



Custom
Manufacturing
Solutions



39 years in small molecule API Development and Manufacturing

Neuland Labs has been supporting innovator Pharma and Biotech companies in custom small molecule API development and manufacturing for over two decades. Three USFDA and cGMP compliant manufacturing facilities, state-of-the-art R&D center, experience in complex chemical processes help handle a range of chemistry services from pre-IND through commercial manufacturing. We offer both small-scale clinical trial quantities and full commercial-scale supply with minimal tech transfer timelines.

Our services

- Designing & Developing manufacturing processes
- Process optimisation for competitiveness
- cGMP manufacturing of APIs & Intermediates
- Filing of CMC/DMF for the API
- Solid state & pre-formulation technologies

Project Management

Reliability, transparency and flexibility are tightly integrated into Neuland's manufacturing operations. Our project management system uses real-time updates to not only give clients a true pulse of the project but also to encourage the completion of tasks to meet the overall project timelines.

Why Neuland?

- 60 novel APIs developed for clinical trials and commercial
- 14+ commercial APIs / Intermediates programs with global innovator companies.
- 11 APIs and intermediates under development for NDA filing in next 3 years
- Manufactured Novel decapeptide (35 Kgs) and the program is in phase 3 clinical trials
- 6 peptides under development (5-50AAs) on 15Kgs to 100s of grams scale for clinical trials
- Agile tech transfer at all stages of drug lifecycle or for scale up
- CMC Documentation
- USFDA pre-approval inspections (PAIs) in manufacturing facilities
- IND filing support for 11 INDs with APIs and CMC documentation of programs in advanced stage of clinical trials
- Filed CMC variation to NDA, MAA and Japan NDAs as an alternate API supplier

For more information please visit www.neulandlabs.com



Infrastructure and Manufacturing Capabilities

Process R&D Center

More than 300 scientists with separate departments for Tech Transfer, Development QA, and Analytical. 11 laboratories, each equipped with 5-6 fume hoods.

Dedicated lab for high-pressure reactions.

Lab-scale micronization.

1 x 0.75 liter, 2 x 1 liter, 2 x 2 liters and 1 x 5 liters autoclaves (Hydrogenation).

Kilo lab with all glass equipment (20 liters to 100 liters).

Neuland has demonstrated expertise in process validation of API for NDA filings, including support for the management of potential genotoxic impurities (investigation and control), solid-state studies using modern equipment like NMR, LCMS, ICPMS, Ion Chromatography, and XRPD.

Peptide R&D Labs

2 laboratories with 12 fume hoods.

2 preparative HPLCs, 7 analytical HPLCs, 3 UPLCs, 2 lyophilizers.

cGMP Kilo Lab (U.S. FDA pre-approval inspection for an NCE API)

All glass vessels ranging from 50 liters to 250 liters, micronizer.

cGMP Pilot Plant

2 production areas with 2 class-100,000 clean rooms. SS reactors from 250 liters to 1600 liters.

Glass lined reactors from 100 liters to 1000 liters. Micronizer (90% <3 microns).

cGMP Peptide Manufacturing Plant

1 x 100 liters glass synthesizer and 2 x 250 liters glass lined reactors, 2 lyophilizers, 2 preparative HPLC systems, dedicated QC area, class 100,000 clean room.

Ability to produce 10-100 kg of peptide APIs, and high-value complex building blocks.

cGMP Peptide Suite

Class 100,000 pharma area. Rotary Evaporators: 1 x 20 liters, 1 preparative HPLC, 2 DAC columns, 2 lyophilizers, 1 VTD (12 trays), 2 x 250 Liter glass lined reactors. API precursors (intermediate stages) are being manufactured in other production blocks.

cGMP Vitamin D2, D3 Suite (High-Potency Containment)

Class 100,000 clean area. Analytical lab attached to facility. 5 x 10 liters 4 neck round bottom flasks.

1 x 5 liters reactors. 1 x 2 liters reactors.

Hydrogenation Capabilities

5, 10 liters SS autoclaves, designed pressure: 100 kg/cm².

250, 1000, 1600, 2500, 3000, 5000 liters SS autoclaves, designed pressure: 10 kg/cm².

Micronization

Small-scale to plant-scale micronization capabilities. Currently micronizing APIs for COPD, Ophthalmic, and Injectables. Achieved PSD of D90, 200 microns to less than 3 microns.

Regulatory Support

DMF/CMC documentation review and preparation, Support during the response to the queries received from the agencies, Preparation of Analytical and Chemical Data in CTD Format, Redacting the CMC section of, IND/IMPD filings, NDA filing support, Changes evaluation

Manufacturing Facilities

Unit 1: U.S. FDA inspected 7 times. All other major regulatory bodies inspected. 7 Production units. 5 class 100,000 clean rooms. Total reactor volume of 233KL. Reactor sizes ranging from 100 liters to 5000 liters (both SS and GLRs).

Unit 2: U.S. FDA inspected 7 times. All other major regulatory bodies inspected. 6 Production units. 5 class 100,000 clean rooms. Total reactor volume of 363KL. Reactor sizes ranging from 100 liters to 8000 liters (both SS and GLRs).

Unit 3: Inspected by USFDA as an Advanced Intermediates site in 2015. 6 Production units. 3 Class 100,000 clean rooms. Total reactor volume of 305KL. Reactor sizes ranging from 100 liters to 10000 liters (both SS and GLRs).



Neuland Highlights

- Scaled more than 300 processes, from gram scale to commercial
- Filed 916+ DMFs worldwide for 60 APIs
- Proprietary project management process
- State-of-the-art manufacturing facilities (USFDA, EDQM and PDMA approved) and R&D facility
- Export to more than 80 countries with more than 500+ active clients
- Experienced in absorption of technology given to customers
- Respected IPR of customers

Capabilities

- Synthesis of Complex Molecules
- Deuterated molecules
- Peptides in solid phase, solution phase and hybrid technology
- Peptide Building Blocks (RSMs)
- Steroidal Bile Acids and Vitamin D derivatives
- Carbohydrate chemistry
- Macrolides/Ketolides
- Heterocyclic compounds
- Chiral compounds manufacturing
- Organometallic Carbon-carbon bond formation

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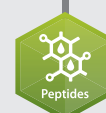
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Generic Drug Substances



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