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Research Progress on the Application and Process Optimization of Nano Drug Delivery Systems in Pharmaceutical Preparations

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Abstract. Nano drug delivery systems can improve the solubility, stability and in vivo distribution of drugs, thereby enhancing their bioavailability and therapeutic efficacy. By regulating drug release behavior, they enhance the accumulation capacity of drugs at lesion sites and enable more precise and sustained drug delivery. Such systems are of great value in reducing drug exposure in normal tissues and improving therapeutic effects. This paper reviews major carrier types including liposomes, polymeric nanoparticles and inorganic nanoparticles, as well as their preparation technologies. It analyzes critical quality attributes such as particle size, zeta potential, encapsulation efficiency and drug loading capacity. The influences of stirring speed, homogenization pressure and preparation temperature on formulation performance are also discussed. Furthermore, their anti-tumor applications are illustrated with albumin-bound paclitaxel and PEGylated liposomal doxorubicin as examples. Nano-delivery technologies possess promising potential for clinical translation. Nevertheless, further efforts are required to improve process stability, batch-to-batch consistency and quality control standards.

Keywords: Nanomedicine Delivery Systems, Nanoformulations, Process Optimization

1. Introduction

Nano-drug delivery systems possess multiple advantages including improving drug solubility, regulating drug release profiles, optimizing in vivo distribution and enhancing biocompatibility, and have become an important research field in pharmaceutics. With the advances in precision medicine and nanotechnology, nano-delivery platforms represented by liposomes and polymeric nanoparticles have been increasingly applied in the treatment of tumours, infectious diseases, neurological disorders and other illnesses. Modulation of carrier structure, particle size and surface properties can improve the in vivo distribution and lesion accumulation of drugs, reduce drug exposure in normal tissues, thereby enhancing therapeutic efficacy and alleviating toxic side effects [1]. After administration, conventional drugs are generally widely distributed via blood circulation. Many drugs lack selectivity towards lesion sites, which tends to raise drug exposure in healthy tissues and trigger systemic adverse reactions. Moreover, numerous drugs suffer from poor water solubility, insufficient stability, or susceptibility to degradation by gastric acid and enzymes, which restrict

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their absorption and bioavailability. Nano-carriers can encapsulate drugs to enhance their stability and dispersibility. Relying on passive or active targeting strategies, nano-carriers modulate the in vivo distribution of drugs and elevate drug accumulation at pathological sites. Nevertheless, upon entering the body, nano-carriers undergo complicated interactions with plasma proteins, cell membranes and the immune system. Their structure and surface characteristics may alter under physiological conditions, and they are also affected by individual variability and disease heterogeneity. Consequently, the in vivo behaviour and delivery mechanisms of nanomedicines remain highly complex.In recent years, progress in materials science, imaging analysis and biointerface research has facilitated in-depth investigations into the structural characterisation, in vivo distribution and cellular interaction mechanisms of nano-carriers. Domestic and international studies mainly focus on carrier structural design, encapsulation and drug loading performance, surface modification and regulation of in vivo behaviour. However, the relationships between the physicochemical properties of carriers, manufacturing processes and biological effects still require further clarification.

Passive targeting mainly relies on the physicochemical properties of nano-carriers and the microenvironment of diseased tissues. Rational regulation of parameters such as particle size, surface potential, hydrophilicity/hydrophobicity and morphology is critical to achieve efficient passive targeting [2]. Appropriate particle size and surface properties help prolong the in vivo circulation of nanoparticles, and facilitate their accumulation at lesion sites via the enhanced permeability and retention (EPR) effect in tumour tissues [3]. In addition, surface modification with hydrophilic materials can reduce non-specific protein adsorption and clearance by the mononuclear phagocyte system, extending the circulation half-life of nanoparticles [4]. Since passive targeting is limited by inter-individual variation of the EPR effect and tumour heterogeneity, active targeting modification has emerged as a vital strategy to improve delivery selectivity. The conjugation of targeting moieties such as antibodies, peptides, small-molecule ligands or aptamers onto nano-carrier surfaces strengthens specific binding with receptors overexpressed on target cells and promotes cellular uptake. In recent years, personalised nano-delivery combined with companion diagnostics, molecular subtyping and biomarker expression profiles has gradually become a key research direction for precision drug delivery.

Stimuli-responsive nano-delivery systems are divided into two categories: endogenous microenvironment-responsive systems and exogenous physical stimulus-responsive systems. Endogenous responsiveness takes advantage of the differences between diseased tissues and normal tissues in pH, redox status and enzyme expression to construct pH-responsive, redox-responsive and enzyme-responsive nano-carriers [5]. Exogenous responsiveness utilises external stimuli such as near-infrared light, ultrasound, magnetic fields and microwaves to control drug release [6]. Precise control over the timing, location and intensity of stimuli enables spatiotemporally controllable drug release. At present, multi-stimuli responsiveness and synergistic regulation have become major research trends for intelligent nano-delivery systems.This article reviews the main types, preparation technologies, critical quality attributes and process parameter optimisation of nano-drug delivery systems. Combined with their applications in anti-tumour therapeutics, the characteristics and limitations of various nano-carriers and preparation techniques are analysed. This work provides references for the rational design, process optimisation and clinical translation of nanoformulations.

2. Types and preparation technologies of nano-drug delivery systems

Nano-drug delivery systems encompass a wide variety of types, mainly including liposomes, polymeric nanoparticles, inorganic nanoparticles, dendrimers and nanoemulsions. As one of the

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most widely adopted nano drug carriers, liposomes are composed of phospholipid bilayers and are capable of encapsulating both hydrophilic and hydrophobic drugs. Conventional liposomes can achieve passive accumulation to a certain extent relying on the physiological characteristics of diseased tissues. After targeted ligands such as antibodies and peptides are conjugated onto their surfaces, their binding affinity to specific cells or receptors can be improved. Solid lipid nanoparticles and nanostructured lipid carriers possess favorable physical stability and drug loading capacity, making them suitable for the delivery of several poorly soluble drugs. Polymeric nanoparticles are generally fabricated from natural or synthetic polymers, and can form structures such as nanospheres and nanocapsules [7]. Natural polymers including chitosan and albumin exhibit excellent biocompatibility; among them, albumin has been utilized for the development of clinical nanoformulations. Degradable synthetic polymers such as poly(lactic-co-glycolic acid) enable controlled drug release by adjusting material composition and degradation rate. Inorganic nanoparticles possess unique optical, magnetic and surface properties, and can integrate drug delivery and imaging functions. Gold nanoparticles feature photothermal conversion properties; mesoporous silica nanoparticles have regular pore structures, large specific surface areas and are easy to undergo surface modification; iron oxide nanoparticles display superparamagnetism, which can be applied in magnetic-responsive delivery and magnetic resonance imaging. Dendrimers are characterized by highly branched and controllable structures with abundant surface functional groups, supporting drug loading and functional modification. Nanoemulsions consist of oil phase, aqueous phase and surfactants, and can enhance the dispersibility and oral absorption of certain poorly soluble drugs.

Distinct structural and physicochemical properties among different nanocarriers lead to varied preparation methods. The emulsion-solvent evaporation method is commonly used to synthesize polymeric nanoparticles, especially for hydrophobic small-molecule drugs. In this approach, polymers and drugs are dissolved in an organic phase, which is subsequently dispersed into an aqueous phase containing emulsifiers to form emulsion droplets. Nanoparticles are generated after solidification of droplets via solvent evaporation. The double emulsion method (W/O/W) can encapsulate water-soluble drugs, proteins and nucleic acids, and is applicable to polymer systems such as PLA, PLGA and PCL. This technique features relatively simple operation and broad applicability, yet it suffers from drawbacks including residual organic solvents, insufficient particle size uniformity and batch-to-batch variation after scale-up [8]. Nanoprecipitation represents a prevalent strategy for preparing polymeric nanoparticles and polymeric micelles. Its fundamental principle lies in dissolving drugs and polymers in water-miscible organic solvents, followed by mixing with the aqueous phase. Nanoparticles form through solvent exchange and polymer self-assembly. Carried out under mild conditions with low shear force, this method achieves favorable repeatability and suits drugs sensitive to harsh preparation conditions. Nevertheless, it has limited encapsulation efficiency for water-soluble drugs, and particle aggregation may occur at high concentrations [9]. The thin-film hydration method serves as a classic technique for liposome fabrication. Lipid materials are dissolved in organic solvents and form thin films by rotary evaporation. Lipid vesicles with relatively uniform particle sizes are then obtained after hydration, sonication or extrusion [10]. With mature operating procedures, this method can produce liposomes encapsulating drugs of different solubility. However, it is restricted by low throughput, numerous processing steps and barriers to large-scale manufacturing. The ionotropic gelation method relies primarily on electrostatic interactions between oppositely charged polymers or crosslinkers to form nanoparticles. A typical system is the crosslinking of chitosan and sodium tripolyphosphate [11]. The whole process can be completed in aqueous media under mild conditions, minimizing the

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adverse impacts of organic solvents on drugs and carriers. It fits several natural polymer nano-systems, whereas limitations remain in drug loading capacity, particle size stability, and tolerance to ionic strength and pH fluctuations. Microfluidic technology regulates the nucleation and assembly of nanoparticles through precise liquid mixing within microchannels, and can be applied to lipid nanoparticles, polymeric nanoparticles, polymeric micelles and other systems. It provides controllable mixing processes, narrow particle size distribution, favorable batch-to-batch repeatability and facilitates continuous production, holding great potential for large-scale preparation and process scaling of nanoformulations [12]. Even so, further optimization is required regarding equipment cost, flow scaling and high-throughput manufacturing conditions. Supercritical fluid technology generally adopts supercritical CO_2 as the medium. Nanocrystallization of drugs and carrier assembly are realized by regulating dissolution, precipitation or recrystallization, and it can be adopted to prepare nanocrystals of poorly soluble drugs and polymeric nanocarriers [13]. This technology helps reduce the consumption and residual levels of traditional organic solvents, yet it imposes strict requirements on equipment and process parameter control, restricting its large-scale deployment. In addition, chemical polymerization can generate polymeric nanospheres via in-situ monomer polymerization, and drugs can be encapsulated during polymerization, which is suitable for certain sustained-release systems. Although the structure is highly tunable, the reaction conditions are relatively complicated. Residual monomers or initiators are potential concerns, limiting its applications in biomacromolecular drugs.

3. Optimization of preparation processes for nano-drug delivery systems

The performance of nanoformulations is mainly governed by critical indicators including particle size and its distribution, zeta potential, encapsulation efficiency and drug loading capacity. Particle size together with the polydispersity index (PDI) jointly reflects the dimension and size homogeneity of nanoparticles. For anti-tumor nanocarriers, particle size is generally controlled within the range of 10–200 nm. Excessively small particle size may accelerate renal clearance, while oversized particles tend to be captured by the hepatic and splenic mononuclear phagocyte system, hindering in vivo circulation and accumulation at lesion sites [14]. An appropriate particle size enables nanoparticles to accumulate in tumor tissues via the enhanced permeability and retention (EPR) effect. A lower PDI indicates a more concentrated particle size distribution, generally corresponding to superior system homogeneity and batch-to-batch stability. A high PDI signifies large discrepancies in particle dimensions, which may raise risks of aggregation, sedimentation during storage and inconsistent in vivo behaviors.Zeta potential characterizes the surface charge properties of nanoparticles and serves as a vital indicator for evaluating colloidal dispersion stability. A high absolute zeta potential strengthens electrostatic repulsion between particles, mitigating the risks of aggregation and sedimentation to a certain extent. When the potential approaches neutrality, electrostatic stabilization weakens, rendering particles prone to aggregation [15]. Positively charged surfaces facilitate interactions between nanoparticles and negatively charged cell membranes. Nevertheless, excessive positive surface charge may promote non-specific binding with plasma proteins, increasing the likelihood of rapid clearance and cytotoxicity. Accordingly, surface potential should be rationally modulated according to administration routes, carrier compositions and target tissues.Encapsulation efficiency refers to the proportion of drugs encapsulated by nanocarriers relative to the total input drug amount. Low encapsulation efficiency elevates the concentration of free drugs in the system, which may trigger premature drug release and compromise formulation stability and delivery efficacy. Improving encapsulation efficiency helps maintain the encapsulated state of drugs and lays a foundation for sustained release or stimulus-responsive drug release [16].

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Drug loading capacity represents the quantity of drug loaded per unit mass of nanoformulation. Insufficient drug loading requires larger carrier dosages to achieve therapeutic effective concentrations, whereas excessive drug loading may disrupt the structural stability of carriers, resulting in drug precipitation or particle aggregation. Hence, drug loading capacity needs to strike a balance between therapeutic dosage and formulation stability .Beyond these core quality attributes, processing parameters such as stirring speed, homogenization pressure and preparation temperature directly affect nanoparticle formation and final performance. Stirring primarily regulates two-phase mixing, solvent diffusion and droplet breakage. In the PLGA emulsion-solvent evaporation system, raising the magnetic stirring speed from 200 rpm to 400 rpm reduces the average nanoparticle size from 198.2±6.1 nm to 179.4±5.2 nm. This demonstrates that moderately elevated stirring enhances mixing and reduces droplet size. However, further increasing stirring speed leads to marginal particle size reduction and may increase PDI and particle aggregation owing to bubble generation [8]. In contrast, particle size remains between 171 nm and 176 nm within the stirring range of 200–400 rpm in nanoprecipitation systems. This indicates that stirring exerts a relatively limited influence on particle size, and nanoparticle formation is predominantly controlled by solvent-antisolvent diffusion and nucleation processes [16]. For solid lipid nanoparticles, high-speed shearing improves pre-dispersion, yet excessive rotation speed causes excessive foaming and deteriorated dispersion homogeneity [17]. Therefore, the effect of stirring speed is closely associated with specific preparation methods, and an optimal range should be determined based on system characteristics.Homogenization pressure is a key parameter in high-pressure homogenization and microfluidization processes. It breaks coarse particles or droplets through shear force, turbulence and cavitation effects. For 10-hydroxycamptothecin nanosuspensions fabricated via precipitation combined with high-pressure homogenization, an average particle size of approximately 131 nm is obtained under 1000 bar after 20 homogenization cycles. Pressures below 600 bar yield insufficient particle disruption, while particle size reduction plateaus above 1200 bar, accompanied by increased mechanical heat generation and particle collision [16]. In PLGA microfluidic homogenization systems, insufficient coarse emulsion breakage occurs under low pressure, whereas excessively high pressure causes system temperature rise, particle fusion and decreased encapsulation efficiency [18]. Overall, particle size generally decreases with rising homogenization pressure before reaching a plateau. Further pressure increase brings limited benefits while raising thermal load and aggregation risks.Preparation temperature mainly affects system viscosity, solvent diffusion, lipid melting and polymer stability, and its optimal range varies with carrier types and manufacturing techniques. During PLGA nanoparticle fabrication, moderate heating accelerates solvent diffusion and particle nucleation. However, overheating may trigger rapid evaporation of organic solvents, local supersaturation and particle aggregation. Mechanical heat generated from high-pressure homogenization may also impair polymer stability, making temperature control essential [19]. When applying the hot homogenization method for solid lipid nanoparticles, the preparation temperature must generally exceed the melting point of lipids. Efavirenz solid lipid nanoparticles exhibit favorable manufacturing outcomes at 70 °C. Inadequate temperature leads to incomplete lipid melting, while excessive temperature raises risks of drug degradation and impaired drug loading performance [17]. For nanosuspensions, elevated temperature weakens the adsorption capacity of stabilizers and promotes Ostwald ripening.

In summary, the optimization of nanoformulation manufacturing is not an independent adjustment of single parameters, but a synergistic effect of stirring speed, homogenization pressure, preparation temperature and other factors. Stirring governs pre-dispersion and two-phase mixing; homogenization pressure modulates particle breakage and particle size; temperature influences

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nanoparticle formation by altering viscosity, diffusion and material stability. Consequently, all parameters should be synergistically optimized in combination with carrier type, preparation technology and target quality indicators, so as to produce nanoformulations with uniform particle size, favorable stability and consistent quality across batches.

4. Application status of nano-drug delivery systems

Traditional small-molecule chemotherapeutic drugs are often hampered by poor water solubility, insufficient tumor selectivity, severe systemic toxic side effects, and rapid in vivo clearance, which restrict their clinical therapeutic efficacy. Nano-drug delivery systems can alter the dissolution state, in vivo distribution and pharmacokinetic behavior of drugs. Combined with the enhanced permeability and retention (EPR) effect or surface targeting modification, these systems facilitate drug accumulation in tumor tissues, thereby improving therapeutic efficacy and reducing toxicity to a certain extent. At present, nanoformulations such as pegylated liposomal doxorubicin and albumin-bound paclitaxel have been translated into clinical practice, serving as representative achievements of nano-delivery technology transformation.Paclitaxel possesses broad-spectrum antitumor activity yet suffers from poor water solubility. Conventional paclitaxel injections utilize polyoxyethylated castor oil and anhydrous ethanol as solubilizers. However, polyoxyethylated castor oil may trigger hypersensitivity and other adverse reactions, which necessitates routine premedication before clinical administration. Albumin-bound paclitaxel adopts albumin nanoparticles as the drug carrier without polyoxyethylated castor oil. It reduces the risk of solubilizer-related hypersensitivity, shortens infusion duration and improves administration convenience [20]. Meanwhile, the albumin carrier optimizes the dispersion state and pharmacokinetic profiles of paclitaxel, and promotes the transport and accumulation of the drug in tumor tissues [21]. Clinical studies have demonstrated that albumin-bound paclitaxel achieves superior outcomes including higher objective response rates compared with conventional paclitaxel for the treatment of metastatic breast cancer [22]. Accordingly, this formulation not only overcomes the pharmaceutical drawbacks of paclitaxel, but also optimizes its safety profile and clinical practicability.Doxorubicin is a widely used anthracycline antitumor agent. Its clinical application is largely limited by dose-dependent cardiotoxicity, myelosuppression, local tissue injury and other adverse reactions. Pegylated long-circulating liposomal doxorubicin encapsulates the drug within liposomes to remodel its in vivo distribution and reduce exposure of free drug in healthy tissues, leading to improved safety. Compared with free doxorubicin, the liposomal formulation diminishes drug infiltration into myocardial tissue and lowers the peak plasma concentration of free drug, thus mitigating the risk of cardiotoxicity [23]. PEG modification inhibits rapid clearance of liposomes by the mononuclear phagocyte system, prolongs blood circulation time, and promotes drug accumulation in certain tumor tissues via the EPR effect [24]. Moreover, liposomal encapsulation attenuates direct irritation of blood vessels and local tissues induced by free doxorubicin, and lowers the risk of severe tissue damage in case of infusion extravasation [25]. Given its distinct toxicity profile from free doxorubicin, pegylated liposomal doxorubicin has been applied to treat ovarian cancer, multiple myeloma, Kaposi's sarcoma, breast cancer and other malignancies.In summary, albumin-bound paclitaxel and pegylated liposomal doxorubicin optimize drug solubilization patterns, modulate in vivo distribution and decrease drug exposure in normal tissues respectively. They illustrate the application value of nano-drug delivery systems in formulation optimization and toxicity management of antitumor agents.

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5. Conclusion

Nano-drug delivery systems can improve drug stability and lesion accumulation capacity as well as reduce drug exposure in normal tissues to a certain extent by optimizing carrier structures, regulating drug release and modifying in vivo distribution. Different nanocarriers and preparation methods possess distinct characteristics, and their performance is jointly affected by factors including particle size, zeta potential, encapsulation efficiency, drug loading capacity, stirring speed, homogenization pressure and preparation temperature. Therefore, collaborative optimization should be carried out according to specific formulation systems. Clinical applications such as albumin-bound paclitaxel and PEGylated liposomal doxorubicin further demonstrate the value of nano-delivery technology in improving the performance of traditional anti-tumor drug formulations and alleviating partial toxicities. In the future, priorities remain to address challenges such as complicated in vivo behaviors, variable targeting efficacy, large-scale production and batch-to-batch consistency control. Moreover, preparation processes and quality evaluation systems need further improvement to enhance the stability, controllability and clinical translation potential of nano-drug delivery systems.

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