

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 .

Units per mg of Serum Gonadotrophin

$$= \text{antilog } M \times \left(\frac{\text{units per mL of the high dose}}{\text{of the standard solution}} \right) \times \frac{b}{a}$$

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

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

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

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

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.

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

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

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

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

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

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

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

<i>n</i>	$t^2 = F_1$	<i>n</i>	$t^2 = F_1$	<i>n</i>	$t^2 = F_1$
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.

$$\begin{aligned} &\text{The ratio of the assayed Units to the labeled Units} \\ &= \text{antilog } M \end{aligned}$$

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 $\text{CaSO}_4 \cdot 2\text{H}_2\text{O}$.

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