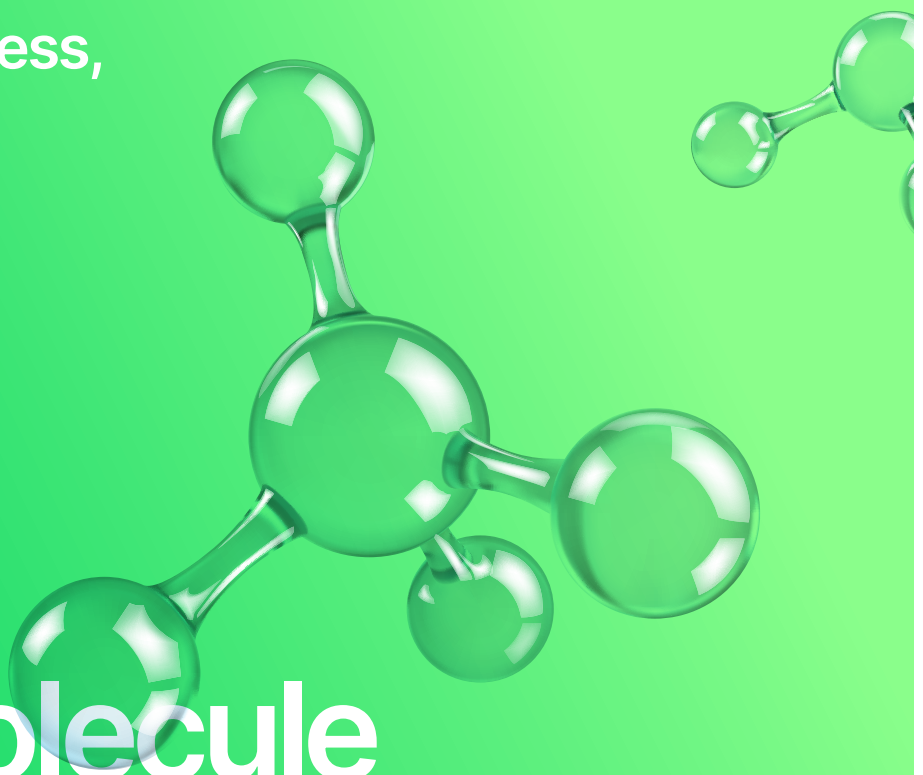
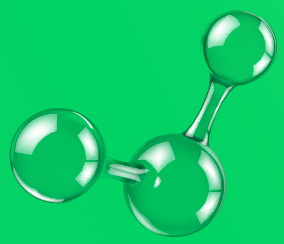
neuland

Empowering progress,
Enriching lives



Small Molecule Custom Development and Manufacturing



Established in 1984, Neuland Labs is a leading global Contract Development and Manufacturing Organization (CDMO) providing an end-to-end continuum of customised NCE development services. We have a team of experienced and dedicated scientists, engineers, and technicians who leverage their expertise and the latest technologies to meet the evolving needs of our customers.

We work with pharma and biotech organisations to advance and support their chemistry requirements from early stage through to commercial manufacturing, including process development, process optimization, analytical testing, and regulatory support.

Whether you need a single step or a complete synthesis, we have the capabilities and the flexibility to handle your projects from start to finish. We offer both small-scale clinical trial quantities and full commercial-scale supply for new chemical entities (NCEs), key starting materials (KSMs), active pharmaceutical ingredients (APIs) and their intermediates with minimal tech transfer timelines.

Our CDMO Services

Custom Development

Process Optimization & Validation – We enhance efficiency and atom economy by analysing and redesigning processes to eliminate steps, reduce waste and increase output. Our QA and validation team ensures consistent quality from design to production.

Technology Transfer – We ensure efficient and seamless tech transfer of products, minimizing disruptions through careful planning and execution.

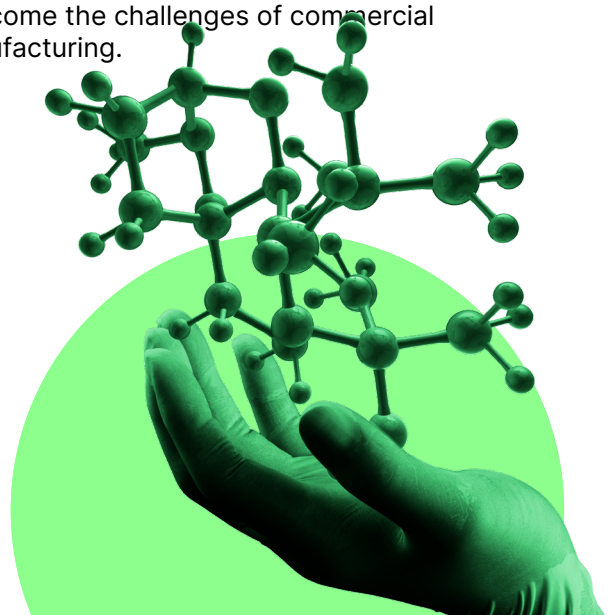
DoE & QbD Studies – Our scientific team employs rigorous tools and methodologies in R&D, including risk management and DoE software, to understand and control processes.

Process & Particle Engineering – Our process engineering team utilizes PAT tools to develop robust processes, providing customers with comprehensive data for pre-formulation.

Custom Manufacturing

Clinical Manufacturing - We have the facilities and capabilities to produce APIs for Phase I through to large Phase III clinical trials. We work closely with our customers to understand their clinical development plans and provide a bespoke clinical manufacturing solution.

Commercial Manufacturing - We have a proven track record of supplying APIs built on safe and robust processes, in regulatory compliant facilities. Our experienced and agile team works with you to overcome the challenges of commercial manufacturing.



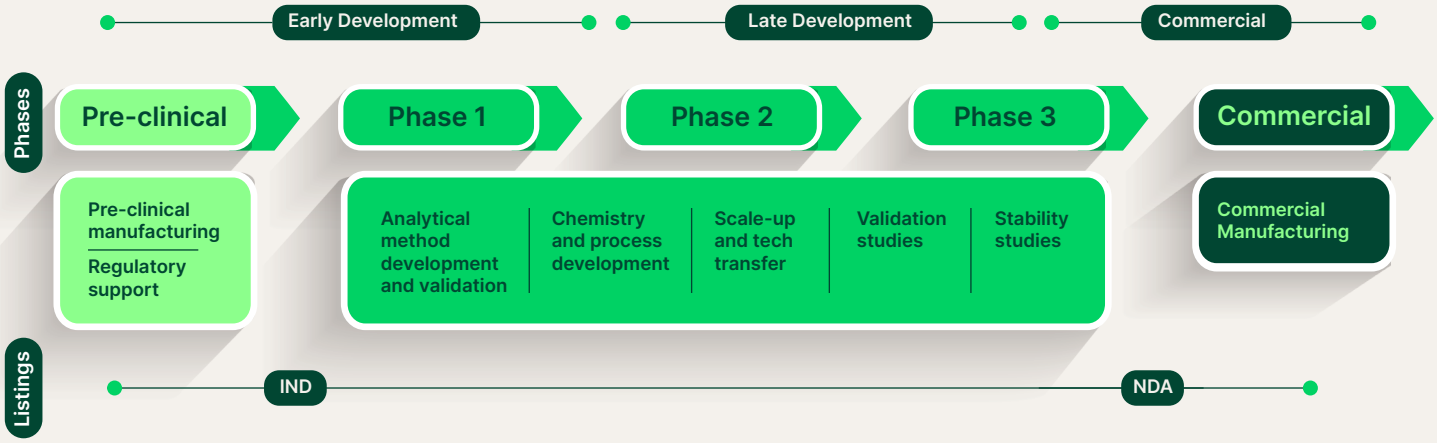
Our Analytical Services

- Method Development for complex molecules
- Synthesis and characterization of impurities
- Genotoxic impurity assessment and Method Development
- Stability studies
- Complete analytical validation package
- Reference standard qualification
- Study of solid-state properties
- Salt screening and optimization

Enabling Services

- Quality Control & Assurance
- Regulatory CMC Services
- Intellectual Property
- Project Management
- Supply Chain Management

We provide phase-appropriate solutions across the entire drug development cycle



Business Highlights

- 18+ commercial APIs / Intermediates programs with global innovator companies
- 88 NCEs projects developed for clinical trials and commercial.
- 5 APIs under development for NDA filing in the next 3 years
- Agile tech transfer at all stages of drug lifecycle & scale-up
- Three cGMP manufacturing facilities compliant with global regulatory standards such as USFDA, EMA, EDQM, PDMA, ANVISA, KFDA, TGA, etc.
- State-of-the-art R&D Center - 15 Development Labs, Analytical, Kilo and Peptides

Manufacturing Facilities

	Unit 1 Bonthapally, Hyderabad 239 KL	Unit 2 Pashamylaram, Hyderabad 382 KL	Unit 3 Gaddapotharam, Hyderabad 320 KL
Blocks	Block - 1,2,3,4,H, KL & S	Block - 1, 2, 3, FC, NMSM, Mini Plant (A&B)	Block - 1,2,4,5,7 & 8
Hydrogenation Reaction Volume	7.4 KL	6KL	5 KL
Solvent Recovery System	100 KL/D	20 KL/D	50 KL/D
Cryogenic Reaction Volume	25 KL	17 KL	15 KL

SILVER 2023 ecovadis Sustainability Rating

S&P Global Ratings

BRITISH SAFETY COUNCIL Five Star Occupational Health and Safety Audit

United Nations Global Compact

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