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Carrier-free dry powder inhaler formulation for pulmonary delivery: insights into stability, safety, and aerodynamic performance

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Introduction: With their vast surface area, the lungs provide an effective drug delivery system, targeting respiratory diseases locally while also serving as an alternative route for systemic delivery (1). **Objective**: Based on our previous research (2), this study aims to evaluate the cytotoxicity, permeability, and stability of a novel carrier-free dry powder inhaler (DPI) formulation containing nanosized ketoprofen. **Materials and methods**: Advanced particle engineering methods were employed to ensure efficient deep lung deposition. Nanosuspensions were first produced via wet media milling, followed by spray drying with optimized parameters to generate an inhalable dry powder. Stability testing was performed under stress conditions (40 °C, 75% RH) in hydroxypropyl methylcellulose (HPMC) capsules following ICH guidelines. Also, cytotoxicity and permeability studies were conducted on both alveolar and bronchial cell lines. **Results and discussion:** Cell line measurements confirmed the formulation's biocompatibility and its potential for effective lung permeation. Stability testing revealed that particle size remained stable, and the partially amorphous state of the drug was preserved. However, exposure to moisture caused surface roughening and partial agglomeration, resulting in a decline in fine particle fraction (FPF) and emitted fraction (EF). Despite these changes, the mass median aerodynamic diameter (MMAD) remained consistent, ensuring the formulation's suitability for pulmonary delivery. **Conclusion**: The developed DPI maintained its quality and performance over time. Future research should focus on optimizing excipients, exploring alternative capsule materials, and refining storage conditions to address moisture-related issues. Overall, the formulation offers a promising solution for pulmonary drug delivery applications, balancing stability, safety and applicability.

References

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