





New!

Introducing P-Gels™
An additional formulation option for high-potency compounds.

High Potency

Patheon is your experienced provider of development and manufacturing services for high-potency active ingredients, having handled more than 150 high-potency compounds at Patheon sites since 2000.

We offer a range of development and manufacturing services for high-potency compounds (including hormones) in solid and liquid dosage forms, including fast dissolve, immediate-release and controlled-release tablets and capsules, nasal sprays, Liquid-Filled Hard Capsules (LFHC), and soft-gelatin capsules. The P-Gels™ line is our service offering for soft-gelatin capsule development and manufacturing. P-Gels offers significant benefits such as API containment, API degradation protection, delivery of low-solubility compounds, and potential to combine multiple actives for highly potent products. Patheon also offers the development of high-potency products in sterile dosage forms.

Our Pharmaceutical Development Services (PDS) scientists offer expertise in formulation development, Clinical Trial Materials (CTM) manufacturing, and scale-up of high-potency products, all comprehensively supported with an extensive range of in-house analytical services. Patheon has experience in developing compounds with Occupational Exposure Limits (OEL) in the low nanogram per cubic meter range.

Our high-potency development programs utilize suites that are designed to meet the challenges of high-potency formulation development and manufacturing.

These facilities offer fully integrated development, scale-up, and commercial manufacturing all in one site.

For more information, email us at doingbusiness@patheon.com

high potency

CASE STUDY



The Challenge

A US-based biotechnology company approached Patheon to develop a high-potency small molecule drug candidate for upcoming Phase I clinical studies and potentially advance the project through to commercial manufacture if approved. The customer had very limited experience in the development and launch of this type of small molecule and lacked the capabilities to develop and manufacture it in-house.

The Solution

The development team was able to accommodate the customer's compound in our specialized development facility at Patheon's Toronto Region Operations site and began developing the customer's Phase I clinical materials almost immediately.

Patheon was able to dedicate the experienced scientific resources and facilities needed to advance the high-potency molecule through the development process to commercialization all in one site. Our team worked through the entire clinical development process, providing comprehensive formulation services backed with analytical and project support, which helped our customer through the complex development process for high-potency small molecule formulations.

The Outcome

The customer was able to commercially launch their new product from the Toronto site's integrated manufacturing facility within five years of our first involvement at the preclinical stage. By surpassing the customer's expectations, we were subsequently chosen to develop and manufacture two additional high-potency compounds for this customer.

For more information about High Potency, contact your Patheon representative or email us at doingbusiness@patheon.com

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