



**Orchid Chemicals & Pharmaceuticals Ltd.**

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**Orchid Chemicals  
& Pharmaceuticals Ltd.**  
Shaping A Dream

- One of India's leading vertically integrated pharmaceutical companies with credentials in research, manufacturing and marketing of oral and injectable antibiotic APIs and oral generics.
- Our operations cover the entire pharmaceutical value chain from discovery to delivery
- State-of-the-art API and formulations manufacturing facilities with approvals from leading global agencies including US FDA, UK MHRA, EDQM, PMDA, DMA, ANVISA, KFDA, TGA, ISO 9001:2008, ISO 14001: 2004, OHSAS 18000: 2007, WHO GMP providing a global competitive edge.
- Reliable track record of regulatory filings and large product pipeline with total addressable market size of US\$65-70 billion
- We possess a footprint across 70 countries through direct presence, alliances and partnerships
- Our CRAMS value proposition encompasses the value chain – bioinformatics to commercial supply – in multiple therapeutic areas across all segments of the pharmaceutical value chain.



# APIs

Specialises in niche APIs for injectables and oral that have limited competition due to high entry barriers (complex chemistry, multi-step manufacturing and a challenging patent environment)

## Cephalosporins API List

### *Cephalosporins - Orals*

Product	Pharmacopeia	US DMF	EDMF	CoS
Cefalexin	USP / EP / BP / JP	√	√	√
Cefadroxil	USP / EP / BP / JP	√	√	√
Cefixime	USP / EP / BP	√	√	√
Cefradine	USP / EP / BP	√	√	√
Cefuroxime Axetil (Amorphous)	USP / EP / BP / JP	√	√	√
Cefuroxime Axetil (Crystalline)	USP	√	√	-
Cefprozil	USP	√	√	-
Cefditoren Pivoxil (Amorphous)	In-house	√	√	-
Cefditoren Pivoxil (Crystalline)	USP / JP	-	√	-
Cefdinir	USP / JP	√	√	-
Cefpodoxime Proxetil	USP / EP / JP	√	-	-
Ceftibuten	In-house	TIP	√	-
Cefcapene Pivoxil Hydrochloride	JP	TIP	TIP	-
Ceftamet Pivoxil	JP	TIP	TIP	-

### *Cephalosporins - Injectables*

Product	Pharmacopeia	US DMF	EDMF	CoS
Cefotaxime Sodium (Sterile)	USP / EP / BP / JP	√	√	√
Ceftriaxone Sodium (Sterile)	USP / EP	√	√	√

Product exploitation, including development, sales and offer for sales are performed where permissible by patent law. This presentation is not and should not constitute as an offer for sale in territories where it is not permitted by law.

US DMF - US Drug Master File  
CoS - Certificate of Suitability  
USP - United States Pharmacopeia  
JP - Japanese Pharmacopeia

TIP - Technical Information Package  
EP - European Pharmacopeia  
BP - British Pharmacopeia  
EDMF - European Drug Master File

*Cephalosporins - Injectables*

Product	Pharmacopeia	US DMF	EDMF	CoS
Ceftazidime Pentahydrate with Sodium Carbonate for Injection	USP / EP / BP / JP	√	√	√
Cefazolin Sodium (Sterile)	USP / EP / BP / JP	√	√	√
Cefoxitin Sodium (Sterile)	USP / EP / BP	√	√	√
Cefepime + Arginine (Sterile)	USP	√	√	-
Cefpirome Sulphate	In-house	-	√	-
Cefuroxime Sodium (Sterile)	USP / EP	√	√	√
Ceforanide + L-Lysine	USP	-	√	-
Cefalothin Sodium Buffered (Sterile)	EP	-	√	-
Ceftizoxime Sodium (Sterile)	USP	-	√	-
Cefoperazone Sodium (Sterile)	JP / EP	TIP	TIP	-
Cefotiam Hexetil	JP	TIP	TIP	-
Cefotiam Hydrochloride	JP	TIP	TIP	-
Cefozopran Hydrochloride	JP	TIP	TIP	-

*Veterinary Products*

Product	Pharmacopeia	US DMF	EDMF	CoS
Cefalonium	BP	-	√	-
Cefquinome Sulphate (Sterile)	In-house	-	√	-
Ceftiofur Hydrochloride	USP	TIP	√	-
Ceftiofur Sodium (Sterile)	In-house	√	√	-

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## Non-Antibiotic API List

Product	Pharmacopeia	US DMF	EDMF	CoS
Aripiprazole	EP	√	√	-
Eszopiclone	In-House	√	-	-
Felodipine	USP / EP / BP	√	-	-
Gemifloxacin Mesylate	In-House	√	-	-
Granisetron Hydrochloride	USP / EP / BP	√	-	√
Ibandronate Sodium	In-House	√	√	-
Memantine Hydrochloride	In-House	√	√	-
Modafinil	USP / EP	√	√	√
Naratriptan Hydrochloride	USP	√	√	-
Olanzapine	USP / EP	√	-	-
Pramipexole Dihydrochloride	USP / EP	√	√	-
Quetiapine Fumarate	In-House	√	-	-
Rasagiline Mesylate	In-House	√	√	-
Rivastigmine Tartrate	USP / EP	√	√	-
Sumatriptan Succinate	USP / EP / BP	√	√	√
Tadalafil	EP	√	√	-
Terbinafine Hydrochloride	USP / EP / BP	√	√	√
Zaleplon	USP	√	-	-

## Non - Antibiotic API Pipeline

Cinacalcet  
Lurasidone  
Silodosin  
Solifenacin Succinate

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# FDFs

We stand for niche global leadership in our operating domains. This is reflected in our ability to develop and manufacture products across therapeutic categories. We are respected for our competence in aseptic manufacture, complex chemistry and challenging formulations.

## EUCTD Dossiers Available

### *Non-Antibiotics*

Product	Dosage Form	Dosage Strength	Therapeutic Area
Memantine	Tablet	10 mg	Neurology
Rivastigmine	Capsule	1.5, 3, 4.5 & 6 mg	Neurology
Naratriptan	Tablet	2.5 mg	Neurology
Modafinil	Tablet	100 & 200 mg	Psychiatry
Aripiprazole	Tablet	5, 10, 15 & 30 mg	Psychiatry
Rasagiline	Tablet	1 mg	Antiparkinsonian
Granisetron	Tablet	1 & 2 mg	Gastrointestinal
Terbinafine	Tablet	250 mg	Antifungal
Terbinafine	Tablet	250 mg	Antifungal

### *Cephalosporins*

Product	Dosage Form	Dosage Strength	Therapeutic Area
Cefalexin	Capsule	250 & 500 mg	Antibiotic
Cefalexin	Oral Suspension	250mg/5ml	Antibiotic
Cefprozil	Tablet	250 & 500 mg	Antibiotic
Cefprozil	Oral Suspension	250mg/5ml	Antibiotic
Cefixime	Tablet	200 & 400 mg	Antibiotic
Cefixime	Dispersible Tablet	400 mg	Antibiotic
Cefixime	Oral Suspension	100mg/5ml	Antibiotic
Cefpodoxime Proxetil	Tablet	100 & 200 mg	Antibiotic
Cefuroxime Axetil	Tablet	125, 250 & 500 mg	Antibiotic

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OD - Orally Disintegrating ER - Extended Release DR - Delayed Release



## EU CTD Dossiers Pipeline

### Non-Antibiotics

Product	Dosage Form	Dosage Strength	Therapeutic Area
Cetirizine Hydrochloride	Tablet	5 & 10 mg	Antiallergics
Roflumilast	Tablet	0.5 mg	Respiratory
Cinacalcet	Tablet	30, 60 & 90 mg	Calcimimetic
Dexlansoprazole	DR Capsule	30 & 60 mg	Gastrointestinal
Pantoprazole	DR Tablet	20 & 40 mg	Gastrointestinal
Felodipine	ER Tablet	2.5, 5 & 10 mg	Cardiovascular
Risedronate Sodium	Tablet	30 & 35 mg	Osteoporosis
Risedronate Sodium	DR Tablet	35 mg	Osteoporosis
Ibandronate Sodium	Tablet	150 mg	Osteoporosis
Silodosin	Capsule	4 & 8 mg	Urology
Solifenacin Succinate	Tablet	5 & 10 mg	Urology
Fesoterodine	ER Tablet	4 & 8 mg	Urology
Sumatriptan Succinate	Tablet	25, 50 & 100 mg	Neurology
Zaleplon	Capsule	5 & 10 mg	Neurology
Zolmitriptan	Tablet	2.5 & 5 mg	Neurology
Droxidopa	Capsule	100, 200 & 300 mg	Neurology
Eszopiclone	Tablet	1, 2 & 3 mg	Neurology
Pramipexole Dihydrochloride	Tablet	0.125, 0.25, 0.5, 0.75, 1 & 1.5 mg	Parkinsonism
Ropinirole Hydrochloride	Tablet	0.25, 0.5, 1, 2, 3, 4 & 5 mg	Parkinsonism
Lurasidone	Tablet	20, 40, 60, 80 & 120 mg	Psychiatry
Olanzapine	OD Tablet	5, 10, 15 & 20 mg	Psychiatry
Olanzapine	Tablet	2.5, 5, 7.5, 10, 15 & 20 mg	Psychiatry

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## EU CTD Dossiers Pipeline

### *Non-Antibiotics*

Product	Dosage Form	Dosage Strength	Therapeutic Area
Vilazodone HCl	Tablet	10, 20 & 40 mg	Psychiatry
Quetiapine Fumarate	Tablet	25, 50, 100, 200, 300 & 400 mg	Psychiatry
Lacosamide	Tablet	50, 100, 150, 200 mg	Anticonvulsant
Eslicarbazepine acetate	Tablet	200, 400, 600, 800 mg	Anticonvulsant
Miltefosine	Capsule	50 mg	Antifungal
Gemifloxacin Mesylate	Tablet	320 mg	Antibacterial
Tapentadol	Tablet	50, 75, 100 mg	Opioid Analgesic
Tapentadol	ER Tablet	25, 50, 100, 150, 200, 250 mg	Opioid Analgesic
Fingolimod Hydrochloride	Capsule	0.5 mg	Immunomodulator
Rivaroxaban	Tablet	2.5, 10, 15, 20 mg	Anticoagulant
Dabigatran mesylate	Capsule	75, 110, 150 mg	Anticoagulant
Varenicline	Tablet	0.5, 1 mg	Nicotine Addiction

### *Cephalosporins*

Product	Dosage Form	Dosage Strength	Therapeutic Area
Cefdinir	Capsule	300 mg	Antibiotic
Cefdinir	Oral Suspension	125mg/5ml & 250mg/5ml	Antibiotic
Ceftibuten	Capsule	200 & 400 mg	Antibiotic
Ceftibuten	Oral Suspension	180mg/5ml	Antibiotic
Cefuroxime Axetil	Oral Suspension	125mg/5ml & 250mg/5ml	Antibiotic
Cefixime	Chewable Tablet	100mg, 150mg & 200 mg	Antibiotic
Cefixime	Capsule	400 mg	Antibiotic

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