

ACTIVE PHARMACEUTICAL INGREDIENTS (APIs)



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 highquality 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.

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 (<10 Kg) and a kilo lab (< 1 Kg) with a total capacity of 750 Kl.

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 facility 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.



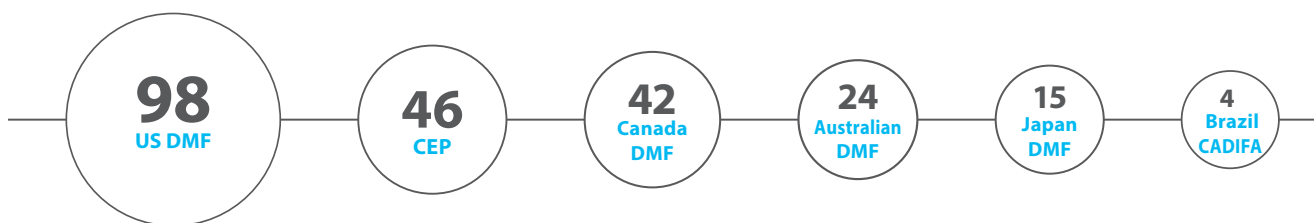
267, 688 sq. mts. site with 33% built-up area, 6 multistream manufacturing blocks and a pilot plant having volumetric capacity of ~760 KL, 18 clean rooms and 170 reactors ranging from 0.1 KL to 15 KL.



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

Jubilant's API Portfolio

Our portfolio also 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 DMF | China DMF | Brazil Cadifa | Russia DMF | JP DMF | Canada DMF | Korea DMF |
|----|--|----------------------|--------------------|--------|---------|-----------|---------------|------------|--------|------------|-----------|
| 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 | Olmесartan Medoxomil | CVS | Anti-hypertensive | ● | ● | | | | ● | | |
| 25 | Oxcarbazepine | CNS | Anti-epileptic | ● | ● | ● | ● | | | ● | ● |
| 26 | Paliperidone Base | CNS | Anti-psychotic | ● | | | | | | | |

FILED & COMMERCIAL APIs

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|----|-----------------------|----------------------|--------------------|--------|---------|-----------|---------------|------------|--------|------------|-----------|
| 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 | Vildagliptin | Anti-diabetic | Anti-diabetic | ● | | | | | | | |
| 40 | Zoledronic acid | Bone disorder | Anti-osteoporosis | ● | ● | ● | ■ | ● | | ● | |
| 41 | Zolmitriptan | CNS | Anti-migraine | ● | ▲ | | | | ● | ● | |

IP Jubilant's own patent

▲ Only Europe DMF ■ Both ANVISA & CADIFA filing

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 | Brexpirazole | CNS | Anti-psychotic | ● | |
| 5 | Cyclobenzaprine HCl | Muscle relaxant | Muscle relaxant | ● | |
| 7 | Histamine Hcl | Anti-allergic | Anti-allergic | ● | |
| 13 | Linezolid [Form I] | Anti-infective | Anti-infective | ● | |
| 8 | Mirabegron | Overactive bladder | Overactive bladder | ● | |
| 13 | Pantoprazole | Gastrointestinal | Anti-ulcerant | ● | ● |
| 9 | Pirfenidone | Anti-fibrotic | Anti-fibrotic | ● | ● |
| 10 | Rivaroxaban | Blood Disorder | Anti-coagulant | ● | ● |
| 12 | Vilazodone HCl | CNS | Anti-depressant | ● | |

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.

Pursuant to the inspection of our API manufacturing facility in December 2022, the U.S. FDA has determined that the inspection classification is "Voluntary Action Indicated (VAI)". Based on this inspection and the U.S. FDA VAI classification, this facility is in compliance with regard to current good manufacturing practices (cGMP). Any ANDA or NDA filed using DMF from the Nanjangud site could be approved by the regulatory agency.

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 and 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 regulatory various studies and expectation and guidelines by conducting various studies & risk assessment for over 40 APIs, which enabled us to supply key products to the US and Europe markets.



U.S. FDA



EDQM



Health Canada



AFSSAPS
(France)



PMDA (Japan)



TGA (Australia)



MFDA (Korea)



ANVISA
(Brazil)



COFEPRIS
(Mexico)

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

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