

## World Class Pharma Ingredients

Our core business and operational expertise has, for over three decades, been the manufacturing and marketing of active pharmaceutical ingredients (APIs). During this time Neuland has become a preferred and reliable source for leading pharmaceutical companies worldwide. This is primarily due to: consistency in product quality; knowledge and ability to deal with niche chemistry; and on-time delivery performance.

The Company's strength in process development, regulatory knowledge, controlled supply chain and online project management makes Neuland an ideal API partner. Additionally, with proven experience of API manufacturing at varied scales, Neuland offers custom manufacturing solutions (CMS) as well as custom synthesis services for small molecules and peptides.

Neuland currently produces more than 75 APIs in diverse therapeutic areas with 673 DMFs filed worldwide.

## Our Facilities

With the recent addition of Unit 3, that increases our reactor capacity by 40%, Neuland now has three world-class API manufacturing facilities capable of handling complex and hazardous reactions. These have been successfully inspected by numerous regulatory agencies and comply with current Good Manufacturing Practices (cGMP).

### Key features:

- Total reactor volume of around 729 KL (222 KL at Unit 1, 310 KL at Unit 2 and 197 KL at Unit 3) and capable of handling a broad range of reactions and wide choice of process parameters
- 7 production blocks in Unit 1 and 6 production blocks in Unit 2 (covering 3,875 m<sup>2</sup> and 3,250m<sup>2</sup> of production area respectively) and a mini-plant for scaling-up of new products
- Unit 3 is a multi-product facility with 5 production blocks for advanced intermediates and API manufacturing
- Quality, EHS and compliance is at the heart of Neuland and across our facilities, with a track record of regulatory approvals (13 successful US FDA inspections)

## Facilities Certification

Authority	Unit 1 Inspection	Unit 2 Inspection
USFDA (USA)	March 1997, May 2004, March 2008 (PAI for NDA), November 2010, April 2014, April 2017	June 1999, February 2002, November 2005, September 2012, August 2015, November 2018
EDQM (Europe)	December 2005	June 2017
EMA (Europe)	January 2013	-
BfArM (Germany)	-	February 2007
AFSSAPS (France)	-	February 2012
PMDA (Japan)	October 2008	October 2008
KFDA (South Korea)	February 2010, July 2014	February 2012
CFDA (China)	December 2017	-
TGA (Australia)	-	April 2011
ANVISA (Brazil)	March 2012, May 2014	April 2011, May 2013
Cofepris (Mexico)	February 2014	February 2014
ISO 14001:2004	July 2010, 2013	May 2010, 2013
OHSAS 18001:2007	July 2010, 2013	May 2010, 2013
WHO	February 2018	-
FSI "SID & GP" (Russia)	-	February 2019

Our R&D centre was USFDA inspected in 2016

## For Business Development Enquiries please contact:

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API Product List

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### Commercial & Commercial-Scale Products

PRODUCT	Therapeutic Segment	USDMF	COS/E-DMF
Albuterol Sulfate/Salbutamol Sulphate	Bronchodilator	✓	CEP
Alcaftadine	Allergic Conjunctivitis	✓	N/A
Apixaban	Anticoagulant	✓	E-DMF
Apremilast	Psoriatic Arthritis	✓	E-DMF
Aripiprazole Anhydrous	Antipsychotic	✓	CEP*
Aripiprazole Lauroxil	Antipsychotic	✓	N/A
Bosentan Monohydrate	Pulmonary Artery Hypertension	✓	E-DMF
Ciprofloxacin Base	Antibacterial	✓	CEP
Ciprofloxacin Hydrochloride	Antibacterial	✓	CEP
Dabigatran Etxilate Mesylate ↓	Anticoagulant	✓	E-DMF
Deferasirox	Iron Chelator	✓	E-DMF
Donepezil Base	Alzheimer's Disease	N/A	E-DMF
Donepezil Hydrochloride	Alzheimer's Disease	✓	E-DMF
Dorzolamide Hydrochloride	Anti-Glaucoma	✓	CEP
Enalapril Maleate	Antihypertensive	✓	CEP
Entacapone	Antiparkinson Agent	✓	CEP
Escitalopram Oxalate	Antidepressant	✓	CEP*
Ezetimibe	Antihyperlipidemic	✓	E-DMF
Ipratropium Bromide	Anticholinergic	✓	CEP
Itraconazole	Antifungal	✓	CEP
Labetalol Hydrochloride	Antihypertensive	✓	CEP
Levetiracetam	Anticonvulsant	✓	CEP
Levofloxacin Hemihydrate	Antibacterial	✓	CEP*
Linezolid	Antibacterial	✓	E-DMF
Lurasidone Hydrochloride	Antipsychotic	✓	E-DMF
Mirtazapine	Antidepressant	✓	CEP
Moxifloxacin Hydrochloride	Antibacterial	✓	CEP*
Moxonidine	Antihypertensive	N/A	CEP
Olanzapine	Antipsychotic	✓	CEP
Paliperidone Palmitate (Sterile) ↓	Antipsychotic	✓	E-DMF
Propofol	Anesthetic	✓	CEP
Posaconazole	Antifungal	✓	E-DMF
Ramipril	Antihypertensive	✓	CEP
Rivaroxaban	Anticoagulant	✓	E-DMF
Ropinirole Base	Antiparkinson Agent	✓	E-DMF
Ropinirole Hydrochloride	Antiparkinson Agent	✓	CEP*
Rotigotine	Antiparkinson Agent	✓	E-DMF
Salmeterol Xinafoate	Bronchodilator	✓	CEP
Sotalol Hydrochloride	Antiarrhythmic	✓	CEP
Voriconazole	Antifungal	✓	CEP

### Development Products

PRODUCT	Therapeutic Segment	USDMF	CEP/E-DMF
Aripiprazole Monohydrate (Sterile)	Antipsychotic	Ⓥ	Ⓥ
Indacaterol Maleate	Bronchodilator	Ⓥ	Ⓥ
Rufinamide ↓	Anticonvulsant	Ⓥ	Ⓥ
Sugammadex ↓	Selective Relaxant Binding Agent (SRBA)	Ⓟ	Ⓟ
Ticagrelor	Platelet Aggregation Inhibitors	Ⓟ	Ⓟ

### R&D Pipeline Products

Product	Therapeutic Segment
Small Molecules	
Brivaracetam	Anticonvulsant
Crisaborole	Dermatology
Edaravone	Neurology
Elagolix sodium	Endometriosis
Sacubutril Calcium	Cardiovascular
Sacubitril-Valsartan	Cardiovascular
Ursodiol	Hepatoprotective agent
Varenicline tartrate	Smoking cessation
Vilanterol	Bronchodilator
Upadacitinib	Rheumatoid arthritis
Prucalopride	Chronic idiopathic constipation
Tafamidis	Familial Amyloid Polyneuropathy
Peptides	
Liraglutide	Antidiabetic
Linaclotide	Chronic constipation
Octreotide	Growth-Hormone Antagonist
Semaglutide	Antidiabetic

E-DMF Filed/Ready for Filing    N/A Not Applicable    ↓ Patents granted in US/Europe    \* Application Filed and Under Review  
Ⓟ Product Validation in Plant Over, DMF Under Preparation    Ⓥ Product Validation Initiated/Under Progress