AURIGENE

PHARMACEUTICAL SERVICES

API Development and Manufacturing

Aurigene Pharmaceutical Services has a legacy of +20 years in developing and manufacturing compounds under cGMP . Our manufacturing plants are spread across 3 continents with facilities in India, UK, and Mexico.

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North America: +1 617 821 0595

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CGMP manufacturing scale at in-house manufacturing sites

Reactor size

- Kilo lab: 50 to 630 L
- Commercial: 500 to 10,000 L

Capacity of Production

- Kilo lab: 1 to 10 Kg
- Commercial: 15 to 500 Kg

MOC

- All glass set-up,Mild Steel Glass Lined (MSGL), stainless steel (SS316) and Hastelloy

Niche reactions

- Cryogenicreactor size (2,000 to 11,000 L)
- Reaction temperature up to -80°C
- Hydrogenator capacity (20 to 500 L) at 4 to 55 bar

Downstream Process

Centrifuge

- 12", 36" and 48"

Nustche Filters

- 25 L to 1 KL

Agitated Nustche Filter Dryer (ANFD)

- 0.1 m^2 to 5.0 m^2

Spray Dryers

- 5 to 50 Kg/Hr

Micronization

- Development (M50)
- Manufacturing (M100 to M2000)

All manufacturing facilities are equipped with particle size regulating equipment including multimill, air jet mill or micronizer, sifter and blenders. Dedicated unit for micronization of steroid products.

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Core technologies development and manufacturing features

Steroid

Development/PoC

- Quantity: 10 to 50 g
- Capacity: Lab scale

Pre-clinical/NGMP

- Quantity: 100 to 250 g
- Capacity: 20 to 50 L

Early Phase

- Quantity: 1 to 3 kg
- Capacity: 20 to 189 L

Late Phase

- Quantity: 5 to 10 Kg
- Capacity: Up to 7000L

Commercial

- Quantity: 25 to 100 Kg
- Capacity: Up to 7000 L

HPAPI (OEB 5/OEL < 1 ug/m^3 for HPAPIs and cytototoxics)

Development/PoC

- Quantity: 10 to 50 g
- Capacity: Lab scale

Pre-clinical/NGMP

- Quantity: 100 to 250 g
- Capacity: Lab scale

Early Phase

- Quantity: 1 to 3 kg
- Capacity: ~20 to 2,000 L

Late Phase

- Quantity: 5 to 10 Kg
- Capacity: 160 to 2000L

Commercial

- Quantity: 10 to 15 Kg
- Capacity: 160 to 2000 L

PEGylation

Development/PoC

- Quantity: 10 to 50 g
- Capacity: Lab scale

Pre-clinical/NGMP

- Quantity: 250 to 500 g
- Capacity: Lab scale

Early Phase

- Quantity: 25 to 50 kg
- Capacity: 50 to 3,000 L

Late Phase

- Quantity: 100 to 250 Kg
- Capacity: 50 to 3000 L

Commercial

- Quantity: 500 to 1000 Kg
- Capacity: 50 to 3000 L

Carbohydrate

Development/PoC

- Quantity: Up to 100 g/batch
- Capacity: Lab scale

Commercial

- Quantity: Upto ~30 Kg/batch
- Capacity: 60 to 250 L

Purification: GPC technique, size -exclusion chromatography, SAX purification, Ion-exchange chromatography

Analytical Equipment

Chromatography

- HPLC (UV, PDA, ELSD&RI detectors with Empower 3 software)
- GC (FID, TCD, ECD detectors with Empower 3 software)
- UPLC instruments

Spectroscopy and Thermal analysis

- UV-Vis, IR, NMR spectroscopy and photometers
- DSC and TGA
- Surface area analyzers

Characterization

- Mass spectrometer (LC-MS & HR-MS)
- AB SCIEX 4500 QQQ instrument
- Waters UPLC with LCT premier XE time of flight detector
- Agilent HPLC with 6410 triple quad mass detector
- Agilent GC with 5975C EI/CI Inert XL detector

Sustainability

Sustainability is one of our core values, and we continue to build on our goals aligned with global standards. Our work in the field of sustainability was recognized by

- DJSI (Dow Jones Sustainability Indices)
- FTSE4Good Index
- CDP (Carbon Disclosure Project)
- S&P BSE Carbonex
- S&P BSE Greenex
- Bloomberg Gender-Equality Index
- CII-SR EHS Excellence Silver Award
- PSCI Audited

Regulatory

Our development center is US FDA audited facility and our manufacturing plants are regularly audited by US FDA, EDQM, KFDA (Korea), MHRA (UK), PMDA, SFDA, CDSCO, DMA, TGA, WHO GMP and COFEPRIS.