



Nikunj Sharma
nikunj.kumar@network18publishing.com

Fermenta Biotech Ltd Delivering green drug solutions

A name to reckon with as the pioneers of PGA enzyme catalyst, Fermenta Biotech Ltd continues to retain its undisputable position as the only biotech unit at Takoli village of Mandi district in Himachal Pradesh. Offering unique capabilities to deliver commercially viable enzyme technologies and integrated Vitamin D3 formulations without compromising on quality to the global marketplace, we explore the PGA pioneering facility here.



Fermenta Biotech Ltd (FBL) is a pioneering and progressive company, founded by late Vasant Kumar Datla in 1986. The success of the company is fundamentally based on research and development, product delivery in the field of biotechnology, speciality pharmaceuticals and environmental solutions. From being a pioneering provider of Penicillin G Amidase (PGA) enzyme solutions for the global market, today the company has evolved into a leading and only Indian manufacturer of integrated Vitamin D3 and other speciality pharmaceuticals such as phenylramidol, dimethicone powder, etc.

From where it all began

FBL has pioneered the production of PGA catalyst way back in 1986. It was the beginning of an era for transformation for making 6-APA, an important intermediate from Pen G. To transform from a well-established and conventional chemical process, into a highly selective and efficient enzymatic process was a real challenge then owing to apprehensions regard the enzymatic processes. However, by simplifying the enzymatic process and making it more manageable and cost-efficient, the company's flagship product, PGA has established itself in the foremost position on this technology front. With constant up gradation of the PGA series products, Fermenta Biotech has become synonymous with the PGA enzyme catalyst.

Research and manufacturing

The company's R&D unit is based in DIL complex at Thane, Maharashtra. Describing the vision of FBL's research initiatives, Vyasa Rajasekar, R&D Head, Biotechnology, Fermenta Biotech Ltd says, "FBL's research platforms are aimed at developing novel enzyme platforms for the synthesis of antibiotics and also focus on providing enzymatic

solutions for a wide range of molecules to change the way they have been made so far."

As a guiding principle, FBL constantly absorbs new technology, while augmenting the production capacity and capabilities. In the last few years, significant investments has been made to set up a new greenfield manufacturing facility at Dahej, Gujarat to focus on the Active Pharmaceutical Ingredient (API) products. In the next phase, a state-of-the-art, biotech plant is on the anvil.

"After conducting technological breakthrough in enzymatic synthesis of antibiotics, the next challenge, R&D was posed with, was cost optimisation and simplification of the entire process. With ingenuity and an innovative approach, FBL has developed enzymatic processes that use the liquid 6-APA (right from the hydrolysed and extracted liquid of Penicillin G), for the production of amoxicillin. This backward integration akin to in-situ synthesis further cuts down the cost of production and also reduces solvent and waste foot print. Similar in-situ approaches are being developed for other antibiotics," avers Suresh Uniyal, Vice President, Manufacturing Operation, Fermenta Biotech Ltd.

The company has two manufacturing facilities, one at Mandi in Himachal Pradesh and a recently put up facility at Dahej, Gujarat.

The success equation

Fermenta has evolved from being an industrial enzyme manufacturer into a multifaceted company expanding presence in API's, biotechnology and environmental solutions. With concerted overall efforts and sustained focus on R&D, the company has been shortlisted among the top 3 companies in the SME sector for the year 2012-13.

Vitamin D3: The sunshine saga continues

FBL took over the Vitamin D3 business from its parent company, now known as DIL Ltd (Duphar Interfran Ltd), the first to harness this technology in India and an erstwhile partner with Philips-Duphar, the innovator company of synthetic Vitamin D. Since 2004, FBL manufactures Vitamin D3 and continues to remain the only company in India to provide leadership offerings in the Vitamin D3 space. The

company's global presence especially for Vitamin D3 spanning across 36 countries exemplifies the preferred supplier status. On the domestic front, the company caters to more than 200 companies with its product line.

"Apart from FBL's leadership position in Vitamin D3, the company has successfully commercialised enzymatic technology for Amoxicillin at a commercial scale. Powered by this success, it is also scaling up other enzymatic technologies for cephalosporin antibiotics," avers Uniyal.

Commercial enzyme technologies

FBL has pioneered the first generation PGA enzyme for the production of β -lactam (beta-lactam) intermediates like 6-APA / 7-ADCA, the key building blocks for the production of antibiotics such as amoxicillin and cephalixin.

Historically, FBL has galvanised the transformation from the chemical process of making intermediate into an enzymatic process, way back in the early 1990s. As a next logical step, FBL R&D has been working on making the next-generation PGA, which can manufacture antibiotics in a greener and cleaner mechanism as compared to conventional chemistry. Through collaborative efforts, FBL has developed a patented enzyme platform, Novel Penicillin G Acylase (NPGA), which works under ambient conditions to synthesise the antibiotics. Further, the company has commercialised enzymes from this platform for amoxicillin and other antibiotics, which are under scale up evaluation. This year FBL has also commercially launched Cal B lipase, an enzyme, applications of which range from the pharmaceutical industry, fine chemicals to bio fuels.

Accreditation and quality standards

The strength of the company lies not only in providing progressive solutions supported by patents, but also in creating a regulatory landscape with various certifications. FBL's certifications include USFDA, CEP, WHO-GMP, ISO 9001, 14001, 18001, HALAL, KOSHER, FAMI-QS, vegetarian association certification, HACCP and BS OHSAS 18001: 2007.

To marinate the quality standards across all floors, Uniyal explains, "As evident from the list of accreditations as above, FBL follows stringent quality management system combined with state-of-the-art, production and



Apart from FBL's leadership position in Vitamin D3, the company has successfully commercialised enzymatic technology for Amoxicillin at a commercial scale. It is also scaling up other enzymatic technologies for cephalosporin antibiotics.

Suresh Uniyal
Vice President, Manufacturing Operation,
Fermenta Biotech Ltd

analytical facility. Under guidance from able and experienced managers, both analytical and production team work in tandem towards continuous improvement, implementing and validating analytical and production systems, thus making Current Good Manufacturing Practice (cGMP) compliance a habit."

Unique approach

When asked about FBL's unique ability to cater its clients, Uniyal reiterates, "FBL is synonymous with trust, value and consistent quality powered by original solutions. The company has differentiated itself through a combination of relentless technical support and quality products underlined with transparent approach."

Today, FBL provides cutting-edge, next generation enzyme solutions for antibiotic synthesis from the biotech division and integrated Vitamin D3 platform to include animal feed additives and human therapeutics from the API division. FBL's continued commitment on upgrading production technologies, QA training, facility audits, capacity and capability augmentation combined with a dedicated team that empowers the growth engine. **MR**



FDA approved, Vitamin D3 facility at FBL