



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 40 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, 345 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	2023 Crossed Rs.1000 Cr. Revenue	

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 345 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	100KL/D	20KL/D	50KL/D
Cryogenic Reaction Volume	25KL	15KL	15KL
Regulatory	USFDA, EDQM, CFDA, PMDA, et. al	USFDA, EDQM, PMDA, ANVISA et. al	Desktop Inspection by USFDA in 2020; USFDA May 2023, ANVISA (Brazil) 2022

Adding capacities for backward integration and new business

Inspection History



USFDA (USA) 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-3 Inspection May 2023 R&D Inspection Feb 2016	EDQM (Europe) Unit-1 Inspection December 2005 June 2023 Unit-2 Inspection June 2017	PMDA (Japan) Unit-1 Inspection October 2008 Unit-2 Inspection October 2008	ANVISA (Brazil) Unit-1 Inspection March 2012, May 2014 Unit-2 Inspection April 2011, May 2013, May 2016 Unit-3 Inspection February 2022	WHO GMP Unit-1 Inspection Feb 2018 Unit-2 Inspection —
EMA (Europe) Unit-1 Inspection January 2013 Unit-2 Inspection —	KFDA / MFDS (South Korea) Unit-1 Inspection Feb. 2010, July 2014 Unit-2 Inspection February 2012	COFEPRIS (Mexico) Unit-1 Inspection February 2014 Unit-2 Inspection February 2014	FSI "SID&GP" (Russia) Unit-1 Inspection — Unit-2 Inspection February 2019	
BfArM (Germany) Unit-1 Inspection — Unit-2 Inspection February 2007	SFDA/CFDA (China) Unit-1 Inspection December 2017 Unit-2 Inspection —	ISO 14001:2004 Unit-1 Inspection July 2010, 2013 Unit-2 Inspection May 2010, 2013	ISO 45001:2018 Unit-1 Inspection August 2019 Unit-2 Inspection August 2019	*Unit 3 and R&D are ISO 45001:2018 Certified in August 2019
AFSSAPS / ANSM (France) Unit-1 Inspection — Unit-2 Inspection February 2012	TGA (Australia) Unit-1 Inspection — Unit-2 Inspection April 2011			

India Corporate Office | Tel: +91 40 67611600
 USA Office | Tel: +1 (888) 617 958
 Europe Office | Tel: +41 75 429 9008
 Japan Office | Tel: +81 3 3526 5171

For more information,
 please write to us at
marketing@neulandlabs.com
www.neulandlabs.com

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