Trimethadione

Trimethadione, when dried, contains not less than 98.0% of $C_6H_5NO_3$.

**Description** Trimethadione occurs as white crystals or crystalline powder. It has a camphor-like odor.

It is very soluble in ethanol (95%) and in chloroform, freely soluble in diethyl ether, and soluble in water.

**Identification** (1) To 5 mL of a solution of Trimethadione (1 in 50) add 2 mL of barium hydroxide TS: a precipitate is formed immediately.

(2) Determine the infrared absorption spectrum of a solution of Trimethadione in chloroform (1 in 50) as directed in the solution method under the Infrared Spectrophotometry, using a 0.1-mm fixed sodium chloride cell, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wave numbers.

**Melting point** 45 – 47°C

**Purity** Heavy metals—Proceed with 2.0 g of Trimethadione according to Method I, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

**Loss on drying** Not more than 0.5% (1 g, silica gel, 6 hours).

**Residue on ignition** Not more than 0.10% (1 g).

**Assay** Weigh accurately about 0.4 g of Trimethadione, previously dried, in a glass-stoppered conical flask, dissolve in 5 mL of ethanol (95%), add exactly measured 50 mL of 0.1 mol/L sodium hydroxide VS, stopper, and allow to stand for 15 minutes with occasional shaking. Titrate the excess sodium hydroxide with 0.1 mol/L hydrochloric acid VS (indicator: 4 drops of cresol red TS). Perform a blank determination.

Each mL of 0.1 mol/L sodium hydroxide VS = 14.314 mg of $C_6H_5NO_3$

**Containers and storage** Containers—Tight containers. Storage—Not exceeding 30°C.

Trimethadione Tablets

Trimethadione Tablets contain not less than 94% and not more than 106% of the labeled amount of trimethadione ($C_6H_5NO_3$: 143.14).

**Method of preparation** Prepare as directed under Tablets, with Trimethadione.

**Identification** (1) Weigh a portion of powdered Trimethadione Tablets, equivalent to 1 g of Trimethadione according to the labeled amount, add 10 mL of petroleum benzine, and shake frequently for 15 minutes. Decant, remove the petroleum benzine, add another 10 mL of petroleum benzine, and repeat the extraction in the same manner. To the residue add 25 mL of diethyl ether, allow to stand for 20 minutes with occasional shaking, filter, evaporate the filtrate at room temperature, and dry the residue in a desiccator (silica gel) for 6 hours: the residue melts between 44°C and 47°C. Proceed with this residue as directed in the Identification (1) under Trimethadione.

(2) Determine the infrared absorption spectrum of a solution of the residue obtained in (1) in chloroform (1 in 50) in a 0.1-mm fixed sodium chloride cell, as directed in the solution method under the Infrared Spectrophotometry: it exhibits absorption at the wave numbers of about 2960 cm⁻¹, 1814 cm⁻¹, 1735 cm⁻¹, 1445 cm⁻¹, 1394 cm⁻¹, 1290 cm⁻¹, 1100 cm⁻¹ and 1055 cm⁻¹.

**Assay** Weigh accurately and powder not less than 20 Trimethadione Tablets. Weigh accurately a portion of the powder, equivalent to about 1 g of trimethadione ($C_6H_5NO_3$), add 50 mL of ethanol (95), and boil gently for 15 minutes under a reflux condenser. Filter the warm ethanol (95) solution into a 100-mL volumetric flask through a glass filter (G4), and wash the residue with three 10-mL portions of warm ethanol (95). Combine the washings with the filtrate in the flask, cool, and add ethanol (95) to make exactly 100 mL. Pipet 25 mL of the solution into a glass-stoppered conical flask, add 25 mL of water and exactly 30 mL of 0.1 mol/L sodium hydroxide VS, stopper, allow to stand for 15 minutes with occasional shaking, and titrate the excess sodium hydroxide with 0.1 mol/L hydrochloric acid VS (indicator: 4 drops of cresol red TS). Perform a blank determination.

Each mL of 0.1 mol/L sodium hydroxide VS = 14.314 mg of $C_6H_5NO_3$

**Containers and storage** Containers—Tight containers. Storage—Not exceeding 30°C.

Trimetoquinol Hydrochloride

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