Custom Manufacturing Solutions

NEULAND
WHERE OPPORTUNITY BECOMES REALITY

Providing CMS solutions for over 30 years

Expedite your discovery-to-market timelines with full confidence in regulatory compliance. Neuland Laboratories' comprehensive, GMP contract manufacturing services manufacture bulk pharmaceutical ingredients and intermediates in accordance with the rigorous expectations of global pharmaceutical standards. We offer over 30 years experience in complex chemistry, a state-of-the-art R&D centre, and two manufacturing facilities with more than 600,000 litres of total reactor volume to accommodate scales from small to validation to commercial manufacturing.

Manufacturing Services

- Manufacture API to customer specifications
- Design and develop manufacturing processes
- Process optimisation for competitiveness
- Filing of DMF/CMC for the API
- Patent protection for processes

Project Management with GuarD™

Reliability, transparency and flexibility are tightly integrated into Neuland's manufacturing operations. Our GuarD 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 as quickly as possible, keeping the focus on meeting the overall project completion date.

Why Neuland?

- Independently owned, financially stable company serving the worldwide pharmaceutical industry
- API-focused business model ensures Neuland does not manufacture generic formulations in conflict with our customers' business
- Proven expertise and success with seven NCE APIs in NDA or commercial stage drugs, 2010-13; several added each year in Phase II and Phase III clinical candidates
- Room to grow with adequate free plant capacity
- Emphasis on API process development with nearly 20% of workforce in R&D, and 40+ projects managed using proprietary project management system

Contact a Neuland Business Development representative for more information on your specific requirements: **cm@neulandlabs.com**
For further details visit: **www.neulandlabs.com**

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Infrastructure and Manufacturing Capabilities

Process R&D Center

180 scientists with separate departments for Tech Transfer, Development QA, and Analytical.

11 laboratories, each equipped with 5 Kewaunee fume hoods.

Dedicated lab for high-pressure reactions.

Lab-scale micronisation.

2x2 litres autoclaves (Hydrogenation). 1 x5 litres autoclave (Hydrogenation).

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

Neuland has demonstrated expertise in validation of APIs including genotoxic impurities management and solid state properties' studies as per current quality guidelines, using modern equipment like LCMS, ICPMS, Ion Chromatography, and XRPD.

Peptide R&D Labs

2 laboratories with 10 fume hoods.

3 preparative HPLCs. 2 analytical HPLCs. 1 lyophilizer.

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

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

cGMP Pilot Plant

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

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

cGMP Peptide Manufacturing Pilant

3x100 litres glass assemblies. 2 lyophiizers, 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 Prostaglandin Suite

U.S. FDA inspected in 2002, class 100,000 pharma area. Rotary Evaporators: 1x5 1itres and 1x20 litres, 1 preparative HPLC, 1 flash column, 1 flash pump.

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

Class 100,000 clean area. Analytical lab attached to facility. 5xl0 litres 4 neck round bottom flasks. 1 x5 litres reactors. 1 x2 litres reactors.

Hydrogenation Capabilities

5, 10 litres SS autoclaves, operating pressure: 100 kg/cm2.

1000, 1600, 2500,3 000, 5000 litres SS autoclaves, designed pressure: 10 kg/cm2.

Micronization

Small-scale to plant-scale micronisation capabilities. Currently micronising APIs for COPD, Ophthlamics, and Injectables. Achieved PSD of D90, 200 microns to less than 3 microns.

Manufacturing Facilities

Unit 1: U.S. FDA inspected 4 times. All other major regulatory bodies inspected. 7 production blocks. 5 class 100,000 clean rooms. Total reactor volume of 195,000 litres. Reactor sizes rangingfrom 100 litres to 5000 litres (both SS and GLRs).

Unit 2: U.S. FDA inspected 4 times. All other major regulatory bodies inspected. 3 production blocks. 5 class 100,000 clean rooms. Total reactor volume of 400,000 litres. Reactor sizes ranging from 100 litres to 6000 litres (both SS and GLRs).

Neuland Highlights

- Scaled more than 300 processes, from gram scale to commercial
- Filed more than 400 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 400 active clients
- Experienced in absorption of technology given to customers
- Respected IPR of customers

Chemistry and Manufacturing Capabilities

- Fluoroquinolones
- Deuterated molecules
- Peptides in solution phase
- Prostaglandins
- Vitamin D2 and D3 chemistry
- Carbohydrate chemistry
- Macrolides/Ketolides
- Complex amino acids
- Heterocyclic compounds
- Chiral compounds manufacture

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APIs | CMS | PEPTIDES