

ACTIVE PHARMACEUTICAL INGREDIENTS (APIs)



About Us

Jubilant is a preferred partner of choice across the globe for Innovator and Generic pharmaceutical companies. Our API business has a prominent presence in North America, LATAM, Europe, Japan, APAC, and the Middle East.

World class cGMP manufacturing facility with 6 plants (multi-ton volume), pilot plant (up to 20 kg) and a kilo lab with a total capacity of ~750 KL.



Jubilant offers large portfolio of commercial APIs across CNS, CVS, anti-diabetic, anti-infective, GI & other therapeutic segments.

- Global leader in Carbamazepine, Oxcarbazepine, Pinaverium, Risperidone, Valsartan and Eslicarbazepine.
- Proven expertise to operate large scale chemical operations, which is key to better cost efficiencies
- Diversified & large external customer base to drive growth across multiple regions
- Business sustainability & supply assurance from vertical integration of key APIs
- Excellent compliance track record resulting from multiple inspections by various regulatory bodies
- Jubilant is one of the world's most reputed manufacturers of APIs and we partner with numerous leading drug formulation companies world-wide to fulfill their requirements of high quality APIs at affordable prices.
- As a global market leader in a few APIs, we strive to consolidate our leadership with sizable capacities and dedicated production streams for several high-volume molecules.

API R&D



State of the art R&D centre in India at Nanjangud, Mysuru



Expertise in complex chemistries like Chiral separation, Low Temp reactions, Bio-transformation, Stereo-selective synthesis, Process intensification (continuous flow reactions)



Dedicated DoE/QbD cell for bringing quality and process robustness during the product development.



Team of dedicated scientists including PhDs



Equipped with latest equipments like LC HRMS, NMR, XRD, LCMS, GCMS, ICP-MS, etc.



Experts in polymorphic characterization and contamination, Genotoxic & Carry over studies, Impurity profiling etc.



Our manufacturing site at Nanjangud, Mysuru, India is a state-of-the-art API manufacturing facility, fully compliant with cGMP, quality & safety requirements.



Experienced team of over 900 personnel.



267, 688 sq. mts. site with 33% built-up area, 6 multistream manufacturing blocks and a pilot plant having volumetric capacity of ~750 KL, 18 clean rooms and 170 reactors ranging from 0.1 KL to 15 KL.



GMP Kilo Lab equipped with Hastelloy & Glass reactors for supporting low volume generic and clinical trial APIs

Jubilant's API Portfolio

Our portfolio includes newly-approved molecules which helps our clients to target first wave launch with cost-effective & high-quality products and strengthens our position as their partner of choice. We are highly committed to sustain our longstanding relationship with formulation companies.



FILED & COMMERCIAL APIs

#	API	Therapeutic Category	Indication	US DMF	CEP	JDMF
1	Aprepitant	Gastrointestinal	Nausea & Vomiting	●	●	
2	Aripiprazole	CNS	Anti-psychotic	●	●	
3	Azithromycin Dihydrate	Anti-infective	Anti-infective	●	●	
4	Azithromycin Monohydrate	Anti-infective	Anti-infective	●	●	
5	Carbamazepine	CNS	Anti-epileptic	●	●	
6	Citalopram Hydrobromide	CNS	Anti-depressant	●	●	
7	Dalfampridine	CNS	Multiple Sclerosis	●	▲	
8	Deferasirox	Blood disorder	Chelating Agent	●	▲	
9	Donepezil Hydrochloride (Form I anhydrous)	CNS	Anti-Alzheimer		▲	
10	Donepezil Hydrochloride (Form III)	CNS	Anti-Alzheimer	●		●
11	Escitalopram Oxalate	CNS	Anti-depressant	●	●	
12	Eslicarbazepine Acetate IP	CNS	Anti-epileptic	●	▲	
13	Esomeprazole Mg Amorphous	Gastrointestinal	Anti-ulcerant	●	▲	
14	Esomeprazole Mg Trihydrate	Gastrointestinal	Anti-ulcerant	●	●	
15	Esomeprazole Sodium	Gastrointestinal	Anti-ulcerant	●	▲	
16	Galantamine HBr	CNS	Anti-Alzheimer	●	●	●
17	Irbesartan	CVS	Anti-hypertensive	●	●	
18	Lacosamide	CNS	Anti-epileptic	●	●	
19	Lamotrigine	CNS	Anti-epileptic	●	●	
20	Losartan Potassium IP	CVS	Anti-hypertensive	●	●	●
21	Meclizine HCl	CNS	Motion sickness	●	●	
22	Olanzapine (Form I)	CNS	Anti-epileptic	●	●	
23	Olanzapine (Form II)	CNS	Anti-epileptic	●		●
24	Olmesartan Medoxomil	CVS	Anti-hypertensive	●	●	●
25	Oxcarbazepine	CNS	Anti-epileptic	●	●	
26	Paliperidone Base	CNS	Anti-psychotic	●		

FILED & COMMERCIAL APIs

#	API	Therapeutic Category	Indication	US DMF	CEP	JDMF
27	Paroxetine HCl	CNS	Anti-depressant	●	●	●
28	Pinaverium Bromide	Gastrointestinal	Anti-spasmodic	●	▲	
29	Quetiapine Fumarate	CNS	Anti-psychotic	●	●	
30	Risedronate Sodium	Bone disorder	Anti-osteoporosis	●	●	●
31	Risperidone	CNS	Anti-psychotic	●	●	●
32	Rivastigmine Tartrate	CNS	Anti-Parkinson	●		
33	Rivastigmine Base	CNS	Anti-Parkinson	●		
34	Sitagliptin Phosphate	Anti-diabetic	Anti-diabetic	●	●	
35	Solifenacin Succinate	Genitourinary	Overactive bladder	●	●	
36	Tramadol HCl	Pain Mgmt.	Analgesic	●	●	●
37	Valsartan	CVS	Anti-hypertensive	●	●	●
38	Varenicline Tartrate	Anti-smoking	Anti-smoking	●		
39	Zoledronic acid	Bone disorder	Anti-osteoporosis	●	●	
40	Zolmitriptan	CNS	Anti-migraine	●	▲	●

IP Jubilant's own patent

▲ Only Europe DMF

FILED & CAMPAIGN-BASED APIs

#	API	Therapeutic Category	Indication	US DMF	CEP
1	Apixaban	Blood Disorder	Anti-coagulant	●	
2	Apremilast	Anti-psoriasis	Anti-psoriasis	●	
3	Azilsartan Medoxomil Potassium	CVS	Anti-hypertensive	●	
4	Brexiprazole	CNS	Anti-psychotic	●	
5	Histamine Dihydrochloride	Anti-allergic	Anti-allergic	●	
6	Linezolid [Form I]	Anti-infective	Anti-infective	●	
7	Mirabegron	Overactive bladder	Overactive bladder	●	
8	Pirfenidone	Anti-fibrotic	Anti-fibrotic	●	●
9	Rivaroxaban	Blood Disorder	Anti-coagulant	●	●
10	Vildagliptin	Anti-diabetic	Anti-diabetic	●	

PIPELINE APIs

#	API	Therapeutic Category	Indication	Jubilant Own Patent / Application (s)
1	Edoxaban Tosylate Monohydrate	Blood Disorder	Anti-coagulant	
2	Ivacaftor	Lung Disorder	Cystic Fibrosis	●
3	Safinamide Mesylate	CNS	Anti-Parkinson	●
4	Vortioxetine HBr	CNS	Anti-depressant	●

All supplies and packages will be governed by the patent law of the importing country.

Regulatory Affiliations

We implement the highest levels of regulatory and quality compliance practices in the API industry with a series of successful inspections by various regulatory agencies.



U.S. FDA



EDQM



Health Canada



AFSSAPS
(France)



PMDA (Japan)



TGA (Australia)



MFDS (Korea)



ANVISA
(Brazil)



COFEPRIS
(Mexico)

Key Initiatives

In line with our commitment towards our partners, we are leading various initiatives to reduce costs by continuously streamlining our operations, enhancing yield, on-boarding alternative vendors, de-risking our operations & supply chain and optimising input material costs. Several cost improvement and process innovation programmes are being undertaken for various commercial APIs as a part of product life cycle management. This will help us maintain market share despite increasing competition and pricing pressure.

Jubilant is aggressively working on reducing the dependence on china for raw materials by ramping up domestic capacity and developing reliable local vendors for sustainability & quality. For the critical APIs, the company is aiming to secure the entire value chain through backward integration.

Since FY 2019, nitrosoamine issues related to sartans affected the whole industry. Stringent guidelines and expectation of non-detectable limits

from the U.S. FDA and other regulators impacted the supplies. We diligently worked to meet the expectation of regulatory guidelines by conducting various studies & risk assessment for over 40 APIs, which enabled us to supply key products to the US & Europe markets.

Jubilant's API R&D centre has been relocated to API manufacturing facility at Nanjangud to facilitate seamless technology transfer and provide timely support to the operations team.

Our new product development philosophy is innovation-led affordability and quality-by-design, giving our customers access to cost-effective APIs, while maintaining consistent global quality standards. Aided by strong process and analytical chemistry capabilities, IP and regulatory expertise, we will continue to focus on developing new products and filings for key markets.



Global Presence in
50+ Markets



Global Leadership
in 5 APIs



Enzyme-Based API
Process



Control for Nitrosamine-
Free API



199 API-Related
Granted Patents



350+ API Patent
Applications Filed

Jubilant Pharmova Limited

Corporate Office:

Plot No. #15, Knowledge Park – II,
Greater Noida - 201306,
Uttar Pradesh, India
Tel.: +91-120-7186000

For enquiry by e-mail: bd.api@jubl.com

R&D and Manufacturing Site:

Plot No. 18, 56, 57 & 58
KIADB Industrial Area,
Nanjangud – 571302
District Mysuru, Karnataka, India
Tel.: +91-8221 228402-08
Fax: +91-8221 228410-11



JUBILANT
PHARMOVA