Cholera Vaccine

コレラワクチン

Cholera Vaccine is a liquid for injection containing inactivated *Vibrio cholerae* of the Ogawa and Inaba strains.

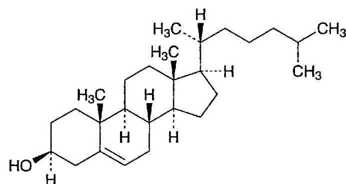
Monotypic products may be manufactured, if necessary.

It conforms to the requirements of Cholera Vaccine in the Minimum Requirements for Biological Products.

Description Cholera Vaccine is a white-turbid liquid.

Cholesterol

コレステロール



$C_{27}H_{46}O$: 386.65
Cholest-5-en-3β-ol [*57-88-5*]

Description Cholesterol occurs as white to pale yellow crystals or granules. It is odorless, or has a slight odor. It is tasteless.

It is freely soluble in chloroform and in diethyl ether, soluble in 1,4-dioxane, sparingly soluble in ethanol (99.5), and practically insoluble in water.

It gradually changes to a yellow to light yellow-brown color by light.

Identification **(1)** Dissolve 0.01 g of Cholesterol in 1 mL of chloroform, add 1 mL of sulfuric acid, and shake: a red color develops in the chloroform layer, and the sulfuric acid layer shows a green fluorescence.

(2) Dissolve 5 mg of Cholesterol in 2 mL of chloroform, add 1 mL of acetic anhydride and 1 drop of sulfuric acid, and shake: a red color is produced, and it changes to green through blue.

Optical rotation $[\alpha]_D^{25}$: -34 - $-38°$ (after drying, 0.2 g, 1,4-dioxane, 10 mL, 100 mm).

Melting point 147 - 150°C

Purity **(1)** Clarity of solution—Place 0.5 g of Cholesterol in a glass-stoppered flask, dissolve in 50 mL of warm ethanol (95), and allow to stand at room temperature for 2 hours: no turbidity or deposit is produced.

(2) Acid—Place 1.0 g of Cholesterol in a flask, dissolve in 10 mL of diethyl ether, add 10.0 mL of 0.1 mol/L sodium hydroxide VS, and shake for 1 minute. Expel the diethyl ether, and boil for 5 minutes. Cool, add 10 mL of water, and titrate with 0.05 mol/L sulfuric acid VS (indicator: 2 drops of phenolphthalein TS). Perform a blank determination.

The volume of 0.1 mol/L sodium hydroxide VS consumed is not more than 0.30 mL.

Loss on drying Not more than 0.30% (1 g, in vacuum, 60°C, 4 hours).

Residue on ignition Not more than 0.10% (1 g).

Containers and storage Containers—Tight containers.
Storage—Light-resistant.

Cimicifuga Rhizome

Cimicifugae Rhizoma

ショウマ

Cimicifuga Rhizome is the rhizome of *Cimicifuga simplex* Wormskjord, *Cimicifuga dahurica* (*Turcz.*) Maximmowicz, *Cimicifuga foetida* Linné or *Cimicifuga heracleifolia* Komarov (*Ranunculaceae*).

Description Knotted, irregularly shaped rhizome, 6 - 18 cm in length, 1 - 2.5 cm in diameter; externally dark brown to blackish brown, with many remains of roots, often with scars of terrestrial stems; the center of the scar dented, and the circumference being pale in color and showing a radial pattern; fractured surface fibrous; pith dark brown in color and often hollow; light and hard in texture. Almost odorless; taste, bitter and slightly astringent.

Purity Rhizome of *Astilbe thunbergii* Miquel—Under a microscope, powdered Cimicifuga Rhizome does not contain crystal druses in the parenchyma.

Total ash Not more than 9.0%.

Acid-insoluble ash Not more than 1.5%.

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

Cinnamon Bark

Cinnamomi Cortex

ケイヒ

Cinnamon Bark is the bark of the trunk of *Cinnamomum cassia* Blume (*Lauraceae*), or such bark from which a part of the periderm has been removed.

Description Usually semi-tubular or tubularly rolled pieces of bark, 0.1 - 0.5 cm in thickness, 5 - 50 cm in length, 1.5 - 5 cm in diameter; the outer surface dark red-brown, and the inner surface red-brown and smooth; brittle; the fractured surface is slightly fibrous, red-brown, exhibiting a light brown, thin layer. Characteristic aroma; taste, sweet and pungent at first, later rather mucilaginous and slightly astringent.

Under a microscope, a transverse section of Cinnamon Bark reveals a primary cortex and a secondary cortex divided

by an almost continuous ring consisting of stone cells; nearly round bundles of fibers in the outer region of the ring; wall of each stone cell often thickened in a U-shape; secondary cortex lacking stone cells, and with a small number of sclerenchymatous fibers coarsely scattered; parenchyma scattered with oil cells, mucilage cells and cells containing starch grains; medullary rays with cells containing fine needles of calcium oxalate.

Identification To 2.0 g of pulverized Cinnamon Bark add 10 mL of diethyl ether, shake for 3 minutes, filter, and use the filtrate as the sample solution. Perform the test with this solution as directed under the Thin-layer Chromatography. Spot 10 μL of the sample solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of hexane and ethyl acetate (2:1) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): a purple spot develops at the *Rf* value of about 0.4. Spray evenly 2,4-dinitrophenylhydrazine TS upon the spot: a yellow-orange color develops.

Loss on drying Not more than 15.5% (6 hours).

Total ash Not more than 5.0%.

Essential oil content Perform the test with 50.0 g of pulverized Cinnamon Bark as directed in the Essential oil content under the Crude Drugs, provided that 1 mL of silicon resin is previously added to the sample in the flask: the volume of essential oil is not less than 0.5 mL.

Powdered Cinnamon Bark

Cinnamomi Cortex Pulveratus

ケイヒ末

Powdered Cinnamon Bark is the powder of Cinnamon Bark.

Description Powdered Cinnamon Bark is red-brown to brown in color. It has a characteristic aroma and a sweet, pungent taste with a slightly mucilaginous and astringent aftertaste.

Under a microscope, Powdered Cinnamon Bark reveals starch grains, fragments of parenchyma cells containing them; fragments of fibers, oil cells containing yellow-brown oil droplets, stone cells, cork stone cells, cork tissue, and fine crystals of calcium oxalate. Starch grains are simple and compound grains 6 to 15 μm in diameter.

Identification To 2.0 g of Powdered Cinnamon Bark add 10 mL of diethyl ether, shake for 3 minutes, filter, and use the filtrate as the sample solution. Perform the test with this solution as directed under the Thin-layer Chromatography. Spot 10 μL of the sample solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of hexane and ethyl acetate (2:1) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): a purple spot develops at the *Rf* value of about 0.4. Spray 2,4-dinitrophenylhydrazine TS upon the spot: a yellow orange color develops.

Purity Petiole—Under a microscope, Powdered Cinnamon Bark does not reveal epidermal cells, hairs, cells containing chlorophyll granules, and fragments of vascular bundle.

Loss on drying Not more than 15.0% (6 hours).

Total ash Not more than 5.0%.

Essential oil content Perform the test with 50.0 g of Powdered Cinnamon Bark as directed in the Essential oil content under the Crude Drugs, provided that 1 mL of silicon resin is previously added to the sample in the flask: the volume of essential oil is not less than 0.35 mL.

Containers and storage Containers—Tight containers.

Cinnamon Oil

Oleum Cinnamomi

ケイヒ油

Cinnamon Oil is the essential oil distilled with steam from the leaves and twigs or bark of *Cinnamomum cassia* Blume or from the bark of *Cinnamomum zeylanicum* Nees (*Lauraceae*).

It contains not less than 60 vol% of the total aldehydes.

Description Cinnamon Oil is a yellow to brown liquid. It has a characteristic, aromatic odor and a sweet, pungent taste.

It is clearly miscible with ethanol (95) and with diethyl ether.

It is practically insoluble in water.

It is weakly acid. Upon aging or long exposure to air, it darkens and becomes viscous.

Specific gravity d_{20}^{20}: 1.010 - 1.065

Identification Shake 4 drops of Cinnamon Oil with 4 drops of nitric acid: the mixture forms white to light yellow crystals at a temperature below 5°C.

Purity **(1)** Rosin—Mix 1.0 mL of Cinnamon Oil with 5 mL of ethanol (95), then add 3 mL of freshly prepared, saturated ethanol solution of lead (II) acetate trihydrate: no precipitate is produced.

(2) Heavy metals—Proceed with 1.0 mL of Cinnamon Oil according to Method 2, and perform the test. Prepare the control solution with 4.0 mL of Standard Lead Solution (not more than 40 ppm).

Assay Pipet 5.0 mL of Cinnamon Oil into a cassia flask, add 70 mL of sodium hydrogensulfite TS, and heat the mixture in a water bath with frequent shaking to dissolve completely. To this solution add sodium hydrogensulfite TS to raise the lower level of the oily layer within the graduate portion of the neck. Allow to stand for 2 hours, and measure the volume (mL) of the separated oily layer.

$$\text{Total aldehydes (vol\%)} = [5.0 - (\text{volume of separated oily layer})] \times 20$$

Containers and storage Containers—Tight containers.

Storage—Light-resistant.