ThermoFisher SCIENTIFIC

SOLVED WITH

SAFETY & SERVICE

patheon

SOLUTIONS FOR HIGH POTENCY

Solutions for high potency

Nearly half of the drugs currently in development worldwide are classified as highly potent. Highly potent compounds require strict adherence to numerous regulatory guidelines. Therefore, special considerations regarding facility design, equipment, operation, and process safety are necessary to manage the risks associated with manufacturing these compounds. Executing an efficient and optimized strategy early on builds a strong foundation when it comes time to scale up manufacturing. Our global network of facilities and industry have the expertise to manage the development, manufacturing, and commercialization of your highly potent compound.

Categorization for highly potent compounds

Within the pharmaceutical industry, compounds are evaluated and characterized into four toxicity categories to determine the handling procedures required. All highly potent compounds fall into category 3 or 4 and need to be manufactured using appropriate containment techniques.

Category 1

Low potency with higher dosage levels. Minimal, reversible acute and chronic health effects and good warning properties. No genic effects (such as mutagenic, carcinogenic, or teratogenic) and no sensitizers. Slow absorption, and no medical intervention required following exposure.

Category 1

Moderate acute or chronic toxicity, but effects are reversible. Weak sensitizers and fair warning properties. Moderate absorption rate. No genic effects, but may require medical intervention after exposure.

Category 3

Elevated potency with high acute or chronic toxicity. Effects may be irreversible. Moderate sensitizers and warning properties are likely to be poor or absent. Rapid absorption rates. Have suspected or known genic effects. Moderate to immediate medical intervention will be required after exposure.

Category 4

High potency and extreme acute and chronic toxicity. Cause irreversible effects and are strong sensitizers. Poor or no warning properties. Rapid absorption rate. Have known genic effects. Require a higher degree of medical intervention after exposure.

Category 1	Low toxicity	OEL > 1000 µg/m³
Category 2	Intermediate potency	OEL 100–1000 µg/m³
Category 3	Highly potent	OEL 5–100 µg/m³
Category 4	Very highly potent	OEL 0.5–5 µg/m³

Compounds in categories 3 and 4 are considered “highly potent.” They can include cytotoxic, carcinogenic, mutagenic, and teratogenic compounds.

Handling and containment

Developing and manufacturing high-potency compounds requires robust planning, extensive training, proper equipment, and closed-system facility design to ensure safe handling. Using process isolation and containment equipment is the most important means of protection, while personal protective equipment (PPE) should be regarded as a secondary control measure. We strive to maximize yield while limiting chemical exposure by following processes proven to limit the pathway of exposure.

Limiting the pathway of exposure

At the source: Material

Containment strategies should always strive to have containment at the source material to prevent the material from initially entering the pathway of exposure.

Path of exposure: Environment

Focus on ventilators, isolators, closed containment systems, and other engineering solutions along the path from material to personnel.

Exposure point: Personnel

Implement PPE such as respiratory protection that acts as a physical barrier between personnel and the exposure point.

Dosage forms

We offer a range of development and manufacturing services for high-potency compounds (including hormones) in solid and liquid dosage forms, including:

Immediate-release and controlled-release tablets	Nasal sprays	Non-sterile liquids
Liquid- and powder-filled capsules	Coated tables	Beads in capsules
Soft-gelatin capsules (twist-off, chewable)	Lyophilized and liquid vials	Powders
Granules	Coated beads	Prefilled syringes and cartridges

Capabilities, expertise, and integrated services

Our global facilities utilize state-of-the-art suites designed to meet the challenges of high-potency formulation development and manufacturing. These facilities offer fully integrated development, scale-up, and commercial manufacturing. At every location, we employ the industry's most knowledgeable scientists, engineers, and technicians who apply a science-driven, risk-based approach to every step of the high-potency development and manufacturing process. Our dedicated experts are here to ensure a safe, efficient, and timely developmental journey for your highly potent compound.

		Early development		Late development			Commercial supply		
		Formulation development	Analytical development	Phase I	Phase II	Phase III	Commercial scale-up	Tech transfer	Regulatory
High Point, NC	Softgel capsules	●	●	●	●	●	●	●	
	Softgel gelcaps	●	●	●	●	●	●	●	
	Softgel chewable gels	●	●	●	●	●	●	●	
Greenville, NC	Liquid vials	●	●	●	●	●	●	●	●
	Lyophilized vials	●	●	●	●	●	●	●	●
	Prefilled syringes					●	●	●	●
	Prefilled cartridges					●	●	●	●
Cincinnati, OH	Tablets	●	●	●	●	●	●	●	●
	Capsules	●	●	●	●	●	●	●	●
	Powders/granules	●	●	●	●	●	●	●	●
Toronto, ON	Tablets	●	●	●	●				
	Capsules	●	●	●	●				
	Powders/granules	●	●	●	●				
Milton Park, UK	Tablets	●	●	●	●	●	●	●	●
	Capsules		●	●	●	●	●	●	●
	Powders/granules	●	●	●	●	●	●	●	●
Ferentino, IT	Tablets	●	●	●	●	●	●	●	●
	Capsules	●	●	●	●	●	●	●	●
	Powders/granules	●	●	●	●	●	●	●	●
	Non sterile liquids	●	●	●	●	●	●	●	●
	Prefilled syringes					●			
	Liquid vials	●	●	●	●	●	●	●	●
Monza, IT	Liquid vials	●	●	●	●	●	●	●	●
	Lyophilized vials	●	●	●	●	●	●	●	●
Bourgoin, FR	Liquid vials	●	●	●	●	●	●	●	●
	Lyophilized vials	●	●	●	●	●	●	●	●
	Prefilled syringes	●	●	●	●	●	●	●	●
	Prefilled cartridges	●	●	●	●	●	●	●	●

Minimize your risks by developing and manufacturing your highly potent compounds at our global facilities featuring the latest safety infrastructure and dedicated industry experts. Learn more at **thermofisher.com/patheon**

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