Chorionic Gonadotrophin for Injection

注射用胎盤性性腺刺激ホルモン

Chorionic Gonadotrophin for Injection is a preparation for injection which is dissolved before use. It contains not less than 80% and not more than 125% of the labeled Units of chorionic gonadotrophin.

Method of preparation Prepare as directed under Injections with Chorionic Gonadotrophin.

Description Chorionic Gonadotrophin for Injection occurs as a white to light yellow-brown powder or masses. It is freely soluble in water.

Identification Proceed as directed in the Identification under Chorionic Gonadotrophin.

Loss on drying Not more than 5.0% (0.1 g, in vacuum, phosphorus (V) oxide, 4 hours).

Pyrogen Dissolve Chorionic Gonadotrophin for Injection in isotonic sodium chloride solution to prepare a solution containing 1000 units per mL according to the labeled Units, inject 1.0 mL of this solution per kg of body mass of rabbit, and perform the test: it meets the requirements of the Pyrogen Test.

Assay Proceed as directed in the Assay under Chorionic Gonadotrophin. The ratio of the assayed Units to the labeled Units should be calculated by the following equation.

The ratio of the assayed Units to the labeled Units = antilog M

Containers and storage Containers—Hermetic containers.
Storage—Light-resistant, and in a cold place.

Serum Gonadotrophin

血清性性腺刺激ホルモン

Serum Gonadotrophin is a dried preparation of gonad-stimulating hormone obtained from the serum of pregnant mares. It contains not less than 1000 serum gonadotrophin Units per mg.

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

Description Serum Gonadotrophin occurs as a white powder, and 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.

$$b = \frac{E}{I}$$

$$E = \frac{Y_3 - Y_4}{f}$$

f: Number of test animals per group.

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

Purity Clarity and color of solution—Dissolve Serum Gonadotrophin in isotonic sodium chloride solution to prepare a solution containing 9000 units per mL according to the labeled Units: the solution is clear and colorless.

Loss on drying Not more than 8.0% (0.1 g, in vacuum, phosphorus (V) oxide, 4 hours).

Toxicity Dissolve Serum Gonadotrophin in isotonic sodium chloride solution to prepare a solution containing 400 units per mL according to the labeled Units, and use this solution as the sample solution. Inject intravenously 0.5 mL of the sample solution to each of five well-fed, healthy albino mice weighing about 20 g: no mouse dies within 48 hours after injection. If any mouse dies within 48 hours, repeat the test using 10 albino mice weighing 19.5 to 20.5 g: all the animals survive for 48 hours.

Pyrogen Dissolve Serum Gonadotrophin in isotonic sodium chloride solution to prepare a solution containing 500 units per mL according to the labeled Units, inject 1.0 mL of this solution per kg of body mass of rabbit, and perform the test: it meets the requirements of the Pyrogen Test.

Assay (i) Test animals—Select healthy female albino rats weighing about 45 g.

(ii) Standard solution—Dissolve a quantity of Serum Gonadotrophin Reference Standard in bovine serum albumin-isotonic sodium chloride solution to prepare four kinds of solutions, containing 10, 20, 40 and 80 units per 0.5 mL, respectively. Inject these solutions into four groups consisting of five test animals each, and weigh their ovaries, as directed in procedure of (iv). Inject bovine serum albumin-isotonic sodium chloride solution to another group, and use this group as the control group. According to the result of this test, designate the concentration of the reference standard which will increase the masses of the ovaries about 3 times the mass of the ovaries of the control group as a low-dose concentration of the standard solution, and the concentration 1.5 to 2.0 times the low-dose concentration as a high-dose concentration. Weigh accurately a suitable quantity of Serum Gonadotrophin Reference Standard, dissolve in bovine serum albumin-isotonic sodium chloride solution, and prepare a high-dose standard solution S_H and a low-dose standard solution S_L whose concentrations are equal to those determined by the above test.

(iii) Sample solution—According to the labeled units, weigh accurately a suitable quantity of Serum Gonadotrophin, dissolve in bovine serum albumin-isotonic sodium chloride solution, and prepare a high-dose sample solution T_H and a low-dose sample solution T_L having Units equal to the standard solutions in equal volumes, respectively.

(iv) Procedure—Divide the test animals at random into 4 groups, A, B, C and D, with not less than 10 animals and equal numbers in each group. Inject once subcutaneously 0.5 mL of S_H, S_L, T_H and T_L in each group. On the sixth day, excise the ovaries, remove the fat and other unwonted tissues attached to the ovaries, and remove the adhering water by lightly pressing between filter paper, and immediately weigh the ovaries.

(v) Calculation—Designate the mass of ovaries by S_H, S_L,

T_H and T_L as y_1, y_2, y_3 and y_4, respectively. Sum up y_1, y_2, y_3 and y_4 on each set to obtain Y_1, Y_2, Y_3 and Y_4.

$$\text{Units per mg of Serum Gonadotrophin} = \text{antilog } M \times \begin{pmatrix}\text{units per mL of the high dose}\\ \text{of the standard solution}\end{pmatrix} \times \frac{b}{a}$$

$$M = \frac{IY_a}{Y_b}$$

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

$$Y_a = -Y_1 - Y_2 + Y_3 + Y_4$$

$$Y_b = Y_1 - Y_2 + Y_3 - Y_4$$

a: Mass (mg) of sample.

b: Total volume (mL) of the high dose of the test solution prepared by diluting with bovine serum albumin-isotonic sodium chloride solution.

F' computed by the following equation should be smaller than F_1 against n when s^2 is calculated. And compute L (P = 0.95) by the following equation: L should be not more than 0.3. If F' exceeds F_1, or if L exceeds 0.3, repeat the test increasing the number of the test animals or arranging the assay method in a better way until F' is smaller than F_1 or L is not more than 0.3.

$$F' = \frac{(Y_1 - Y_2 - Y_3 + Y_4)^2}{4fs^2}$$

f: Number of test animals per group.

$$s^2 = \frac{\Sigma y^2 - \frac{Y}{f}}{n}$$

Σy^2: The sum of the squares of each y_1, y_2, y_3 and y_4.

$$Y = Y_1^2 + Y_2^2 + Y_3^2 + Y_4^2$$

$$n = 4(f - 1)$$

$$L = 2\sqrt{(C-1)(CM^2 + I^2)}$$

$$C = \frac{Y_b^2}{Y_b^2 - 4fs^2t^2}$$

t^2: Value shown in the following table against n used to calculate s^2.

n	$t^2 = F_1$	n	$t^2 = F_1$	n	$t^2 = F_1$
1	161.45	13	4.667	25	4.242
2	18.51	14	4.600	26	4.225
3	10.129	15	4.543	27	4.210
4	7.709	16	4.494	28	4.196
5	6.608	17	4.451	29	4.183
6	5.987	18	4.414	30	4.171
7	5.591	19	4.381	40	4.085
8	5.318	20	4.351	60	4.001
9	5.117	21	4.325	120	3.920
10	4.965	22	4.301	∞	3.841
11	4.844	23	4.279		
12	4.747	24	4.260		

Containers and storage Containers—Tight containers. Storage—Light-resistant, and in a cold place.

Serum Gonadotrophin for Injection

注射用血清性性腺刺激ホルモン

Serum Gonadotrophin for Injection is a preparation for injection which is dissolved before use. It contains not less than 80% and not more than 125% of the labeled amount of Serum Gonadotrophin.

Method of preparation Prepare as directed under Injections with Serum Gonadotrophin.

Description Serum Gonadotrophin for Injection occurs as white powder or masses. It is freely soluble in water.

Identification Proceed as directed in the Identification under Serum Gonadotrophin.

Loss on drying Not more than 5.0% (0.1 g, in vacuum, phosphorus (V) oxide, 4 hours).

Pyrogen Dissolve Serum Gonadotrophin for Injection in isotonic sodium chloride solution to prepare a solution containing 500 units per mL according to the labeled Units, inject 1.0 mL of this solution per kg of body mass of rabbit, and perform the test: it meets the requirements of the Pyrogen Test.

Assay Proceed as directed in the Assay under Serum Gonadotrophin. The ratio of the Units assayed to the labeled Units should be calculated by the following equation.

The ratio of the assayed Units to the labeled Units = antilog M

Containers and storage Containers—Hermetic containers. Storage—Light-resistant, and in a cold place.

Gypsum

Gypsum Fibrosum

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Gypsum is natural hydrous calcium sulfate. It possibly corresponds to the formula $CaSO_4.2H_2O$.

Description Gypsum occurs as lustrous, white, heavy, fibrous, crystalline masses, which easily split into needles or very fine crystalline powder.

It is odorless and tasteless.

It is slightly soluble in water.

Identification To 1 g of pulverized Gypsum add 20 mL of water, allow to stand with occasional shaking for 30 minutes, and filter: the filtrate responds to the Qualitative Tests (2) and (3) for calcium salt and to the Qualitative Tests for sulfate.

Purity (1) Heavy metals—Biol 4.0 g of pulverized Gypsum with 4 mL of acetic acid (100) and 96 mL of water for 10 minutes, cool, add water to make exactly 100 mL, and filter. Perform the test using 50 mL of the filtrate as the test solution. Prepare the control solution as follows: to 4.0 mL