



INHALATION PRODUCT DEVELOPMENT

Seeking expertise to overcome your inhalation challenges?

Broadest Capabilities From pre-formulation to commercialization, we have the capabilities, experience and expertise to assist you at any stage of development. These capabilities were developed with your needs in mind and have been successfully applied to all dosage forms.

- Pressurized metered-dose inhalers (pMDIs)
- Dry powder inhalers (DPIs)
- Nasal sprays (solutions/suspensions)
- Nebulizers and liquid inhalers

Integrated Services Our offerings can be tailored to meet your needs and expedite your product from concept and feasibility studies through all stages of the product life cycle, whether you are seeking a single service or a turn-key development option.

- Dosage form selection and technology assessment
- Pre-formulation and formulation services
- Analytical testing
- Clinical packaging trial supply
- Blinding of clinical materials
- Commercial-scale manufacturing and packaging

Experience You Can Trust For over 20 years, our deep expertise and reliable execution has been sought out and applied to numerous product approvals resulting in reduced development time. We continually make significant investments in top scientific talent, technologies, resources and capacity to ensure superior results for your products.



DEVELOPMENT



DELIVERY



SUPPLY

Value

Our project managers and scientists will collaborate with your team to ensure effectiveness and efficiency. Whether you require only a single service or a comprehensive plan to expedite your product on the path to commercialization, our best-in-class solutions are your best choice for long-term success. And with the widest range of capabilities from a single source, we can minimize and smooth transitions—reducing your time to market—while providing the expertise you need.

- Thorough understanding of U.S. and European regulatory requirements and submission protocols with an exemplary track record
- Potent compounds and DEA Schedules I-IV capabilities
- Assistance in defining submission strategies on Chemistry, Manufacturing and Controls (CMC) to avert potential issues by using the best possible solutions
- Active leadership and participation in industry expert groups including IPAC-RS, INTFG, PQRI
- Catalent's reputation is built on our work with 49 of the top 50 global pharmaceutical companies, 44 of the top 50 global biotech companies and hundreds of the most promising emerging firms.

Catalent Inhalation at Work

	CLIENT A
SITUATION	<ul style="list-style-type: none">· Agglomeration and loss of the API fine-particle mass for dry powder inhaler (DPI) was observed during storage caused by recrystallization of amorphous solids generated during milling.· Attempts to mitigate this problem by optimizing the formulation and milling processes were not successful.
SOLUTION	<ul style="list-style-type: none">· Optiform™ technologies were used to perform salt screening studies to identify an alternative salt.· Within 4 weeks, several novel candidate salts of the API were discovered and characterized. Detailed assessment including milling studies afforded the identification of a suitable salt that enabled the progression of a DPI formulation into clinical studies.

Bring us your compound, and we will help you formulate it and bring it to market.

Discover more solutions with Catalent.

more products.
better treatments.
reliably supplied.™

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