



END-TO-END INHALATION SOLUTIONSTake your API from particle to patient

Broad Capabilities From pre-formulation to commercialization, we have the capabilities and expertise to assist you at any stage of development. Catalent offers a

- · Metered Dose Inhalers (MDIs)
- · Nebulized liquid blow-fill-seal products

broad range of capabilities across all dosage forms:

- · Nasal sprays (liquid and powder)
- · Dry Powder Inhalers (DPIs)

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.

- · Dosage form selection and technology assessment
- · Pre-formulation and formulation services
- · Analytical testing
- · Particle size reduction
- · Clinical-scale and small-batch manufacturing
- · Clinical supply services (packaging, comparator sourcing, distribution and project/supply management)
- · Finished product and dose testing
- · Commercial-scale manufacturing and packaging

Expert Development For over 25 years, our deep expertise and reliable execution have been applied to numerous product approvals resulting in reduced development timelines. We continually make significant investments in top scientific talent, technologies, resources and capacity to ensure superior results for your products.







Flexible Manufacturing

Catalent's flexible manufacturing solutions provide reliable supply at scales appropriate for pre-clinical evaluation, clinical trials, and full-commercialization. Our manufacturing operations have a track record of regulatory excellence, and we routinely manufacture inhalation products for clients around the globe.

- · Full, high-speed commercial-scale operations for MDIs, nasal powder and nebulized blow-fill-seal products
- · Small-scale commercial manufacture for unit/bi-dose liquid nasal spray
- · Clinical-scale manufacture for MDI, unit/bi-dose nasal, DPI, nasal powder, and blow-fill-seal products

Features:

- · Low-humidity environment options to support moisture-sensitive materials
- · Sterile liquid manufacturing solutions for temperature, light, oxygen and delivery-sensitive products.
- · Process-analytical technologies
- · Flexible warehouse space
- · Supply-chain and project management services

Catalent Expertise at Work

	CUSTOMER CASE STUDY
SITUATION	 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	 Optiform® API 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.

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