



Dependable Partners for
Development with Growth



Who We Are

We (formerly Zandu Chemicals Ltd.) are one of the fastest growing Pharmaceutical companies in India that combines the power of Science & Technology together. Established in 1991, we are headquartered in Mumbai and have a state-of-the-art US FDA and EDQM successfully inspected/audited facility with a capacity of 214,000 L (56,500 gallon) along with strong research & development capabilities strategically located in the industrial park of Ankleshwar, Gujarat.

We are a 100% EOU (Export Oriented Unit) engaged in manufacturing and exports of advanced drug intermediates and Active Pharma Ingredients (APIs). We are a specialized Pharma company focusing on the niche therapeutic areas of CNS, ARVs and Controlled substances having tremendous future growth potential. By virtue of this niche focus we have registered an impressive growth over the years.

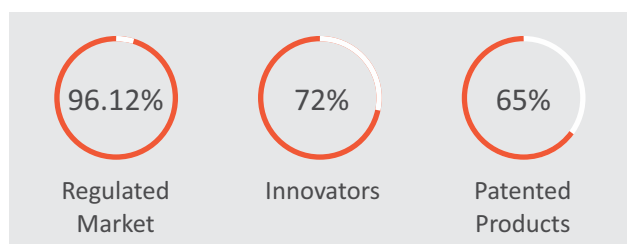
Our strategy going forward is to further consolidate our pre-eminent position in the high growth therapeutic areas by expanding our capacity for present advanced intermediates and moving up the value chain by expanding capacity for APIs and diversifying product portfolio into the other high growth therapeutic areas like Anti-diabetic, Anti-coagulants and others.

We are a US FDA, EDQM, KFDA, WHO-GMP and Japanese MOH accredited company having certifications of ISO 9001, ISO 14001 and OHSAS 18001. We are a member of EcoVadis (Silver category) and have Integrated SAP system in place.

While over 90% of our revenue is from established markets, we are growing rapidly in the emerging markets. We have an established track record in pharma business with focus on low to medium volume and high value products.



Geographic and business spread



Where we are

- Strategically located in the “Golden Corridor of India” Ankleshwar, GIDC (Gujarat Industrial Development Corporation) which is 192 miles / 320 km North of Mumbai.
- GIDC Ankleshwar - An ideal location for industrialization; more than 12000 varied industries.

Customer-centric approach

We have spent years creating a culture around the customer and their needs.

Our customer-centric approach has won the status of a preferred supplier/strategic partner from global pharmaceutical innovators and generic companies. We have aligned the entire organization to be decisive and agile that keeps us winning our customers’ appreciation.

Our commitment is to keep up our tradition of delivering customer value and having our valuable customers in the very heart of our corporate focus.

Manufacturing capabilities

- Four multi-purpose, multi-product cGMP manufacturing units
- Five powder processing areas as per class ISO 8 (Class 100,000)
- Designed to conform to cGMP and approvable by international regulatory bodies (US FDA, EU GMP, PMDA, TGA, ANVISA, WHO)
- Dedicated Cryogenic and Hydrogenation suites
- Reaction Temperature ranging from -78 deg C to +220deg C
- High vacuum distillation at 1 Torr and high pressure reactions at 20 Bar in combination of 200°C temperature
- Installed Reaction capacity of 214, 000 L with 68 reactors - 31 SSR, 36 GLR, One Cryogenic reactor, ranging from 100 L to 8,000 L
- 20 Centrifuges – (24-60”) Stainless Steel, halar-coated and peeler
- 18 Dryers : RCVD, VTD, FBD, ANFD, TD and Nauta
- Blenders with 300 to 3000 L volume
- Air Jet mill Micronizer and Multi-mill
- Purified water system to meet current USP quality

Chemistry Competence

Expertise in Hydrogenation, Chiral, Asymmetric transformation, Cyclization, Acylation and Alkylation Chemistry.

- **Acylation and Alkylation**
- **Asymmetric transformations**
- Assorted : bromination, nitration
- Azide chemistry
- Chlorosulfonation
- **Couplings (Suzuki, Negishi, Stille, Buchwald-Hartwig, Heck, Ullmann)**
- Cyclization/Cyclocondensations
- Enantioselective Hydrolysis
- Epoxidation
- Enantioseparation/Resolution
- Grignard
- Hydrogenations (up to 20 bar/160°C)
- Hydrolysis (Ester/Nitrile/Amide)
- **Oxidation (Peracetic acid/Pinnick)**
- Phase Transfer Catalysis
- Reductions (Conventional/Customized)
- **Reductive Amination**
- Ritter reaction
- **Reductions (Ra-Ni/Pd-C/Pt-C/SnCl₂/Conventional agents)**
- Name Reactions (On scale) - (Dieckmann/Hantzsch/Ritter/Wittig/Several others)
- Sandmeyer reaction
- Solid distillation (Upto 0.01 torr)
- Borylations (Suzuki-Miyaura precursors)
- Regioselective Lithiations (LDA/n-Hex-Li)
- Wilgerodt Reaction

Research & Development

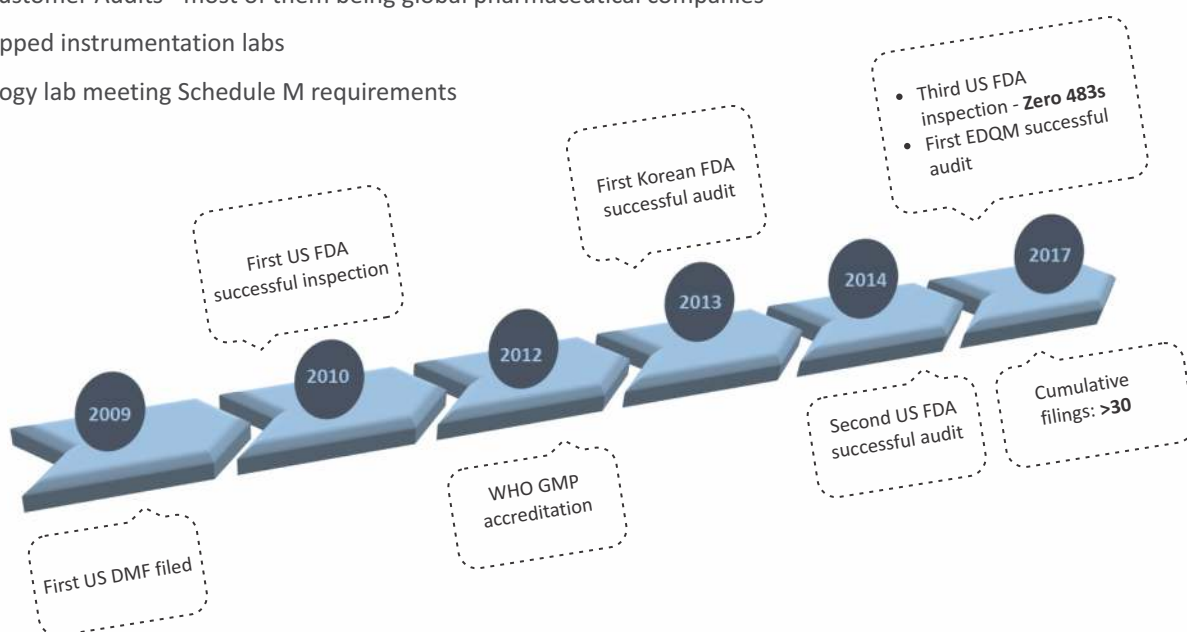
Located in our Ankleshwar facility, State-of-the-art R&D Centre has four furnished labs equipped with some of the latest analytical equipment and managed by experienced scientists and qualified professionals.

- Proven record for developing complex and quality products for big pharma companies worldwide
- Expertise in developing novel Polymorphs and non-infringing processes (>30 process patent)
- Specialization in Controlled substances, CNS, Anti-diabetic and Anti-coagulant molecules
- Collaborative R&D and CMO projects under confidentiality agreement
- Seamless interface with operations resulting in credible deliverance



Regulatory & Quality Management

- Successfully inspected by USFDA, EDQM and KFDA
- Adherence to ICH Q7A & ISO 9001 quality standards
- Regular Customer Audits - most of them being global pharmaceutical companies
- Well-equipped instrumentation labs
- Microbiology lab meeting Schedule M requirements



Active Pharma Ingredients (APIs)

| Product | Status | Pharmacopeia | CAS No. | Therapeutic Use |
|-----------------------------|------------------------|--------------|-------------|--|
| Alprazolam | Tech pack | USP/EP | 28981-97-7 | Anxiolytic |
| Aripiprazole | USDMF*, CEP | USP/EP | 129722-12-9 | Anti-depressant/Anti-psychotic |
| Atomoxetine HCl | CEP, USDMF, TDMF, IDL* | USP/EP | 82248-59-7 | Attention Deficit Hyperactivity Disorder (ADHD) |
| Betahistine Dihydrochloride | CEP, TDMF | USP/BP/EP/IP | 5579-84-0 | Vertigo |
| Betahistine Mesylate | Tech pack | EP/JP/IP | 54856-23-4 | Vertigo |
| Clozapine | USDMF*, CEP* | USP/EP/IP | 5786-21-0 | Anti-psychotic |
| Dexmethylphenidate HCl | Tech pack | Inhouse | 19262-68-1 | Attention Deficit Hyperactivity Disorder (ADHD) |
| Eslicarbazepine Acetate | USDMF*, EDMF* | In-house/IP | 236395-14-5 | Anti-epileptic |
| Felbinac | EDMF, JDMF* | BP/EP/JP | 5728-52-9 | Anti-inflammatory |
| Fluvoxamine Maleate | USDMF*, CEP, TDMF | USP/BP/EP/IP | 61718-82-9 | Anti-depressant |
| Levomepromazine Maleate | CEP* | EP/JP | 7104-38-3 | Anti-psychotic |
| Loxoprofen sodium | Tech pack | JP | 80382-23-6 | Anti-inflammatory, Analgesic |
| Lurasidone HCl | USDMF | In-house | 367514-88-3 | Anti-psychotic |
| Memantine HCl | USDMF, AUSDMF | USP | 41100-52-1 | Alzheimer Disease |
| Methylphenidate Hcl | CEP | USP/EP | 298-59-9 | Attention Deficit Hyperactivity Disorder (ADHD) |
| Mirabegron | Tech pack | In-house | 223673-61-8 | Treatment of overactive bladder |
| Modafinil | Tech pack | USP/EP | 68693-11-8 | CNS Stimulant |
| Olanzapine | Tech pack | USP | 132539-06-1 | Anti-psychotic |
| Phenylephrine hydrochloride | Tech pack | EP/IP | 61-76-7 | Decongestant |
| Pirfenidone | USDMF* & CEP | EP/IP | 53179-13-8 | Anti-inflammatory / Anti-Rheumatic |
| Pregabalin | Tech pack | In-house | 148553-50-8 | Epilepsy, Neuropathic pain and generalized anxiety disorder. |
| Quetiapine Fumarate | USDMF*, AUSDMF & CEP | USP/EP | 111974-72-2 | Anti-psychotic |
| Rivaroxaban | USDMF | In-house | 366789-02-8 | Anti-coagulant |
| Trifluoperazine HCl | Tech pack | USP/BP/EP/IP | 440-17-5 | Anti-psychotic |
| Zaltoprofen | KDMF | JP | 74711-43-6 | Anti-inflammatory |
| Zonisamide | USDMF | USP | 68291-97-4 | Anti-convulsant |

Product Pipeline

| | | | | |
|---------------------------------------|-------------------|----------|-------------|--------------------------------------|
| Dapagliflozin propanediol monohydrate | Under development | In-house | 960404-48-2 | Anti-diabetic |
| Darunavir ethanolate | Under development | In-house | 635728-49-3 | Treatment of AIDS and HIV infections |
| Empagliflozin | Under development | In-house | 864070-44-0 | Anti-diabetic |

Products under evaluation

| | | | | |
|----------------------|------------------|----------|--------------|---------------------------------------|
| Betrixaban | Under evaluation | In-house | 330942-05-7 | Anticoagulant |
| Brivaracetam | Under evaluation | In-house | 357336-20-0 | Anti-Epileptics; Analgesics |
| Edaravone | Under evaluation | In-house | 89-25-8 | Neurology(Orphan drug) |
| Ertugliflozin | Under evaluation | In-house | 1210344-57-2 | Anti-diabetic |
| Pimavanserin | Under evaluation | In-house | 706779-91-1 | Antipsychotic |
| Safinamide Mesylate | Under evaluation | In-house | 133865-89-1 | Anti-Epileptics; Anti-Parkinson Drugs |
| Valbenazine tosylate | Under evaluation | In-house | 1639208-54-0 | Tardive dyskinesia |

* Under filing, + DMF Info Available for Reference

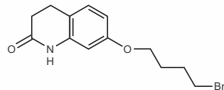
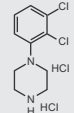
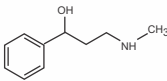
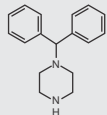
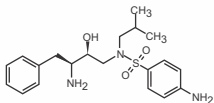
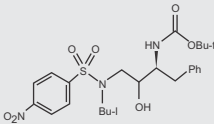
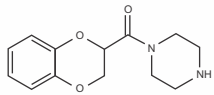
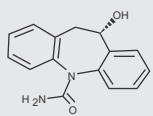
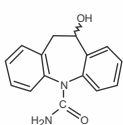
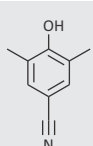
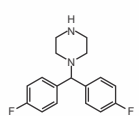
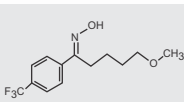
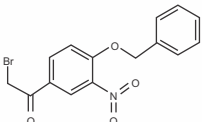
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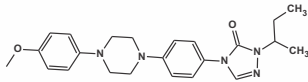
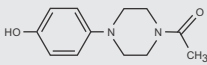
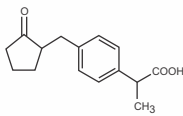
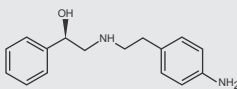
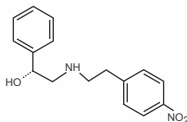
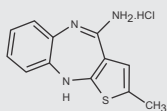
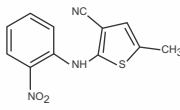
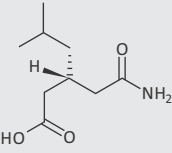

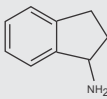
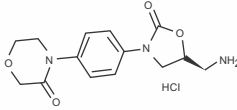
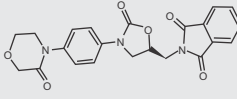
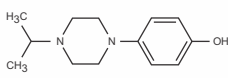
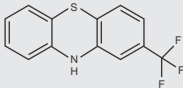
Patented Products are available for R&D use as per permitted under 35 USC ¶ 271 (e) (1)

March 2018

Advanced Intermediates

| Product | CAS No. | End Use | Structure |
|--|--------------|---|---|
| (1H)-7-(4'-bromobutoxy)-3,4-dihydro-2-quinolinone | 1297225-34-5 | Aripiprazole |  |
| 1-(2,3-Dichlorophenyl) Piperazine HCl | 119532-26-2 | Aripiprazole |  |
| 3-(methylamino)-1-phenylpropan-1-ol | 42142-52-9 | Atomoxetine Fluoxetine Nisoxetine |  |
| N-Benzhydrylpiperazine | 841-77-0 | Cinnarizine |  |
| Benzenesulfonamide, 4-amino-N-[(2R,3S)-3-amino-2-hydroxy-4-phenylbutyl]-N-(2-methylpropyl) | 169280-56-2 | Darunavir |  |
| Carbamic acid, N-[(1S,2R)-2-hydroxy-3-[(2-methylpropyl)[(4-nitrophenyl)sulfonyl]amino]-1-(phenylmethyl)propyl]-,1,1-dimethylethylester | 191226-98-9 | Darunavir, Fosamprenavir |  |
| N-(1,4-Benzodioxan-2-carbonyl)-piperazine | 70918-00-2 | Doxazosin |  |
| (10S)-10,11-Dihydro-10-hydroxy-5H-dibenz[b,f]azepine-5-carboxamide | 104746-04-5 | Eslicarbazepine acetate |  |
| 10,11-Dihydro-10-hydroxy-5H-dibenz[b,f]azepine-5-carboxamide | 29331-92-8 | Eslicarbazepine acetate |  |
| 4-Hydroxy-3, 5-dimethyl benzonitrile | 4198-90-7 | Etravirine |  |
| 4,4'-Difluorobenzhydrylpiperazine | 27469-60-9 | Flunarizine |  |
| (1E)-N-Hydroxy-5-Methoxy-1-(4-Trifluoromethylphenyl)Pentan-1-Imine | 61747-22-6 | Fluvoxamine |  |
| 2-Bromo-4'-benzyloxy-3'-nitroacetophenone | 43229-01-2 | Formoterol |  |

Advanced Intermediates

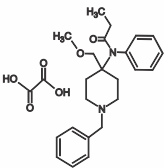
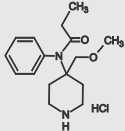
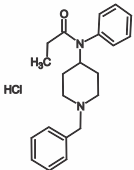
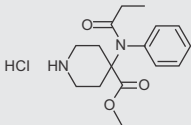
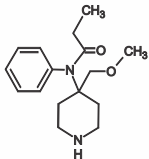
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|--|-------------|-------------------|---|
| 2,4-Dihydro-4-[4-[4-(4-methoxyphenyl)-1-piperazinyl]phenyl]-2-(1-methyl propyl)-3H-1,2,4-triazol-3-one | 252964-68-4 | Itraconazole |  |
| 1-Acetyl-4-(4-hydroxyphenyl) piperazine | 67914-60-7 | Ketoconazole |  |
| 2-[4-[(2-oxocyclopentyl)methyl]phenyl]propanoic acid | 68767-14-6 | Loxoprofen Sodium |  |
| (1R)-2-[[2-(4-aminophenyl)ethyl]amino]-1-phenylethanol | 391901-45-4 | Mirabegron |  |
| (1R)-2-[[2-(4-nitrophenyl)ethyl]amino]-1-phenylethanol | 223673-34-5 | Mirabegron |  |
| 2-Methyl-10H-thieno[2,3-b][1,5] benzo diazepine-4-amine HCl | 138564-60-0 | Olanzapine |  |
| 5-methyl-2-(2-nitrophenylamino) thiophene-3-carbonitrile | 138564-59-7 | Olanzapine |  |
| (R)-(-)-3-Carbamoylmethyl-5-methylhexanoic acid | 181289-33-8 | Pregabalin |  |
| 5-methylpyridin-2(1H)-one (synonym : 2-Hydroxy-5-methylpyridine) | 1003-68-5 | Pirfenidone |  |
| 1-Aminoindan | 34698-41-4 | Rasagiline |  |
| 4-[4-[(5S)-5-(aminomethyl)-2-oxo-1,3-oxazolidin-3-yl]phenyl]morpholin-3-one hydrochloride | 898543-06-1 | Rivaroxaban |  |
| 2-(((5S)-2-oxo-3-[4-(3-oxomorpholin-4-yl) phenyl]-1,3-oxazolidin-5-yl)methyl)-1H-isoindole-1,3(2H)-dione | 446292-08-6 | Rivaroxaban |  |
| N-Isopropyl-4-(4-hydroxyphenyl)-piperazine | 67914-97-0 | Terconazole |  |
| 2-(Trifluoromethyl)-phenothiazine | 92-30-8 | Trifluoperazine |  |

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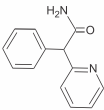
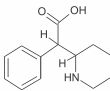
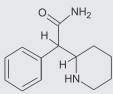
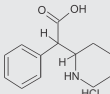
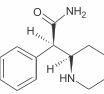
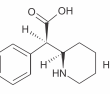
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Intermediate for controlled substances

| Product | CAS No. | End Use | Structure |
|--|------------|-------------------------|---|
| N-[1-(benzyl)-4-(methoxymethyl)-4-piperidinyl]-N-phenyl Propanamide oxalate | 61086-13-3 | Alfentanil & Sufentanil |  |
| N-[4-(methoxymethyl)-piperidine-4-yl]-N-phenyl propanamide monohydrochloride | 84196-16-7 | Alfentanil & Sufentanil |  |
| N-(1-Benzylpiperidin-4-yl)-N-phenylpropanamide Hydrochloride | 5156-58-1 | Fentanyl |  |
| Methyl 4-(phenyl-propionyl-amino)-piperidine-4-carboxylate HCl | 61085-87-8 | Remifentanyl |  |
| N-[(4-Methoxymethyl)-4-piperidinyl]-N-phenyl propanamide | 61086-18-8 | Sufentanil |  |

Methyl Phenidate Series

| Product | CAS No. | Structure | Product | CAS No. | Structure |
|-------------------------------------|------------|---|---------------------------------------|--------------|---|
| Phenyl-(2-pyridyl acetamide) | 7251-52-7 |  | dl-threo ritalinic acid* | 54631-24-2 |  |
| Phenyl-2-(2'-piperidyl)acetamide | 19395-39-2 |  | dl-Threo-Ritalinic acid HCl | 1382859-13-3 |  |
| Threo phenyl-2-piperidyl acetamide* | 50288-62-5 |  | d-threo ritalinic acid hydrochloride* | 741705-70-4 |  |

*USDMF available

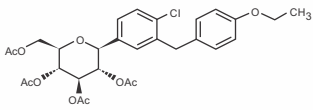
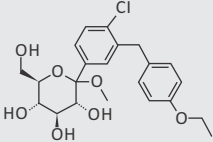
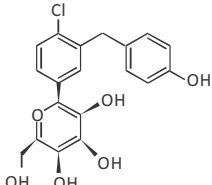
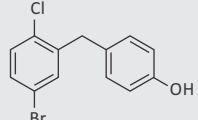
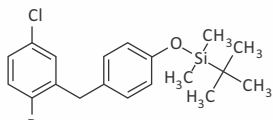
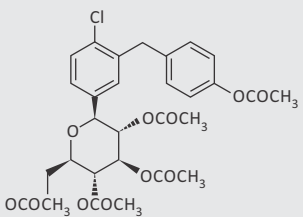
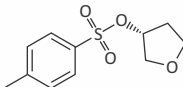
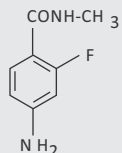
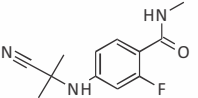
Disclaimer : Users are responsible for all patent related issue for our offered products.

The therapeutic use shown against each product is indicative only and is not for advertising ZCL products.

Patented Products are available for R&D use as per permitted under 35 USC § 271 (e) (1)

March 2018

Under Scale-up / New Development

| Product | CAS No. | End Use | Status | Structure |
|---|-------------|----------------------------|-------------------|--|
| 1,5-anhydro-1-C-[4-chloro-3-[(4-ethoxyphenyl)methyl]phenyl]-,2,3,4,6-tetraacetate, (1S)- D-Glucitol | 461432-25-7 | Dapagliflozin propanediol | Under development |  |
| (2S,3R,4S,5S,6R)-2-[4-Chloro-3-(4-ethoxybenzyl)phenyl]-6-(hydroxymethyl)-2-methoxytetrahydro-2H-pyran-3,4,5-triol | 714269-57-5 | Dapagliflozin propanediol | Under development |  |
| 1-Chloro-4-(B-D-glucopyranos-1yl)-2-(4-hydroxy-benzyl)-benzene | 864070-37-1 | Empagliflozin | Under development |  |
| 4-(5-bromo-2-chlorobenzyl) phenol (synonym : [(5-bromo-2-chlorobenzyl)-methyl] phenol | 864070-18-8 | Empagliflozin | Under development |  |
| (4-(5-bromo-2-chlorobenzyl)phenoxy) (tertbutyl)dimethylsilane | 864070-19-9 | Empagliflozin | Under development |  (Semi Solid mass-Best before 90 days) |
| (2S,3S,4R,5R,6R)-2-(3-(4-acetoxybenzyl)-4-chlorophenyl)-6-(acetoxymethyl) tetrahydro-2Hpyran-3,4,5-triyl triacetate | 912917-85-2 | Empagliflozin | Under development |  |
| (R)-tetrahydrofuran-3-yl 4-methylbenzene sulfonate | 219823-47-9 | Empagliflozin | Under development |  |
| 4-Amino-2-fluoro-N-methylbenzamide | 915087-25-1 | Apalutamide / Enzalutamide | Under scale-up |  |
| N-Methyl-2-fluoro-4-(1,1-dimethyl cyanomethyl) aminobenzamide | 915087-32-0 | Apalutamide / Enzalutamide | Under scale-up |  |

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March 2018



Environment, Health, Safety & Sustainability (EHS&S)

We aim to use natural resources efficiently and minimize the environmental impacts of our activities and products during their life cycles.

- ISO 14001 and OHSAS 18001 certified facility.
- Multiple effect evaporator and reverse osmosis facility.
- Recycle waste water treatment facility aiming towards ZERO discharge.
- HAZOP studies of processes after development.
- Emergency response measures to control and limit the impact of incidents.
- Compliant with state & local EHS regulations.
- EHS practices approved by global pharmaceutical companies.
- Member of EcoVadis and CDP Supply Chain Program.

We are committed to

Manufacture and supply safe and high quality products to meet customers' needs and expectations.

- Provide comfortable and safe workplace for employees as well as our associates and third party personnel.
- Enhance quality, environment, health and safety standards.
- Strengthen our Corporate Social Obligation (CSO) initiatives.

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