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Integrating Device Engineering and User-Centered Design for High-Performance Dry Powder Inhalers Using a Particle-Engineered Formulation

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BACKGROUND

The Sunriser® DPI was developed using an integrated approach and outperformed a leading marketed DPI in both technical and ergonomic metrics

Figure 1. Sunriser® DPI

- DPIs are popular for respiratory drug delivery due to **convenience and stability** but **achieving consistent aerosol performance** while keeping devices **user-friendly** is challenging.
- **Carrier-based blends** work at **low doses** but fail at high loads due to weak interactions and cohesion; **carrier-free spray-dried powders** suit **high doses** but often agglomerate and aerosolize poorly, especially for biologics and vaccines and emergency therapies.
- A stepwise, feedback-driven development strategy—using a spray-dried for **device engineering,** with rapid prototyping (e.g., 3D printing)—enables iterative testing and refinement, with real-time usability and lab feedback **improving** both **technical performance** and **user experience**.

The objective of this work is to develop a high-performance, user-friendly DPI by integrating formulation science, device engineering, and user feedback to overcome current limitations and enhance lung deposition and patient compliance.

METHODS

PARTICLE ENGINEERED FORMULATION

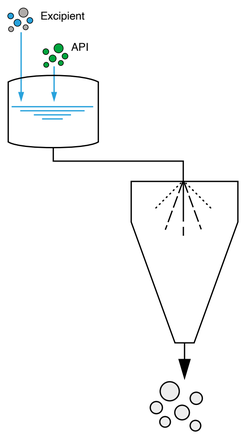
Excipient	
L-Leucine (25% w/w)	

+

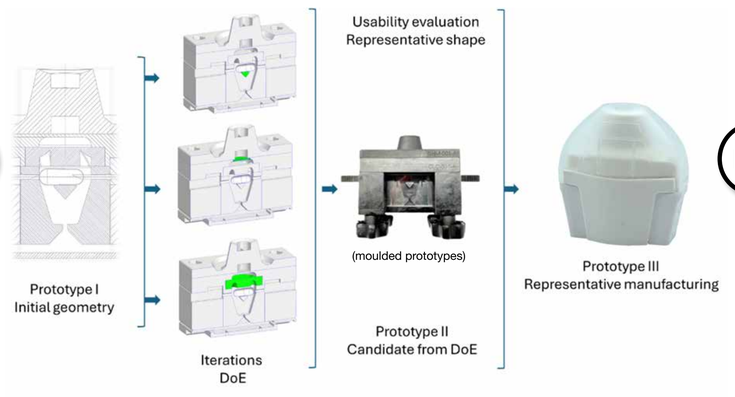
Drug	
API (75% w/w)	

+

Capsule	
HPMC (size #3) 30 ± 1.5 mg fill-weight	



DEVICE DEVELOPMENT



ANALYTICAL CHARACTERIZATION

PERFORMANCE TESTING

	Sunriser	Marketed Device
Flow rate @ 4 kPa	45 LPM	65 LPM

AERODYNAMIC PERFORMANCE

USP <601> NGI	
HPLC - UV	

KEY METRICS & STATISTICAL ANALYSIS

- Emitted Dose (ED)
- Fine Particle Dose (FPD)
- One-way ANOVA + Tukey's post-hoc test

RESULTS AND DISCUSSION

USER-CENTERED DESIGN

- 30-participant survey assessed ergonomics (grip, cap, button placement).
- Feedback informed refinements in Prototype III:

Improved tactile features → Simplified assembly → Enhanced alignment and handling

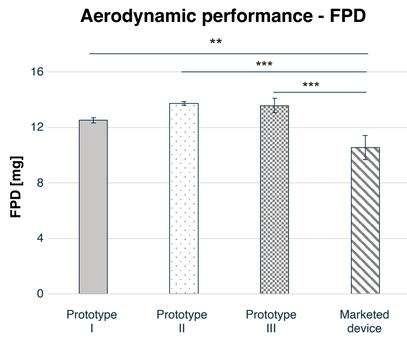
PROTOTYPE EVOLUTION

PROTOTYPE I — Lower ED due to unoptimized geometry

PROTOTYPE II — Improved ED and FPD via refined internal design

PROTOTYPE III — Matched marketed DPI in ED and exceeded in FPD

- Iterative prototyping enabled rapid optimization of aerodynamic and ergonomic features.
- Transition from 3D printing to injection molding ensured manufacturing scalability and regulatory alignment.
- Final design (Prototype III) combines high technical performance with user-friendly features, ready for production with minimal adjustments.



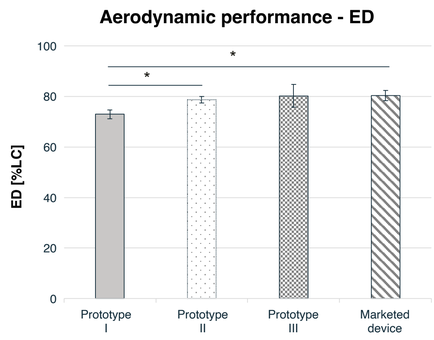


Figure 2. FPD and ED of the marketed device compared with the three-stage prototypes. Asterisks indicate significant pairwise differences (*p < 0.05; **p < 0.01; **p < 0.001).

Table 1. Analytical performance of three prototype stages using an engineered formulation, compared with marketed device (LC – label claim, N=3)

	Marketed device	Prototype I Initial 3D printed	Prototype II Optimized 3D printed	Prototype III Representative
ED (% LC ± SD)	80.4 ± 0.45	72.9 ± 2.12	78.6 ± 1.31	80.5 ± 4.32
FPD (mg ± SD)	10.5 ± 0.88	12.5 ± 0.48	13.7 ± 0.14	13.6 ± 0.50

CONCLUSIONS

PROTOTYPE EVOLUTION

The Sunriser® DPI demonstrates how a structured, multidisciplinary development strategy can overcome limitations of conventional DPIs.

FORMULATION SCIENCE, DEVICE ENGINEERING, AND USER FEEDBACK

Integration of formulation science, device engineering, and user feedback led to a production-ready inhaler with superior performance and usability.

FUTURE DPI INNOVATION

This approach sets a benchmark for future DPI innovation, especially for high-dose and biologic therapies.

References
[1] Groß R, et al., J Pharmaceutics 2022; 14 pp1185–1199.
[2] Omidian H, et al., Pharmaceuticals 2025; 18(2): pp 175.
[3] Ye, Y, et al., Int J Pharmaceutics 2022; 25:614:121457
[4] Saldanha S, et al., DDL 2023.
[5] Abrego Morales L, et al., Pharmaceutics 2025; 17(3): pp 359.
[6] Kobler M, et al., ISAM 2025.
[7] Churro R, et al., RDD 2025; pp 75–79.
[8] Kobler M, et al., Respiratory Drug Delivery 2024; 1: 231-234.