



**LUPIN
MANUFACTURING
SOLUTIONS**

HPAPI CDMO Services

End-to-end services for highly potent APIs, empowering oncology innovation from clinical to commercial.

THE PROMISE OF LMS ONCOLOGY

At Lupin Manufacturing Solutions (LMS), we enable global pharmaceutical innovators to bring oncology therapies to market faster, safer and compliant. With deep scientific expertise, advanced containment infrastructure, and phase-appropriate manufacturing flexibility, we serve as an end-to-end CDMO partner for the development and production of highly potent oncology APIs and intermediates. Backed by the global legacy of Lupin Limited, our oncology operations combine scientific rigor, regulatory excellence, and scalable manufacturing from lab to commercial scale.

Preclinical

Clinical

Validation

Commercial

Lifecycle Support

LMS supports the full drug development continuum

END-TO-END PROCESS RESEARCH & DEVELOPMENT SUPPORT

- 25+ scientists specializing in process research and development dedicated to HPAPIs
- Dedicated Process Development Laboratory (PDL) equipped with isolators
- Early stage route scouting, impurity profiling, and analytical development
- Lab-scale synthesis (up to 5 L) with OEL containment $\leq 0.05 \mu\text{g}/\text{m}^3$

PHASE APPROPRIATE CLINICAL & SCALE-UP MANUFACTURING

- Seamless scale-up from lab to pilot (1-10 kg batches)
- Process optimization, validation, and technology transfer
- 20+ containment isolators ensuring safe handling of potent compounds

At LMS, we are redefining oncology manufacturing through science-driven containment and speed-to-market support.

EXCELLENCE IN COMMERCIAL MANUFACTURING

- 20 reactors (250 L-2000 L) with MOC SS316, GL, and Hastelloy with isolator capabilities
- Flexible batch sizes from 1 kg to 35 kg
- Controlled environment ($\leq 25^\circ\text{C}$, $\leq 45\% \text{RH}$) with integrated SCADA
- Two-stage scrubbers and separate detoxification facility for effluent management

UNCOMPROMISED QUALITY & COMPLIANCE

- Dedicated Quality Control Laboratory for analysis and testing of potent compounds
- Global regulatory compliance aligned with cGMP and TAC/NBC standard
- Comprehensive documentation support for DMFs





GLOBAL STANDARDS OF SAFETY & CONTAINMENT

- Isolator-based operations across all process stages including dispensing, reaction, filtration, drying, powder processing and packing
- Oxygen sensors, fire-retardant materials, and spark-proof installations
- Personnel protection via air showers, mist showers, and Tyvek suit systems
- Dedicated detoxification facility for effluent treatment



Facility Area
4270 sqm (G+3)

Dedicated oncology block within LMS Vizag



Reactors
20 (SS, GL, Hastelloy)

Enables scalability across all phases



Isolators
20+ units

Ensures containment up to 0.05 µg/m³



Batch Sizes
1 Kg-35 Kg

Clinical to commercial flexibility



Dedicated Labs
PDL+QC

Integrated process & quality systems



Temperature Control
<25°C, RH <45%

GMP-compliant environment

Class-leading infrastructure that empowers oncology innovation

WHY PARTNER WITH LMS



Proven track record in API manufacturing



Regulatory readiness for global fillings (US, EU, Japan, etc.)



Integration of R&D, scale-up, and commercial manufacturing under one organization



Commitment to sustainability and safety in high-containment operations

If Oncology is precise by design, your manufacturing partner should be too. Is your CDMO precise enough?

Partner with LMS to advance your oncology pipeline

Lupin Manufacturing Solutions Limited (LMS), a wholly-owned subsidiary of Lupin Limited, is a leading manufacturer of active pharmaceutical ingredients (APIs) and a global contract development and manufacturing organization (CDMO) offering standalone & integrated solutions across drug substance, complex chemistry, drug product, and advanced modalities including ADCs and peptides. Leveraging Lupin's legacy of scientific rigor and regulatory expertise, LMS supports biopharma innovators from early development to commercial scale. With state-of-the-art facilities, a client-first approach, and a team of 250+ scientists, LMS accelerates the path to market for transformative therapies.

LMS is where science meets speed, and innovation meets execution.

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