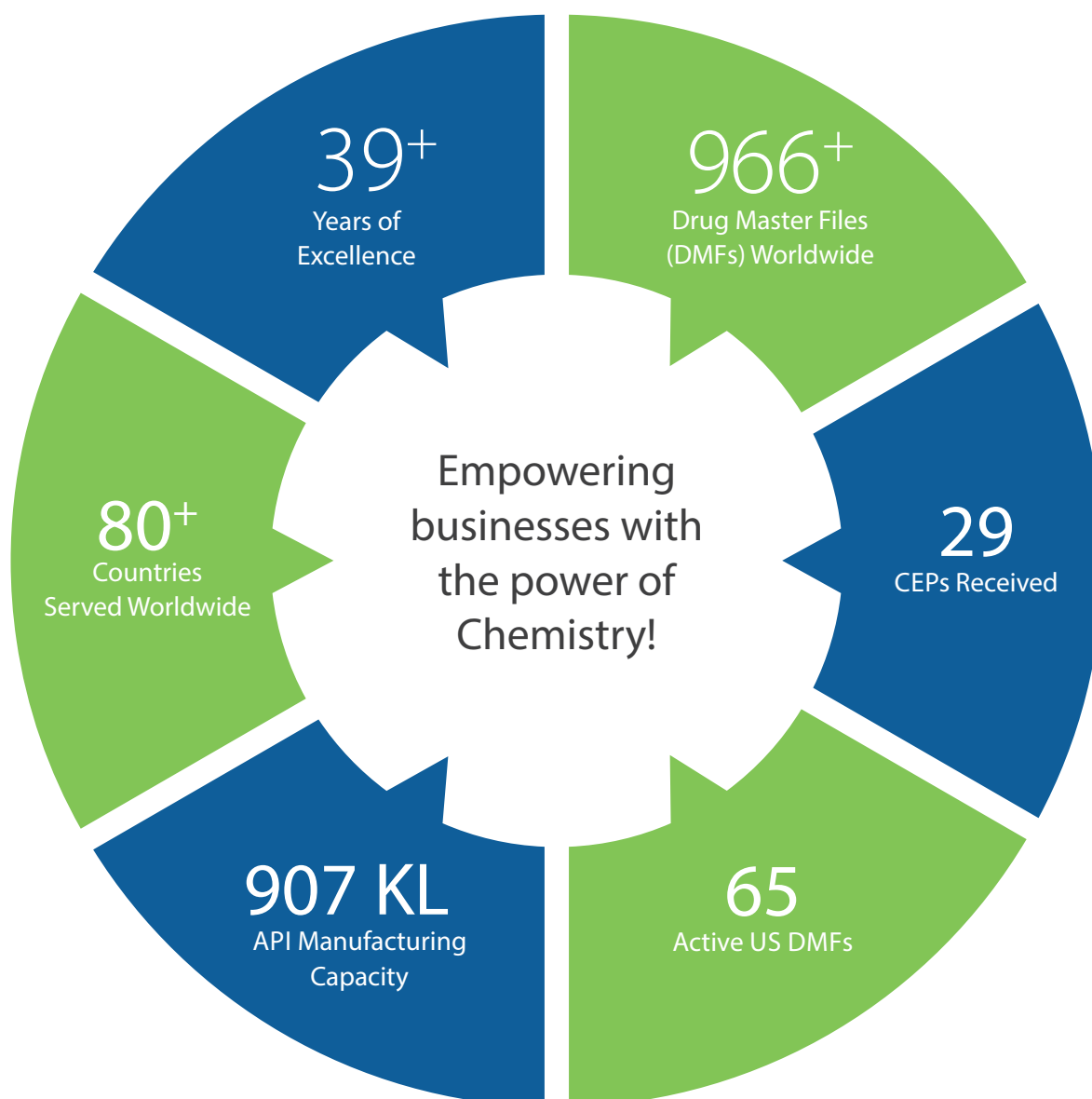

API Product List

About Us

Established in 1984, Neuland Laboratories is a leading manufacturer of active pharmaceutical ingredients (APIs) and an end-to-end solutions provider for the pharmaceutical industry for chemistry-related services. Our expertise extends across generic API manufacturing, advanced intermediates as well as the development and commercialization of APIs for new chemical

entities (NCEs). Neuland is a no-compromise, pureplay API manufacturing service provider, offering worldwide compliant manufacturing facilities to its customers that it guarantees not to compete within finished product. Neuland is a trusted provider of APIs and advanced intermediates in over 80 countries across US, Europe, Japan, APAC, India, MENA and LATAM.

Key Highlights



Key Milestones

Successfully cleared
16 USFDA inspections

Multiple audits passed
with no failures

1984 - 2003

Laying Strong
Foundation

2004 - 2012

Deepening
Our Capabilities

2013 - Today

Increased
Sustainable Growth

2023

Touched 500 Mn
in market cap,
US FDA Audit of Unit-3,
EDQM Audit of Unit-1

2021

Unit – 3
Commercialization
305 KL
Reaction volume

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

2020

100 Mn+ Revenue over
75 Live CMS Projects
US FDA Audit of Unit-2

2019

Increased flow of projects from
CMS Japan Active emphasis
on supply chain de-risking

2016

R&D Facility approved
by US FDA

2009

PMDA,
Japan Approval
First NCE
Approval

2008

R&D Centre
established; EDQM
Audit of Unit-1

2013

Strategic alignment of
business towards niche
API's & Custom Manu-
facturing Solutions

1986

First API sale of
Salbutamol Sulphate /
Albuterol Sulphate

1997

First US FDA
Audit

2007

Japan
Subsidiary

1994

Neuland
goes public

2004


USA Operation


1984


Incorporated


Facilities Aligned With Customer Requirements

We have systematically expanded into multiple production facilities, broadened our capabilities and built a robust track record of global regulatory excellence. Investments in infrastructure enhancements continue for meeting evolving customer needs and driving long-term competitiveness.

UNIT 1: Bonthapally, Hyderabad		Block: 1,2,3,4, H, KL & S		
	Year of Establishment	API manufacturing capacity	Hydrogenation Reaction Volume	
	1986	233 KL	7.4 KL	
	Solvent Recovery System	Cryogenic Reaction Volume	Regulatory approvals	
	100 KL/D	25 KL	US FDA, EDQM, CFDA, PMDA, et al	

UNIT 2: Pashamylaram, Hyderabad		Block: 34 Block-1, 2, 3, FC, NMSM, Mini plant 6		
	Year of Establishment	API manufacturing capacity	Hydrogenation Reaction Volume	
	1994	363 KL	6 KL	
	Solvent Recovery System	Cryogenic Reaction Volume	Regulatory approvals	
	20 KL/D	15 KL	US FDA, EDQM, PMDA, ANVISA, et al.	

UNIT 3: Gaddapotharam, Hyderabad		Block: 1, 2, 4		
	Year of Establishment	API manufacturing capacity	Hydrogenation Reaction Volume	
	2017	305 KL	Facility Creation Under Process	
	Solvent Recovery System	Cryogenic Reaction Volume	Regulatory approvals	
	50 KL/D	15 KL	USFDA, ANVISA, et al.	

Research & Development Centre						
	Development Labs	Fume hoods	Analytical Labs	Dedicated kilo Lab for	R&D team of	
	15	60	—	Scaleup	311 People	
	Dedicated labs for	Separate facility for	Approvals			
	Peptides	D2 analogues	Department of Scientific and Industrial Research (DSIR), Government of India and US FDA			

Significant R&D Achievements

Several NCE APIs added in NDA or commercial stage drugs	Support for multiple APIs each year in Phase 2 and Phase 3 clinical candidates	900+ DMFs filed 300+ API processes developed	204+ patents filed 3 new DMFs filed
---	--	---	--

COMMERCIAL & COMMERCIAL-SCALE PRODUCTS				
	Product	Therapeutic Segment	USDMF	COS/E-DMF
A	Albuterol Sulfate/Salbutamol Sulphate	Bronchodilator	✓	CEP
	Apixaban	Anticoagulant	✓	E-DMF
	Apremilast ‡	Psoriatic Arthritis	✓	E-DMF
	Aripiprazole Anhydrous	Antipsychotic	✓	CEP
	Aripiprazole Lauroxil ‡	Antipsychotic	✓	E-DMF
	Aripiprazole Monohydrate (Sterile)	Antipsychotic	✓	E-DMF
B	Brinzolamide	Antiglaucoma	✓	E-DMF
C	Ciprofloxacin Base ‡	Antibacterial	✓	CEP
	Ciprofloxacin Hydrochloride	Antibacterial	✓	CEP
D	Dabigatran Etxilate Mesylate	Anticoagulant	✓	E-DMF
	Deferasirox	Iron Chelator	✓	CEP
	Donepezil Base	Alzheimer's Disease	✓	E-DMF
	Donepezil Hydrochloride	Alzheimer's Disease	✓	CEP
	Dorzolamide Hydrochloride	Antiglaucoma	✓	CEP
E	Edaravone §	Neurology	✓	E-DMF
	Elagolix Sodium	Endometriosis	✓	N/A
	Enalapril Maleate	Antihypertensive	✓	CEP
	Entacapone	Antiparkinson Agent	✓	CEP
	Escitalopram Oxalate	Antidepressant	✓	CEP
	Ezetimibe	Antihyperlipidemic	✓	E-DMF
I	Ipratropium Bromide	Bronchodilator	✓	CEP
	Indacaterol Maleate	Bronchodilator	✓	E-DMF
L	Labetalol Hydrochloride	Antihypertensive	✓	CEP
	Levetiracetam	Anticonvulsant	✓	CEP
	Levofloxacin Hemihydrate	Antibacterial	✓	CEP
	Linezolid	Antibacterial	✓	E-DMF
	Lurasidone Hydrochloride	Antipsychotic	✓	E-DMF
M	Mirabegron	Overactive bladder	✓	CEP*
	Mirtazapine ‡	Antidepressant	✓	CEP
	Moxonidine	Antihypertensive	NA	CEP
O	Olanzapine	Antipsychotic	✓	CEP
P	Paliperidone Palmitate Sterile ‡	Antipsychotic	✓	E-DMF
	Propofol	Anesthetic	✓	CEP
	Posaconazole	Antifungal	✓	E-DMF
R	Ramipril	Antihypertensive	✓	CEP
	Rivaroxaban	Anticoagulant	✓	CEP
	Ropinirole Base	Antiparkinson Agent	✓	E-DMF
	Ropinirole Hydrochloride	Antiparkinson Agent	✓	CEP
	Rotigotine §	Antiparkinson Agent	✓	CEP

COMMERCIAL & COMMERCIAL-SCALE PRODUCTS				
	Product	Therapeutic Segment	USDMF	COS/E-DMF
S	Salmeterol Xinafoate ‡	Bronchodilator	✓	CEP
	Sotalol Hydrochloride	Antiarrhythmic	✓	CEP
	Sugammadex	Selective Relaxant Binding Agent (SRBA)	✓	E-DMF
T	Tafamidis Meglumine	Familial Amyloid Polyneuropathy/Cardiomyopathy	✓	E-DMF
	Ticagrelor	Platelet Aggregation Inhibitors	✓	E-DMF
V	Vilanterol Trifenatate	Bronchodilator	✓	E-DMF
	Voxelotor Cocystal §	Sickle cell disease	✓	E-DMF
	Voxelotor §	Sickle cell disease	✓	E-DMF

CEP* implies CEP/COS applied. E-DMF implies E-DMF filed or ready for submission

‡ Patents granted in US/Europe

§ Patent application filed

PRODUCTS UNDER DEVELOPMENT	
Product	Therapeutic Segment
Azilsartan	Antihypertensive
Azilsartan Kamedoxomil	Antihypertensive
Dapagliflozin	Antidiabetic
Dapagliflozin Propanediol	Antidiabetic
Edoxaban §	Anticoagulant
Empagliflozin	Antidiabetic
Fezolinetant	Women's Health
Indacaterol Acetate §	Bronchodilator
Sitagliptin Hydrochloride	Antidiabetic
Sitagliptin Phosphate	Antidiabetic
Tapinarof §	Plaque Psoriasis
Vonoprazan §	Antiulcerant

PEPTIDES	
Product	Therapeutic Segment
Difelikefalin §	Antipruritic
Semaglutide §	Antidiabetic
Tirzepatide §	Antidiabetic

§ Patent application filed

Disclaimer: No information in this Catalog – including any reference to any product or service – constitutes an offer for sale or be constructed as representing an offer for sale. Products protected under valid patents are not offered or supplied for commercial use. However, under Bolar Provision the research quantities of such products may be offered for the purpose of regulatory submissions, wherever such regulatory exemptions exist. The buyers should make their independent evaluation of patent scenario for their respective markets and will be responsible for all patent related liabilities.

Our Global Market Presence



Neuland Labs awarded with
'Silver Sustainability Rating'
89 Percentile among industry peers
By Ecovadis - The Worlds Most
Trusted Business Sustainability Rating

S&P Global Score 2022
92 Percentile
among industry peers

REGULATORY ACCREDITATION



USFDA



EDQM



Italy



Japan



Australia



BfArM (Germany)



ANVISA (Brazil)



France



Mexico



Korea



China



WHO - Geneva



(The Ministry of Health
of the Russian Federation)



ISO 9001, ISO 14001,
ISO 45001 and ISO 27001

India Corporate Office | Tel: +91 40 6761 1600
USA Office | Tel: +1 (888) 617 9587
Japan Office | Tel: +81 3 3526 5171

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

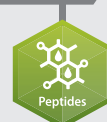
The Dedicated 100% API Provider



Generic Drug
Substances



Custom Manufacturing
Solutions



Peptides