## 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 740 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 $m^2$ and 3,250$m^2$ 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 (14 successful USFDA 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 2019 | 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 2018 |
| 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**


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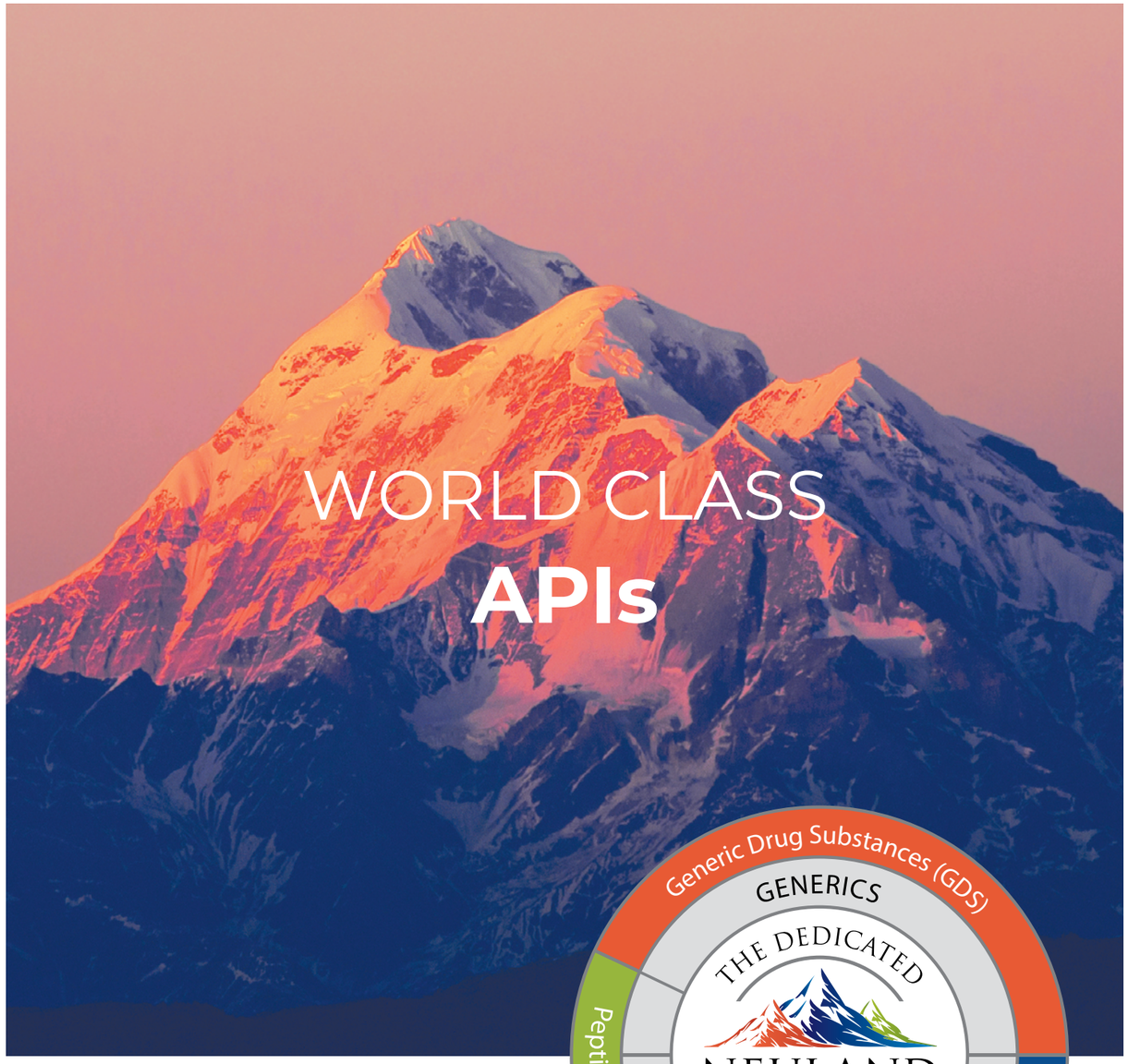


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API Product List
November 2019

## 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 Etexilate Mesylate | Anticoagulant | ✓ | E-DMF |
| Deferasirox ‡ | Iron Chelator | ✓ | E-DMF |
| Donepezil Base | Alzheimer's Disease | N/A | E-DMF |
| Donepezil Hydrochloride | Alzheimer's Disease | ✓ | CEP* |
| 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 |
| Paliperidone Palmitate ‡ | Antipsychotic | ✓ | E-DMF |
| 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 | ✓ | CEP* |
| Salmeterol Xinafoate | Bronchodilator | ✓ | CEP |
| Sotalol Hydrochloride | Antiarrhythmic | ✓ | CEP |
| Sugammadex ‡ | Selective Relaxant Binding Agent (SRBA) | ✓ | N/A |
| Ticagrelor | Platelet Aggregation Inhibitors | ✓ | E-DMF |
| Voriconazole | Antifungal | ✓ | CEP |

## DEVELOPMENT PRODUCTS

| PRODUCT | THERAPEUTIC SEGMENT | USDMF | CEP/E-DMF |
|---|---|---|---|
| **SMALL MOLECULES** | | | |
| Aripiprazole Monohydrate (Sterile) | Antipsychotic | Ⓥ | Ⓥ |
| Indacaterol Maleate ‡ | Bronchodilator | Ⓟ | Ⓟ |
| Edaravone | Neurology | Ⓥ | Ⓥ |
| Ursodiol (UDCA) | Hepatoprotective Agent | Ⓥ | Ⓥ |
| **PEPTIDES** | | | |
| Linaclotide | Chronic Constipation | Ⓥ | Ⓥ |

## R&D PIPELINE PRODUCTS

| PRODUCT | THERAPEUTIC SEGMENT |
|---|---|
| **SMALL MOLECULES** | |
| Crisaborole | Dermatology |
| Elagolix Sodium | Endometriosis |
| Edoxaban | Anticoagulant |
| Sacubitril-Valsartan | Cardiovascular |
| Upadacitinib | Rheumatoid Arthritis |
| Varenicline Tartrate | Smoking Cessation |
| Vilanterol Trifenatate | Bronchodilator |
| Tafamidis/Tafamidis Meglumine | Familial Amyloid Polyneuropathy |
| **PEPTIDES** | |
| Liraglutide | Antidiabetic |
| Octreotide | Growth-Hormone Antagonist |
| Semaglutide | Antidiabetic |

**For further details visit:** www.neulandlabs.com
**Disclaimer:** The above Product list includes some products which are still under patent protection in India and other countries. These products will be available for supply after expiry of respective patents.

**E-DMF** Filed/Ready for Filing
**N/A** Not Applicable ‡ Patents granted in US/Europe
*Application filed under review
Ⓟ Product Validation in Plant Over DMF Under Preparation
Ⓥ Product Validation Initiated/Under Progress