



PUBLIC ASSESSMENT SUMMARY REPORT
DTwP - Diphtheria, Tetanus and Pertussis Vaccine (Adsorbed)

What is DTwP Vaccine?

Diphtheria, Tetanus and Pertussis Vaccine (Adsorbed) is an inactivated combined vaccine against diphtheria, tetanus and pertussis with the following composition:

Each dose of 0.5ml contains:

Diphtheria Toxoid	25 Lf (≥ 30 IU)
Tetanus Toxoid	5.5 Lf (≥ 60 IU)*
B. Pertussis	16 IOU (≥ 4.0 IU)**
Adsorbed on Aluminium Phosphate ($AlPO_4$)	≥ 1.5 mg
Preservative: Thiomersal	0.01 % w/v

*(≥ 40 IU when tested in guinea pigs and ≥ 60 IU when tested in mice.

** The lower fiducial limit ($p=0.95$) of the estimated potency is not less than 2.0 IU.

Diphtheria, Tetanus and whole cell Pertussis Vaccine (Adsorbed) is a liquid vaccine presented in transparent glass vials and is a white turbid suspension.

VVM type 14

What is DTwP Vaccine used for?

Diphtheria, Tetanus and whole cell Pertussis Vaccine (Adsorbed) is indicated for primary immunization against diphtheria, tetanus and whooping cough diseases.

How is DTwP Vaccine used?

Diphtheria, Tetanus and whole cell Pertussis Vaccine (Adsorbed) is administered intramuscularly. The first dose should be given at approximately 6 weeks of age. Three doses of 0.5mL of the vaccine should be given at 4 week interval between doses for infants, above the age of 6 weeks. The anterolateral aspect of the upper thigh is the preferred site of injection. (An injection into a child's buttocks may cause injury to the sciatic nerve and is not recommended). The vaccine must not be injected in to the skin as this may give rise to local reaction. During the course of primary immunization, injection should not be administered more than once at the same site.

Only sterile syringes and needles should be used for each injection. The vaccine should be well shaken before use. Product which has been exposed to freezing should not be used.

What are the vaccine characteristics?

Diphtheria, Tetanus and whole cell Pertussis Vaccine (Adsorbed) must be stored at 2-8°C. Under these recommended storage conditions, the vaccine is stable for 24 months after the date of manufacture.

Who is the regulatory authority responsible for its oversight vis a vis WHO?

Diphtheria, Tetanus and whole cell Pertussis Vaccine (Adsorbed) is licensed in India, its country of manufacture, by the Central Drugs Standard Control Organization (CDSCO) of India. CDSCO is the authority responsible for the continuing oversight of this WHO prequalified vaccine.

How has DTwP Vaccine been studied from the clinical point of view?

All the three individual antigens in this trivalent vaccine have undergone extensive clinical studies as monovalent (Tetanus toxoid) and in combination with other antigens (bivalent Td, tetravalent DTwP-rHepB and Pentavalent DTwP-rHepB-HIB vaccines). These studies demonstrated the safety and immunogenicity of the three components of DTwP.

Two pivotal phase-III DTwP containing combination vaccine clinical trials and two phase-IV post marketing studies have been completed. Both reconstituted and the fully liquid DTwP containing Pentavalent vaccines are currently licensed for marketing in India and are prequalified by WHO.

Biological E.'s trivalent DTwP vaccine is in market since 1970 and has an established safety and immunogenicity profile in India.

Other information about evaluation of DTwP Vaccine:

As part of the prequalification process for DTwP the Product Summary File and the responses provided by manufacturer to observations made by WHO has been reviewed for quality, safety and efficacy by WHO experts, and found to meet WHO requirements of WHO TRS 800, Annex 2 and WHO TRS 927, Annex 5.

The manufacturing facility was not audited due to earlier WHO audits of the facility for related WHO prequalified diphtheria, tetanus and pertussis antigen containing vaccines produced on site when WHO GMP requirements [WHO TRS 822, Annex 3; TRS 961, Annexes 2, 3 and 6] were met.

WHO has conducted independent testing of batches of the vaccine for critical release parameters in contracted laboratories qualified by WHO with acceptable results.

