



BLAS/STN Number: 125145/0

BLAS Sponsor: Sanofi Pasteur Limited

BLAS Product: DtaP-IPV/Hib (PENTACEL™)

BLAS Purpose: Vaccine for the prevention of diphtheria, tetanus, pertussis, poliomyelitis and invasive disease caused by *Haemophilus influenzae* type b.

To: File

From: Gennady Rezapkin, LMD/DVP/OVRR

Thru: Konstantin Chumakov, LMD/DVP/OVRR

Memo Date: January 25, 2007

Revision Date: June 17, 2008

APPROVED

By Konstantin Chumakov at 4:44 pm, Jun 17, 2008

Signature:

APPROVED

By Gennady Rezapkin at 5:08 pm, Jun 17, 2008

PENTACEL™ (DtaP-IPV/Hib or HCPDT-IPV) is the combination of *Haemophilus b* Conjugate Vaccine (Tetanus Protein-Conjugate) reconstituted with Component Pertussis Vaccine Combined with Diphtheria, Tetanus Toxoids and Poliovirus Vaccine Inactivated (IPV) Adsorbed. This review relates to the chemical manufacturing procedures and quality control tests (CMC) used for preparation of IPV component of this vaccine. Formalin-treated wild type polio strains, known as: Mahoney (type 1), MEF 1 (type 2), and Saukett (type 3) are the active components of trivalent Inactivated Poliovirus Vaccine. The mixture of these purified and inactivated polioviruses is used for production by Sanofi Pasteur (SP) of two IPV products: IPOL® (virus grows on Monkey Kidney Cell) and POLIOVAX® (virus grows on Human Diploid Cell MRC-5). Both vaccines are lessened in the US and IPOL® is widely used in this country for many years. IPV component of Pentacel is produced exactly as POLIOVAX® from the same lots of The Poliovirus Vaccine Inactivated Trivalent Concentrate (see file stability.pdf of submission, page 69, table 33).

Besides POLIOVAX®, some others components of HCPDT-IPV Vaccine also are licensed in US and the testing of the individual biologic and chemical substances is conducted according to the requirements and in-process test methodology currently used for release of the licensed products used in the U.S. market.

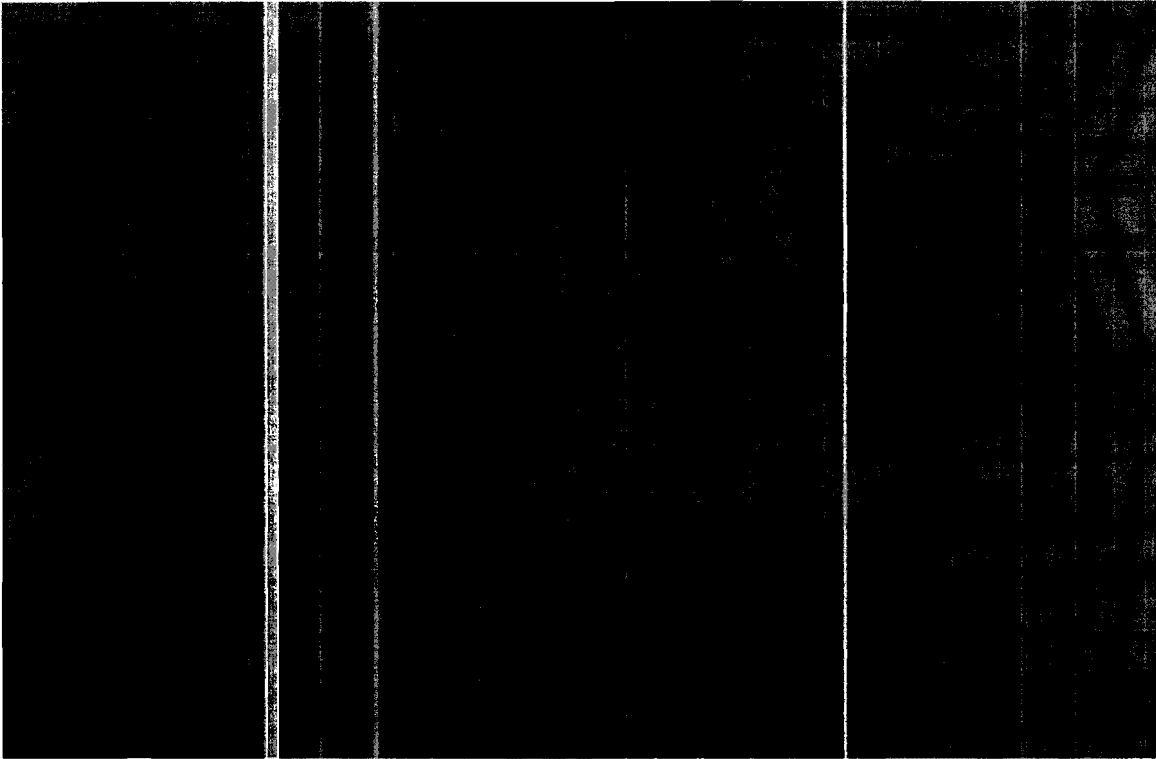
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TO BE

NOT RELEASABLE



Overall conclusion:

The application can be approved in part related to the Chemical Manufacturing and Controls IPV component of DtaP-IPV/Hib (PENTACEL™).