INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: https://www.ijpsjournal.com

Review Article

Pulmonary Nanoparticle-Based Inhalation Systems

Harshad Mane*, Mayuri Bhadalekar, Atharv Kandale, Dr. Nilesh Chougule

Ashokrao Mane Institute of Pharmacy, Ambap, Maharashtra, India.

ARTICLE INFO

Published: 16 May 2026
Keywords:
pulmonary drug delivery, nanoparticles, inhalation, dry powder inhaler, nebulization, lipid nanoparticles, polymeric nanoparticles, lung targeting, toxicity, clinical translation.
DOI:
10.5281/zenodo.20237886

ABSTRACT

Pulmonary delivery of therapeutics using nanoparticle (NP) carriers has emerged as a powerful approach to treat local lung disease (infections, inflammation, fibrosis, and cancer) and as a route for systemic or genetic therapies (e.g., mRNA). Nanoparticles—including liposomes, polymeric nanoparticles, lipid nanoparticles (LNPs), solid lipid NPs, dendrimers, inorganic particles, and hybrid systems—can improve drug solubility, enable controlled or stimuli-responsive release, protect fragile biologics, and enable cell targeting. However, successful translation requires engineering particle physicochemical properties (size, density, surface charge, elasticity, and surface ligands), suitable aerosolization formats (nebulized suspensions, pressurized metered dose, or dry powder inhalers), device–formulation compatibility, and mitigation of lung clearance mechanisms (mucociliary clearance, alveolar macrophage phagocytosis). Safety and immunotoxicity remain key hurdles: inhaled NPs can provoke oxidative stress, inflammation, and off-target systemic exposure depending on composition and dose. Manufacturing, scale-up, regulatory pathways, and robust preclinical models that predict human lung deposition and toxicity are additional bottlenecks. This review synthesizes recent advances (2020–2025) in materials and formulation strategies, delivery devices, biological fate, therapeutic applications, safety considerations, and translational outlook — and proposes design heuristics and research priorities to accelerate clinical translation of inhalable nanoparticle medicines.

INTRODUCTION

Delivering drugs directly to the lung via inhalation brings several advantages: very high local drug concentrations at disease sites, rapid onset of action, reduced systemic exposure for locally acting drugs, and potential for noninvasive systemic delivery of biologics and nucleic acids. Over the past decade, the convergence of nanotechnology and inhalation science has produced a large body of preclinical work leveraging nanoparticle carriers to overcome limitations of small-molecule and biologic therapeutics when administered via the pulmonary route. The interest has intensified recently because

***Corresponding Author:** Harshad Mane
Address: *Ashokrao Mane Institute of Pharmacy, Ambap, Maharashtra, India.*
Email : mharshad6610@gmail.com

Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

of successes in lipid nanoparticle (LNP) technologies (e.g., mRNA vaccines) and their potential adaptation for inhaled delivery to treat respiratory infections and lung diseases. However, the lung is a complex organ with anatomical, physiological, and immunological barriers that require careful formulation and device choices to realize this promise. This review provides an integrated, up-to-date synthesis of the field, focusing on design principles, formulation and device strategies, biological fate, therapeutic applications, toxicology, and translation challenges.

2. Lung anatomy, physiology and delivery barriers

Key features that shape inhaled nanoparticle design include airway geometry, branching, regional airflow patterns, airway surface liquid and mucus, mucociliary clearance in the conducting airways, alveolar surfactant and resident immune cells (especially alveolar macrophages), and the alveolar–capillary barrier that controls systemic uptake. Particle aerodynamic diameter (which depends on geometric diameter, shape, and particle density) determines regional deposition: particles with aerodynamic diameters ~1–5 µm deposit efficiently in the lower airways and alveoli, while nanoparticles (<100–200 nm) behave differently — they may agglomerate, deposit within alveoli depending on carrier properties, or be exhaled if presented as isolated nanoscale aerosols. Additionally, soluble drug release, mucus interactions, and enzymatic degradation in the lung lining fluid are major challenges. Understanding and engineering around these physiological constraints is essential for successful pulmonary NP delivery.

3. Types of nanoparticles used for pulmonary delivery

A wide variety of nanoparticle classes have been studied for inhalation. Each class offers different strengths and tradeoffs.

3.1 Lipid-based nanoparticles (liposomes, solid lipid NPs, lipid nanoparticles / LNPs)

Liposomes and LNPs are attractive for pulmonary delivery because of their biocompatibility, ability to encapsulate hydrophilic and lipophilic drugs, and capacity to carry nucleic acids (mRNA, siRNA). LNPs (ionizable lipids + helper lipids) have been adapted for pulmonary gene delivery, though formulation stability during aerosolization is critical. Solid lipid nanoparticles offer improved physical stability versus liposomes but can have distinct release profiles.

3.2 Polymeric nanoparticles (PLGA, PEGylated polymers, chitosan, etc.)

Biodegradable polymers (e.g., PLGA) enable sustained release and tunable degradation. Chitosan and other mucoadhesive polymers can improve residence time in the airway but may increase mucus entanglement and clearance challenges. Polymer–lipid hybrids combine attributes of both classes.

3.3 Protein and peptide nanoparticles

Protein nanocarriers (e.g., albumin-based) can carry biologics while offering enzymatic stability benefits. Formulation and aerosolization must preserve biological activity.

3.4 Inorganic nanoparticles (gold, silica, iron oxide)

Inorganic NPs are used for imaging, hyperthermia, or as delivery scaffolds. Their limited biodegradability raises safety concerns for chronic inhalation.

3.5 Dendrimers, micelles, and nanogels

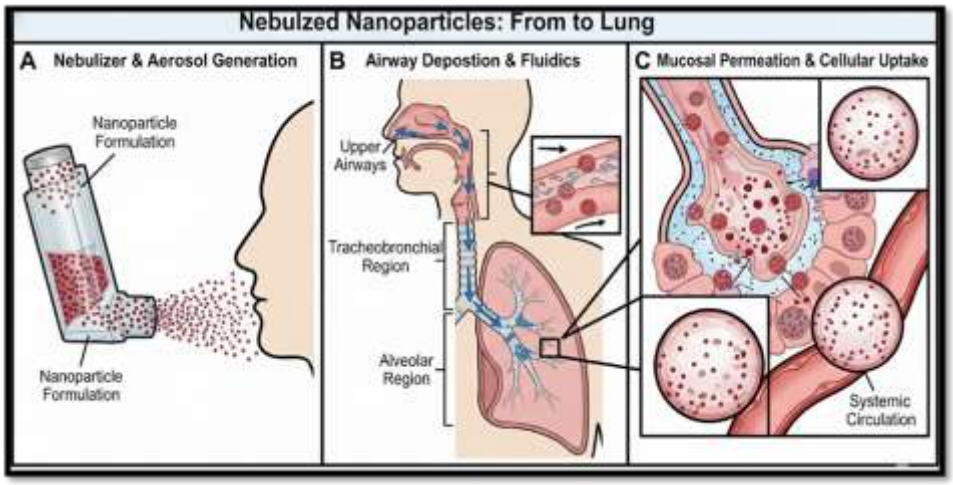
Dendrimers and micellar systems offer high drug loading and surface modification possibilities. Nanogels can be stimulus-responsive (pH, ROS) for triggered release in inflamed lungs.

4. Formulation formats and aerosolization strategies

Translating a nanoparticle into an inhalable product requires converting nanosuspensions or solids into aerosols compatible with clinical devices. Three major formats dominate:

4.1 Wet aerosols / nebulized nanoparticles

Nebulizers generate liquid aerosols from nanoparticulate suspensions or emulsions. Jet, ultrasonic, and vibrating mesh nebulizers are used; vibrating mesh tends to be gentler for fragile biologics and LNPs. Key issues: droplet size control, nanoparticle aggregation during nebulization, and stability under shear and air–liquid interfaces. Nebulized formulations permit adjustable dosing and are suitable for hospitalized patients.



4.2 Pressurized metered dose inhalers (pMDIs)

pMDIs use propellants to deliver drug suspensions or solutions. Formulating NPs for pMDIs is challenging because of compatibility with propellants, particle suspension stability, and limited payload per actuation.

4.3 Dry powder inhalers (DPIs)

DPIs are appealing for outpatient use, long-term therapy, and improved stability. Two nanoparticle-based DPI strategies are common: (a) micronized carrier particles (1–5 μm) embedding or adsorbing nanoparticles (so-called nano-in-micro or aggregated NP) and (b) nanoparticle-spray-dried microparticles where NP are trapped inside porous or matrix microparticles that disaggregate upon inhalation to release NPs. Spray drying, spray freeze drying, and supercritical drying are key manufacturing methods. Controlling interparticle forces, humidity sensitivity, and aerodynamic performance is critical.

5. Design parameters and engineering heuristics

Successfully designing inhalable NPs requires balancing many interdependent parameters:

- **Aerodynamic diameter (D_aero):** For deep lung deposition D_aero ≈ 1–3 μm is often

targeted; nano-in-micro approaches tune D_aero via low-density porous microparticles.

- **Geometric particle size vs. density:** Porous or low-density microparticles deliver nanoscale payloads while maintaining respirable D_aero.
- **Surface chemistry:** PEGylation reduces protein adsorption and clearance; targeting ligands (e.g., antibodies, peptides) help cell-specific uptake but may change aggregation and mucin binding.
- **Charge:** Moderately negative or neutral surfaces avoid mucin entrapment and reduce cationic toxicity (but cationic surfaces can enhance cell uptake for nucleic acids).
- **Elasticity and deformability:** Soft particles can better avoid macrophage uptake and squeeze through mucus meshes.
- **Release kinetics and stimuli-responsiveness:** pH, ROS, enzyme, and redox-responsive linkers enable on-demand drug release in inflamed microenvironments.
- **Stability during aerosolization:** Surfactants and stabilizers are often required to prevent NP aggregation at air–liquid interfaces during nebulization or during spray drying.

6. Biological fate after inhalation: deposition, clearance, and transport

6.1 Deposition and initial distribution

Regional deposition depends on aerodynamic size and inhalation flow. Once deposited, nanoparticles interact with airway mucus, surfactant, epithelial cells, and immune cells. Small NPs may penetrate mucus pores or be trapped depending on surface chemistry.

6.2 Mucociliary clearance and macrophage phagocytosis

Mucociliary clearance rapidly removes particles in conducting airways, while alveolar macrophages patrol the alveoli and phagocytose particulates. Strategies to evade uptake include muco-penetrating coatings (e.g., dense PEG), size tuning, and surface modifications that reduce opsonization.

6.3 Cellular uptake and transcytosis

Endocytic pathways (clathrin, caveolin, macropinocytosis) mediate epithelial and immune cell uptake. For systemic delivery, transcytosis across the alveolar–capillary barrier or paracellular transport is possible but tightly regulated.

6.4 Clearance to systemic circulation

Small NPs or released drug may cross into circulation through the alveolar capillary network; this can be desirable for systemic therapies but may increase off-target toxicity. Pharmacokinetic modeling of lung retention vs systemic absorption is essential for dose selection.

7. Therapeutic applications

7.1 Antimicrobial and anti-tuberculosis therapy

Inhaled NPs can deliver high local concentrations of antibiotics or combination regimens for tuberculosis and other pulmonary infections. Encapsulation reduces systemic toxicity and may overcome intracellular pathogens by facilitating macrophage uptake. Several preclinical studies

show improved bacterial clearance; clinical translation has lagged.

7.2 Cystic fibrosis and genetic diseases (gene therapy / mRNA)

Delivery of nucleic acids (siRNA, mRNA, gene editors) via inhaled lipid or polymeric NPs offers the prospect of treating cystic fibrosis and other monogenic pulmonary diseases. LNP formulations tailored for local delivery and optimized for mucosal penetration are active areas of research. Nonviral vectors avoid insertional mutagenesis risks but must overcome mucus and cellular barriers.

7.3 Pulmonary fibrosis and inflammatory disease

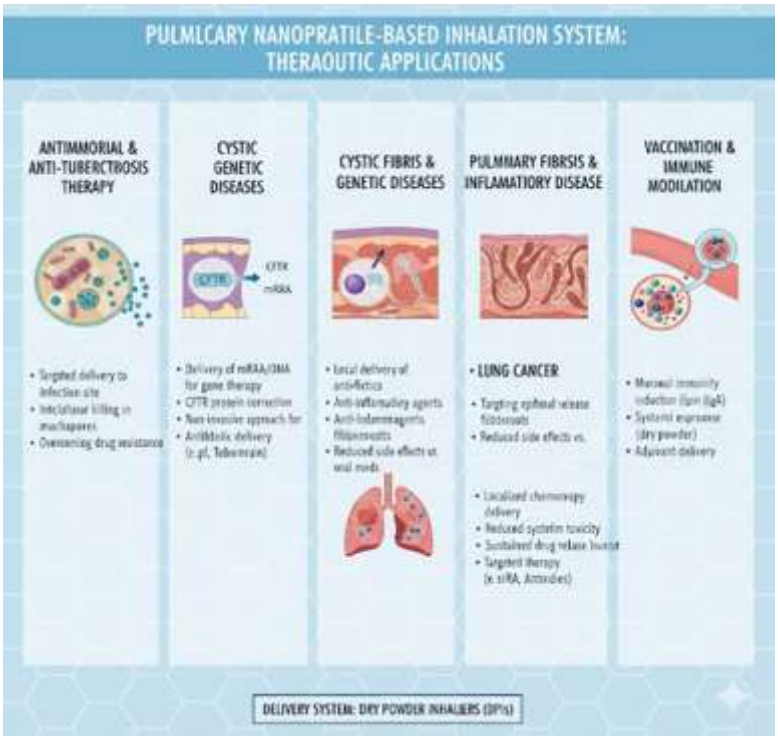
Anti-fibrotic drugs, anti-inflammatory small molecules, or siRNA delivered by inhalation can achieve high local effect. Nanocarriers can enable sustained release and targeting to fibroblasts or immune cells. Preclinical studies in fibrosis models show promise but clinical data are limited.

7.4 Lung cancer

Inhaled nanoparticle chemotherapy targets lung tumors directly with reduced systemic exposure. Both local deposition and nanoparticle modification for tumor penetration are studied. Challenges include tumor heterogeneity and the need for deep alveolar deposition for peripheral lesions.

7.5 Vaccination and immune modulation

Pulmonary vaccination using NP adjuvants or antigen-carrying particles can elicit mucosal and systemic immunity. NP physicochemistry and adjuvant composition tune antigen presentation and immune polarization. Inhaled mRNA vaccines delivered via LNPs is an emerging concept.



8. Preclinical models and translational considerations

8.1 In vitro models

Air–liquid interface (ALI) cultures, organoids, and lung-on-chip systems simulate epithelial barriers and mucociliary function. These models help predict barrier crossing and cytotoxicity but have limitations in reproducing complex immune interactions.

8.2 Ex vivo and in vivo animal models

Rodent models (mice, rats) are widely used for deposition and efficacy studies, but differences in lung anatomy and breathing patterns complicate extrapolation to humans. Larger animals (sheep, nonhuman primates) better represent human deposition but are costly. Standardized inhalation exposure systems and aerosol characterization are crucial for reproducibility

8.3 Predictive assays for toxicity and immunogenicity

Because inhaled NPs can trigger oxidative stress and inflammation, robust in vitro and in vivo assays (including cytokine profiling, oxidative stress markers, and lung function tests) are necessary. Long-term and repeated-dose studies are particularly important for chronic indications.

9. Safety and toxicology

Safety remains a central concern for inhaled nanoparticle systems. Potential adverse effects include:

- **Acute lung inflammation** — many NP materials can induce proinflammatory cytokine release and neutrophil infiltration depending on dose and composition.
- **Oxidative stress and epithelial injury** — reactive surfaces or metal content may generate ROS and damage cells.
- **Fibrotic responses** — chronic exposure to certain particles can promote fibrotic remodeling.
- **Immunogenicity and allergic responses** — proteinaceous carriers or certain adjuvants may sensitize the airway.
- **Systemic toxicity** — translocated NPs can reach other organs (liver, spleen, brain), producing off-target effects.

Material selection, dose minimization, biodegradability, and thorough preclinical toxicology studies are necessary to mitigate these risks. Regulatory guidance emphasizes the need for inhalation-specific toxicology protocols (including inhalation exposure chambers, repeated dosing, and recovery periods).

10. Manufacturing, scale-up, and quality control

Transitioning from bench to clinic requires scalable, reproducible manufacturing processes and robust analytical characterization:

- **Scale-up methods:** scalable nanoprecipitation, high-pressure homogenization, microfluidic mixing (for LNPs), spray drying for DPIs, and freeze drying with excipients for stability are commonly used. Microfluidic mixing has been crucial for reproducible LNP manufacturing (as seen in systemic mRNA vaccines) and is being adapted for inhalable formulations.
- **Critical quality attributes (CQAs):** particle size distribution, polydispersity, surface charge, encapsulation efficiency, residual solvents, moisture content (for DPIs), aerodynamic performance (MMAD, GSD), and sterility.

- **Device compatibility:** the interplay of formulation with inhaler device (wet vs dry, shear forces) must be validated. Device design and user factors (inhalation flow rate) influence delivered dose and deposition.

- **Stability:** physical (aggregation), chemical (lipid oxidation), and biological (mRNA degradation) stability need robust controls and appropriate excipients (antioxidants, cryoprotectants).

11. Regulatory landscape and clinical translation

Despite many promising preclinical studies, few inhaled NP therapeutics have reached late-stage clinical development. Key regulatory and translational hurdles include:

- **Complexity of demonstrating safety for novel nanomaterials** — regulators expect comprehensive inhalation toxicology tailored to chronic exposure scenarios.

- **Defining bioequivalence and potency** — for complex carriers, batch-to-batch consistency and potency assays are challenging.

- **Device–formulation co-development requirements** — the inhaler is often considered part of the medicinal product, increasing development complexity.

- **Clinical trial design challenges** — endpoint selection (physiological, imaging, biomarker), patient inhalation variability, and recruitment for rare pulmonary diseases.

- **Manufacturing compliance and cost** — GMP production of NPs, aseptic manufacturing for nebulized biologics, and cold-chain needs (for nucleic acids) can be expensive.

Effective translation benefits from early dialogue with regulatory agencies, cross-disciplinary teams (formulation scientists, device engineers, clinicians, toxicologists), and standardized preclinical testing frameworks.

12. Recent breakthroughs and notable studies

Several trends and notable advances have accelerated progress recently:

- **Improved LNP formulations for pulmonary nucleic acid delivery** — publications in 2024–2025 describe ionizable lipids and LNP architectures tailored to mucosal delivery and aerosol stability. These studies highlight strategies to protect mRNA during nebulization and enhance epithelial uptake.

- **Nano-in-micro spray-dried powders with high dispersibility** — advances in spray drying and excipient selection have produced low-density microparticles that deliver nanoparticulate payloads deep into the lung with improved stability for DPIs.

- **Immune-targeting nanoparticles and inhaled immunomodulators** — work on pulmonary immune engineering demonstrates the capacity to direct NPs to alveolar macrophages or dendritic cell subtypes to reshape local immune responses, relevant for infections and immunotherapy.

- **Better in vitro and organ-on-chip models** — more physiologically relevant lung models improve prediction of deposition, toxicity, and drug transport compared with submerged cultures.

These advances collectively reduce the technical gaps between bench successes and clinical testing,

though regulatory and longitudinal safety data remain constraints.

13. Challenges and unresolved research questions

Despite progress, several critical challenges persist:

1. **Predictive translation from animals to humans:** Anatomical and breathing differences make dosimetry and deposition extrapolation difficult.
2. **Long-term safety for chronic indications:** Repeated inhalation over months/years raises unanswered questions about accumulation and chronic inflammation.
3. **Standardized aerosol characterization:** Differences in aerosol generation and measurement impede cross-study comparisons.
4. **Formulation–device co-optimization:** Many studies test NP suspensions without fully considering real-world devices and patient use.
5. **Manufacturing and cost:** Produce sterile, stable, scalable inhaled NP products affordably.
6. **Regulatory guidance specific to novel nanomaterials for inhalation:** Harmonized frameworks and guidelines would accelerate development.

14. Future directions and recommended priorities

To accelerate clinical translation and safe use of inhalable nanoparticle therapeutics, we recommend:

- **Standardization:** Develop common standards for aerosol testing, inhalation toxicology protocols, and reporting of CQAs to improve reproducibility and regulatory review.
- **Integrated device–formulation development:** Embed device considerations early; design patient-centric devices that ensure consistent dose delivery across inhalation patterns.
- **Predictive preclinical platforms:** Invest in human-relevant ALI models, lung-on-chip systems, and physiologically based pharmacokinetic (PBPK) models for reliable dose scaling.
- **Safety-by-design:** Prioritize biodegradable, well-characterized materials; minimize proinflammatory surface chemistries; and include long-term repeated-dose studies.
- **Clinical demonstration in clear unmet needs:** Focus early clinical programs on indications with high unmet need and clear local endpoints (e.g., drug-resistant pulmonary infections, localized lung cancer, gene therapy for cystic fibrosis) where inhaled delivery provides strong rationale.
- **Cross-disciplinary consortia and regulatory engagement:** Foster partnerships between academia, industry, clinicians, and regulators to design translational roadmaps and accelerated guidance for inhaled nanomedicines.

15. CONCLUSION

Pulmonary nanoparticle-based inhalation systems hold transformational potential for a wide spectrum of respiratory and systemic therapies. Advances in materials science, aerosol

engineering, and biological targeting have addressed many early obstacles; yet translational success depends on solving persistent challenges in aerosol stability, safety, device integration, and clinical predictability. By adopting standardized testing, safety-by-design principles, and device-aware formulation strategies, the field is well positioned to move promising candidates into clinical trials and eventually to patients. Continued interdisciplinary collaboration and rigorous long-term toxicology will be the keys to safe, effective, and scalable inhaled nanomedicines.

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HOW TO CITE: Harshad Mane, Mayuri Bhadalekar, Atharv Kandale, Dr. Nilesh Chougule, Pulmonary Nanoparticle-Based Inhalation Systems, Int. J. of Pharm. Sci., 2026, Vol 4, Issue 5, 4119-4128. https://doi.org/10.5281/zenodo.20237886