

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 .

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

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

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

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

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

セッコウ

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

of Standard Lead Solution add 2 mL of dilute acetic acid and water to make 50 mL (not more than 20 ppm).

(2) Arsenic—Prepare the test solution with 0.40 g of pulverized Gypsum according to Method 2, and perform the test using Apparatus B (not more than 5 ppm).

Containers and storage Containers—Well-closed containers.

Exsiccated Gypsum

Gypsum Exsiccatum

焼セッコウ

Exsiccated Gypsum possibly corresponds to the formula $\text{CaSO}_4 \cdot \frac{1}{2}\text{H}_2\text{O}$.

Description Exsiccated Gypsum occurs as a white to grayish white powder. It is odorless and tasteless.

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

It absorbs moisture slowly on standing in air to lose its solidifying property.

When it is heated to yield an anhydrous compound at a temperature above 200°C, it loses its solidifying property.

Identification Shake 1 g of Exsiccated Gypsum with 20 mL of water for 5 minutes, and filter: the filtrate responds to the Qualitative Tests (2) and (3) for calcium salt and to the Qualitative Tests for sulfate.

Purity Alkali—Take 3.0 g of Exsiccated Gypsum in a glass-stoppered test tube, add 10 mL of water and 1 drop of phenolphthalein TS, and shake vigorously: no red color develops.

Solidification To 10.0 g of Exsiccated Gypsum add 10 mL of water, stir immediately for 3 minutes, and allow to stand: the period necessary for water no longer to separate, upon pressing with a finger, is not more than 10 minutes from the time when water was first added.

Containers and storage Containers—Tight containers.

Adsorbed Habu-venom Toxoid

沈降はぶトキソイド

Adsorbed Habu-venom Toxoid is a liquid for injection containing habu toxoid prepared by treating toxic substances produced by habu (*Trimeresurus flavoviridis*) with formaldehyde by a method involving no appreciable loss of the immunogenicity and rendered insoluble by the addition of aluminum salt.

It conforms to the requirements of Adsorbed Habu-venom Toxoid in the Minimum Requirements for Biological Products.

Description Adsorbed Habu-venom Toxoid becomes a uniform whitish turbid liquid on shaking.

Freeze-dried Habu Antivenom, Equine

乾燥はぶウマ抗毒素

Freeze-dried Habu Antivenom, Equine, is a preparation for injection which is dissolved before use. It contains *Trimeresurus flavoviridis* antivenom in immunoglobulin of horse origin.

It conforms to the requirements of Freeze-dried Habu Anti-venom, Equine, in the Minimum Requirements for Biological Products.

Description Freeze-dried Habu Antivenom, Equine, becomes colorless or light yellow-brown, clear liquid or a slightly whitish turbid liquid on addition of solvent.

Adsorbed Hepatitis B Vaccine

沈降B型肝炎ワクチン

Adsorbed Hepatitis B Vaccine is a liquid for injection prepared by adding an aluminum salt to a liquid containing a surface antigen of hepatitis B virus to make the HBs antigen insoluble.

It conforms to the requirements of Adsorbed Hepatitis B Vaccine in the Minimum Requirements for Biological Products.

Description Adsorbed Hepatitis B Vaccine becomes a homogeneous, whitish turbid liquid on shaking.

Honey

Mel

ハチミツ

Honey is the saccharine substances obtained from the honeycomb of *Apis mellifera* Linné or *Apis indica* Radoszkowski (*Apidae*).

Description Honey is a light yellow to light yellow-brown, syrupy liquid. Usually it is transparent, but often opaque with separated crystals.

It has a characteristic odor and a sweet taste.

Specific gravity Mix 50.0 g of Honey with 100 mL of water: the specific gravity of the solution is not less than d_{20}^{20} : 1.111.

Purity (1) Acid—Mix 10 g of Honey with 50 mL of water, and neutralize with 1 mol/L potassium hydroxide VS (indicator: 2 drops of phenolphthalein TS): not more than 0.5 mL is required.

(2) Sulfate—Mix 1.0 g of Honey with 2.0 mL of water, and filter. To the filtrate add 2 drops of barium chloride TS: the solution does not change immediately.