

minutes, centrifuge, and use the supernatant liquid as the sample solution. Proceed as directed in the Identification under Glycyrrhiza.

Purity Insoluble matter—Dissolve 2.0 g of Glycyrrhiza Extract in 18 mL of water, and filter. To 10 mL of the filtrate add 5 mL of ethanol (95): a clear solution results.

Assay Weigh accurately about 0.15 g of Glycyrrhiza Extract, place in a glass-stoppered, centrifuge tube, add 25 mL of dilute ethanol, and heat at 50°C for 30 minutes with occasional shaking. Cool, centrifuge, and separate the supernatant liquid. To the residue add 20 mL of dilute ethanol, and proceed in the same manner. Combine the extracts, add dilute ethanol to make exactly 100 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.02 g of Glycyrrhizic Acid Reference Standard (separately determine the water content), dissolve in dilute ethanol to make exactly 100 mL, and use this solution as the standard solution. Proceed as directed in the Assay under Glycyrrhiza.

$$\begin{aligned} & \text{Amount (mg) of glycyrrhizic acid (C}_{42}\text{H}_{62}\text{O}_{16}) \\ &= \text{amount (mg) of Glycyrrhizic Acid Reference} \\ & \quad \text{Standard, calculated on the anhydrous basis} \\ & \quad \times \frac{A_T}{A_S} \end{aligned}$$

Containers and storage Containers—Tight containers.

Crude Glycyrrhiza Extract

カンゾウ粗エキス

Glycyrrhiza Extract contains not less than 6.0% of glycyrrhizic acid (C₄₂H₆₂O₁₆: 822.93).

Method of preparation Boil coarse powder of Glycyrrhiza or the root and stolon of *Glycyrrhiza glabra* Linné (*Leguminosae*) which meets the requirement of Glycyrrhiza with Water or Purified Water, filter the solution under pressure, and evaporate the filtrate.

Description Crude Glycyrrhiza Extract occurs as lustrous, dark yellow-red to blackish brown plates, rods or masses. It is comparatively brittle when cold, and the fractured surface is dark yellow-red, shell-like, and lustrous. It softens when warmed.

It has a characteristic odor and a sweet taste.

It dissolves in water with turbidity.

Identification To 0.6 g of Crude Glycyrrhiza Extract add 10 mL of a mixture of ethanol (95) and water (7:3), dissolve by warming if necessary, cool, centrifuge, and use the supernatant liquid as the sample solution. Proceed as directed in the Identification under Glycyrrhiza.

Purity (1) Water-insoluble substances—Boil 5.0 g of pulverized Crude Glycyrrhiza Extract with 100 mL of water. After cooling, filter the mixture through tared filter paper, wash with water, and dry the residue at 105°C for 5 hours: the mass of the residue is not more than 1.25 g.

(2) Foreign matter—The filtrate obtained in (1) does not have a strong bitter taste.

(3) Starch—To about 1 g of pulverized Crude Glycyrrhi-

za Extract add water to make 20 mL, shake the mixture thoroughly, and filter. Examine the insoluble substance on the filter paper under a microscope: the residue contains no starch grains.

Total ash Not more than 12.0% (1 g, proceed as directed in the Total ash under Crude Drugs).

Assay Weigh accurately about 0.15 g of Crude Glycyrrhiza Extract, place in a glass-stoppered, centrifuge tube, add 25 mL of dilute ethanol, and heat at 50°C for 30 minutes with occasional shaking. Cool, centrifuge, and separate the supernatant liquid. To the residue add 20 mL of dilute ethanol, and proceed in the same manner. Combine the extracts, add dilute ethanol to make exactly 100 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.02 g of Glycyrrhizic Acid Reference Standard (separately determine the water content), dissolve in dilute ethanol to make exactly 100 mL, and use this solution as the standard solution. Proceed as directed in the Assay under Glycyrrhiza.

$$\begin{aligned} & \text{Amount (mg) of glycyrrhizic acid (C}_{42}\text{H}_{62}\text{O}_{16}) \\ &= \text{amount (mg) of Glycyrrhizic Acid Reference} \\ & \quad \text{Standard, calculated on the anhydrous basis} \\ & \quad \times \frac{A_T}{A_S} \end{aligned}$$

Containers and storage Containers—Tight containers.

Chorionic Gonadotrophin

胎盤性性腺刺激ホルモン

Chorionic Gonadotrophin is a dried preparation of gonad-stimulating hormone obtained from the urine of pregnant women or from the placenta. It contains not less than 1500 chorionic gonadotrophin Units per mg.

It contains not less than 80% and not more than 125% of the labeled Units of chorionic gonadotrophin.

Description Chorionic Gonadotrophin occurs as a white to light yellow-brown powder. It is odorless.

It is freely soluble in water and practically insoluble in diethyl ether.

Identification Calculate *b* by the following equation, using *Y*₃ and *Y*₄ obtained in the Assay: *b* is not less than 120.

$$\begin{aligned} b &= \frac{E}{I} \\ E &= \frac{Y_3 - Y_4}{f} \end{aligned}$$

f: Number of test animals per group.

$$I = \log \frac{T_H}{T_L}$$

Purity (1) Clarity and color of solution—Dissolve 0.05 g of Chorionic Gonadotrophin in 5 mL of isotonic sodium chloride solution: the solution is clear and colorless or light yellow.

(2) Estrogen—Inject subcutaneously into each of three female albino rats or albino mice ovariectomized at least two