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Inhalable nanoparticle-based dry powder formulations: A new horizon in pulmonary medicine

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Abstract
The prevalence of respiratory diseases has driven significant interest in inhalable nanoparticle-based pharmaceutical formulations. These innovative treatments offer a promising approach for next-generation respiratory therapies. Traditional methods for managing lung diseases, such as oral medications, injectables, nebulizers, and aerosols, often require frequent administration and involve complex delivery systems, placing a substantial burden on patients both physically and financially. Inhalable dry powder formulations incorporating nanoparticles are emerging as superior alternatives due to their ease of use, stability, and long-term effectiveness. This advanced drug delivery system demonstrates improved efficacy and reduced dosage requirements for lung-related disorders. Key advantages include enhanced penetration into lung tissues, targeted deposition in specific lung regions, improved solubility, increased bioavailability, storage stability, and a high degree of customization. These formulations typically utilize finely milled or freeze-dried nanoparticles. The rise of novel respiratory infections, such as COVID-19, and the rapid development of nanoparticle-based vaccines have further spotlighted the potential of these technologies. Among the various aerosol delivery systems available, dry powder inhalers (DPIs) stand out as a preferred method for delivering nanoparticles to the respiratory tract. Over the past two decades, the success of dry powder inhalation therapies has inspired further exploration into their use for systemic diseases. While challenges remain, the potential of these therapies to revolutionize treatment options for systemic disorders remains immense.

Keywords: Pulmonary drug delivery, lung diseases, dry powder inhalers, nanoparticles, inhalation devices, particle engineering

Introduction
Inhalable dry powder formulations have garnered significant attention in the past two decades due to their potential in targeted pulmonary drug delivery. Pulmonary drug delivery is a non-invasive and efficient approach for treating chronic respiratory and systemic diseases. The unique characteristics of the lungs, such as a large surface area (~100 m²), extensive vascularization, a thin epithelial layer (0.2–0.7 µm), low enzymatic activity, and the ability to bypass first-pass metabolism, make the pulmonary route particularly advantageous for drug delivery [1,2]. These features enable rapid therapeutic action and improved drug targeting.

Particle deposition in the lungs is influenced by mechanisms such as sedimentation, inertial impaction, and diffusion, which depend on aerodynamic particle size, shape, and density. Particles within the aerodynamic diameter range of 1–5 µm exhibit optimal deposition in the respiratory tract, whereas smaller particles (<1 µm) are exhaled, and larger particles (>5 µm) deposit in the upper airways [3, 4]. Upon deposition in the deep lung, soluble drug particles dissolve to produce either a local or systemic effect, depending on the physicochemical properties of the drug and carrier particles [5, 6].

Nanoparticles have revolutionized pulmonary drug delivery by offering enhanced therapeutic efficacy and precision. Their nanoscale size enables better penetration across alveolar barriers, protection of active agents from enzymatic degradation, and evasion of macrophage clearance [7, 8]. Functionalization with ligands such as antibodies or peptides facilitates targeted drug delivery, making nanoparticles particularly effective for diseases like lung cancer and tuberculosis [9, 10].

Moreover, nanoparticles can enable sustained or controlled drug release through property modulation, presenting significant advantages over traditional formulations [11, 12].

Among available delivery devices, dry powder inhalers (DPIs) stand out due to their portability, ease of use, and suitability for nanoparticle-based formulations. Dry powders are engineered using techniques such as adsorption onto carriers, agglomeration, or uniform distribution in a powder matrix. These powders are designed to disperse into nanoparticles upon deposition in the lungs, ensuring effective therapeutic action. However, challenges like nanoparticle aggregation due to high surface energy necessitate advanced engineering strategies to enhance formulation stability [13, 14].

Recent advancements, including nano-in-micro delivery systems, have further improved pulmonary drug delivery. Embedding nanoparticles in biopolymer matrices, such as chitosan, enhances delivery to deep lung regions, reduces macrophage clearance, and ensures efficient drug release [15, 16]. Pulmonary drug delivery has been widely used for local diseases such as asthma, COPD, and cystic fibrosis, as well as systemic diseases like diabetes and Parkinson's disease. Its needle-free administration and bypass of gastrointestinal effects make it particularly attractive for patients [17-22].

With ongoing advancements [23-33] in nanotechnology and particle engineering, inhalable nanoparticle-based dry powders hold immense promise for addressing both respiratory and systemic diseases.

Various Inhalation Devices

Inhalation devices are commonly used in clinical settings and can be broadly categorized into three types: metered-dose inhalers (MDIs), dry powder inhalers (DPIs), and nebulizers. Each device employs distinct mechanisms and is tailored to specific formulations and patient conditions. The selection of an appropriate inhalation device depends on factors such as the patient's physical condition, inspiratory flow rate, and ability to perform inhalation manoeuvres.

Metered-Dose Inhalers (MDIs)

MDIs are widely utilized inhalation devices that encapsulate drug-containing solutions, emulsions, or suspensions in pressure-resistant containers. These devices use hydrofluoroalkanes (HFAs) as environmentally friendly propellants, replacing the previously used chlorofluorocarbons (CFCs). The propellant ejects the aerosolized drug, requiring patients to coordinate inhalation with activation. However, this coordination can be challenging for children, elderly individuals, and those with physical limitations.

The deposition efficiency of MDIs is relatively low, with only 10–20% of the drug reaching the lungs. To improve deposition, a valved holding chamber (VHC) can be used as an intermediary between the MDI and the patient's mouth. The VHC acts as a buffer, reducing the velocity of the aerosol and improving drug delivery to the respiratory tract.

Dry Powder Inhalers (DPIs)

DPIs deliver powdered drugs without the need for propellants, relying on the patient's inhalation effort to disperse the medication. These formulations consist of micronized active pharmaceutical ingredients (APIs) or dry powders combined with suitable carriers. DPIs are available in single-dose, multi-unit dose, and multi-dose formats, offering deposition rates that typically range from 12–40%.

Advantages of DPIs include their solid-state stability, long shelf life, and minimal environmental impact. However, their efficacy depends on the patient's inhalation ability and speed. Recent advancements in DPI technology have focused on simplifying device designs, reducing inspiratory flow rate requirements, improving dose uniformity, and incorporating inhalation feedback mechanisms.

Nebulizers

Nebulizers convert drug-containing solutions or suspensions into aerosols for inhalation, making them suitable for patients who cannot perform coordinated inhalation maneuvers. Nebulizers are categorized into three main types.

Jet Nebulizers: This uses compressed gas to create aerosols based on the Venturi effect. Jet nebulizers are versatile, cost-effective, and capable of delivering solutions, suspensions, antimicrobials, and biologics. However, they are bulky, noisy, and require longer treatment times.

Ultrasonic Nebulizers: These devices employ high-frequency mechanical vibrations to generate aerosols. While faster and more compact than jet nebulizers, ultrasonic nebulizers can heat the liquid, potentially destabilizing thermolabile drugs and suspensions. They are unsuitable for oxygen-sensitive or protein-based formulations.

Vibrating Mesh Nebulizers

This newer generation of nebulizers utilizes ultrasonic vibrations and a mesh with micro-sized pores to produce uniform aerosols. Although more expensive and requiring maintenance, vibrating mesh nebulizers offer high precision and are promising for clinical applications.

Pulmonary Drug Delivery Systems

Polymeric particulate systems have shown immense potential in pulmonary drug delivery. Biodegradable and biocompatible polymers, including natural options like chitosan, hyaluronic acid, and gelatin, and synthetic options such as poly (Lactic acid) (PLA) and poly (vinyl alcohol) (PVA), enable a wide range of applications. These systems offer controlled release profiles, enhanced stability, and targeted delivery, making them valuable for treating respiratory diseases.

Types of Nanoparticles

Inhaled nanoparticles (NPs) predominantly accumulate in the alveolar region, with slow release over time. Recent advancements in NP-based inhalation therapies focus on minimizing side effects, improving therapeutic efficiency, and optimizing lung-specific drug delivery. Figure 3 illustrates the most promising nanoparticles for inhalation therapy, broadly categorized into the following types:

1. Lipid-Based Nanoparticles (LNPs).
2. Polymeric Nanoparticles (PNPs).
3. Metallic Nanoparticles (MNPs).
4. Silica Nanoparticles.
5. Quantum Dots (QDs).
6. Protein-Based Nanoparticles (PBNPs).
7. Inorganic Nanoparticles.
8. Exosome-Mimetic Nanoparticles (EMNPs).

Lipid-Based Nanoparticles (LNPs)

LNPs are versatile carriers, leveraging their structural properties to enhance drug delivery and therapeutic outcomes. Comprising ionizable lipids, surfactants, cholesterol, and polyethylene glycol, they ensure stability and controlled release. LNPs are particularly effective for delivering genetic therapies targeting lung conditions such as cystic fibrosis (CF) and for localized drug delivery in lung cancer treatments.

Polymeric Nanoparticles (PNPs)

Constructed from biocompatible polymers such as chitosan and PLGA, PNPs encapsulate a range of therapeutic agents, including antibiotics, proteins, and nucleic acids. These nanoparticles employ mechanisms like endocytosis and endosomal escape for effective drug delivery. For instance, PNPs are explored for treating bacterial infections in CF patients and delivering genetic material in gene therapy applications.

Mechanisms and Applications of Polymeric Nanoparticles

Polymer	Mechanism of Action	Applications
Chitosan	Mucoadhesion, endosomal escape, cellular uptake	Asthma, lung cancer
Gelatin	Endosomal escape	Tuberculosis, protein delivery
PLGA	Mucoadhesion, cellular uptake	CF, asthma, COPD, tuberculosis

Metallic Nanoparticles (MNPs)

MNPs consist of metals like gold, silver, and zinc, enhanced with functional groups for stability and specificity. They exhibit unique properties, such as reactive oxygen species production and DNA damage, making them effective against infections and in cancer therapy. Despite their benefits, some MNPs pose health risks, including inflammation and allergy exacerbation.

Silica Nanoparticles

Silica nanoparticles offer controlled sizes, large surface areas, and biocompatibility, making them ideal carriers for anti-inflammatory drugs. They are utilized in inhalation therapies for airway inflammation and genetic disorders like CF. Research shows silica NPs enhance anticancer drug delivery and efficacy, particularly in lung cancer models.

Quantum Dots (QDs): QDs are highly versatile for imaging and drug delivery in pulmonary applications. Enhanced with surface modifiers, they enable optical tracing for diagnosing lung diseases and precise delivery of therapeutic agents. Applications include targeting alveolar macrophages and delivering anticancer agents.

Protein-Based Nanoparticles (PBNPs)

PBNPs, composed of proteins like albumin and gelatin, exhibit low immunogenicity and high specificity. They are used in inhalation therapies for asthma, COPD, and acute respiratory distress syndrome. Protein-based systems are also explored for targeted anticancer treatments, demonstrating efficacy in preclinical models.

Inorganic Nanoparticles

Inorganic nanoparticles like cerium oxide and calcium phosphate offer unique properties, such as enzyme mimetic activities and pH-dependent solubility. These features are advantageous for oxidative stress management in lung cancer and for delivering nucleic acids in respiratory therapies.

Exosome-Mimetic Nanoparticles (EMNPs)

EMNPs mimic natural exosomes, ensuring stability and sustained release of therapeutic agents. They are promising in respiratory medicine, particularly for delivering chemotherapeutic drugs with high specificity, thereby reducing systemic side effects.

Engineering of Nanoparticulate Powders for Inhalation

Preparation methods significantly influence the performance of nanoparticle formulations. Two primary approaches are used:

1. **Bottom-Up:** Precipitation of nanoparticles from a solution.
2. **Top-Down:** Milling larger particles to nanoscale sizes.

Common Preparation Methods

Method	Key Features
Milling	Particle size reduction through wet or dry milling.
High-Pressure Homogenization	Produces solid-lipid nanoparticles via lipid solidification.
Spray Drying	High-throughput method for dry powders with adjustable properties.
Spray Freeze Drying	Produces low-density particles with smooth surfaces.
Supercritical Fluid Extraction	Precipitates particles using supercritical CO2.
Inverse Phase Nanoprecipitation	Produces nanoparticles with high encapsulation efficiency.
PRINT Technology	Fabricates monodisperse particles with controlled size and shape.
Condensation Aerosol Growth	Creates inhalable aerosols through condensation mechanisms.

Particle Deposition Patterns

Particle deposition in the respiratory tract depends on patient physiology and particle properties such as size, shape, and hygroscopicity. Key mechanisms include:

- **Inertial Impaction:** Larger particles (>5 µm) deposit in the upper respiratory tract.
- **Sedimentation:** Medium-sized particles (1–5 µm) settle in the bronchioles.
- **Brownian Diffusion:** Smaller particles (<1 µm) reach the alveolar region or are exhaled.

Studies indicate that smaller particles (1.5–3 µm) achieve higher deposition in central and peripheral airways compared to larger ones. However, particles below 0.5 µm are often exhaled, highlighting the importance of optimizing particle size for effective lung deposition.

Formulation Strategies for Inhalable Nanoparticle-Loaded Dry Powders: Inhalable nanoparticle-loaded dry powders are categorized into three primary types: nano-embedded microparticles, nano-agglomerate microparticles, and nanoparticle-carrier systems. These designs and their dispersion mechanisms within the respiratory tract.

Nano-Embedded Microparticles

Nano-embedded microparticles, also termed nano-in microparticles, consist of drug-loaded nanoparticles embedded within a micron-sized matrix. These particles are typically formed by drying nanosuspensions with dissolved bulking or shell-forming agents, which create a protective matrix around the nanoparticles during the drying process. The resulting particles are generally spherical, with dispersed nanoparticles visible within the matrix.

Upon deposition in the lungs, the matrix degrades in the lung lining fluid, releasing the nanoparticles. However, this approach often involves a high proportion of excipients, leading to low drug loading. Consequently, nano-embedded microparticles are most suitable for delivering nanoparticles encapsulating highly potent drugs. Commonly used bulking agents include disaccharides such as lactose and trehalose, as well as alcohol sugars like mannitol. Regulatory authorities have approved the use of lactose and mannitol in oral inhalation products, making them popular choices.

Nano-Agglomerate Microparticles: Nano-agglomerate microparticles, also known as nanoaggregates or Trojan microparticles, are engineered by agglomerating nanoparticles into hollow or porous structures. These structures facilitate low particle density and superior aerosolization. The particles are produced by drying nanosuspensions with dissolved protectants and optional dispersion enhancers, such as leucine, in small quantities.

The protectants serve dual purposes: protecting primary nanoparticles from structural damage during drying and forming bridges between agglomerated nanoparticles to enable redispersion upon contact with lung lining fluid. Lactose and mannitol are frequently used protectants, but each has limitations. Mannitol, for instance, undergoes recrystallization upon heating or freezing, reducing its protective function and potentially compromising aqueous dispersibility.

Nanoparticle-Carrier Systems

Nanoparticle-carrier systems involve the physical adsorption of dried nanoparticles onto a coarse inert carrier, typically lactose, via coating or blending. Unlike the previous strategies, this method relies on the physical detachment of nanoparticles from the carrier, requiring high airflow rates that may be challenging for patients with impaired pulmonary function. As a result, nanoparticle-carrier systems are less preferred compared to nano-embedded and nano-agglomerate microparticles.

Examples of Drugs in Nano-Formulations for Dry Powder Inhalers (DPIs)

Drug/Agent	Class	Condition	Route of Administration
Vancomycin	Antibiotic	Infection	DPI
Clarithromycin	Antibiotic	Infection	DPI
Salmon calcitonin	Hormone	Hypocalcemia	DPI
Tacrolimus, Cyclosporine A	Immunosuppressant	Lung transplant rejection prevention	DPI
Budesonide	Glucocorticoid	Asthma and COPD	DPI
Tranilast	Antiallergic Agent	Bronchial asthma	DPI
Diatrizoic acid	Radio contrast agent	Imaging of airway	DPI
Ciprofloxacin	Antibiotic	Cystic fibrosis	DPI
Rifampicin	Antibiotic	Tuberculosis	DPI
Paclitaxel	Microtubule inhibitor	Lung cancer	DPI
Tobramycin	Antibiotic	Infection	DPI
Azithromycin	Antibiotic	Infection	DPI
Fluticasone propionate/Albuterol sulfate	Anti-inflammatory/β2-agonist	Asthma and COPD	DPI

Tuberculosis: A Focus on Inhalable Drug Delivery

Challenges in Tuberculosis Treatment

Tuberculosis (TB), caused by *Mycobacterium tuberculosis*, remains a major global health concern. One-third of the world's population is infected, and conventional therapies face significant limitations, including poor drug penetration, systemic toxicity, drug resistance, and extended treatment duration. Novel inhalable drug delivery systems offer localized drug delivery, avoiding first-pass metabolism, enhancing bioavailability, reducing systemic side effects, and potentially shortening treatment duration. However, challenges such as formulation instability and poor delivery efficiency due to nanoparticle exhalation must be addressed.

Rifampicin-Based Inhalable Dry Powder Formulations

Rifampicin, a key anti-TB drug, has been developed into inhalable dry powder nano-formulations to enhance local drug concentrations in the lungs, minimize systemic side effects, and shorten treatment duration. The spray-drying method used for these formulations involves:

1. **Preparation of Feed Solution:** Rifampicin is dissolved or dispersed in a solvent system with stabilizers and excipients.
2. **Atomization:** The feed solution is atomized into fine droplets using a spray nozzle.
3. **Drying:** Droplets are dried with a hot gas (e.g., air or nitrogen) to produce particles.
4. **Collection:** The resulting powder is collected via a cyclone separator or filter.
5. **Optimization:** The powder's aerodynamic properties are optimized for efficient lung deposition.
6. **Testing:** Formulations are tested for stability, release profiles, and inhalation performance.

Mechanism of Action

Rifampicin nanoparticles delivered via DPI reach the deep lung regions (alveoli) and are taken up by alveolar macrophages, the primary site of *M. tuberculosis* infection. The drug inhibits bacterial RNA polymerase, targeting

intracellular bacteria. This localized delivery enhances therapeutic efficacy and minimizes systemic exposure.

Applications of Rifampicin

Rifampicin is primarily used for

1. Treating latent and active TB, often in combination with other drugs to prevent resistance.
2. Managing leprosy as part of multi-drug therapy.
3. Prophylaxis of meningococcal meningitis.
4. Treating staphylococcal infections, such as osteomyelitis.
5. Addressing brucellosis and other bacterial infections.

Inhalable rifampicin formulations hold promise for advancing TB treatment by improving efficacy and reducing the burden of systemic side effects.

Conclusion

The development of inhalable nanoparticle-loaded dry powders represents a significant advancement in pulmonary drug delivery, offering localized treatment with enhanced bioavailability and reduced systemic side effects. Among the various strategies, nano-embedded microparticles, nano-agglomerate microparticles, and nanoparticle-carrier systems exhibit distinct advantages and challenges in drug formulation and delivery. While nano-embedded and nano-agglomerate systems demonstrate superior release and dispersion profiles, the nanoparticle-carrier approach remains limited due to its dependence on patient-specific inhalation dynamics.

The use of these innovative formulations, such as rifampicin-based dry powder inhalers for tuberculosis treatment, highlights the potential to overcome conventional therapy limitations, including poor drug penetration and systemic toxicity. By targeting the lungs directly, these approaches enhance therapeutic efficacy, minimize adverse effects, and shorten treatment durations. Further optimization of these systems, along with addressing formulation and stability challenges, is essential to realize their full clinical potential. Continued research in this domain will pave the way for improved management of respiratory and systemic diseases through inhalation therapy.

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