

Development and *In Vitro* and *In Silico* Evaluation of "Nano-in-Micro" Dry Powder Inhalers Loaded with Meloxicam

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Introduction

The advancement of drug delivery systems has significantly impacted the therapeutic landscape, particularly in pulmonary drug delivery. One emerging approach is the "nano-in-micro" Dry Powder Inhaler (DPI) system, which combines the advantages of nanoscale drug particles and microscale carriers to improve drug stability, delivery efficiency, and patient outcomes. This commentary focuses on the development, *in vitro* characterization, and *in silico* evaluation of a novel "nano-in-micro" DPI formulation containing meloxicam, a Nonsteroidal Anti-Inflammatory Drug (NSAID), emphasizing its potential applications and challenges in pulmonary drug delivery.

Meloxicam is widely used for its anti-inflammatory and analgesic properties in conditions like rheumatoid arthritis and osteoarthritis. However, systemic delivery of meloxicam is often associated with gastrointestinal side effects and suboptimal bioavailability. Pulmonary delivery offers a promising alternative, enabling direct drug deposition into the respiratory tract, rapid therapeutic action, and reduced systemic exposure. The incorporation of meloxicam into a "nano-in-micro" DPI formulation addresses the challenges of solubility and stability, presenting an innovative solution for treating localized or systemic inflammation via the respiratory route. The "nano-in-micro" strategy involves the encapsulation of drug nanoparticles within larger microparticles, typically composed of excipients such as lactose or mannitol. This dual-scale approach leverages the high surface area and enhanced dissolution properties of nanoparticles while maintaining the flowability and dispersibility of microparticles for effective pulmonary delivery. In the case of meloxicam, the nanoparticle formulation improves its aqueous solubility and dissolution rate, overcoming a major limitation of the drug's intrinsic hydrophobicity. The microscale carrier facilitates aerosolization and ensures efficient deposition in the lower respiratory tract.

Description

In vitro characterization of the meloxicam-loaded "nano-in-micro" DPI includes assessments of particle size, morphology, aerodynamic performance, and dissolution behavior. Particle size distribution is a critical parameter, as it determines the deposition profile within the respiratory tract. The nanoscale meloxicam particles must be sufficiently small ($<1\ \mu\text{m}$) to enhance solubility, while the microscale carriers typically range between 1 and 5 μm for optimal pulmonary deposition. Advanced techniques such as Dynamic Light Scattering (DLS) and Scanning Electron Microscopy (SEM) are employed to confirm the particle size and surface morphology, ensuring the uniformity and stability of the formulation. Aerodynamic performance, evaluated using cascade impactors or Next-Generation Impactors (NGIs), provides insights into the Fine Particle Fraction (FPF), emitted dose, and respirable fraction of the DPI. These parameters are essential for predicting the formulation's ability to deliver the drug to the desired lung regions. The inclusion of meloxicam

nanoparticles within the microparticle matrix enhances the aerodynamic properties, resulting in improved deposition efficiency and reduced drug wastage. Additionally, the formulation's dissolution behavior is tested under simulated lung conditions, demonstrating the rapid release of meloxicam nanoparticles from the microparticle carriers and subsequent absorption [1,2].

In silico modeling complements *in vitro* studies by simulating drug deposition, dissolution, and absorption in the respiratory tract. Computational Fluid Dynamics (CFD) and Physiologically Based Pharmacokinetic (PBPK) models are commonly used to predict the fate of inhaled drug particles. For the meloxicam "nano-in-micro" DPI, *in silico* studies provide valuable insights into the influence of particle size, shape, and inhalation flow rate on drug deposition patterns. These models also evaluate the systemic and localized pharmacokinetics of meloxicam, guiding the optimization of formulation parameters to achieve the desired therapeutic outcomes. The integration of *in silico* and *in vitro* approaches streamlines the development process, reducing the reliance on animal testing and accelerating the translation of the "nano-in-micro" DPI to clinical trials. *In silico* models can predict the impact of patient-specific factors, such as lung morphology and breathing patterns, on drug delivery performance. This personalized approach ensures that the formulation is optimized for diverse patient populations, including those with respiratory conditions like asthma or Chronic Obstructive Pulmonary Disease (COPD). Despite its promise, the development of "nano-in-micro" DPIs faces several challenges. One primary concern is the stability of the nanoparticles within the microparticle matrix. Aggregation or degradation of nanoparticles during storage or aerosolization can compromise the formulation's efficacy. To address this, advanced manufacturing techniques such as spray drying, freeze drying, and supercritical fluid processing are employed to produce stable, reproducible "nano-in-micro" formulations. These techniques allow precise control over particle size, composition, and morphology, ensuring consistent performance. Another challenge is the selection of suitable excipients that maintain the integrity of the nanoparticles while providing the desired aerodynamic properties. Excipients must be biocompatible, non-irritating, and capable of supporting the stability and dispersibility of the microparticles. For meloxicam, hydrophilic carriers like mannitol and lactose are commonly used to enhance the dissolution and deposition efficiency. Additionally, excipients may be functionalized with surfactants or stabilizers to prevent nanoparticle aggregation and improve dispersibility [3].

Regulatory considerations also play a significant role in the development of "nano-in-micro" DPIs. The incorporation of nanotechnology in drug delivery raises concerns regarding safety, efficacy, and quality control. Regulatory agencies require comprehensive data on the characterization, toxicity, and pharmacokinetics of nanomaterials to ensure patient safety. The meloxicam "nano-in-micro" DPI must undergo rigorous testing to demonstrate its stability, bioavailability, and therapeutic efficacy compared to existing formulations. Collaboration with regulatory bodies and adherence to standardized guidelines are essential for successful market approval. The therapeutic potential of meloxicam-loaded "nano-in-micro" DPIs extends beyond pulmonary drug delivery. By leveraging the enhanced solubility and bioavailability of nanoparticles, this formulation can be adapted for systemic delivery of other hydrophobic drugs. The modular nature of the "nano-in-micro" platform allows customization of particle size, release profiles, and drug loading for various applications. For instance, this approach could be explored for delivering anti-cancer agents, vaccines, or biologics, expanding its impact on global health [4,5].

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Received: 01 October, 2024, Manuscript No. Jcrdc-24-153706; **Editor Assigned:** 03 October, 2024, PreQC No. P-153706; **Reviewed:** 18 October, 2024, QC No. Q-153706; **Revised:** 24 October, 2024, Manuscript No. R-153706; **Published:** 31 October, 2024, DOI: 10.37421/2472-1247.2024.10.331

Conclusion

Development and characterization of "nano-in-micro" dry powder inhalers containing meloxicam represent a significant advancement in pulmonary drug delivery. This innovative approach addresses the challenges of drug solubility, stability, and deposition, offering a promising solution for localized and systemic inflammation management. *In vitro* and *in silico* studies provide a comprehensive understanding of the formulation's performance, guiding its optimization and clinical translation. While challenges remain, continued research and innovation in this field have the potential to revolutionize drug delivery systems and improve patient outcomes across a wide range of therapeutic areas.

Acknowledgement

None.

Conflict of Interest

None.

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How to cite this article: Elin, Shuai. "Development and *In Vitro* and *In Silico* Evaluation of "Nano-in-Micro" Dry Powder Inhalers Loaded with Meloxicam." *J Clin Respir Dis Care* 10 (2024): 331.