

## **Bharat Serums and Vaccines**

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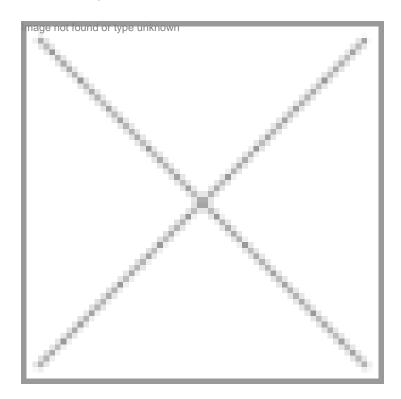


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## **Plasma Maker**

Bharat Serums and Vaccines holds a formidable market share in India for plasma derivatives and is constantly expanding its range of products.

It was a strategic decision at Bharat Serums and Vaccines Ltd (BSV) to expand its existing biological facility considering a double-digit growth for biologicals in the coming years, following which its biological unit was partially shut down. Its effect can be seen on its sales that have seen a negative growth of 3.64 percent with its biotech sales for 2005-06 recording Rs 78.05 crore against last year's sales of Rs 81 crore. During 2004-05, Bharat Serums and Vaccines registered a marginal growth of 1.66 percent over the previous year's sales of Rs 79.68 crore.

Bharat Serums and Vaccines, a flagship company floated by Dr Vinod G Daftary, received a total sum of Rs 10.48 crore for two of its projects costing Rs 7.07 crore and Rs 3.41 crore from Department of Science and Technology, Government of India, as loan for research and development work pertaining to medicines. Besides this, BSV is investing about seven percent of its total revenue in R&D infrastructure including high quality laboratory facilities, experienced research scientists and personnel. The R&D activities have been granted recognition by the Department of Scientific and Industrial Research.

BSV has distinct R&D divisions working extensively on New Drug Discovery System (NDDS) and biotechnology. It has developed its competency in the areas of NDDS and in development and purification of equine-based therapeutic products. On the biotechnology front, the team has been working on developing new generation recombinant therapeutics that replace the traditional plasma products which are in short supply worldwide due to the dependence on human donors, and runs the risk of viral infections like HIV etc. It has an in-house expertise to conduct genetic engineering, process development and scale-up activities in the biotechnology space.

Bharat Serums and Vaccines has set up a joint venture company with Cadila Healthcare Ltd to produce a NDDS for an approved anti-cancer product for the global markets. The 50:50 joint venture company will develop, manufacture and market a non-infringing and proprietary NDDS. As per the agreement, both companies will undertake a core development program and are initiating clinical trials for product registration in leading pharmaceutical markets for potential treatment of multiple types of cancer. Cadila Healthcare and Bharat Serums have also evolved a global development program to maximize the commercial potential of the product.

During 2005, Bharat Serums and Vaccines received a US patent for one its novel formulation, Amphotericin B Emulsion. All the excipeints used for this formulation are US FDA approved for injectable formulations. BSV has already received the marketing permission for this drug in India for Visceral Leishmaniasis and is in process of conducting clinical trials for obtaining the permission in treatment of fungal infections. BSV has also conducted a Pre IND meeting with the US FDA for the clinical path and is in process of filing the IND by Quarter I 2006. BSV expects that a safer Amphotericin formulation would be in a position to capture a substantial share of the global anti-fungal market.

Bharat Serums and Vaccines that imports blood products from Human Serums Production & Medicine Mfg. Co. Ltd. Hungary, Hardis Spa., Italy , Hematalog Ltd., Russia and Grifols, USA, commissioned a new state-of-the-art injectibles manufacturing plant at Ambernath in 2002. The plant has been constructed as per the guidelines of the UK-MCA to enable access to European markets. The design and the engineering of the facility has been developed to enable the manufacture of the products in accordance with the best international GMP. It has also been accorded the WHO-GMP certification. Its plants have got the approval and accreditations from WHO and DGCI to manufacture pharmaceutical products.

A marketing team of 20 individuals at BSV supports the sales team of over 300 managers, executives and medical representatives who cover the length and breadth of the country. BSV is able to cater to over 100,000 retail outlets and hospitals all over the country. It has also appointed distributors in over 30 countries for various products to enable continuous availability of its products in these countries.