Freeze-dried Inactivated Tissue Culture Rabies Vaccine

乾燥組織培養不活化狂犬病ワクチン

Freeze-dried Inactivated Tissue Culture Rabies Vaccine is a dried preparation containing inactivated rabies virus.

It conforms to the requirements of Freeze-dried Inactivated Tissue Culture Rabies Vaccine in the Minimum Requirements of Biologic Products.

Description Freeze-dried Inactivated Tissue Culture Rabies Vaccine becomes a colorless or light yellow-red clear liquid on addition of solvent.

Rape Seed Oil

Oleum Rapae

ナタネ油

Rape Seed Oil is the fixed oil obtained from the seed of *Brassica campestris* Linné subsp. *napus* Hooker fil. et Anderson var. *nippo-oleifera* Makino (*Cruciferae*).

Description Rape Seed Oil is a clear, pale yellow, slightly viscous oil. It is odorless or has a slight odor and a mild taste.

It is miscible with diethyl ether and with petroleum diethyl ether. It is slightly soluble in ethanol (95).

Specific gravity d_{25}^{25}: 0.906 – 0.920

Acid value Not more than 0.2.

Saponification value 169 – 195

Unsaponifiable matters Not more than 1.5%.

Iodine value 95 – 127

Containers and storage Containers—Tight containers.

Red Ginseng

Ginseng Radix Rubra

コウジン

Red Ginseng is the root of *Panax ginseng* C. A. Meyer (*Panax schinseng* Nees) (*Araliaceae*), after being steamed.

Description Thin and long cylindrical to fusiform root, often branching out into 2 to 5 lateral roots from the middle; 5 – 25 cm in length, main root 0.5 – 3 cm in diameter; externally light yellow-brown to red-brown, and translucent and with longitudinal wrinkles; crown somewhat constricted, and sometimes with short remains of stem; fractured surface flat; horny and hard in texture. Odor, characteristic; taste, at first slightly sweet, followed by a slight bitterness.

Identification (1) To 0.2 g of pulverized Red Ginseng add 2 mL of acetic anhydride, warm on a water bath for 2 minutes, and filter. To 1 mL of the filtrate add gently 0.5 mL of sulfuric acid to make two layers: a red-brown color develops at the zone of contact.

(2) To 2.0 g of pulverized Red Ginseng add 20 mL of methanol, boil gently under a reflux condenser on a water bath for 15 minutes, cool, filter, and use the filtrate as the sample solution. Separately, dissolve 1 mg of ginsenoside Rg_1 for thin-layer chromatography in 1 mL of methanol, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 10 μL each of the sample solution and the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with the lower layer of a mixture of chloroform, methanol and water (13:7:2) to a distance of about 10 cm, and air-dry the plate. Spray evenly dilute sulfuric acid on the plate, and heat at 110°C for 5 minutes: one spot among the spots from the sample solution and a red-purple spot from the standard solution show the same color tone and the same *Rf* value.

Purity (1) Foreign matter—The amount of stems and other foreign matter contained in Red Ginseng does not exceed 2.0%.

(2) Heavy metals—Proceed with 1.0 g of pulverized Red Ginseng according to Method 4, and perform the test. Prepare the control solution with 1.5 mL of Standard Lead Solution (not more than 15 ppm).

(3) Arsenic—Prepare the test solution with 1.0 g of pulverized Red Ginseng according to Method 4, and perform the test using Apparatus B (not more than 2 ppm).

(4) Total BHC's and total DDT's—Sodium chloride, anhydrous sodium sulfate and synthetic magnesium silicate for column chromatography used in this procedure are used after drying by heating at about 130°C for more than 12 hours and cooling in a desiccator (silica gel). Chromatographic column is prepared as follows: Place 20 g of synthetic magnesium silicate for column chromatography in a 200-mL flask, add 50 mL of hexane for Purity of crude drug, shake vigorously, and immediately pour the mixture into a chromatographic tube about 2 cm in inside diameter and about 30 cm in length. Drip until the depth of hexane layer at the upper part is about 5 cm, introduce 8 g of anhydrous sodium sulfate from the top, and further drip until a small quantity of hexane is left at the upper part.

Weigh accurately about 5 g of pulverized Red Ginseng, place in a glass-stoppered centrifuge tube, add 30 mL of a mixture of acetone for Purity of crude drug and water (5:2), stopper tightly, shake for 15 minutes, centrifuge, and separate the supernatant liquid. Repeat the same procedure twice with the residue using two 30-mL portions of a mixture of acetone for Purity of crude drug and water (5:2). Combine all the supernatant liquids, and evaporate in a vacuum at a temperature not higher than 40°C until the order of acetone is faint. Transfer the evaporated solution to a separator containing 100 mL of sodium chloride TS, and shake twice with two 50-mL portions of hexane for Purity of crude drug for 5 minutes each. Combine the hexane solutions, transfer to a separator containing 50 mL of sodium chloride TS, and shake for 5 minutes. Take the hexane layer, dry over 30 g of

anhydrous sodium sulfate, and filter. Wash the residue on the filter paper with 20 mL of hexane for Purity of crude drug. Combine the filtrate and the washings, and evaporate in a vacuum at a temperature not higher than 40°C to about 5 mL. Transfer this solution to the chromatographic column and allow to pass with 300 mL of a mixture of hexane for Purity of crude drug and diethyl ether for Purity of crude drug (17:3) at a rate of not more than 5 mL per minute. After evaporating the eluate in a vacuum at a temperature not higher than 40°C, add hexane for Purity of crude drug to make exactly 5 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.01 g each of α-BHC, β-BHC, γ-BHC, δ-BHC, *o,p'*-DDT, *p,p'*-DDT, *p,p'*-DDD and *p,p'*-DDE, dissolve in 5 mL of acetone for Purity of crude drug and add hexane for Purity of crude drug to make exactly 100 mL. Pipet 10 mL of this solution, and add hexane for Purity of crude drug to make exactly 100 mL. Pipet 1 mL of this solution, add hexane for Purity of crude drug to make exactly 100 mL, and use this solution as the standard solution. Perform the test with 1 μL each of the sample solution and the standard solution as directed under Gas Chromatography according to the following conditions, and determine the peak areas corresponding to α-BHC, β-BHC, γ-BHC, δ-BHC, *o,p'*-DDT, *p,p'*-DDT, *p,p'*-DDD and *p,p'*-DDE from each solution, A_{TA} and A_{SA}; A_{TB} and A_{SB}; A_{TC} and A_{SC}; A_{TD} and A_{SD}; A_{TE} and A_{SE}; A_{TF} and A_{SF}; A_{TG} and A_{SG}; A_{TH} and A_{SH}. Calculate the content of each of α-BHC, β-BHC, γ-BHC, δ-BHC, *o,p'*-DDT, *p,p'*-DDT, *p,p'*-DDD and *p,p'*-DDE by means of the following equations, and determine the content of total BHC's and that of total DDT's: the content of total BHC's and that of total DDT's are each not more than 0.2 ppm.

Content (ppm) of α-BHC

$$= \frac{\text{amount (g) of } \alpha\text{-BHC}}{W} \times \frac{A_{TA}}{A_{SA}} \times 50$$

Content (ppm) of β-BHC

$$= \frac{\text{amount (g) of } \beta\text{-BHC}}{W} \times \frac{A_{TB}}{A_{SB}} \times 50$$

Content (ppm) of γ-BHC

$$= \frac{\text{amount (g) of } \gamma\text{-BHC}}{W} \times \frac{A_{TC}}{A_{SC}} \times 50$$

Content (ppm) of δ-BHC

$$= \frac{\text{amount (g) of } \delta\text{-BHC}}{W} \times \frac{A_{TD}}{A_{SD}} \times 50$$

Content (ppm) of *o,p'*-DDT

$$= \frac{\text{amount (g) of } o,p'\text{-DDT}}{W} \times \frac{A_{TE}}{A_{SE}} \times 50$$

Content (ppm) of *p,p'*-DDT

$$= \frac{\text{amount (g) of } p,p'\text{-DDT}}{W} \times \frac{A_{TF}}{A_{SF}} \times 50$$

Content (ppm) of *p,p'*-DDD

$$= \frac{\text{amount (g) of } p,p'\text{-DDD}}{W} \times \frac{A_{TG}}{A_{SG}} \times 50$$

Content (ppm) of *p,p'*-DDE

$$= \frac{\text{amount (g) of } p,p'\text{-DDE}}{W} \times \frac{A_{TH}}{A_{SH}} \times 50$$

W: Amount (g) of pulverized Red Ginseng

Content (ppm) of total BHC's
= content (ppm) of α-BHC + content (ppm) of β-BHC + content (ppm) of γ-BHC + content (ppm) of δ-BHC

Content (ppm) of total DDT's
= content (ppm) of *o,p'*-DDT + content (ppm) of *p,p'*-DDT + content (ppm) of *p,p'*-DDD + content (ppm) of *p,p'*-DDE

Operating conditions—

Detector: An electron capture detector

Sample injection system: A splitless injection system

Column: A fused silica capillary column about 0.3 mm in inside diameter and about 30 m in length, coated the inside wall with 7% cyanopropyl-7% phenylmethylsilicone polymer for gas chromatography in a thickness of 0.25 to 1.0 μm.

Column temperature: Maintain the temperature at 60°C for 2 minutes after injection, program to increase the temperature at a rate of 10°C per minute to 200°C, and then program to increase the temperature at a rate of 2°C per minute to 260°C.

Carrier gas: Helium

Flow rate: Adjust the flow rate so that the retention times of the objective compounds are between 10 and 30 minutes.

Selection of column: Proceed with 1 μL of the standard solution under the above operating conditions. Use a column clearly separating each peak.

System repeatability: Repeat the test 6 times with the standard solution under the above operating conditions: the relative standard deviation of the peak area is not more than 10% for any objective compound.

Total ash Not more than 4.5%.

Extract content Dilute ethanol-soluble extract: not less than 18.0%.

Rehmannia Root

Rehmanniae Radix

ジオウ

Rehmannia Root is the root of *Rehmannia glutinosa* Liboschitz var. *purpurea* Makino or *Rehmania glutinosa* Liboschitz (*Scrophulariaceae*), with or without the application of steaming.

Description Thin and long, usually, fusiform root, 5 - 10 cm in length, 0.5 - 1.5 cm in diameter, often broken or markedly deformed in shape; externally yellow-brown to blackish brown, with deep, longitudinal wrinkles and constrictions; soft in texture and mucous; cross section yellow-brown to blackish brown, and cortex darker than xylem in color; pith hardly observable. Odor, characteristic; taste, slightly sweet at first, followed by a slight bitterness.

Under a microscope, a transverse section reveals 7 to 15 layers of cork; cortex composed entirely of parenchyma cells; outer region of cortex with scattered cells containing brown secretes; xylem practically filled with parenchyma; vessels radially lined, mainly reticulate vessels.