



Company
Profile and
Infrastructure



An Overview of Neuland

“ Neuland is a no-compromise, pharmaceutical services provider, offering worldwide compliant manufacturing facilities to its customers which it guarantees not to compete with in finished product. ”





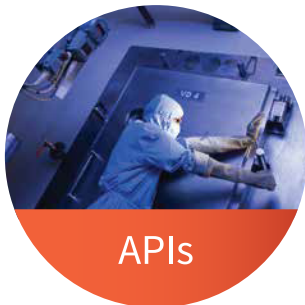
Brief Overview

History: Neuland Laboratories Limited is a publicly listed company headquartered in Hyderabad, India. Neuland is a leading manufacturer of active pharmaceutical ingredients (APIs) and an end-to-end solution provider for the pharmaceutical industry for chemistry related services. Our main business is manufacturing of API's and advanced intermediates from our FDA approved facilities and we are end-to-end solution provider for the pharmaceutical industry for chemistry related services from synthesis of library compounds to supply NCEs and intermediates at various clinical phases up to commercial scale.

For over 38 years, Neuland has been at the forefront of facilitating and accelerating drug development and cGMP manufacturing of APIs. The Company's technical and scientific teams provide reliable solutions and services to the global pharmaceutical industry.

Employees: Over 1500 employees, 300 scientists with over 31 Ph.Ds. in the R&D Centre.

Our markets: We are a reliable manufacturing and development partner to customers in over 80 countries across US, Europe, Japan, APAC, India, MENA and LATAM.



APIs

Business Verticals

APIs: The Company's core business and operational expertise since inception has been the manufacturing of Active Pharmaceutical Ingredients (APIs). Neuland has earned the identity of a preferred and reliable source in the pharmaceutical industry primarily due to:

- Consistency in product quality
- Knowledge and ability to deal with niche chemistry
- On-time delivery performance

Neuland has 3 USFDA and cGMP compliant manufacturing facilities with collective capacity of 907 KL to produce more than 100 APIs across 10 diverse therapeutic areas.



CMS

Custom Manufacturing Solutions: Neuland's Custom Manufacturing Solutions (CMS) derives from its proven expertise in chemical process development to manufacturing at varied scales, a deep understanding of complex chemical processes and manufacturing. Its facilities are compliant as per cGMP requirement and meeting environment and safety standards.



Peptides

Peptides: The Company is currently a supplier of high quality Peptide building blocks like Pseudoproline Dipeptides and other complex Fmoc building blocks. The Company plans to enter into GMP manufacturing of Peptide APIs in the near future.

Our Peptide Synthesis Services include production of peptides from milligrams to multi-kilogram scale by standard sequential chemical peptide synthesis and segment condensation strategies.

Our Journey - Key Milestones

Successfully cleared 15 USFDA inspections | Multiple audits passed with no failures

Laying Strong Foundation (1984-2003) – Deepening Our Capabilities (2004-2012) – Increased Sustainable Growth (2013-Today)

1984 Incorporated	1986 First API sale of Salbutamol Sulphate / Albuterol Sulphate	1994 Neuland goes public	1997 First US FDA Audit	2004 USA Operation	2007 Japan Subsidiary	2008 R&D Centre established; EDQM Audit of Unit-1	2009 PMDA, Japan Approval First NCE Approval
2013 Strategic alignment of business towards niche API's & Custom Manufacturing Solutions	2015 10th US FDA Audit	2016 R&D Facility approved by US FDA	2017 Among first 3 API facilities in India to be audited by CFDA (Unit-1) EDQM Audit of Unit-2	2018 Acquisition of advanced intermediates & API Facility	2019 Increased flow of projects from CMS Japan Active emphasis on supply chain de-risking	2020 100 Mn+ Revenue over 75 Live CMS Projects 15th US FDA Audit of Unit-2	2021 Unit-3 Commercialization 271 KL Reaction volume

Research and Development Centre

Neuland has a dedicated 40,000 sq.ft. R&D centre located near Hyderabad. Our highly experienced and qualified R&D staff comprises of over 300 scientists educated in India, US and Europe. Our R&D Centre, Pilot Plant and Kilo Labs are suited for performing

a variety of reactions over broad temperature ranges. Neuland's customers have successfully launched many complex molecules efficiently as a result of Neuland's ability to develop non-infringing processes and its superior diverse knowledge and expertise.



R&D Facilities

Development

- 15 Development Labs with space for expansion
- 60 Fume hoods
- Analytical Labs
- Dedicated kilo Lab for Scale up
- Dedicated Labs for Peptides
- Separate facility for D2 analogues

Analytical Infrastructure

- HPLC with UV/PDA/ RI/CAD/ELSD detectors (Waters / Shimadzu / Agilent)
- UHPLC with PDA detector (Shimadzu)
- FT-IR (Perkin Elmer)
- UV-Vis spectrophotometer (Perkin Elmer)
- Preparatory HPLC (SHIMADZU)
- GC and GC-MS with FID (Shimadzu / Perkin Elmer)
- DSC (Perkin Elmer)
- Digital Polari meter
- TGA (Perkin Elmer)
- KF Titrator (Metrohm)



Manufacturing Facilities Overview



UNIT-1
Bonthapally, Hyderabad 233 KL



UNIT-2
Pashamylaram, Hyderabad 363 KL



UNIT-3
Gaddapotharam, Hyderabad 305 KL

Year of Establishment	1986	1994	2017*
Blocks	Block - 1, 2, 3, 4, H, KL & S	34 Block - 1, 2, 3, FC, NMSM, Mini plant6	Block - 1, 2, 4, 5
Hydrogenation Reaction Volume	7.4KL	6KL	Facility creation under process
Solvent Recovery System	100 KLD	20KLD	50 KLD
Cryogenic Reaction Volume	25 KL	15 KL	15 KL
Regulatory	USFDA, EDQM, CFDA, PMDA, et. al	USFDA, EDQM, PMDA, ANVISA et. al	Desktop Inspection by USFDA in 2020; ANVISA (Brazil) 2022

Adding capacities for backward integration and new business

Inspection History



Unit-1 Inspection
March 1997, May 2004, March 2008 (PAI for NDA), November 2010, April 2014, April 2017, June 2019

Unit-2 Inspection
June 1999, February 2002, November 2005, September 2012, August 2015, November 2018, February 2020



Unit-1 Inspection
December 2005
Unit-2 Inspection
June 2017



Unit-1 Inspection
October 2008
Unit-2 Inspection
October 2008



Unit-1 Inspection
March 2012, May 2014
Unit-2 Inspection
April 2011, May 2013
Unit-3 Inspection
February 2022



Unit-1 Inspection
May 2017
Unit-2 Inspection
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Unit-1 Inspection
January 2013
Unit-2 Inspection
—



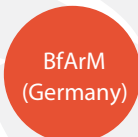
Unit-1 Inspection
Feb. 2010, July 2014
Unit-2 Inspection
February 2012



Unit-1 Inspection
February 2014
Unit-2 Inspection
February 2014



Unit-1 Inspection
—
Unit-2 Inspection
February 2019



Unit-1 Inspection
—
Unit-2 Inspection
February 2017



Unit-1 Inspection
December 2017
Unit-2 Inspection
—



Unit-1 Inspection
July 2010, 2013
Unit-2 Inspection
May 2010, 2013

*Unit III was USFDA inspected in 2015 and our R&D centre was USFDA inspected in 2016



Unit-1 Inspection
—
Unit-2 Inspection
February 2012



Unit-1 Inspection
—
Unit-2 Inspection
April 2011



Unit-1 Inspection
August 2019
Unit-2 Inspection
August 2019

*Unit III and R&D are ISO 45001:2018 Certified in August 2019

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Peptides