TCG Lifesciences | Chembiotek

Process, Analytical Research, Development & Demonstration of Scalability

We offer comprehensive services covering the entire development lifecycle, from discovery to commercialization. We also support all IND-enabling activities in accordance with international guidelines and assist in reducing IND and NDA filing timelines and accelerating drug launch to market.

❖ Process, analytical & manufacturing services

- Integrated project execution: route design and scouting, process and analytical development, validation, and commercial manufacturing
- Process optimization through Quality by Design (QbD) and Design of Experiments (DoE)-driven development, combined with control strategy implementation and impurity management including profiling, synthesis, and fate & purge studies
- Rapid scale-up: lab to kilo and plant scale for early tox and clinical supply
- Generic molecule development: non-infringing route design, IP protection, validation, and commercialization
- cGMP manufacturing: end-to-end GMP production and timely delivery through its own subsidiary, TCGGC manufacturing in Hyderabad

❖ Specialized capabilities

- Asymmetric synthesis: stereoselective routes for chiral molecules
- Salts, polymorph & crystallization studies: form screening, selection, and optimization
- Flow chemistry: continuous processing for scalable and efficient manufacturing
- Sustainable process development: reduced PMI, greener reagents, and lower GHG emissions aligned with carbon footprint targets using AI-driven software

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❖ Process development & technology transfer

- Process understanding: identification of critical process parameters (CPPs), critical material attributes (CMAs), and critical quality attributes (CQAs) aligned with the quality target product profile (QTPP)
- Impurity risk mitigation: early identification and control strategies to minimize impurity formation
- Quality risk assessment: comprehensive evaluation and mitigation of process risks
- GTI & nitrosamine assessment: risk evaluation and analytical method development
- Effective technology transfer: robust, well-defined strategies to ensure seamless scale-up and reliable manufacturing. Within the R&D framework, a dedicated scale-up laboratory equipped with reactors and utilities that simulate plant infrastructure enables engineers to execute and validate the developed process under plant-representative conditions prior to transfer for larger-scale manufacturing.
- Quality systems: strong quality management system (QMS) ensuring compliance with global regulatory requirements (FDA, EMA, and others)
- Sustainability focus: application of green chemistry principles supported by sustainability databases to minimize PMI, carbon footprint, and environmental impact

❖ Kilo laboratory capabilities- demonstration of scalability

We have a kilo lab based in Kolkata for the synthesis of compounds ranging from multi-gram to kilogram scale. During kilo-scale synthesis, we consistently focus on cost effectiveness. Kilo scale synthesis involves development and optimization of safe, eco-friendly, and cost-effective processes.

Key features of kilo lab

- Access to international-quality infrastructure and analytical laboratories at the same location
- Equipped with 20 L to 200 L capacity reactors to handle a wide range of reactions across a temperature range of −80°C to +200°C
- Thorough understanding of chemistry to enable seamless technology transfer from R&D laboratories to kilo-scale synthesis
- Hazard and Operability (HAZOP) studies conducted prior to undertaking any unknown reaction, along with other health, safety, and environment (HSE) measures
- Strong project management expertise enabling real-time troubleshooting and problem solving
- High efficiency, optimized timelines, innovative analytical approaches, and the highest QC standards
- Independent and dedicated development quality assurance (DQA) function ensuring strict adherence to international guidelines and established SOPs
- Experienced production and DQA professionals

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❖ Analytical validation services (US-FDA inspected facility)

Our highly experienced analytical team supports early- and late-phase drug development with regulatory-compliant, reliable data.

Analytical capabilities include:

- Method development, validation, and transfer
- Impurity isolation, characterization, and qualification
- Reference standard qualification
- Stability studies
- GTI and nitrosamine method development
- Forced degradation studies

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