PUBLIC ASSESSMENT SUMMARY REPORT
Diphtheria and Tetanus Vaccine (Adsorbed, Reduced Antigen(s) content)
Biological E. Corporation Limited

What is Td Vaccine

Diphtheria and Tetanus Vaccine (Adsorbed, with Reduced Diphtheria Antigen(s) content) is an inactivated combined vaccine with the following composition:

Each dose of 0.5ml contains:

Diphtheria Toxoid	2 Lf (≥2 IU)
Tetanus Toxoid	8.8 Lf (≥ 20 IU)
Adsorbed on Aluminium Phosphate ($AlP0_4$)	≥ 1.5 mg
Preservative: Thiomersal	0.01 % w/v

Diphtheria and Tetanus Vaccine (Adsorbed, Reduced Antigen(s) content) is a liquid vaccine (white turbid suspension) presented in transparent glass vials.

VVM type 30

What is Td Vaccine used for?

Diphtheria and Tetanus Vaccine (Adsorbed, Reduced Antigen(s) content) is indicated for active immunization of children 7 years of age and older, and adults against diphtheria and tetanus.

How is Td Vaccine used?

Diphtheria and Tetanus Vaccine (Adsorbed, Reduced Antigen(s) content) should be administered intramuscularly. The preferred site for injection is deltoid muscle of the upper arm. Care should be taken not to inject into blood vessel or the skin. 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 and Tetanus Vaccine (Adsorbed, Reduced Antigen(s) content) must be stored at 2-8°C. Under recommended storage conditions, the vaccine is stable for 36 months after the date of manufacture.

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

Diphtheria and Tetanus Vaccine (Adsorbed, Reduced Antigen(s) content) 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 Td Vaccine been studied from the clinical point of view?

A phase-IV safety and immunogenicity non-inferiority study for Diphtheria and Tetanus Vaccine (Adsorbed, Reduced Antigen(s) content) demonstrated comparable safety and immunogenicity, i.e. non-inferiority with a licensed comparator product, also WHO prequalified.

Diphtheria and Tetanus Vaccine (Adsorbed, Reduced Antigen(s) content) offers reduced Diphtheria content to boost the waning antibody titres in children > 7 years of age, adolescents and adults. The data from Pentavalent DTwP containing combination vaccine studies helped in complementing the safety and immunogenicity of these two antigens in full doses:

Two pivotal phase-III Pentavalent DTwP combination vaccine clinical trials have been carried out which demonstrated the safety and immunogenicity of the Tetanus and Diphtheria components. Both reconstituted and the fully liquid pentavalent vaccines were investigated in these trials which are currently licensed for marketing in India and are prequalified by WHO.

Other information about evaluation of Diphtheria and Tetanus Vaccine (Adsorbed, Reduced Antigen(s) content):

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.

During the review of the application WHO has not conducted independent testing of batches of the vaccine for critical release parameters in contracted laboratories qualified by WHO, however the product was placed on its post-prequalification testing programme.