Residue on ignition Being specified separately.

Bacterial endotoxins Less than 0.12 EU/mg (potency).

Assay Weigh accurately an amount of Meropenem Trihydrate and Meropenem Trihydrate Reference Standard, equivalent to about 0.05 g (potency), add exactly 10 mL of the internal standard solution to dissolve, add triethylamine-phosphate buffer solution, pH 5.0 to make 100 mL, and use these solutions as the sample solution and the standard solution, respectively. Perform the test with 5 μL of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following conditions, and calculate the ratios, Q_T and Q_S, of the peak area of meropenem to that of the internal standard.

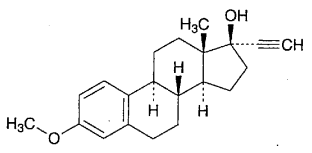
Amount [μg (potency)] of meropenem ($C_{17}H_{25}N_3O_5S$)
= amount [mg (potency)] of Meropenem Trihydrate Reference Standard $\times \frac{Q_T}{Q_S} \times 1000$

Internal standard solution—A solution of benzyl alcohol in triethylamine-phosphate buffer solution, pH 5.0 (1 in 300).
Operating conditions—
Detector: An ultraviolet absorption photometer (wavelength: 220 nm).
Column: A stainless steel column 6.0 mm in inside diameter and 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).
Column temperature: A constant temperature of about 25°C.
Mobile phase: A mixture of triethylamine-phosphate buffer solution, pH 5.0 and methanol (5:1).
Flow rate: Adjust the flow rate so that the retention time of meropenem is about 7 minutes.
System suitability—
System performance: When the procedure is run with 5 μL of the standard solution under the above operating conditions, meropenem and the internal standard are eluted in this order with the resolution between these peaks being not less than 20.
System repeatability: When the test is repeated 5 times with 5 μL of the standard solution under the above operating conditions, the relative standard deviation of the ratios of the peak area of meropenem to that of the internal standard is not more than 2.0%.

Containers and storage Containers—Tight containers.

Mestranol

メストラノール



$C_{21}H_{26}O_2$: 310.43
3-Methoxy-19-nor-17α-pregna-1,3,5(10)-trien-20-yn-17-ol
[*72-33-3*]

Mestranol, when dried, contains not less than 97.0% and not more than 102.0% of $C_{21}H_{26}O_2$.

Description Mestranol occurs as a white to pale yellowish white, crystalline powder. It is odorless.

It is freely soluble in chloroform, soluble in 1,4-dioxane, sparingly soluble in ethanol (99.5) and in diethyl ether, and practically insoluble in water.

Identification **(1)** Dissolve 2 mg of Mestranol in 1 mL of a mixture of sulfuric acid and ethanol (99.5) (2:1): a red-purple color develops with a yellow-green fluorescence.

(2) Determine the absorption spectrum of a solution of Mestranol in ethanol (99.5) (1 in 10,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum or the spectrum of a solution of Mestranol Reference Standard prepared in the same manner as the sample solution: both spectra exhibit similar intensities of absorption at the same wavelengths.

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

Optical rotation $[\alpha]_D^{20}$: +2 – +8° (after drying, 0.2 g, 1,4-dioxane, 10 mL, 100 mm).

Melting point 148 – 154°C

Purity **(1)** Heavy metals—Proceed with 1.0 g of Mestranol 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).

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

(3) Other steroids—Dissolve 0.10 g of Mestranol in 20 mL of chloroform, and use this solution as the sample solution. Pipet 1 mL of the sample solution, add chloroform to make exactly 200 mL, 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 (99.5) (29:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly diluted sulfuric acid (1 in 5) on the plate, and heat at 105°C for 15 minutes: the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

Loss on drying Not more than 0.5% (0.5 g, 105°C, 3 hours).

Residue on ignition Not more than 0.1% (0.5 g).

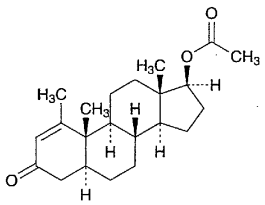
Assay Weigh accurately about 0.01 g each of Mestranol and Mestranol Reference Standard, previously dried, dissolve in ethanol (99.5) to make exactly 100 mL, and use these solutions as the sample solution and the standard solution, respectively. Determine the absorbances, A_T and A_S, of the sample solution and the standard solution at 279 nm as directed under the Ultraviolet-visible Spectrophotometry.

Amount (mg) of $C_{21}H_{26}O_2$
= amount (mg) of Mestranol Reference Standard
$\times \frac{A_T}{A_S}$

Containers and storage Containers—Tight containers. Storage—Light-resistant.

Metenolone Acetate

酢酸メテノロン



$C_{22}H_{32}O_3$: 344.49
1-Methyl-3-oxo-5α-androst-1-en-17β-yl acetate [*434-05-9*]

Metenolone Acetate, when dried, contains not less than 97.0% and not more than 103.0% of $C_{22}H_{32}O_3$.

Description Metenolone Acetate occurs as a white to pale yellowish white, crystalline powder. It is odorless.

It is freely soluble in acetone, in 1,4-dioxane and in chloroform, soluble in ethanol (95) and in methanol, sparingly soluble in diethyl ether and in sesame oil, slightly soluble in hexane and in petroleum ether, and practically insoluble in water.

Identification (1) Dissolve 1 mg of Metenolone Acetate in 5 mL of a mixture of ethanol (95) and sulfuric acid (1:1), and heat for 30 minutes in a water bath: a red-brown color develops.

(2) To 0.01 g of Metenolone Acetate add 0.5 mL of dilute sodium hydroxide-ethanol TS, and heat for 1 minute on a water bath. After cooling, add 0.5 mL of diluted sulfuric acid (1 in 2), and boil gently for 1 minute: the odor of ethyl acetate is perceptible.

(3) Dissolve 0.05 g of Metenolone Acetate in 3 mL of methanol, add 0.3 mL of a solution of potassium carbonate (1 in 6), and boil for 2 hours under a reflux condenser. After cooling, add this solution gradually to 50 mL of cold water, and stir for 15 minutes. Filter the precipitate so obtained by suction through a glass filter (G4), wash with 10 mL of water, and dry at 105°C for 1 hour: it melts between 157°C and 161°C.

(4) Determine the infrared absorption spectrum of Metenolone Acetate, 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.

Optical rotation $[\alpha]_D^{20}$: +39 - +42° (after drying, 0.2 g, chloroform, 10 mL, 100 mm).

Melting point 141 - 144°C

Purity (1) Clarity and color of solution—Dissolve 0.50 g of Metenolone Acetate in 10 mL of 1,4-dioxane: the solution is clear and colorless to pale yellow.

(2) Heavy metals—Proceed with 2.0 g of Metenolone Acetate 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).

(3) Other steroids—Dissolve 0.035 g of Metenolone Acetate in 20 mL of chloroform, and use this solution as the sample solution. Pipet 1 mL of the sample solution, dilute with chloroform to exactly 250 mL, 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 with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of cyclohexane and ethyl acetate (1:1) to a distance of about 12 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

Loss on drying Not more than 0.5% (0.5 g, 105°C, 3 hours).

Residue on ignition Not more than 0.1% (0.5 g).

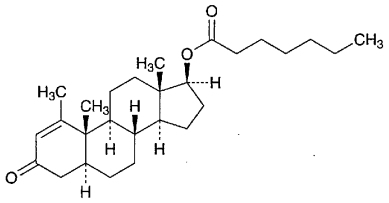
Assay Weigh accurately about 0.01 g of Metenolone Acetate, previously dried, and dissolve in methanol to make exactly 100 mL. Pipet 5 mL of this solution, and dilute with methanol to exactly 50 mL. Determine the absorbance A of this solution at the wavelength of maximum absorption at about 242 nm.

$$\text{Amount (mg) of } C_{22}H_{32}O_3 = \frac{A}{391} \times 10{,}000$$

Containers and storage Containers—Tight containers. Storage—Light-resistant.

Metenolone Enanthate

エナント酸メテノロン



$C_{27}H_{42}O_3$: 414.62
1-Methyl-3-oxo-5α-androst-1-en-17β-yl heptanoate
[*303-42-4*]

Metenolone Enanthate, when dried, contains not less than 97.0% and not more than 103.0% of $C_{27}H_{42}O_3$.

Description Metenolone Enanthate occurs as white crystals or crystalline powder. It is odorless.

It is very soluble in ethanol (95), in acetone, in 1,4-dioxane and in chloroform, freely soluble in methanol, in ethyl acetate, in diethyl ether, in cyclohexane, in petroleum