

kles and warty protrusions. Almost odorless; taste, bitter.

Under a microscope, a transverse section reveals extremely thick-walled stone cells in primary cortex and pericycle; irregular-sized vessels lined nearly stepwise in the vessel portion; cells of medullary ray mostly not lignified, and extremely thick-walled and large stone cells scattered here and there; primary cortex containing needle crystals of calcium oxalate; medullary rays containing starch grains, simple grain, 3–10 μm in diameter, and small needle crystals of calcium oxalate.

Identification To 0.5 g of pulverized *Sinomenium* Stem add 10 mL of dilute acetic acid, heat for 2 minutes on a water bath with frequent shaking, cool, and filter. To 5 mL of the filtrate add 2 drops of Dragendorff's TS: immediately, an orange-yellow precipitate is produced.

Total ash Not more than 6.0%.

Acid-insoluble ash Not more than 0.5%.

Freeze-dried Smallpox Vaccine

乾燥痘そうワクチン

Freeze-dried Smallpox Vaccine is a preparation for injection which is dissolved before use. It contains live vaccinia virus.

It conforms to the requirements of Freeze-dried Smallpox Vaccine in the Minimum Requirements for Biological Products.

Description Freeze-dried Smallpox Vaccine becomes a white to gray, turbid liquid on addition of solvent.

Freeze-dried Smallpox Vaccine Prepared in Cell Culture

乾燥細胞培養痘そうワクチン

Freeze-dried Smallpox Vaccine Prepared in Cell Culture is a preparation for injection which is dissolved before use. It contains live vaccinia virus.

It conforms to the requirements of Freeze-dried Smallpox Vaccine Prepared in Cell Culture in the Minimum Requirements for Biological Products.

Description Freeze-dried Smallpox Vaccine Prepared in Cell Culture becomes a reddish clear liquid on addition of solvent.

Smilax Rhizome

Smilacis Rhizoma

サンキライ

Smilax Rhizome is the tuber of *Smilax glabra* Roxburgh (*Liliaceae*).

Description Flattened and irregular cylindrical tuber, often with node-like branches; usually 5–15 cm in length, 2–5 cm in diameter; the outer surface grayish yellow-brown to yellow-brown, and the upper surface scattered with knotty remains of stem; cross section irregular elliptical to obtuse triangular, consisting of extremely thin cortical layer and mostly of stele. Odor, slight; almost tasteless.

Under a microscope, a transverse section reveals a 2- to 3-cell-wide cork layer, with extremely narrow cortical layer, usually consisting of a 2- to 4-cell-wide, thick-walled parenchyma cells, showing large mucilage cells here and there; mucilage cell containing raphides of calcium oxalate; stele consisting chiefly of parenchyma cells, and scattered with vascular bundles; parenchyma cells containing starch grains composed mostly of simple grains, 12–36 μm in diameter, and sometimes mixed with 2- to 4-compound grains.

Total ash Not more than 5.0%.

Powdered Smilax Rhizome

Smilacis Rhizoma Pulveratum

サンキライ末

Powdered Smilax Rhizome is the powder of Smilax Rhizome.

Description Powdered Smilax Rhizome occurs as a light yellow-brown powder, and has a slight odor, and is practically tasteless.

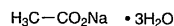
Under a microscope, Powdered Smilax Rhizome reveals starch grains and fragments of parenchyma cells containing them; fragments of raphides of calcium oxalate contained in mucilage masses; fragments of lignified parenchyma cells of cortical layer; fragments of cork cells and scalariform vessels; starch grains composed mostly of simple grains, and mixed with a few 2- to 4-compound grains 12–36 μm in diameter.

Purity Foreign matter—Under a microscope, Powdered Smilax Rhizome does not show a large quantity of stone cells or thick-walled fibers.

Total ash Not more than 5.0%.

Sodium Acetate

酢酸ナトリウム



$\text{C}_2\text{H}_3\text{NaO}_2 \cdot 3\text{H}_2\text{O}$: 136.08
Monosodium acetate trihydrate [6131-90-4]

Sodium Acetate, when dried, contains not less than 99.5% of $\text{C}_2\text{H}_3\text{NaO}_2$: 82.03.

Description Sodium Acetate occurs as colorless crystals or a white, crystalline powder. It is odorless or has a slight, acetous odor. It has a cool, saline and slightly bitter taste.

It is very soluble in water, freely soluble in acetic acid (100), soluble in ethanol (95), and practically insoluble in diethyl ether.

It is efflorescent in warm, dry air.

Identification A solution of Sodium Acetate (1 in 10) responds to the Qualitative Tests for acetate and sodium salt.

Purity (1) Clarity and color of solution—Dissolve 2.0 g of Sodium Acetate in 20 mL of water: the solution is clear and colorless.

(2) Acid or alkali—Dissolve 1.0 g of Sodium Acetate in 20 mL of freshly boiled and cooled water, and add 3 drops of phenolphthalein TS: a red color develops. When cooled to 10°C, or 1.0 mL of 0.01 mol/L hydrochloric acid VS is added after cooling to 10°C, the red color disappears.

(3) Chloride—Perform the test with 1.0 g of Sodium Acetate. Prepare the control solution with 0.30 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.011%).

(4) Sulfate—Perform the test with 1.0 g of Sodium Acetate. Prepare the control solution with 0.35 mL of 0.005 mol/L sulfuric acid VS (not more than 0.017%).

(5) Heavy metals—Proceed with 2.0 g of Sodium Acetate according to Method 1, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

(6) Calcium and magnesium—Dissolve 4.0 g of Sodium Acetate in 25 mL of water, add 6 g of ammonium chloride, 20 mL of ammonia solution (28) and 0.25 mL of a solution of sodium hydrogensulfite (1 in 10), and titrate with 0.01 mol/L disodium dihydrogen ethylenediamine tetraacetate VS until the blue color changes to grayish blue (indicator: 0.1 g of methylthymol blue-potassium nitrate indicator): the amount of 0.01 mol/L disodium dihydrogen ethylenediamine tetraacetate VS consumed is not more than 0.5 mL.

(7) Arsenic—Prepare the test solution with 1.0 g of Sodium Acetate, according to Method 1, and perform the test using Apparatus B (not more than 2 ppm).

(8) Potassium permanganate-reducing substance—Dissolve 1.0 g of Sodium Acetate in 100 mL of water, add 5 mL of dilute sulfuric acid, boil, add 0.50 mL of 0.002 mol/L potassium permanganate VS, and further boil for 5 minutes: the red color of the solution does not disappear.

Loss on drying 39.0 – 40.5% (1 g, first at 80°C for 2 hours, and then at 130°C for 2 hours).

Assay Weigh accurately about 0.2 g of Sodium Acetate, previously dried, dissolve in 50 mL of acetic acid (100), and titrate with 0.1 mol/L perchloric acid VS until the color of the solution changes from yellow to green (indicator: 1 mL of *p*-naphtholbenzein TS). Perform a blank determination, and make any necessary correction.

$$\begin{aligned} \text{Each mL of 0.1 mol/L perchloric acid VS} \\ = 8.203 \text{ mg of } \text{C}_2\text{H}_3\text{NaO}_2 \end{aligned}$$

Containers and storage Containers—Tight containers.

Sodium Bicarbonate and Bitter Tincture Mixture

苦味重曹水

Method of preparation

Sodium Bicarbonate	30 g
Bitter Tincture	20 mL
Water or Purified Water	a sufficient quantity
To make 1000 mL	

Prepare before use, with the above ingredients.

Description Sodium Bicarbonate and Bitter Tincture Mixture is a clear, yellowish liquid, having a bitter taste.

Containers and storage Containers—Tight containers.

Sodium Bisulfite

Sodium Hydrogen Sulfite

亜硫酸水素ナトリウム

NaHSO₃: 104.06

Sodium Bisulfite is a mixture of sodium hydrogensulfite and sodium pyrosulfite. It contains not less than 64.0% and not more than 67.4% of sulfur dioxide (SO₂: 64.06).

Description Sodium Bisulfite occurs as white granules or powder, having the odor of sulfur dioxide.

Sodium Bisulfite is freely soluble in water and practically insoluble in ethanol (95) and in diethyl ether.

A solution of Sodium Bisulfite (1 in 20) is acid.

Sodium Bisulfite is slowly affected by air or by light.

Identification A solution of Sodium Bisulfite (1 in 20) responds to the Qualitative Tests for sodium salt and for bisulfite.

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Sodium Bisulfite in 10 mL of water: the solution is clear and colorless.

(2) Thiosulfate—Dissolve 1.0 g of Sodium Bisulfite in 15 mL of water, add slowly 5 mL of dilute hydrochloric acid, shake, and allow to stand for 5 minutes: no turbidity is produced.

(3) Heavy metals—Dissolve 1.0 g of Sodium Bisulfite in 10 mL of water, add 5 mL of hydrochloric acid, and evaporate on a water bath to dryness. To the residue add 2 mL of dilute acetic acid and water to make 50 mL, and perform the test using this solution as the test solution. Prepare the control solution as follows: evaporate 5 mL of hydrochloric acid on a water bath to dryness, and add 2 mL of dilute acetic acid and 2.0 mL of Standard Lead Solution, and dilute with water to make 50 mL (not more than 20 ppm).

(4) Iron—Prepare the test solution with 1.0 g of Sodium Bisulfite according to Method 1, and perform the test according to Method A. Prepare the control solution with 2.0 mL of Standard Iron Solution (not more than 20 ppm).