



**JUBILANT  
PHARMOVA**

**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 markets such as North America, LATAM, Europe, Japan, APAC, and the Middle East.

World class manufacturing cGMP facility with 6 plants & a pilot plant with a total capacity of 750 KL.

46  
EDQM

15  
Japan  
DMF

98  
US DMF

41  
Canada  
DMF

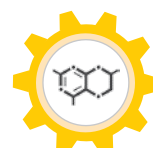
Jubilant offers large portfolio of commercial APIs across CNS, CVS, anti-diabetic, anti-infective, GI & other therapeutic segments.

- 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 fulfil 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 sizeable capacities and dedicated production streams for certain high-volume molecules.

### API R&D



State of the art R&D centres in India at Noida and Nanjangud, Mysore



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 more than 150 dedicated scientists including PhDs



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



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





Our portfolio also includes numerous 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 large formulation companies.

During initial quarter of last year, our Nanjangud plant operations were impacted due to COVID-19. Our business is now fully functional with COVID protocols and we are running with full capacity and serving all our orders on time which makes us partner of choice.

### Regulatory Affiliations

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



USFDA



EDQM



B FARM  
(German Health)



PMDA (Japan)



TGA (Australia)



AFSSAPS  
(France)



ANVISA  
(Brazil)



KFDA (Korea)



Health Canada



COFEPRIS  
(Mexico)



Russia (The Ministry of  
Health of the Russian  
Foundation)



China FDA  
(China)

However, the USFDA has assigned the facility an Official Action Indicated (OAI) classification since 2019. We have completed the remediation activities and await USFDA inspection and are hopeful of resolution of the regulatory status.

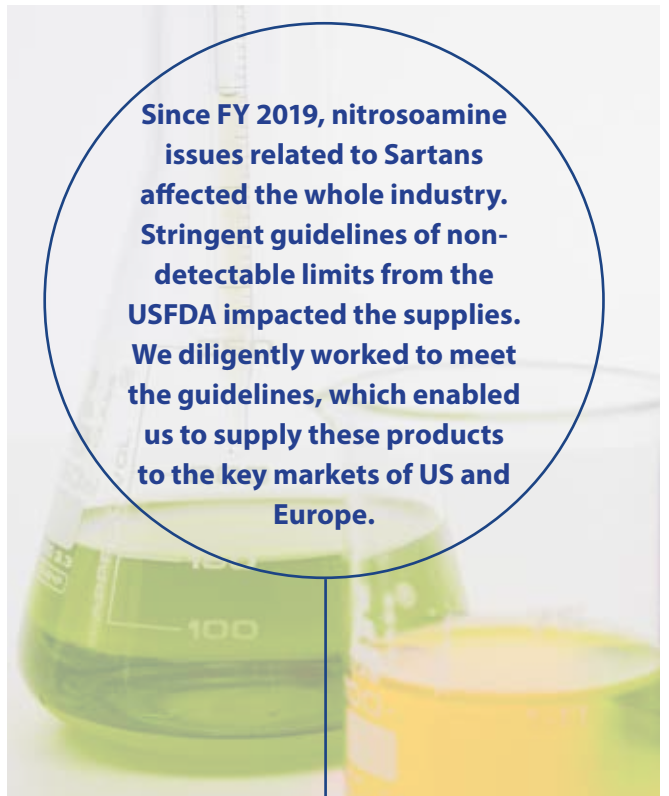
In line with our commitment towards our partners, we are leading various initiatives to reduce costs by continuously streamlining our operations, enhancing yield, on-boarding alternative vendors, de-risking our operations and supply chain and optimising input material costs. Several cost improvement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

According to estimates, 70% of India's API requirement is met through China. 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.

We have further future-proofed our manufacturing process to address similar regulatory changes, while ensuring compliance with all guidelines.

**Since FY 2019, nitrosoamine issues related to Sartans affected the whole industry. Stringent guidelines of non-detectable limits from the USFDA impacted the supplies. We diligently worked to meet the guidelines, which enabled us to supply these products to the key markets of US and Europe.**



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 3 APIs**



**350+ API Patent  
Applications Filed**



**Control for Nitrosamine-  
Free API**



**199 API-Related  
Granted Patents**



**Enzyme-Based API  
Process**

The Company has decided to demerge its Active Pharmaceutical Ingredients business, currently an undertaking of Jubilant Generics Limited (JGL) and vesting of the same with the Company on a going concern basis.

This demerger is to be implemented through a scheme of arrangement between JGL and the Company and their respective shareholders and creditors under Sections 230 to 232 and other applicable provisions of the Companies Act, 2013.

### **The business rationale behind this reorganization:**

- Creation of a small molecule discovery and chemistry focused vertical present across value chain of CRO & CDMO of Innovative and Generic API.
- This will strengthen and sustain long-term growth, profitability, market share, customer service, risk management as it requires focused management attention, different skill sets and resources.
- Synergies between CRO & CDMO businesses can be realised more effectively in a Holding / Subsidiary Company structure as compared to fellow subsidiary structure.
- This would also help in supporting our customers for their needs from early stage of research to commercialisation of active ingredients and will provide competitive edge to this business.

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#### **Jubilant Pharmova Limited**

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