Loss on drying Not more than 0.20% (1 g, 105°C, 2 hours).

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

Assay Weigh accurately about 0.4 g of Prazepam, previously dried, dissolve in 60 mL of acetic anhydride, and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS
= 32.481 mg of $C_{19}H_{17}ClN_2O$

Containers and storage Containers—Tight containers.

Prazepam Tablets

プラゼパム錠

Prazepam Tablets contain not less than 93% and not more than 107% of the labeled amount of prazepam ($C_{19}H_{17}ClN_2O$: 324.80).

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

Identification (1) To a quantity of powdered Prazepam Tablets, equivalent to 0.05 g of Prazepam according to the labeled amount, add 25 mL of acetone, shake well, and filter. Take 5 mL of the filtrate, evaporate on a water bath to dryness, and dissolve the residue in 3 mL of sulfuric acid. With this solution, proceed as directed in the Identification (1) under Prazepam.

(2) To a quantity of powdered Prazepam Tablets, equivalent to 0.02 g of Prazepam according to the labeled amount, add 200 mL of a solution of sulfuric acid in ethanol (99.5) (3 in 1000), shake well, and filter. To 5 mL of the filtrate add a solution of sulfuric acid in ethanol (99.5) (3 in 1000) to make 50 mL, and determine the absorption spectrum as directed under the Ultraviolet-visible Spectrophotometry: it exhibits maxima between 241 nm and 245 nm, between 283 nm and 287 nm and between 363 nm and 367 nm, and minima between 263 nm and 267 nm and between 334 nm and 338 nm.

Dissolution test Proceed with 1 tablet of Prazepam Tablets according to Method (1) in the Dissolution Test, and perform the test, using 900 mL of 0.1 mol/L hydrochloric acid TS as the test solution at 100 rotations per minute. 30 minutes after starting the test, separate 20 mL or more of the dissolved solution, and filter with a membrane filter with pore size not more than 0.8 μm. Discard the first 10 mL of the filtrate, measure exactly the subsequent V mL of the filtrate, add 0.1 mol/L hydrochloric acid TS to make exactly V' mL so that each mL of this solution might contain about 5 μg of prazepam ($C_{19}H_{17}ClN_2O$) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 5 mg of prazepam for assay, previously dried at 105°C for 2 hours, add 200 mL of 0.1 mol/L hydrochloric acid TS and dissolve with shaking, or by ultrasonication if necessary, add 0.1 mol/L hydrochloric acid TS to make exactly 1000 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 240 nm as directed under the Ultraviolet-visible Spectrophotometry.

The dissolution rate of Prazepam Tablets during 30 minutes is not less than 80%: it meets the Dissolution Test.

Dissolution rate (%) of prazepam ($C_{19}H_{17}ClN_2O$) to the labeled amount
$$= W_S \times \frac{A_T}{A_S} \times \frac{V'}{V} \times \frac{90}{C}$$

W_S: Amount (mg) of prazepam for assay.
C: Labeled amount (mg) of prazepam ($C_{19}H_{17}ClN_2O$) in each tablet.

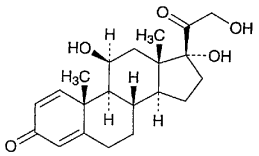
Assay Weigh accurately not less than 20 Prazepam Tablets, and powder. Weigh accurately a quantity of the powder, equivalent to about 0.05 g of prazepam ($C_{19}H_{17}ClN_2O$), add 30 mL of acetone, shake well, centrifuge, and separate the supernatant. Repeat the same procedure twice with 30 mL each of acetone, combine all the supernatants, and evaporate on a water bath to dryness. Dissolve the residue in 50 mL of a mixture of acetic anhydride and acetic acid (100) (7:3), and titrate with 0.02 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

Each mL of 0.02 mol/L perchloric acid VS
= 6.496 mg of $C_{19}H_{17}ClN_2O$

Containers and storage Containers—Tight containers.

Prednisolone

プレドニゾロン



$C_{21}H_{28}O_5$: 360.44
11β,17,21-Trihydroxypregna-1,4-diene-3,20-dione
[*50-24-8*]

Prednisolone, when dried, contains not less than 97.0% and not more than 102.0% of $C_{21}H_{28}O_5$.

Description Prednisolone occurs as a white, crystalline powder.

It is soluble in methanol and in ethanol (95), slightly soluble in ethyl acetate and in chloroform, and very slightly soluble in water.

Melting point: about 235°C (with decomposition).

Identification (1) To 2 mg of Prednisolone add 2 mL of sulfuric acid, and allow to stand for 2 to 3 minutes: a deep red color, without fluorescence, develops. To this solution add 10 mL of water cautiously: the color disappears and a gray, flocculent precipitate is formed.

(2) Determine the infrared absorption spectrum of Prednisolone, previously dried, as directed in the potassium