



Dependable Partners for  
Development with Growth

OUR CHEMISTRY, **OUR SUCCESS**

## 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 galon) along with strong Research & Development capabilities strategically located in the industrial park of Ankleshwar, Gujarat.

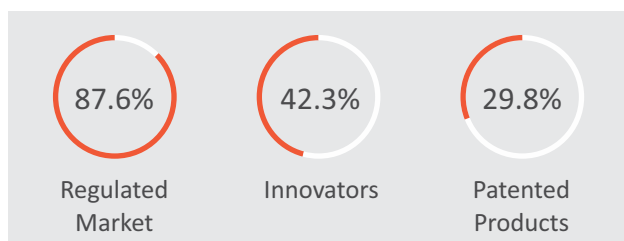
We are a 100% EOU (Export Oriented Unit) engaged in manufacturing and exports of advanced drug intermediates and Active Pharma Ingredients (APIs). We are a specialized Pharma company focusing on the niche therapeutic areas of CNS, ARVs and Controlled Substances having tremendous future growth potential. 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, COFEPRIS, WHO-GMP and Japanese MOH accredited company having certifications of ISO 9001, ISO 14001 and ISO 45001. Silver category company in EcoVadis - 2018 and have Integrated SAP system in place. While over 85% 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.
- I 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 customer’s 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.

## Facility at a glance

- 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 -90°C to +220°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 L to 3000 L volume
- Air Jet mill Micronizer and Multi-mill
- Purified water system to meet current USP quality



## Research & Development

- Specialization in central nervous system, cardio-vascular, anti-diabetic, anti-coagulants & controlled substances
- Expertise in patent scanning & developing non-infringing processes
- Development & Validation of test methods and Genotoxic Impurities evaluation
- Collaborative Programs under confidentiality agreements

## Capabilities - Complex Chemistry

### Core

Acylation and Alkylation

Asymmetric transformation

Chiral separations

Coupling reaction (Heck, Stille, Suzuki)

Cyclization

Oxidation (Peracetic acid)

Reductions - by chemical and catalytical methods

Reductive Amination

Bromination

Chlorosulfonation

Hydrolysis

Phase Transfer Catalysis

Epoxidation

Friedel-Craft

Grignard

Sandmeyer reaction

Solid distillation (Upto 0.01 torr)

Ullmann Reaction

Willgerodt Reaction

Azide synthesis

Ritter reaction

Decarboxylation

## Compliance Trail



2010 Onwards



2010, 2014 & 2017



2017



2014



2018



2020



## Active Pharma Ingredients (APIs)

Product	Status	Pharmacopeia	CAS No.	Therapeutic Use
Apixaban	DMF*	In-house	503612-47-3	Anticoagulant
Aripiprazole	USDMF, CEP, KDMF	USP/EP	129722-12-9	Anti-depressant/Anti-psychotic
Atomoxetine HCl	CEP, USDMF, TDMF, IDL, CA-DMF	USP/EP	82248-59-7	Attention Deficit Hyperactivity Disorder (ADHD)
Betahistine Dihydrochloride	CEP, TDMF, CA-DMF, ANVISA, Jordan, Thailand DMF	USP/BP/EP/IP	5579-84-0	Anti-Vertigo
Clozapine	USDMF, CEP*, CA-DMF	USP/EP/IP	5786-21-0	Anti-psychotic
Dapagliflozin propanediol monohydrate	USDMF	In-house	960404-48-2	Anti-diabetic
Dapsone	DMF*	USP/EP/IP	80-08-0	Anti fungal, Anti acne, Anti-leprosy
Dexmethylphenidate HCl	Tech pack	In-house	19262-68-1	Attention Deficit Hyperactivity Disorder (ADHD)
Empagliflozin	Tech pack	In-house	864070-44-0	Anti-diabetic
Eslicarbazepine Acetate	USDMF	In-house/IP	236395-14-5	Anti-epileptic
Felbinac	EDMF	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*, EDMF	EP	7104-38-3	Anti-psychotic
Lurasidone HCl	USDMF	In-house	367514-88-3	Anti-psychotic
Memantine HCl	USDMF, AUSDMF, KDMF, EDMF	USP/IP	41100-52-1	Alzheimer Disease
Methylphenidate HCl	CEP	USP/EP	298-59-9	Attention Deficit Hyperactivity Disorder (ADHD)
Mirabegron	USDMF	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
Pirfenidone	USDMF & CEP	EP/IP	53179-13-8	Anti-Inflammatory / Anti-Rheumatic
Quetiapine Fumarate	USDMF, AUSDMF, CEP & KDMF, CADMF	USP/EP	111974-72-2	Anti-psychotic
Rivaroxaban	USDMF, EDMF, CA-DMF, TDMF	In-house	366789-02-8	Anti-coagulant
Ticagrelor	Tech pack	In-house/IP	274693-27-5	Platelet aggregation inhibitor
Zonisamide	USDMF, JDMF*, Indonesia DMF	USP, JP	68291-97-4	Anti-convulsant

### Product under development / evaluation

Cannabidiol	Under Development	In-house	13956-29-1	Anti-Epileptics
Darunavir (Amorphous)	Under Development	In-house	206361-99-1	Antiretroviral
Laninamivir octanoate monohydrate	Under Development	In-house	203120-46-1	Influenza antiviral
Maraviroc	Under Development	In-house	376348-65-1	Antiretroviral
Memantine base	Under Development	In-house	19982-08-02	Alzheimer Disease
Ranolazine	Under development	In-house	95635-55-5	Cardiovascular
Dabigatran Etxilate mesylate	Under Evaluation	In-house	872728-81-9	Anti-Coagulant
Darunavir ethanolate	Under Evaluation	In-house	635728-49-3	Treatment of AIDS and HIV infections
Ivabradine HCl	Under Evaluation	In-house	148849-67-6	Cardiovascular
Miglustat	Under Evaluation	In-house	72599-27-0	Gaucher Disease
Solifenacin Succinate	Under Evaluation	EP/USP	242478-38-2	Urologicals

\* Under filing

October 2019

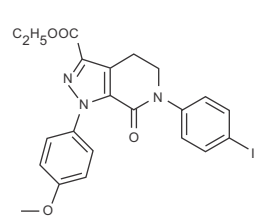
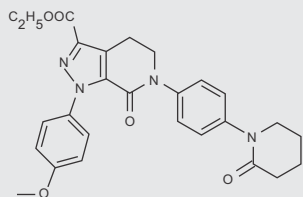
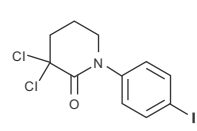
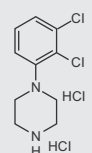
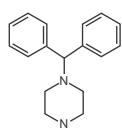
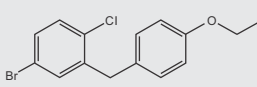
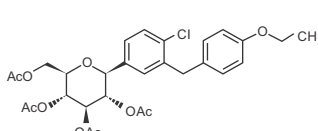
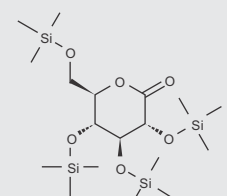
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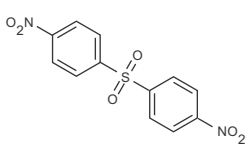
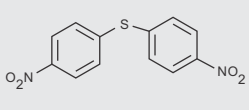
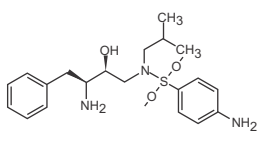
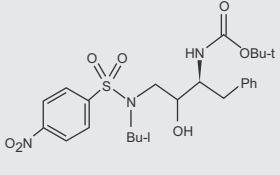
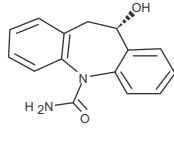
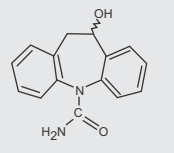
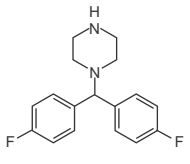
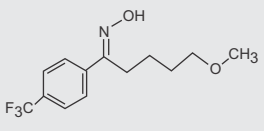
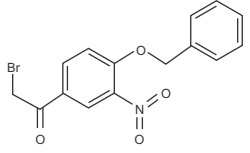
The therapeutic use shown against each product is indicative only and is not for advertising ZCL products.

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

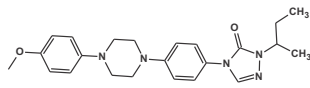
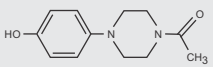
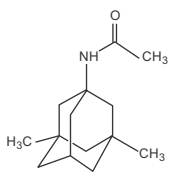
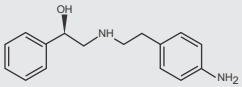
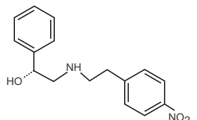
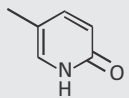
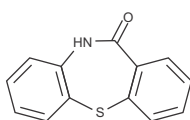
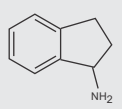
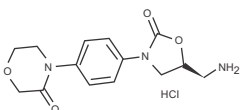
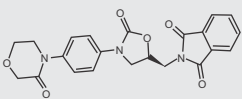
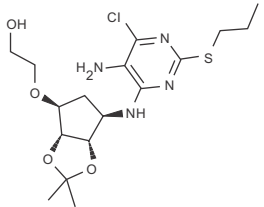
## Advanced Intermediates

Product	CAS No.	End Use	Structure
Ethyl 6-(4-iodophenyl)-1-(4-methoxy phenyl)-7-oxo-4,5,6,7-tetrahydro-1H-pyrazolo[3,4-c]pyridine-3-carboxylate	473927-64-9	Apixaban	
Ethyl 1-(4-Methoxyphenyl)-7-oxo-6-(4-(2-oxopiperidin-1-yl)phenyl)-4,5,6,7-tetrahydro-1H-pyrazolo[3,4-c]pyridine-3-carboxylate;	503614-91-3	Apixaban	
3, 3-dichloro-1-(4-iodophenyl) piperidin-2-one	545445-10-1	Apixaban	
1-(2,3-Dichlorophenyl) Piperazine HCl	119532-26-2	Aripiprazole	
N-Benzhydrylpiperazine	841-77-0	Cinnarizine	
5-Bromo-2-chloro-4'ethoxydiphenylmethane	461432-23-5	Dapagliflozin propanediol	
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	
2,3,4,6-tetra-O-trimethylsilyl-β-D-glucolactone	32384-65-9	Dapagliflozin, Empagliflozin	

## Advanced Intermediates

Product	CAS No.	End Use	Structure
4,4'-sulfonylbis(nitrobenzene)	1156-50-9	Dapsone	
Bis(4-nitrophenyl)sulfane	1223-31-0	Dapsone	
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-[(2methylpropyl)[(4-nitrophenyl)sulfonyl]amino]-1-(phenylmethyl)propyl]-,1,1-dimethylethylester	191226-98-9	Darunavir, Fosamprenavir	
(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	
4,4'-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

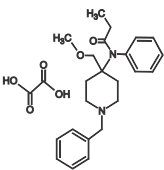
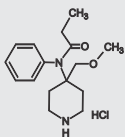
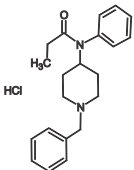
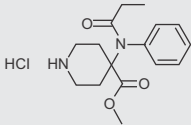
Product	CAS No.	End Use	Structure
2,4-Dihydro-4-[4-[4-(4-methoxyphenyl)-1-piperazinyl]phenyl]-2-(1-methyl propyl)-3H-1,2,4-triazol-3-one	252964-68-4	Itraconazole	
1-Acetyl-4-(4-hydroxyphenyl) piperazine	67914-60-7	Ketoconazole	
1-Acetamido 3,5-dimethyl Adamantane*	19982-07-1	Memantine	
(1R)-2-[[2-(4-aminophenyl)ethyl]amino]-1-phenylethanol	391901-45-4	Mirabegron	
(1R)-2-[[2-(4-nitrophenyl)ethyl]amino]-1-phenylethanol	223673-34-5	Mirabegron	
5-methylpyridin-2(1H)-one/2-Hydroxy-5-methylpyridine	1003-68-5	Pirfenidone	
Dibenzo [b, f] [1, 4] thiazepin-11(10H)-one	3159-07-7	Quetiapine fumarate	
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	
2-(((3aR,4S,6R,6aS)-6-((5-amino-6-chloro-2-(propylthio)pyrimidin-4-yl)amino)-2,2-dimethyltetrahydro-3aH-cyclopenta[d][1,3]dioxol-4-yl)oxy)ethanol	376608-74-1	Ticagrelor	

\*USDMF available

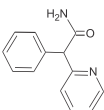
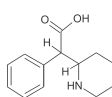
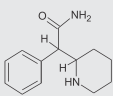
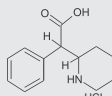
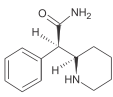
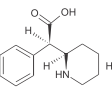
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## Intermediates for controlled substances

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 & Base	84196-16-7 & 61086-18-8	Alfentanil & Sufentanil	
N-(1-Benzylpiperidin-4-yl)-N-phenylpropanamide Hydrochloride	5156-58-1	Fentanil	
Methyl 4-(phenyl-propionyl-amino)-piperidine-4-carboxylate HCl	61085-87-8	Remifentanil	

## Methylphenidate 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 HCl*	741705-70-4	

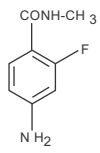
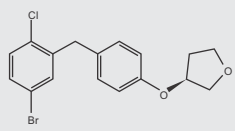
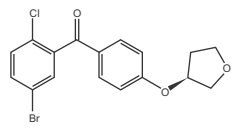
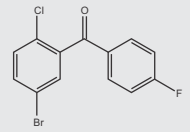
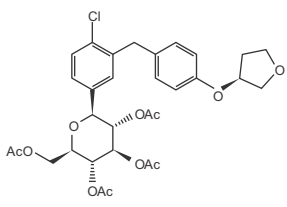
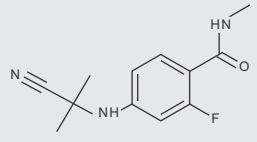
\*USDMF available

October 2019

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## Under Scale-up / New Development

Product	CAS No.	End Use	Status	Structure
4-Amino-2-fluoro-N-methylbenzamide	915087-25-1	Apalutamide, Enzalutamide	Under scale-up	
(3S)-3-[4-[(5-Bromo-2-chlorophenyl)methyl]phenoxy]tetrahydrofuran	915095-89-5	Empagliflozin	Under Scale-up	
(S)-(5-bromo-2-chlorophenyl)(4-((tetrahydrofuran-3-yl)oxy)phenyl)methanone	915095-84-0	Empagliflozin	Under scale-up	
(5-bromo-2-chlorophenyl)(4-fluorophenyl)methanone	915095-85-1	Empagliflozin	Under scale-up	
(2R,3R,4R,5S,6S)-2-(acetoxymethyl)-6-(4-chloro-3-(4-(((S)-tetrahydrofuran-3-yl)oxy)benzyl)phenyl)tetrahydro-2H-pyran-3,4,5-triyl triacetate	915095-99-7	Empagliflozin	Under scale-up	
N-Methyl-2-fluoro-4-(1,1-dimethylcyanomethyl)aminobenzamide	915087-32-0	Enzalutamide	Under scale-up	

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## 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 ISO 45001 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.
- Silver Category Member in EcoVadis - 2018

## We are committed to

Manufacture and supply safe and high quality products to meet customer's 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 Responsibility (CSR) initiatives.

### Registered Office

#### ZCL Chemicals Ltd.

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### Manufacturing

#### ZCL Chemicals Ltd.

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