







## Geographical spread:

Established Markets: 94%

Emerging Markets (Including India): 6%

#### **About Us**

ZCL Chemicals Ltd is one of the fastest growing Pharmaceutical companies in India that combines the power of Science & Technology. Established in 1991, ZCL Chemicals Ltd (ZCL) is Head quartered in Mumbai. The cGMP-manufacturing facility and state-of-the art R&D Center are located in the Industrial park of Ankleshwar in Gujarat State.

Develops and manufactures Active Pharmaceutical Ingredients (APIs) & Intermediates and offers Contract Manufacturing and other services.

An ISO 9001, ISO 14001 and OHSAS 18001 certified company with the manufacturing facility successfully inspected/ audited by the US FDA (2010 and 2014), KFDA (2014), WHO-GMP and some of the leading Pharmaceutical companies.

### Manufacturing

Strategically located at Ankleshwar, Gujarat which is 192 miles/320 km North of Mumbai.

- Three Multi-purpose cGMP Manufacturing plants
- Installed Reaction capacity 107 KL; 21 Stainless Steel reactors, 22 Glass Lined reactors ranging from 100 L to 8,000 L
- 16 Centrifuges Stainless Steel and halar-coated
- 14 Dryers RCVD, VTD, FBD, TD and Nauta
- Reaction Temperature ranging from -25 deg C to +220 deg C
- High vacuum distillation at 1 Torr and high pressure reactions at 5 Bar

## Customer-centric approach

ZCL's customer-centric approach has won the status of preferred supplier and strategic partner from Global Pharmaceutical companies. 70% of revenue share is from the business with the major Innovators.

## **New API facility**

ZCL is on an expansion mode to set up a modern multipurpose, multi-product API in the existing site at Ankleshwar (Gujarat, India). The facility will take care of small trials up to full commercial scale production for partners/customers world-wide.

To be operational by May 2016

- The state-of-the-art plant is designed to conform to cGMP as well as US FDA, EU GMP, TGA, ANVISA, PMDA, WHO guidelines besides meeting local FDA guidelines.
- The plant is also designed to meet OHSAS and ISO guidelines on EHS and Quality.
- Production Capacity: 104 KL
- Three dedicated Streams of final Crystallization with Powder Processing areas
- Operating temperature: -70 deg C to +220 deg C



### **Reaction Capabilities**

- Acylation and Alkylation
- Asymmetric transformation
- Azide synthesis
- Bromination
- Chiral separations
- Chlorosulfonation
- Coupling reaction (Heck, Stille)
- Cyclization

- Decarboxylation
- Epoxidation
- Friedel-Craft
- Grignard
- Hydrolysis
- Oxidation
- Phase Transfer Catalysis

- Reductions by chemical and catalytical methods
- Reductive Amination
- Ritter reaction
- Sandmeyer reaction
- Solid distillation (Upto 0.01 torr)
- Ullmann Reaction
- Willgerodt 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 track record for developing complex and quality products
- Expertise in developing non-infringing processes (20 process patents)
- Collaborative research and development under confidentiality agreements
- Seamless interface with operations resulting in credible deliverance





## **Quality Systems**

- Successfully inspected by USFDA 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	Dharmacachaia	CAS No.	Therapeutic Use
	Status	Pharmacoepeia		
Alprazolam	Tech pack	USP/EP	28981-97-7	Anxiolytic
Aripiprazole	USDMF & CEP	USP/EP	129722-12-9	Anti-depressant/Anti-psychotic
Atomoxetine HCI	CEP+, USDMF & TDMF	USP/EP	82248-59-7	Attention Deficit Hyperactivity Disorder (ADHD)
Betahistine Dihydrochloride <sup>^</sup>	CEP	USP/BP/EP/IP	5579-84-0	Vertigo
Betahistine Mesylate	Tech pack	EP/JP/IP	54856-23-4	Vertigo
Cilostazol	Tech pack	USP	73963-72-1	Anti-thrombotic, Anti-platelet agent
Clozapine	USDMF* & CEP*	USP/EP/IP	5786-21-0	Anti-psychotic
Dexmethylphenidate HCl	Tech pack	Inhouse	19262-68-1	Attention Deficit Hyperactivity Disorder (ADHD)
Felbinac^	EDMF* & JDMF*	BP/EP/JP	5728-52-9	Anti-inflammatory
Flupirtine Maleate	Tech pack	EP	75507-68-5	Analgesic
Fluvoxamine Maleate^	CEP, USDMF & TDMF	USP/BP/EP/IP/JP	61718-82-9	Anti-depressant
Guanfacine HCl	Tech pack	USP	29110-48-3	Attention Deficit Hyperactivity Disorder (ADHD), Hypertension
Levomepromazine Maleate^	CEP*	EP	7104-38-3	Anti-psychotic
Loxoprofen sodium	Tech pack	JP	80382-23-6	Anti-inflammatory, Analgesic
Memantine HCI^	USDMF	USP	41100-52-1	Alzheimer Disease
Methylphenidate HCl	Tech pack	USP/EP	298-59-9	Attention Deficit Hyperactivity Disorder (ADHD)
Modafinil	Tech pack	USP/EP	68693-11-8	CNS Stimulant
Olanzapine	USDMF*	USP	132539-06-1	Anti-psychotic
Oxazepam	Tech pack	EP	604-75-1	Anxiolytic
Quetiapine Fumarate	USDMF* & CEP*	USP/EP	111974-72-2	Anti-psychotic
Trifluoperazine HCl	Tech pack	USP/BP/EP/IP	440-17-5	Anti-psychotic
Zaltoprofen	KDMF	JP	74711-43-6	Anti-inflammatory
Zonisamide	Tech pack	USP/EP	68291-97-4	Anti-convulsant
Under Scale-up/New Developn	nent			
Bromazepam	Under Scale up	EP	1812-30-2	Anxiolytic
Lurasidone HCl	Under Scale up	In-house	367514-88-3	Anti-psychotic
Rivaroxaban	Under Scale up	In-house	366789-02-8	Anti-coagulant
Dapagliflozin	Under development	In-house	461432-26-8	Anti-diabetic
Empagliflozin	Under development	In-house	864070-44-0	Anti-diabetic
Eslicarbazepine Acetate	Under development	In-house	236395-14-5	Anti-epileptic
Mirabegron	Under development	In-house	223673-61-8	Treatment of overactive bladder
Pirfenidone	Under development	In-house	53179-13-8	Anti-Inflammatory / Anti-Rheumatic

February 2016



# **Active Pharma Ingredients (APIs) for North America**

Product	Status	Pharmacoepeia	CAS No.	Therapeutic Use
Aripiprazole	USDMF* & EDMF*	USP	129722-12-9	Anti-depressant/Anti-psychotic
Atomoxetine HCl	USDMF & CEP	USP/EP	82248-59-7	Attention Deficit Hyperactivity Disorder (ADHD)
Betahistine Dihydrochloride ^	CEP#	USP/BP/EP/IP	5579-84-0	Vertigo
Cilostazol	Tech pack	USP	73963-72-1	Anti-thrombotic, Anti-platelet agent
Clozapine	CEP*	USP/EP	5786-21-0	Anti-psychotic
Felbinac^	EDMF* & JDMF*	BP/EP/JP	5728-52-9	Anti-inflammatory
Fluvoxamine Maleate^	CEP, USDMF & TDMF	USP/BP/EP/IP/JP	61718-82-9	Anti-depressant
Guanfacine HCl	Tech pack	USP	29110-48-3	Attention Deficit Hyperactivity Disorder (ADHD) Hypertension
Levomepromazine Maleate ^	CEP*	EP	7104-38-3	Antipsychotic
Memantine HCI	USDMF	USP	41100-52-1	Alzheimer Disease
Modafinil	Tech pack	USP/EP	68693-11-8	CNS Stimulant
Olanzapine	USDMF*	USP	132539-06-1	Anti-psychotic
Oxazepam	Tech pack	EP	604-75-1	Anxiolytic
Quetiapine Fumarate	USDMF* & CEP*	USP/EP	111974-72-2	Anti-psychotic
Trifluoperazine HCl	Tech pack	USP/BP/EP/IP	440-17-5	Anti-psychotic
Zonisamide	Tech pack	USP/EP	68291-97-4	Anti-convulsant
Under Scale-up/New Developm	ent			
Lurasidone hydrochloride	Under Scale up	In-house	367514-88-3	Anti-psychotic
Rivaroxaban	Under Scale up	In-house	366789-02-8	Anti-coagulant
Dapagliflozin	Under development	In-house	461432-26-8	Anti-diabetic
Empagliflozin	Under development	In-house	864070-44-0	Anti-diabetic
Eslicarbazepine Acetate	Under development	In-house	236395-14-5	Anti-epileptic
Mirabegron	Under development	In-house	223673-61-8	Treatment of overactive bladder
Pirfenidone	Under development	In-house	53179-13-8	Anti-Inflammatory / Anti-Rheumatic

<sup>\*</sup> Under filing # NDC Number available ^ Written confirmation available

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



## **Advanced Intermediates**

Product	CAS No.	End Use	Structure
7-Hydroxy-3, 4-dihydroquinolin-2(1H)-one	22246-18-0	Aripiprazole	ON OH
(1H)-7-(4'-bromobutoxy)-3,4-dihydro-2-quinolinone	1297225-34-5	Aripiprazole	o N H O N Br
1-(2,3-Dichlorophenyl) Piperazine HCl	119532-26-2	Aripiprazole	CI CI N HCI N HCI
3-(methylamino)-1-phenylpropan-1-ol	42142-52-9	Atomoxetine Fluoxetine Nisoxetine	OH CH <sub>3</sub>
Chloromethyl cyclopropane	5911-08-0	Buprenorphine	CI
Bromomethyl cyclopropane	7051-34-5	Buprenorphine	Br
N-Benzhydrylpiperazine	841-77-0	Cinnarizine	N N N N N N N N N N N N N N N N N N N
Benzenesulfonamide, 4-amino-N-[(2R,3S)-3-amino-2-hydroxy-4-phenylbutyl]-N-(2-methylpropyl)	169280-56-2	Darunavir	OH CH <sub>3</sub> OH CH <sub>3</sub> NH <sub>2</sub> NH <sub>2</sub>
Carbamic acid, N-[(1S,2R)-2-hydroxy-3- [(2-methylpropyl)[(4-nitrophenyl)sulfonyl]amino]-1- (phenylmethyl)propyl]-,1,1-dimethylethylester	191226-98-9	Darunavir	O O HN OBU-t ODAN Ph
Benzenesulfonamide, N-[(2R,3S)-3-amino-2-hydroxy-4-phenylbutyl]-N-(2-methylpropyl)-4-nitro	251105-80-3	Darunavir	OH CH <sub>3</sub> OH N <sub>O</sub> NH <sub>2</sub> NO <sub>2</sub>
N-(1,4-Benzodioxan-2-carbonyl)-piperazine	70918-00-2	Doxazosin	O NH
4-Hydroxy-3, 5-dimethyl benzonitrile	4198-90-7	Etravirine	H <sub>3</sub> C CH <sub>3</sub>



# **Advanced Intermediates**

Product	CAS No.	End Use	Structure
4,4'-Difluorobenzhydrylpiperazine	27469-60-9	Flunarizine	H N N F
(1E)-N-Hydroxy-5-Methoxy-1-(4- Trifluoromethylphenyl)Pentan-1-Imine	61747-22-6	Fluvoxamine	F <sub>3</sub> C OH
2-Bromo-4'-benzyloxy-3'-nitroacetophenone	43229-01-2	Formoterol	Br O N O
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	ltraconazole	>
1-Acetyl-4-(4-hydroxyphenyl) piperazine	67914-60-7	Ketoconazole	HO-N-N-CH <sub>3</sub>
(S)-1-chloro-3-[(4-chloro-E-benzylidene)-amino]-propan-2-ol	1345879-87-9	Linezolid	OH CI N
2-{4-[(2-oxocyclopentyl)methyl]phenyl}propanoic acid	68767-14-6	Loxoprofen Sodium	соон
2-Methyl-10H-thieno[2,3-b][1,5] benzo diazepine-4-amine HCl	138564-60-0	Olanzapine	NH <sub>2</sub> .HCl
5-methyl-2-(2-nitrophenylamino) thiophene-3-carbonitrile	138564-59-7	Olanzapine	NC NC CH <sub>3</sub>
N-Isopropyl-4-(4-hydroxyphenyl)-piperazine	67914-97-0	Terconazole	OH N N N CH <sub>3</sub>
2-(Trifluoromethyl)-phenothiazine	92-30-8	Trifluoperazine	S N H F F



## 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	H <sub>3</sub> C O=
1-(2-bromoethyl)-4-ethyl-1,4-dihydro-5H- tetrazol-5- one	84501-67-7	Alfentanil	H <sub>3</sub> C N N Br
N-[(4-methoxymethyl-1-benzyl)-4-piperidinyl] -N-phenyl propanamide monohydrochloride	84255-05-0	Alfentanil & Sufentanil	CH <sub>3</sub> N HCI
N-[4-(methoxymethyl)-piperidine-4-yl]-N-phenyl propanamide monohydrochloride	84196-16-7	Alfentanil & Sufentanil	CH <sub>3</sub> O CH <sub>3</sub> HCI
N-(1-Benzylpiperidin-4-yl)-N-phenylpropanamide Hydrochloride	5156-58-1	Fentanil	CI-H
N-[(4-Methoxymethyl)-4-piperidinyl]-N-phenyl propanamide	61086-18-8	Sufentanil	CH <sub>3</sub> O CH <sub>3</sub>

# **Methyl Phenidate Series**

Product	CAS No.	Structure
Phenyl-(2-pyridyl acetamide)	7251-52-7	H <sub>2</sub> N = O
Phenyl-2-(2'-piperidyl)acetamide	19395-39-2	O NH <sub>2</sub>
Threo phenyl-2-piperidyl acetamide*	50288-62-5	O NH <sub>2</sub> H <sub>1/1,1</sub> H <sup>3''</sup> HN
dl-threo ritalinic acid*	19395-41-6	O OH H HN
d-threo ritalinic acid hydrohloride*	82993-81-5	H <sub>I/m</sub> HCI

\*USDMF available February 2016



# **Under Scale-up / New Development**

Product	CAS No.	End Use	3-4 Months	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	Aco OAc CI O CH3
α-D-Glucopyranoside, methyl 1-C- [4-chloro-3-[(4-ethoxyphenyl)methyl] phenyl]-, 2,3,4,6-tetraacetate	714269-58-6	Dapagliflozin propanediol	Under development	AcO CH <sub>3</sub> AcO CH <sub>3</sub> OAc
(10S)-10,11-Dihydro-10-hydroxy-5H-dibenz[b,f]azepine-5-carboxamide	104746-04-5	Eslicarbazepine acetate	Under development	H <sub>2</sub> N OH
10,11-Dihydro-10-hydroxy-5H-dibenz [b,f]azepine-5-carboxamide	29331-92-8	Eslicarbazepine acetate	Under development	OH H <sub>2</sub> N O
1-Bromo-3,5-dimethyladamantane	941-37-7	Memantine HCl	Under development	H <sub>3</sub> C CH <sub>3</sub>
2-Chloro-1-Dimethylaminopropane HCl	4584-49-0	Methadone	Under development	H <sub>3</sub> C CH <sub>3</sub> HCI
1R)-2-{[2-(4-aminophenyl)ethyl]amino} -1-phenylethanol hydrochloride	521284-22-0	Mirabegron	Under development	OH NH NH NH <sub>2</sub>
(1R)-2-{[2-(4-nitrophenyl)ethyl]amino} -1-phenylethanol	223673-34-5	Mirabegron	Under development	HONH NO2
2-(2-[3-(3-[2-(7-chloroquinolin-2-yl) ethenyl) phenyl)-3-hydroxy-n-propyl] phenyl)-2-propan-1-ol	142569-70-8	Montelukast	Under scale-up	HO HO CH <sub>3</sub>
1-Aminoindan	34698-41-4	Rasagiline	Under scale-up	NH <sub>2</sub>
4-{4-[(5S)-5-(aminomethyl)-2-oxo-1,3-oxazolidin-3-yl]phenyl}morpholin-3-one hydrochloride	898543-06-1	Rivaroxaban	Under scale-up	O N HCI NH2
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	Under scale-up	
1,2,4-Triazolo[4,3-a]pyridin-3(2H)-one	6969-71-7	Trazodone	Under scale-up	N NH



### 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 Big Pharmaceutical companies.

Member of EcoVadis, Rx-360 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.

### **Registered Office**

#### **ZCL** Chemicals Ltd.

C Wing, 819-821, 215 Atrium, Andheri Kurla Road, Chakala, Andheri (E), Mumbai- 400093, India Tel: +91 22 61539999

Fax: +91 22 61539997

Email: enquiries@zclchemicals.com

#### Manufacturing

#### **ZCL Chemicals Ltd.**

Plot No. 3102/B, G.I.D.C., Ankleshwar - 393 002 Gujarat - India.