HPAPI

Aurigene Pharmaceutical Services has the experience, expertise and infrastructure to develop and manufacture oncology drug candidates including HPAPI. Our integrated teams of scientists, toxicologists, regulatory and analytical experts provide end-to-end services for drug substance and drug products, applying stringent containment measures.

Development Infrastructure Includes:

- Dedicated containment facility designed to handle high potent molecules up to 0.1µg/m³ OEL limit
- State-of-the-art negative isolators and multipurpose solid handling suites
- Dedicated analytical labs
- Pass boxes to enable safe and clean material handling
- State-of-the-art HVAC system and HEPA filtered air systems
- Lab scale operations up to 50g per batch

Manufacturing Infrastructure Includes:

API:

Three cGMP HPAPI manufacturing plants located in India. Each facility has reactors to meet different capacity requirements from 60L to 2KL. All facilities are regularly inspected by international regulatory authorities, such as the US FDA, EDQM, EMA, KFDA, TGA, EDQM and COFEPRIS.

- Access to dedicated multi mill, micronizer and spray dryers to cater to size reduction and dehydration operations
- Downstream process like milling, blending and packing are carried out under isolation
- Separate effluent detoxification plant to ensure sustainable operations

Formulations:

Two large scale cGMP formulation manufacturing plant based in India have capabilities to produce solid injectables and solid oral dosages. Equipped to produce small volume parenteral injectables at a capacity of 7 million units per annum and lyophilized power vials at a capacity of 0.3 million units per annum. Our solid oral dosage facility can manufacture tablet and capsule at capacity of 40 million units per annum. We also offer CMC support for regulatory submission and our facilities are regularly inspected by international regulatory authorities, such as the US FDA, BfArM, PMDA, ANVISA, SAHPRA and KFDA.