

## “Avantor has proactively positioned itself to support Indian manufacturing”

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By : Rahul Koul - January 11, 2017



TECH TALK

**Avantor's new products  
are very well positioned  
to address key needs  
of our customers**



*US based multinational, Avantor manufactures several respected brand names, including the J T Baker, Macron Fine Chemicals, Rankem, BeneSphera, and POCH brands. In a recent exclusive interaction with BioVoice's Rahul Koul, Mr Devashish Ohri, Executive Vice President, APAC, Avantor Performance Materials, shared details about his company's operations in India. Read the full interview below:*



## **When and why did Avantor decide to produce cGMP-quality high-purity, low-endotoxin sugars at its plant in Panoli, India? Is it only for Indian market or entire Asia-Pacific?**

J T Baker brand high-purity low-endotoxin (HPLE) sugars are being produced in Panoli, India, and are available to Avantor's global customer base. In 2014, Avantor developed an innovative manufacturing process to produce a new line of HPLE sugars. The new process was born out of collaboration with a major pharmaceutical customer that was concerned about meeting new ICH and USP requirements.

At the time, we began manufacturing J T Baker brand HPLE sugars at a pilot facility in Phillipsburg, New Jersey (USA), while we established plans to scale up our operations in Panoli, India. The Panoli site's location positions it to serve our global pharmaceutical and biopharmaceutical customers in the most efficient manner possible, regardless of their locations. The site is located in west India within 70-80 km from multiple international ports, and is situated in one of the most industrialized states in the country. While the site services Avantor's global customers, its location is also advantageous for Indian pharmaceutical customers, 95 percent of which are located in western and southern India.

Our Panoli facility is one of the three global cGMP manufacturing sites operated by Avantor using the company's proven quality standards and processes. Avantor is one of the few companies in our space with in-house excipient manufacturing capabilities for producing multi-compendial cGMP excipients.

**“The South Asia including India region is uniquely positioned to become a global player because it has clear-cut regulatory guidelines for biologics and vaccines, offers a highly skilled workforce, and has R&D and a manufacturing infrastructure.”**



## **What are the major reasons behind biosuppliers setting up cGMP enabled manufacturing setups outside Europe/US?**

A majority 80 percent of the world's population resides outside of Europe and North America. Meeting their healthcare needs in a high-quality and cost-effective manner is driving pharmaceutical companies to set up operations closer to their patients. This is especially true in the Asia Pacific region, which has a large patient base (60 percent of the world's population). The economies of scale offered in the region lead to cost-effective drugs, which can help reduce healthcare costs in the developing and developed world. As an example, one out of three OTC drugs in North America are

The South Asia including India region is uniquely positioned to become a global player because it has clear-cut regulatory guidelines for biologics and vaccines, offers a highly skilled workforce, and has R&D and a manufacturing infrastructure that is on par with the most advanced countries in the world. Fast-paced clearances for greenfield and brownfield projects are important, as are the world-class institutes and universities available in the region.

Avantor has proactively positioned itself to support the above trends by creating a cGMP manufacturing and commercial infrastructure in the region, which ensures that we are developing, testing and selling relevant products in the region.



### **Which are the new innovative products that Avantor has come up to boost biopharmaceutical manufacturing? How do you view the global trends?**

The biopharmaceutical industry is crossing traditional dividing lines, as innovators are developing branded generics, and small molecule manufacturers are moving into biosimilars. CROs and CMOs are springing up to take advantage of scale, and generic manufacturers are moving up the value curve by launching innovator drugs. All these trends are being driven by the growing need for cost-effective, high-quality healthcare. Plus, most of the top 50 innovator drugs are going off patent in the next five years, spurring launch plans for hundreds of biosimilars.

Avantor's new products are very well positioned to address the key needs of our customers in this setting. Our J T Baker HPLE sugars have demonstrated very low endotoxin levels, in addition to high purity, making them attractive excipients for vaccines and other critical drugs. The sugars also reduce API degradation, which enhances cost effectiveness. J T Baker HPLE sugars are now being manufactured in our state-of-the-art cGMP manufacturing plant in Panoli, India.

Avantor's protein purification resins are multi-modal in nature, which reduces the need for an additional step in purification; therefore, our resins increase yield (yield gets reduced in every successive step, so avoiding steps is desirable), while meeting quality requirements.

**“Avantor’s capabilities and experience in providing global regulatory documentation support at the product development stage has helped us become a preferred supplier.”**

Avantor's J T Baker Direct Dispense packaging was recently developed to meet the customer need for automation and speed in plants. These disposable bags increase speed of production by allowing for assembly line type mixing, flexible bag sizes and no clumping of excipients, reducing manual

intervention. The packaging is increasingly being adopted by customers around the globe who are sensitive to quality and time.



**How has been the company's performance in India (including percentage of growth YOY) since last few years?**

While Avantor, as a private company, does not disclose financial information, I can tell you that since 2011 Avantor India revenue has grown at a healthy pace, with CAGR significantly exceeding the industry trend of 6-7 percent growth annually.



**Please share with us your few unique experiences/learnings (customer behaviour, regulatory dealings or partners) in Indian market.**

India has become a sourcing and manufacturing hub for generic drugs. Advanced countries, including the U.S., Europe and Japan, have very strict regulations (e.g., regulations established by the USFDA, MHRA UK, TGA Australia, WHO GMP, etc.). To meet regulatory muster, many pharma companies that sell into these advanced economies are seeking excipient suppliers that offer cGMP products that comply with Pharmacopeia specifications.

Avantor's capabilities and experience in providing global regulatory documentation support at the product development stage has helped us become a preferred supplier.



**How big is the market and how do you look at its potential opportunities?**

Our J T Baker HPLE sugars are used in the manufacturing of biosimilars and vaccines. This market is at a nascent stage. The current base market is around 1.5 – 2 MT and should grow at 18 percent per year.



**What kind of future outlook do you have for your company, as well as the industry?**

The pharmaceuticals industry in India is going through a major transformation, the key elements of which are:

- Small molecule drug manufacturers are targeting markets in the developed world to get a better return on their investments;
- Indian regulators are tightening quality standards in pharma sourcing and manufacturing;

- The FDA is increasing scrutiny of cGMP manufacturing for Indian generic/biosimilar exporters, including issuing warning letters, shutting down plants, etc.;
- Top Indian pharmaceutical companies are entering the CMO space and partnering with global pharma leaders; and
- Generic manufacturers are launching biosimilar offshoots to capture a higher-value customer segment (e.g., Oncology, Cardio etc.).

Due to these factors, pharma companies need excipients of the highest quality, which is exactly what we provide at Avantor. Some of our new products also help in reducing time and improving yield, giving our customers an edge to capture market share.

Avantor's advantage is the completeness of the support ecosystem we provide to customers: world-class cGMP manufacturing, high quality standards, technical support and product development through scientists and labs (including five labs in APAC), key account managers on the ground, and an effective supply chain through warehouses, planners and dealers. Due to these factors—and the high-growth markets in which we operate—we are extremely confident in our ability to generate industry-leading growth, while meeting the unique needs of our global customers.