Detection sensitivity: Adjust the detection sensitivity so that the peak height of fosfestrol obtained from 10 μL of the standard solution is between 5 mm and 15 mm.

Time span of measurement: Three times as long as the retention time of fosfestrol.

Loss on drying Not more than 1.0% (1 g, 105°C, 4 hours).

Assay Weigh accurately about 0.2 g of Fosfestrol, previously dried, dissolve in 60 mL of water, and titrate with 0.1 mol/L sodium hydroxide VS (potentiometric titration). The end point is the second equivalent point. Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L sodium hydroxide VS
= 10.708 mg of $C_{18}H_{22}O_8P_2$

Containers and storage Containers—Tight containers.

Fosfestrol Tablets

Diethylstilbestrol Diphosphate Tablets

ホスフェストロール錠

Fosfestrol Tablets contain not less than 93% and not more than 107% of the labeled amount of fosfestrol ($C_{18}H_{22}O_8P_2$: 428.31).

Method of preparation Prepare as directed under the Tablets, with Fosfestrol.

Identification **(1)** To a quantity of powdered Fosfestrol Tablets, equivalent to 0.5 g of Fosfestrol according to the labeled amount, add 50 mL of 0.1 mol/L hydrochloric acid TS, shake well, and filter. To the filtrate add 100 mL of diethyl ether, extract, and evaporate carefully the diethyl ether extract on a water bath to dryness. Proceed with 0.015 g of the residue as directed in the Identification (1) under Fosfestrol.

(2) Dry 0.01 g of the residue obtained in (1) at 105°C for 4 hours, and determine the infrared absorption spectrum as directed in the potassium bromide disk method under the Infrared Spectrometry: it exhibits absorption at the wave numbers of about 2970 cm^{-1}, 1605 cm^{-1}, 1505 cm^{-1}, 1207 cm^{-1} and 1006 cm^{-1}.

Dissolution test Perform the test with 1 tablet of Fosfestrol Tablets at 50 revolutions per minute according to Method 2 under the Dissolution Test, using 900 mL of water. Take 20 mL or more of the dissolved solution 20 minutes after starting the test, and filter through a membrane filter with pore size of not more than 0.8 μm. Discard the first 10 mL of the filtrate, pipet 2 mL of the subsequent, add a solution of sodium hydroxide (1 in 250) to make exactly 20 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.05 g of Fosfestrol Reference Standard, previously dried at 105°C for 4 hours, and dissolve in a solution of sodium hydroxide (1 in 250) to make exactly 100 mL. Pipet 2 mL of this solution, add a solution of sodium hydroxide (1 in 250) to make exactly 100 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 242 nm as directed under the Ultraviolet-visible Spectrophotometry.

The dissolution rate of Fosfestrol Tablets in 20 minutes is not less than 80%.

Dissolution rate (%) with respect to the labeled amount of fosfestrol ($C_{18}H_{22}O_8P_2$)

$$= W_S \times \frac{A_T}{A_S} \times \frac{1}{C} \times 180$$

W_S: Amount (mg) of Fosfestrol Reference Standard.
C: Labeled amount (mg) of fosfestrol ($C_{18}H_{22}O_8P_2$) in 1 tablet.

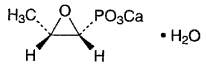
Assay Weigh accurately not less than 20 Fosfestrol Tablets, and powder. Weigh accurately a quantity of the powder, equivalent to about 1 g of fosfestrol ($C_{18}H_{22}O_8P_2$) according to the labeled amount, add 100 mL of a solution of sodium hydroxide (1 in 125), shake well, add water to make exactly 500 mL. Filter this solution, discard the first 30 mL of the filtrate, pipet the subsequent 2 mL of the filtrate, add 30 mL of a solution of sodium hydroxide (1 in 125) and water to make exactly 250 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.08 g of Fosfestrol Reference Standard, previously dried at 105°C for 4 hours, and dissolve in a solution of sodium hydroxide (1 in 125) to make exactly 50 mL. Pipet 1 mL of this solution, add 10 mL of a solution of sodium hydroxide (1 in 125) and water to make exactly 100 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 242 nm as directed under the Ultraviolet-visible Spectrophotometry.

Amount (mg) of fosfestrol ($C_{18}H_{22}O_8P_2$)
= amount (mg) of Fosfestrol Reference Standard
$\times \frac{A_T}{A_S} \times \frac{25}{2}$

Containers and storage Containers—Tight containers.

Fosfomycin Calcium

ホスホマイシンカルシウム



$C_3H_5CaO_4P.H_2O$: 194.14
Monocalcium (2*R*,3*S*)-3-methyloxiran-2-ylphosphonate monohydrate [*26016-98-8*]

Fosfomycin Calcium contains not less than 725 μg (potency) per mg, calculated on the anhydrous basis. The potency of Fosfomycin Calcium is expressed as mass (potency) of fosfomycin ($C_3H_7O_4P$: 138.06).

Description Fosfomycin Calcium occurs as a white crystalline powder.

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

Identification **(1)** Determine the infrared absorption spectrum of Fosfomycin Calcium as directed in the potassium bromide disk method under the Infrared Spectrophotometry, and compare the spectrum with the Reference Spectrum: