Methyltestosterone Tablets

メチルテストステロン錠

Methyltestosterone Tablets contain not less than 90% and not more than 110% of the labeled amount of methyltestosterone ($C_{20}H_{30}O_2$: 302.45).

Method of preparation Prepare as directed under Tablets, with Methyltestosterone.

Identification **(1)** To a portion of powdered Methyltestosterone Tablets, equivalent to 0.01 g of Methyltestosterone according to the labeled amount, add 50 mL of chloroform, shake for 30 minutes, and filter. Evaporate the filtrate to dryness, dissolve the residue in 10 mL of acetone, and use this solution as the sample solution. Separately, dissolve 0.01 g of methyltestosterone in 10 mL of acetone, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 10 μL each of the sample solution and the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of chloroform and ethanol (95) (9:1) to a distance of about 12 cm, and air-dry the plate. Spray evenly dilute sulfuric acid on the plate, and heat at 110°C for 10 minutes: the spots from the sample solution and the standard solution show the same *R*f value.

(2) Evaporate 1 mL of the sample solution obtained in (1) to dryness, and proceed with the residue as directed in the Identification (1) under Methyltestosterone.

Content uniformity To 1 tablet of Methyltestosterone Tablets add 5 mL of water to disintegrate, add 50 mL of methanol, and shake for 30 minutes. Add methanol to make exactly 100 mL, and centrifuge. Measure exactly x mL of the supernatant liquid, add methanol to make exactly V mL of a solution containing about 10 μg of methyltestosterone ($C_{20}H_{30}O_2$) per ml, and use this solution as the sample solution. Separately, weigh accurately about 0.01 g of Methyltestosterone Reference Standard, previously dried in a desiccator (in vacuum, phosphorus (V) oxide) for 10 hours, and dissolve in 5 mL of water and 50 mL of methanol, then add methanol to make exactly 100 mL. Pipet 5 mL of this solution, add methanol to make exactly 50 mL, and use this solution as the standard solution. Determine the absorbances, A_T and A_S, of the sample solution and the standard solution at the wavelength of maximum absorption at about 241 nm, respectively, as directed under the Ultraviolet-visible Spectrophotometry.

$$\text{Amount (mg) of methyltestosterone } (C_{20}H_{30}O_2) = \text{amount (mg) of Methyltestosterone Reference Standard} \times \frac{A_T}{A_S} \times \frac{V}{10} \times \frac{1}{x}$$

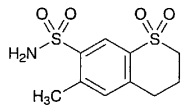
Assay Weigh accurately and powder not less than 20 Methyltestosterone Tablets. Weigh accurately a portion of the powder, equivalent to about 0.01 g of methyltestosterone ($C_{20}H_{30}O_2$), transfer to a 100-mL separator with 5 mL of water, and extract with four 25-mL portions of chloroform. Filter the combined chloroform extracts through dry filter paper, evaporate the filtrate to dryness by heating on a water bath with the aid of a current of air. Dissolve the residue in ethanol (95) to make exactly 50 mL, measure exactly 5 mL of this solution, add ethanol (95) to make exactly 100 mL, and determine the absorbance A of this solution at the wavelength of maximum absorption at about 241 nm as directed under the Ultraviolet-visible Spectrophotometry.

$$\text{Amount (mg) of methyltestosterone } (C_{20}H_{30}O_2) = \frac{A}{536} \times 10{,}000$$

Containers and storage Containers—Tight containers.

Meticrane

メチクラン



$C_{10}H_{13}NO_4S_2$: 275.35
6-Methylthiochroman-7-sulfonamide 1,1-dioxide
[*1084-65-7*]

Meticrane, when dried, contains not less than 98.0% of $C_{10}H_{13}NO_4S_2$.

Description Meticrane occurs as white, crystals or crystalline powder. It is odorless and has a slight bitter taste.

It is freely soluble in dimethylformamide, slightly soluble in acetonitrile and in methanol, very slightly soluble in ethanol (95), and practically insoluble in water.

Melting point: about 234°C (with decomposition).

Identification **(1)** Determine the absorption spectrum of a solution of Meticrane in methanol (3 in 10,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wavelengths.

(2) Determine the infrared absorption spectrum of Meticrane, previously dried, as directed in the potassium bromide disk method under the Infrared Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wave numbers.

Purity **(1)** Ammonium—Perform the test with 0.10 g of Meticrane. Prepare the control solution with 3.0 mL of Standard Ammonium Solution (not more than 0.03%).

(2) Heavy metals—Proceed with 1.0 g of Meticrane according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(3) Arsenic—Prepare the test solution with 1.0 g of Meticrane according to Method 3, and perform the test using Apparatus B (not more than 2 ppm).

(4) Related substances—Dissolve 0.05 g of Meticrane in 50 mL of acetonitrile, and use this solution as the sample solution. Pipet 1 mL of the sample solution, add acetonitrile to make exactly 100 mL, and use this solution as the standard solution. Perform the test with 2 μL each of the sample