



Bharat Biotech Announces COVAXIN® Capacity Expansion to Support vaccination campaigns in India and Worldwide.

- Capacity expansion has been implemented across multiple facilities in Hyderabad and Bangalore, to reach ~ 700 million doses / year, one of the largest production capacities for Inactivated viral vaccines worldwide,
- IMDG agonist molecule synthesis and manufacturing has been successfully implemented in India eliminating dependency on imports,
- Raw materials, packing materials and single use consumables for manufacturing have been secured to meet our capacity requirements,

Hyderabad, India, April 20th, 2021: Bharat Biotech announces scale up of manufacturing capacity to produce ~ 700 million doses of COVAXIN® annually.

Manufacturing scale up has been carried out in a stepwise manner across multiple facilities at Hyderabad, and Bangalore. Inactivated vaccines, while highly safe, are extremely complex and expensive to manufacture, resulting in lower yields when compared to live virus vaccines.

Capacity expansion in vaccines manufacturing is a long and tedious process, requiring investments of several millions of rupees and several years. Bharat Biotech is able to expand COVAXIN® manufacturing capacity in a short timeline, mainly due to the availability of new specially designed BSL- 3 facilities, first of its kind for manufacturing in India that have been repurposed and preexisting expertise and know how to manufacture, test and release highly purified inactivated viral vaccines.

Manufacturing partnerships are being explored with our partners in other countries, who have prior expertise with commercial scale manufacture of inactivated viral vaccines under biosafety containment.

To further increase capacities, Bharat Biotech has partnered with Indian Immunologicals (IIL) to manufacture the drug substance for COVAXIN®. The technology transfer process is well underway and IIL has the capabilities and expertise to manufacture inactivated viral vaccines at commercial scale and under biosafety containment.



Bharat Biotech uses a proprietary adjuvant Algel-IMDG, that has now proven to be a safe and effective adjuvant, especially to stimulate memory T cell responses. The synthesis and manufacture of the IMDG component has been successfully indigenized and will be manufactured at commercial scale within the country. This is the first instance where a novel adjuvant has been commercialized in India.

The protocols for manufacturing, testing and release of inactivated vaccines have been tried, tested and validated across several of our vaccines, these also meet the requirements of WHO, Indian and other regulatory authorities. These protocols have delivered consistent results over a 15-year period with more than 300 million doses supplied globally, with excellent safety and performance record.

COVAXIN® has received Emergency Use Authorizations in several countries across the globe with another 60 in process. EUA's have now been obtained from Mexico, Philippines, Iran, Paraguay, Guatemala, Nicaragua, Guyana, Venezuela, Botswana, Zimbabwe, among several other countries. EUA's are in process in the USA and several European countries. Pricing for international markets and supplies to gov'ts under EUA's have been established between \$15 - 20 / dose.

About Bharat Biotech

Bharat Biotech has established an excellent track record of innovation with more than 145 global patents, a wide product portfolio of more than 16 vaccines, 4 bio-therapeutics, registrations in more than 123 countries, and the World Health Organization (WHO) Pre-qualifications. Located in Genome Valley in Hyderabad, India, a hub for the global biotech industry, Bharat Biotech has built a world-class vaccine & bio-therapeutics, research & product development, Bio-Safety Level 3 manufacturing, and vaccine supply and distribution.

Having delivered more than 4 billion doses of vaccines worldwide, Bharat Biotech continues to lead innovation and has developed vaccines for influenza H1N1, Rotavirus, Japanese Encephalitis (JENVAC®), Rabies, Chikungunya, Zika, Cholera, and the world's first tetanus-toxoid conjugated vaccine for Typhoid. Bharat's commitment to global social innovation programs and public-private partnerships resulted in introducing path-breaking WHO pre-qualified vaccines BIOPOLIO®, ROTAVAC®, and Typbar TCV® combatting polio, rotavirus, typhoid infections, respectively. The acquisition of Chiron Behring Vaccines, has positioned Bharat Biotech as the world's largest rabies vaccine manufacturer with Chirorab® and Indirab®. To learn more about Bharat Biotech, visit www.bharatbiotech.com.

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