

Highly Potent Active Pharmaceutical Ingredients (HPAPIs)



A streamlined approach to handling your HPAPI development and manufacturing

Our expertise across HPAPI development and manufacturing brings you a safe and streamlined pathway for your molecule. We ensure able handling of all aspects of the project life cycle spanning process development, analytical development, particle engineering, warehousing, pilot, scale up, sampling, QC, powder processing, effluent treatment, packing, transportation and stability services. By connecting the dots through effective collaboration and project management, we deliver the best for your compound.

Highly Potent API Development, Hyderabad, India

Key design features

- Dispensing / Weighing (Isolator) → Reaction (Fume hood with glove ports on sash) → Purification / Isolation (Fume hood with gloves) → Drying (Isolators) → Packing (Isolators)
- Designed and validated to handle high potent molecules less than 1 µg/m³ containment
- Designed to handle 2 streams at a time
- Isolators and fume hoods with necessary breach alarms and safety interlocks – HEPA followed by wet scrubbers
 - IPQC Isolator for testing
- Mist shower chamber
- Decontamination facility

Equipment List

- Reactors from 250ml to 2000ml
- Filters
- Rotavapors
- Dryers
- Isolators & fume hoods with gloves

Highly Potent API Manufacturing, Bidar, India

Key design features

- Designed and validated to handle high potent molecules less than 1 µg/m³ containment
- Inbuilt warehouse to store the KSMs, intermediates and finished goods
- Dedicated sampling / dispensing area with isolators

Opened a new Highly Potent API (HPAPI) manufacturing facility at our Bidar campus in Jan 2023. First commercial production batch has commenced.

- 3 independent streams to handle commercial scale batches
- Reactors to handle multiple unit operations equipped with isolators and split butterfly valves (SBVs)
 - Filter dryers with isolators for off-loading and heel cake removal
 - Closed sampling devices for reactors and ANFDs
- Powder processing and packing area with isolators
 - Dedicated isolator train for Quality Control testing
- Deactivation facility
 - Mist shower chamber



Process Equipment

Equipment	MOC	Qty	Capacity (Litres)
Reactor	Hastelloy	1	250
	Hastelloy	1	500
	SS316	1	100
	MSGL	1	1000
	SS316	1	250
	SS316	1	500
ANFD	Hastelloy	1	70
	Hastelloy	1	100
	SS316	1	100

For more information contact: contact@sailife.com