

High Potent API (HPAPI) Development & Manufacturing



End-to-End Integrated Services Across

Discovery



Development



Manufacturing



15+

Years of HPAPI
Experience

50+

HPAPIs
Manufactured

200+

High Potent
Stages Handled

OEB5

Up to **0.1** µg/m³
Containment

Aurigene's approach to handling HPAPI

Risk Assessment	OEL & Containment	Engineering Controls	Operational Controls	Dedicated Equipment	Packaging & Storage
Assess potency & exposure risk	Define OEL and containment strategy	Closed systems & safe powder handling	QC, manufacturing controls & PPE	Specialized isolators for key operations	Segregated packaging and storage

Quality & Compliance

Regulatory Excellence



Sustainability



Integrated HPAPI Development & Manufacturing

Built for High Potency. Designed for Scale.

OEB5 Containment | Process Safety Studies | Integrated DS+DP | cGMP Manufacturing



Development

- Route scouting & optimization
- Process development
- Analytical development
- Polymorph & salt screening
- Process safety studies
- Hazard assessment



Scale-Up

- 25-50 g development batches
- Kilo lab support
- Technology transfer
- Engineering batches
- Process robustness studies



Manufacturing

Three Dedicated cGMP HPAPI Manufacturing Facilities

- Reactors from 60 L to 2.5 KL
- Contained processing infrastructure
- Effluent detoxification systems

Micronisation and spray drying performed within isolators at OEB5 containment.

Integrated DS + DP Capabilities

Drug Substance

- HPAPI Process Development
- Analytical Development
- Clinical & Commercial Manufacturing

Drug Product

- Sterile Injectables (SVP)
- Lyophilized Powder Vials
- Oral Solid Dosage Forms (Tablets & Capsules)
- Clinical & Commercial Manufacturing

Manufacturing Capacity

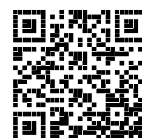
- 7Mn SVP Units/Year
- 0.3Mn Lyophilized Vials/Year
- 40Mn Tablets & Capsules/Year

For more information

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Website



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