



SGD Pharma quality, made in India

More than 9000 tonnes of moulded Type I pharmaceutical glass containers and 4000 tonnes of tubular vials and ampoules (corresponding to more than 700 million pieces) are produced annually at the Vemula (India) glassworks of SGD Pharma. Sardar Akshay Singh, Managing Director of SGD Pharma India, spoke to *Glass Worldwide* (preferred international AIGMF journal) about the fully integrated facility's extensive capabilities, prospects and opportunities.



Sardar Akshay Singh, Managing Director of SGD Pharma India.

The Indian pharmaceutical sector has been the subject of impressive growth rates in recent years, a trend that continues to benefit specialist Type I moulded and tubular glassmakers like

SGD Pharma India Ltd. Collectively, the sector was valued at US\$33 billion in 2017 and is expected to reach US\$55 billion by 2020. India's pharmaceutical exports stood at US\$17.27 billion in 2018 and have reached US\$10.80 billion in the current financial year (up to October 2018).

Indian pharmaceutical companies and their subsidiaries have established a strong presence in the USA during the past couple of years, with higher ANDA approvals. The loss of patent exclusivity and cost cutting measures adopted by several nations has pushed demand for generic products. Indian pharmaceutical companies have enhanced their investments in research and development and successfully received higher approvals from the USA's FDA within the last decade. Out of a total of 5350 ANDA approvals between 2009 and 2018,

Indian companies have secured 34.4% of these approvals and received a total of 1842 ANDA final approvals. Furthermore, of the 1310 tentative approvals, Indian companies are responsible for 500 from the USA FDA, which works out to over 38.2%.

In 2018, Indian pharmaceutical companies received 290 ANDA approvals from the USA FDA. In total, the FDA approved 813 ANDAs in 2018, slightly lower than the previous year's figure of 846. Thus, Indian pharmaceutical companies captured 35.7% of total approvals in 2018. Similarly, the USA FDA approved 194 tentative products during 2018, against 174 products a year earlier and Indian companies secured 77 tentative approvals in 2018, compared to 61 in 2017. Furthermore, the country accounts for approximately 30% (by volume) and about 10% (value) of the \$70-80 billion USA generics market. The local biotechnology industry is also expected to expand at average annual growth rates of about 30% and reach US\$100 billion by 2025.

The high quality tubular market for India and neighbouring countries in Asia Pacific corresponds to approximately 70,000 tons of tubing. With high growth rates in the pharmaceutical sector and a change of regulations for China, there has been a significant increase in demand for glass primary packaging, for which the raw material suppliers, especially glass tubing, are investing in capacity expansions in China and India.

As a result, Akshay Singh anticipates positive local market opportunities for his borosilicate glass business. The SGD Pharma India Ltd Managing Director has been associated with the Hyderabad-based pharmaceutical glassware specialist since its creation as Cogent Glass Ltd a decade ago. He has led a major investment at the Vemula glass production site and overseen its growing importance within the international SGD Pharma organisation. With five plants in France, in Germany, China and India, the company manufactures more than eight million vials every day. Its mission is to improve and protect patient health by supplying high quality, reliable and innovative glass primary packaging. Through continuous improvement and innovation, SGD Pharma is committed to reinforcing patient safety by improving the physical, chemical and cosmetic properties of its products.

Integrated infrastructure

SGD Pharma is a world leader in glass pharmaceutical packaging for healthcare. To improve market share, its offering to customers and to increase the company's geographical advantage, SGD Pharma acquired Cogent Glass, a moulded and tubular Type I glass manufacturing facility in 2013.

The SGD Pharma India glass plant is strategically ▶



Tubular vials from SGD Pharma India.



A wide range of tubular ampoules are available.



The addition of amber glass to the portfolio and the introduction of technology to produce larger bottles should help the company to gain further market share of moulded Type I borosilicate pharmaceutical glass packaging in India and internationally.

located on the Hyderabad-Bangalore highway, approximately 120km away from Hyderabad and spread across 36 acres. The new corporate office is located in Hyderabad, which is an important pharmaceutical hub in the country.

All manufacturing equipment is sourced from the world's leading manufacturers of glass forming machinery. For example, the batch plant is from ZIPPE (Germany), the melting furnace from SORG (Germany), lehrs from Antonini (Italy) and inspection equipment from Tiama (France). The glassmaker's tubular vial and ampoule manufacturing equipment comes from Spami, KYP, OCMI and

Moderne Mecanique.

According to Akshay Singh, SGD India is the only composite manufacturer in the world, with an integrated infrastructure for moulded and tubular vials and ampoules. Moulded and tubular vials are manufactured in accordance with GMP standards and conform to the requirements of Drug Master Files for product registration, ensuring the use of quality raw materials and glass containers, matching global benchmarks and pharmacopoeia like USA, European, Indian and Japanese standards.

SGD Pharma India has acquired a substantial market share since 2013. The addition of amber glass to the portfolio and the introduction of technology to produce larger bottles should help the company to gain further market share of Type I in India and internationally. The result of 35% CAGR growth reflects the trust in quality levels SGD Pharma India has maintained over the years and will continue to do so to establish the organisation as the market leader for Type I glass in India. Exports represent 15% of global sales, with a special focus on Asia, European markets and in the USA. This is primarily due to the geographical advantage and position of the company's production site. Most products destined for domestic markets are also sold to USA FDA-approved facilities, wherein the end product is exported to the USA and Europe.

Experienced team

SGD Pharma India employs approximately 800 people. This includes the best available talent in their respective fields. Depending on skill matrix analytics, sufficient training is provided to all employees to maintain the company's position as a world leader for glass primary packaging. Most employees come from highly specialised backgrounds. The focus at SGD Pharma India is to benefit from those skill sets

and extensive knowledge in order to meet global standards in training and safety.

Training is an important focus, via a specialist department and team. For 2018, the company's average training man hours exceeded 3000 per month. An important training focus relates to GMPs, 5S, safety, quality, process and HR. Inter-company departmental exchanges, monthly calls and senior management quarterly meetings have enhanced Vemula to respect global standardisation of processes and practices followed within the group and vice versa.

SGD Pharma India complies with all environmental compliance norms, prescribed by the pollution control board. Periodic checks are performed and the results are shared with governmental authorities and within the group to ensure full compliance on environmental topics. Based on the company's growth over the last three years, a significant investment in both moulded and tubular glass containers is anticipated in the next four years. ●

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