tests Determine whether the nano-transport system causes an abnormal immune response. It will start working. Nanoparticles can be recognized by immune cells, such as macrophages and dendritic cells; at the same time, bioidentity may be changed due to protein coronary artery disease, and clearance is reduced.

Immune Response to these substances. The first three will be mentioned below. Inflammatory factors, immune cell activation, macrophage phagocytosis, and complementary reactions. Delivery systems with a long-term implant have the following characteristics. A prolonged-action drug or an extended-release form will continuously suppress the immune system for an extended period. Address Memory Exceptions for debugging. Local tissue responses and in vivo safety tests are used to assess the effectiveness and safety of Nanotransport Systems in realistic physiological environments.

Local tissue reactions refer to a lack of irritation, no inflammation, no tissue death, and no impaired regeneration at the site of application, and are particularly relevant for systems such as hydrogels. Nanofiber membranes and locally controlled-release particles that need to stay at the target site for a relatively long time. In vivo safety evaluation study of tissue distribution and organ accumulation. Metabolic Pathways, Elimination Efficiency, and Long-term Toxicity of Nanoparticles. Need to combine tests of liver and kidney function, blood tests, biochemical parameters, etc. Histopathological examination of the primary organs and in vivo imaging for inorganic. The long-term stability and persistence of nanomaterials need to be studied by researchers. Persistence: The principal assessment items and often used indices are shown in Table 1.

Table 1. Biocompatibility evaluation dimensions and common indicators

Evaluation dimension	Main purpose	Common indicators or methods
Cytotoxicity	Assess effects on cell viability and membrane integrity	MTT, CCK-8, LDH release, Live/Dead staining
Hemocompatibility	Assess effects on blood components	Hemolysis rate, coagulation function, platelet adhesion, and complement activation
Immunocompatibility	Assess immune activation and inflammatory response	Cytokines, macrophage uptake, and immune cell activation
Local tissue response	Assess irritation and tissue repair at the application site	Inflammation, tissue necrosis, histological observation
In vivo safety	Assess distribution, clearance, and systemic toxicity	Organ accumulation, liver/kidney function, blood tests, pathological sections

3.2 Biocompatibility assessment procedures

Biocompatibility tests for nanopharmaceutical delivery systems are to be conducted in a suitable environment. The order is as follows: Material Characterization - In vitro Experiments - In Vivo Validation. The first stage is generally for physical and chemical analysis of the starting materials. particle size, morphology, surface charge, dispersion stability, drug loading, release curve, etc.

Degradation Behaviour. Physicochemical properties are directly related to safety. Particle size relates to tissue distribution and cell uptake; surface charge is affected. Protein adsorption and blood response, as well as release behaviour, are all related to local drug concentration. Concentration and Exposure Time. Therefore, the first series of experiments will be conducted in a laboratory. The three types are cytotoxicity, haematological, and others. Immunocompatibility tests to determine whether the material is highly immunogenic. A high-risk state is shown by multiple factors, not by a single number of nanasystems. Good results of the cell viability experiment do not necessarily indicate reliable blood or immune system compatibility. Results of short-term cell experiments cannot substitute for long-term in vivo safety studies directly.

Based on in vitro screening, safety studies in local tissues and in vivo have been conducted for validation. Necessary. The Drug-Release Performance and Stability of Local Delivery Systems will be Evaluated. inflammatory response and tissue repair at the site of injury. Systems that will enter the system. circulation, distribution, accumulation, and elimination in the organs of the liver, spleen, and Exercise for the kidneys. In vivo studies can help confirm the safety of the drug in people and for comparison with the results of in vitro experiments. Through an unbroken process of physicochemical characterization, in vitro evaluation, in vivo validation, and design optimisation, evaluation results can guide the selection of materials, surface modification, release control, etc., and dosage adjustments to extend the coverage and reliability of safety assessments. Nanopharmaceutical Delivery Systems.

4. Safety Factors and Optimization of Nanomedicine Delivery Systems

The safety of nanopharmaceutical delivery systems is determined not by a single factor but by the interaction of material structure, surface properties, route of administration, drug release behavior, and in vivo results. Even when using the same material, differences in particle size, morphology, surface charge, or modification method can lead to different cellular responses, blood reactions, immune recognition, and tissue distribution. Therefore, safety studies should not be limited to the "low toxicity" of the material but should comprehensively evaluate aspects such as material design, biological processes, and metabolic clearance in vivo.

4.1 Factors Affecting Safety

Particle size and morphology influence the in vivo behavior of nanotransport systems. Particle size influences nanoparticle uptake by cells, tissue penetration, residence time in the bloodstream, and elimination pathways. Larger particles penetrate tissue barriers less effectively and are more easily recognized and eliminated by mononuclear phagocytes. Smaller particles, while facilitating tissue penetration, can also penetrate non-target tissues, leading to uncontrolled distribution and potential toxicity. Morphology also influences the interaction of materials with cell membranes, immune cells, and tissue structures. Spherical, rod-shaped, sheet-shaped, and fibrous materials vary in endocytosis efficiency, tissue retention, and immune system recognition. A high aspect ratio or sharp edges can increase the risk of mechanical irritation and membrane damage. Therefore, when determining particle size and morphology, both transport efficiency and biosafety must be considered. Surface charge and surface modifications directly influence the interaction of

nanoparticles with cell membranes, plasma proteins, and the immune system. Positively charged nanomaterials typically readily bind to negatively charged cell membranes, thereby enhancing cellular uptake. However, excessive positive charge can reduce cell membrane stability and potentially lead to cytotoxicity, hemolysis, or inflammatory reactions. Neutral or slightly negatively charged materials generally exhibit good stability in blood, but their ability to target and cellular uptake may be relatively limited. Surface modifications can improve particle dispersibility, reduce nonspecific protein adsorption, and promote accumulation at injury sites; however, more complex modifications are not always superior to other methods. Excessive functionalization can alter particle size, charge, and metabolic pathways, and may even induce new immune-stimulating responses. To quantify hemolysis, the hemolysis rate can be calculated as follows:

$$\text{Cumulativerelease}(\%) = \frac{M_t}{M_0} \times 100\%$$

where Mt represents the amount of drug released at time t, and M0 represents the total amount of drug loaded in the nanocarrier.

The composition of a material and its degradation products are critical to the safety of nanotransport systems. Materials such as polylactic acid , PLA-glycolic acid copolymer (PLGA), chitosan, collagen, and hydrogels generally exhibit good biodegradability and tissue compatibility, making them suitable for topical application, sustained drug release, and tissue repair. In contrast, inorganic materials such as metal nanoparticles, carbon-containing nanomaterials, and quantum dots are structurally stable, multifunctional, and exhibit high drug delivery potential. However, they face significant challenges related to long-term persistence, organ accumulation, and in vivo clearance. Some polymeric materials can release acidic small molecules during degradation, which, at excessively high local concentrations, can alter the tissue microenvironment and induce inflammation. Furthermore, some inorganic materials can release metal ions or drugs, which potentially cause oxidative stress and cellular damage. The route of administration and in vivo distribution determine the range of action of a nanotransport system. With intravenous administration, nanoparticles enter directly into the systemic circulation. Therefore, blood compatibility, the immune response, organ distribution, and elimination efficiency must be carefully considered. With oral administration, the gastrointestinal environment, mucosal barrier, and stability of digestive juices must be considered. Although topical application can reduce systemic exposure, the impact of drug residues, irritation, and degradation in local tissues must be assessed.

Table 2. Key factors affecting the safety of nanomedicine delivery systems

Safety factor	Main influence	Possible safety risk
Particle size	Affects cellular uptake, tissue penetration, circulation time, and clearance	Non-target distribution, organ accumulation, unclear clearance
Morphology	Changes contact with cell membranes and immune cells	Membrane damage, mechanical irritation, and immune recognition
Surface charge	Influences protein adsorption and blood interaction	Cytotoxicity, hemolysis, inflammation, and complement activation
Material composition	Determines degradation behavior and baseline compatibility	Chronic toxicity, acidic degradation products, and metal ion release
Administration route	Determines the exposure range and target tissue contact	Systemic exposure, local irritation, and organ burden
Release behavior	Affects local drug concentration and exposure duration	Tissue irritation, insufficient efficacy, and prolonged carrier retention

The release characteristics of active pharmaceutical ingredients and the exposure time affect safety risks. Nanoparticles can accumulate in the body, particularly in the liver, spleen, kidneys, lungs, or diseased tissues. Prolonged residence in vital metabolic organs can lead to chronic inflammation, tissue damage, or impaired function. Therefore, distribution and elimination processes from the body are critical for assessing long-term safety. Rapid release of the API can lead to a short-term increase in local API concentrations and potentially cause cellular irritation and tissue damage. Conversely, sustained-release systems may not achieve effective therapeutic concentrations, resulting in longer carrier residence in the body. For sustained-release systems, embedded hydrogels, and persistent inorganic nanomaterials, good short-term experimental results do not guarantee long-term safety. Safety assessments should consider not only acute toxicity but also chronic inflammation, immune activation, organ accumulation, and long-term metabolic stress. The main safety-related factors and their possible biological effects are summarized in Table 2.

4.2 Security Optimization Strategy

The safety of nanopharmaceutical delivery systems can be improved from four perspectives: material selection, surface modification, release control, and evaluation of control systems. It is crucial not only to reduce material activity but also to minimize its distribution in non-specific tissues and harmful biological reactions while maintaining delivery efficiency, as well as to improve biodegradability and clearance. Material Selection Is The Beginning. A good carrier should be biocompatible, have reasonable structural stability, be gradually degraded, and not irritate tissues. For delivery systems that need to be retained for a long time or released locally, researchers may choose biodegradable, low-toxicity materials with relatively well-defined metabolic pathways, such as polylactic acid, chitosan, collagen, and hydrogels. For inorganic nanomaterials, in addition to drug loading and function, long-term accumulation in the body, ion release, chronic toxicity, and elimination by vital organs must also be considered in the assessment. The safety of the material does not ensure the safety of the whole delivery system. Changes in toxicity and other biological behaviour after the addition, modification, or complexation of drugs also need to be re-evaluated

A general introduction to the improvement of biocompatibility through surface modification. Hydrophilic polymer coatings, modification of natural polymers, targeted ligand binding, or the addition of functional molecules can all be employed to improve the dispersion stability of particles, reduce non-specific protein adsorption, slow down the rate of drug clearance by the immune system, and promote lesion recognition. Increase the stability of the blood with hydrophilic modification; enhance the accumulation of drugs at the target site by targeted ligand modification; and improve the local biocompatibility of natural polymers through modification. The surface modification should serve only a particular function and not be multi-functional at the same time. If it is too high, then it will be impossible to produce; otherwise, the basic attributes of the material will be altered, and a new immune response or metabolic stress may arise. Controlled Release reduces off-target toxicity. Nanotube carriers are highly controllable systems that can adjust the release speed of drugs by modifying material structure, cross-linking density, pore size, drug-loading methods, and environment-sensitive reaction mechanisms. Release systems can be developed for diseases with particular microenvironments, such as inflammation, tumors, and infections, that are sensitive to changes in pH, enzymes, temperature, light, and redox conditions to promote the release of drugs at the site of injury and reduce their exposure in healthy tissue. The way the drug is released after this reaction should also be stable and predictable so as not to release it too early. In addition, for sustained-release systems, the degradation and carrier elimination after drug release need to be examined simultaneously to avoid the formation of new safety risks from

residual substances.

An all-weather general-purpose evaluation system will be developed. Given that nanopharmaceutical delivery systems use various materials with different structures and in vivo behaviours, single-cell analyses or short-term toxicity tests are not sufficient to assess all safety risks. The three levels of the evaluation system are physicochemical characterization, in vitro experiments, and in vivo safety studies. Physicochemical characteristics generally refer to the size and shape of particles, surface charge, dispersion stability, drug content, release profile, and degradation behaviour. The first types of tests in a lab are cytotoxicity and blood compatibility. Organisms are used in live experiments to obtain data on how various organs or tissues are distributed, metabolism, and excretion pathways, acute and chronic toxicity, organ damage, etc. Set up an all-inclusive evaluation system that examines material properties, biological responses, and in vivo results and thus improve the consistency of safety assessments for nanopharmaceutical delivery systems.

5. Conclusion

Nanoparticles as drug delivery systems can improve drug solubility, enhance delivery efficiency, prolong the duration of action, and enhance the local therapeutic effect. However, their small size, surface activity, and complex in vivo interactions complicate safety assessment. Compared with traditional drug carriers, nanoparticle-based delivery systems cannot focus solely on drug loading and therapeutic effect; analysis of interactions between the material and cells, blood, the immune system, and organs/tissues is also necessary. This paper analyzes the biocompatibility and safety aspects of nanoparticle-based drug delivery systems. Studies show that aspects such as cytotoxicity, hematological compatibility, immunocompatibility, local tissue reactions, and in vivo safety must be considered when assessing the safety of nanoparticle-based delivery systems. In addition, factors such as particle size, morphology, surface charge, material composition, degradation products, administration route, release pattern, and exposure time must be analyzed. These various factors do not act in isolation but, together, influence the interactions between the material and cells, blood, the immune system, and organs/tissues. Because of this, safety studies cannot rely solely on the results of individual experiments but require a continuous analytical process, from physicochemical characterization to in vitro evaluation and in vivo validation.

In terms of improving safety, future nanopharmaceutical delivery systems should consider three aspects: When selecting materials, preference should be given to biodegradable, low-toxicity materials with well-defined metabolic pathways to minimize the risk of long-term persistence and accumulation in organs. Regarding the design of the delivery system, precision should be improved through surface modification, target design, and controlled release to reduce exposure to non-target tissues and harmful biological reactions. Regarding the evaluation methods, a standardized multi-stage risk-based evaluation system should be established to strengthen the coordination between physicochemical characterization, in vitro experiments, animal studies, and clinical trials. Only by clarifying the safety limits of materials and the mechanisms of action in vivo will nanopharmaceutical delivery systems make a sustainable contribution to precision therapy, tissue repair, and biomedical applications.

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