

Diphtheria Toxoid for Adult Use in the Minimum Requirements of Biological Products.

Description Adsorbed Diphtheria Toxoid for Adult Use becomes a homogeneous, whitish turbid liquid on shaking.

Diphtheria-Tetanus Combined Toxoid

ジフテリア破傷風混合トキソイド

Diphtheria-Tetanus Combined Toxoid is a liquid for injection containing diphtheria toxoid and tetanus toxoid which are prepared by treating diphtheria toxin and tetanus toxin, respectively, with formaldehyde by a method involving no appreciable loss of the immunogenicity.

It conforms to the requirements of Diphtheria-Tetanus Combined Toxoid in the Minimum Requirements of Biological Products.

Description Diphtheria-Tetanus Combined Toxoid is a colorless or light yellow-brown, clear liquid.

Adsorbed Diphtheria-Tetanus Combined Toxoid

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Adsorbed Diphtheria-Tetanus Combined Toxoid is a liquid for injection containing diphtheria toxoid and tetanus toxoid which are prepared by treating diphtheria toxin and tetanus toxin, respectively, with formaldehyde by a method involving no appreciable loss of the immunogenicity and rendered insoluble by adding aluminum salt.

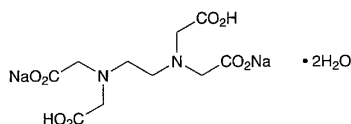
It conforms to the requirements of Adsorbed Diphtheria-Tetanus Combined Toxoid in the Minimum Requirements for Biological Products.

Description Adsorbed Diphtheria-Tetanus Combined Toxoid becomes a homogeneous, whitish turbid liquid on shaking.

Disodium Edetate

Disodium Ethylenediaminetetraacetate EDTA Sodium

エデト酸ナトリウム



$C_{10}H_{14}N_2Na_2O_8 \cdot 2H_2O$: 372.24

Disodium dihydrogen ethylenediaminetetraacetate dihydrate [6381-92-6]

Disodium Edetate contains not less than 99.0% of $C_{10}H_{14}N_2Na_2O_8 \cdot 2H_2O$.

Description Disodium Edetate occurs as white crystals or crystalline powder. It is odorless and has a slight, acid taste.

It is soluble in water, and practically insoluble in ethanol (95) and in diethyl ether.

Identification (1) Dissolve 0.01 g of Disodium Edetate in 5 mL of water, add 2 mL of a solution of potassium chromate (1 in 200) and 2 mL of arsenic (III) trioxide TS, and heat in a water bath for 2 minutes: a purple color develops.

(2) Dissolve 0.5 g of Disodium Edetate in 20 mL of water, and add 1 mL of dilute hydrochloric acid: a white precipitate is produced. Collect the precipitate, wash with 50 mL of water, and dry at 105°C for 1 hour: the precipitate melts between 240°C and 244°C (with decomposition).

(3) A solution of Disodium Edetate (1 in 20) responds to the Qualitative Tests (1) for sodium salt.

pH Dissolve 1 g of Disodium Edetate in 100 mL of water: the pH of this solution is between 4.3 and 4.7.

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Disodium Edetate in 50 mL of water: the solution is clear and colorless.

(2) Cyanide—Transfer 1.0 g of Disodium Edetate to a round-bottomed flask, dissolve in 100 mL of water, add 10 mL of phosphoric acid, and distil. Place 15 mL of 0.5 mol/L sodium hydroxide VS in a 100-mL measuring cylinder, which is used as a receiver, and immerse the bottom end of the condenser into the solution. Distil the mixture until the distillate measures 100 mL, and use this solution as the sample solution. Transfer 20 mL of the sample solution to a glass-stoppered test tube, add 1 drop of phenolphthalein TS, neutralize with dilute acetic acid, and add 5 mL of phosphate buffer solution, pH 6.8, and 1.0 mL of diluted sodium toluenesulfonchloramide TS (1 in 5). Immediately stopper the tube, mix gently, and allow to stand for a few minutes. Mix well with 5 mL of pyridine-pyrazolone TS, and allow to stand between 20°C and 30°C for 50 minutes: the solution has no more color than the following control solution.

Control solution: Pipet 1.0 mL of Standard Cyanide Solution, add 15 mL of 0.5 mol/L sodium hydroxide VS and water to make exactly 1000 mL, transfer 20 mL of this solution to a glass-stoppered test tube, and proceed as directed for the sample solution.

(3) Heavy metals—Proceed with 2.0 g of Disodium Edetate according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

(4) Arsenic—Prepare the test solution with 1.0 g of Disodium Edetate according to Method 1, and perform the test using Apparatus B (not more than 2 ppm).

Residue on ignition 37.0 – 39.0% (1 g).

Assay Weigh accurately about 1 g of Disodium Edetate, dissolve in 50 mL of water, add 2 mL of ammonia-ammonium chloride buffer solution, pH 10.7, and 0.04 g of eriochrome black T-sodium chloride indicator, and titrate with 0.1 mol/L zinc VS until the color of the solution changes from blue to red.