Document Name	**Summary of Product Characteristics (SmPC):** Diphtheria and Tetanus vaccine (Adsorbed) for Adults and Adolescents I.P. (Td Vaccine).

1. NAME OF THE MEDICINAL PRODUCT:

Diphtheria and Tetanus vaccine (Adsorbed) for Adults and Adolescents I.P. (Td Vaccine), Injectable, Whitish turbid liquid.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

S. No.	Component	Active/Inactive	Unitage (As per label)
1.	Diphtheria Toxoid	Active	≤ 5 Lf/SHD
2.	Tetanus Toxoid	Active	5 to 25 Lf/SHD
3.	Aluminium content	Inactive	≤1.25 mg/SHD
4.	Thiomersal	Inactive	≤0.01% (w/v)
5.	Free formaldehyde	Process related impurity	≤0.02%

3. PHARMACEUTICAL FORM: Whitish turbid liquid for injection.

4. CLINICAL PARTICULARS:

4.1. Therapeutic indications: Booster dose at 10 years of the age, Booster dose at the age of 16 years, Two dose/Single booster dose given to pregnant women.

4.2. Posology and method of administration:

4.2.1. **Posology:** For the purpose of booster immunization it is recommended that 2 doses of 0.5 ml should be inoculated on 2 separate occasions at 10 and 16 years intervals to the population already pre-immunized with DPT group of vaccines.

4.2.2. **Administration:** Td Vaccine should be injected intramuscularly. The deltoid muscle is the preferred site of injection. As Td vaccine may give rise to local reaction, should not be injected into the skin. For each injection sterile needles and syringes should be used. The vaccine should be well shaken before use. Once opened, multi-dose vials should

be kept between 2°C to 8°C. May be used for further immunization purpose, provided that all of the following conditions are met:

- The vaccine has not passed the Expiry date.
- The vaccines has stored under cold chain conditions;
- Aseptic technique has been used to withdraw all doses;
- The vaccine vial monitoring (VVM) has not reached the discard point.

The vaccine should be visually inspected for any foreign particulate matter and / or variation of physical aspect prior to administration. In event of either being observed, discard the vaccine.

4.3. **Contraindications:** A second or subsequent dose of Td should not be given to an individual who suffers a severe reaction to the previous dose of either Td vaccine or Tetanus toxoid or Diphtheria toxoid containing vaccine. Based on uncertainty as to which component of the vaccine may be responsible, none of the components should be administered. Alternatively, such individuals may be referred to an allergist for evaluation if further immunizations are to be considered.

4.4. **Special warnings and precautions:** A frequent administration of the Td vaccine may be associated with increased incidence and severity of adverse reactions. Persons who experienced an Arthus-type hypersensitivity reaction following a prior dose of a tetanus/Diphtheria toxoid-containing vaccine should not receive Td vaccine more frequently than every 10 years, even for tetanus prophylaxis as part of wound management. The person with Guillain-Barré syndrome within 6 weeks of a previous tetanus toxoid-containing vaccine should be carefully consider based on the need and benefit and risk ratio for administration of Td vaccine.

4.5. **Interaction with other medicinal products and other forms of interaction:** No safety and immunogenicity data are available on the concomitant administration of Td vaccine with other vaccines licensed in India.

4.6. **Pregnancy and lactation:** With respect to Td vaccine Animal reproduction studies have not been conducted, so whether Td vaccine can cause any fetal

harm when administered to a pregnant woman is unknown or it can affect reproduction capacity. It should be given to the pregnant woman only if clearly needed. No clinical data on use during pregnancies are available with this vaccine.

4.7. **Effects on the ability to drive and use machines:** No data available.

4.8. **Undesirable effects:** Common adverse events in a mean age of 39 years (range 18- 85 years), This included pain 43%, discomfort with arm movement 14%, swelling 3.8%, malaise 5.1%, and fever (axillary temperature greater than or equal to 38 degrees C) 1.7%. Local and general reactions were considered as mild by almost two-thirds of vaccinees. Moderate plus severe local reactions more commonly reported in the 18 to 35 year old group than in the 36 to 65 year old group.

4.9. **Overdose:** No data available.

5. PHARMACOLOGICAL PROPERTIES

5.1. **Pharmacodynamic properties**: Pharmacotherapeutic group – Vaccines. Tetanus toxoid in combination with diphtheria toxoid.

5.2. **Immunological Data**: Immunogenicity and reactogenicity of the vaccine is well established and proved that the vaccine is efficacious.

5.3. **Pharmacokinetic properties**: Pharmacokinetic studies are not required for vaccines.

5.4. **Preclinical safety data**: No data available.

6. PRECLINICAL SAFETY DATA (NON-CLINICAL PROPERTIES)

6.1. **Animal Toxicology or Pharmacology:** No data available.

7. **DESCRIPTION:** The Td vaccine is a preparation of diphtheria formal toxoid and tetanus formal toxoid adsorbed on aluminium phosphate gel. The formol toxoids are prepared from the toxins produced by the growth of *Corynebacterium diphtheriae* and *Clostridium tetani* respectively.

8. PHARMACEUTICAL PARTICULARS

8.1. List of Excipients Aluminium Phosphate (Prepared from Aluminium potassium chloride + Tri-sodium phosphate) Thiomersal, Sodium chloride, Sodium Carbonate and Water for Injection

8.2. Incompatibilities As no compatibility studies data is available with this product must not be mixed with other medicinal products.

8.3. Shelf-life: 18 months from the date of manufacturing (this may be further extended based on the RT stability data).

9. NATURE AND CONTENTS OF CONTAINER

Multidose vial: 10 dose vial of 5 ml.

9.1. Storage and Handling Instructions:

9.1.1. Special precautions for storage: The Td vaccine should be stored in a dark place at a temperature between 2°C -8°C. Transportation should also be at 2°C - 8°C. DO NOT FREEZE.

9.1.2. Special precautions for disposal: Any unused product or waste material should be disposed of in accordance with local requirements.

10. PATIENT COUNCELLING INFORMATION: Not Applicable

11. MARKETING AUTHORIZATION HOLDER

Name and Address: Central Research Institute, Kasauli, Distt. Solan, HP-173204.

Telephone: 01792 273105

Email: director-crik-hp@gov.in

12. DETAILS OF MARKETING AUTHORIZATION NUMBER(S)

Permission No.: MF/BIO/21/000112 dated 08-10-2021

Manufacturing License No. 21-MB on Form -26H

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Assistant Director & Head QA Division
CRI Kasauli

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