

Highly Potent Active Pharmaceutical Ingredients (HPAPIs)



Unparalleled Efficiency and Precision in HPAPI Development and Manufacturing

At Aragen, we combine our extensive experience and expertise to provide a comprehensive and streamlined process for both HPAPI development and manufacturing, ensuring skilled handling of all aspects of the product life cycle. Our state-of-the-art HPAPI manufacturing facilities offer you an exceptional experience, setting a new standard for quality and efficiency in the industry.

HPAPI Facility- Hyderabad

- Designed to handle highly potent molecules like ADC payloads and linkers with occupational exposure limits (OEL) up to 10 ng/m³
- In-Process Quality Control (IPQC) isolators for analytical testing
- Isolators and fume hoods equipped with breach alarms and safety interlocks
- Personnel entry/exit supported by air shower cabin or water shower chamber
- Dedicated decontamination facility for equipment, materials, and waste streams

High-Containment Infrastructure

- Dedicated manufacturing equipment with isolators and once-through air handling units
- Comprehensive suite of unit operations designed for safe handling of high-potency compounds including ADC payloads and toxins (up to 10 ng/m³)
- Contained sampling and dispensing areas equipped with isolators
- Reactors to handle multiple unit operations, including glass-lined, Hastelloy, Pressure Nutsche Filter (PNF), and Vacuum Tray Dryer (VTD).
- Reactor capacities ranging from 50–100 L, expandable to 250–500 L
- Powder processing zones under isolator-based containment
- Dedicated packaging facility for HPAPI under controlled environment
- Quality Control (QC) laboratory for HPAPI analytical testing
- Operator protection through air shower cabin or water shower chamber
- Deactivation and neutralization facility for effluents and residues

HPAPI Facility

