

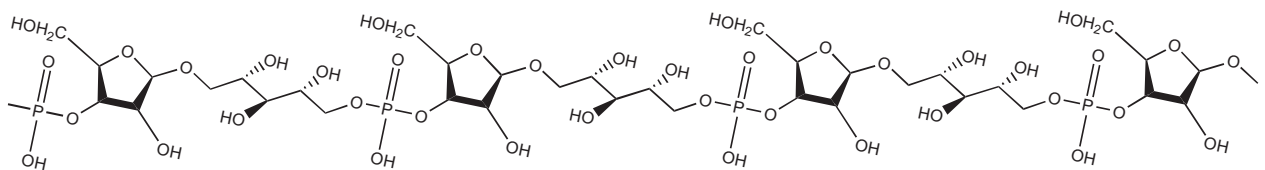


intravacc

innovating vaccines

A conjugate vaccine protecting against *Haemophilus influenzae* type b

Validated, proven and patented processes for the manufacturing of a polysaccharide conjugate vaccine



Introduction

The current available *Haemophilus influenzae* type b (Hib) vaccines rely on the production, purification and conjugation of the capsular polysaccharide polyribosyl-ribitol-phosphate (PRP) to Tetanus toxoid. Intravacc developed a patented manufacturing method for such a conjugate vaccine. This technology was transferred successfully to multiple partners and resulted in marketed products.

Competitive Advantage of Intravacc Technology

The Hib vaccine technology provided by Intravacc has generated a reliable track record since 2008. The process is simple, scalable, affordable and robust, and results in stable intermediate and final products. The vaccine production has a high yield, which is a good indicator for cost effectiveness. Both the active ingredient PRP and the final conjugated PRP-T vaccine comply with World Health Organisation (WHO) and European Pharmacopoeia (EP) legislation and guidelines.

Formulations

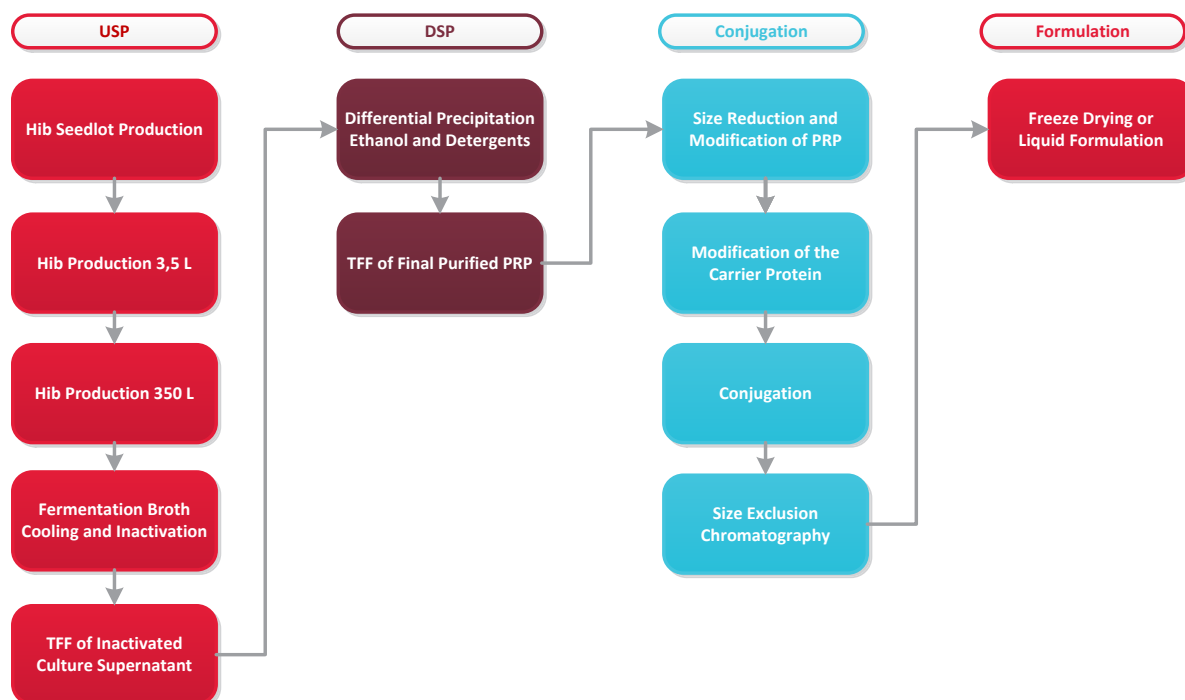
The Hib conjugate technology can be used for both lyophilized and liquid formulations for either standalone or combination vaccines.

Technology Status

The successful technology transfer of the production process includes related quality control tests (both In-process controls and release tests). This has led to the licensing and production of several Hib vaccines (liquid - standalone and in combination with other vaccines - and freeze-dried) in India. These vaccines are currently available for the national and international market.

Features Intravacc Technology

- Seeds: A fully defined seed lot of *Haemophilus influenzae* type b.
- USP: A patented, reproducible and scalable animal component free production process, with high yields of PRP.
- DSP: A patented, simple PRP purification process comprising of differential precipitations using ethanol and detergents.
- Conjugation: A generic, reproducible and scalable conjugation process including simple purification.
- Quality control QC tests are available for all production steps: USP, DSP and conjugation - including all intermediate and end-products.
- Formulation: Conjugate vaccine technology resulting in an immunogenic Hib vaccine for use as a standalone vaccine or in combination with other childhood vaccines.



Proven Safety and Effectiveness

Intravacc has performed a repeated-dose toxicity study in rats, from which extensive data are available. Furthermore, clinical data are available from studies performed by established technology transfer partners. These studies have proven that the Intravacc Hib vaccine is immunogenic, safe and effective, and has successfully passed non-inferiority testing.

Clinical Program Design

As part of a collaboration on a Hib technology transfer program, Intravacc supports and advises partners on the design and development of clinical trial protocols.

Partnering Opportunity

Intravacc offers partners:

- A license for technology and Intellectual Property (IP) to manufacture a Hib conjugate vaccine for specific geographical regions. The IP comprises the production, purification and conjugation of Hib PRP, which is based on patents WO 2005/024038 A2, US Pat. 7,582,459 B2 and EU Pat. 1 664 319 B1.
- All related Quality Control testing.
- Technology transfer through hands-on training by experienced scientists, both in-house and on-site.

Intravacc

The Institute for Translational Vaccinology is an experienced, not-for-profit R&D organization. With our unique capabilities and infrastructure, we are able to optimize vaccines, vaccine processes and vaccine technologies. Our aim is to increase equality in access to vaccines throughout the world in order to contribute to public health. We achieve this by transferring our knowledge and technologies to public and private partners worldwide and collaborative R&D. A team of 150 professionals is at your disposal at Science Park Bilthoven in The Netherlands.

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