AURIGENE
PHARMACEUTICAL SERVICES

High Potent API (HPAPI) Development & Manufacturing

End-to-End Integrated Services Across

Discovery | **Development** | **Manufacturing**

15+	50+	200+	OEB5
Years of HPAPI Experience	HPAPIs Manufactured	High Potent Stages Handled	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

U.S. FOOD & DRUG ADMINISTRATION · EUROPEAN UNION GMP · Health Canada · CDSCO · ANVISA · KOREA MFDS · Pmda

Sustainability

ecovadis · Bloomberg Gender-Equality Index · Dow Jones Sustainability Indices · CDP

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

AURIGENE
PHARMACEUTICAL SERVICES

For more information

Please write to contactapsl@aurigeneservices.com

Visit www.aurigeneservices.com

Website

Linkedin