

is whitish in color and adheres well to the skin.

Containers and storage Containers—Well-closed containers.

Storage—Light-resistant.

Salicylic Acid Spirit

サリチル酸精

Salicylic Acid Spirit contains not less than 2.7 w/v% and not more than 3.3 w/v% of salicylic acid ($C_7H_6O_3$: 138.12).

Method of preparation

Salicylic Acid	30 g
Glycerin	50 mL
Ethanol	a sufficient quantity
To make 1000 mL	

Prepare as directed under Medicated Spirits, with the above ingredients.

Description Salicylic Acid Spirit is a clear, colorless liquid.
Specific gravity d_{20}^{20} : about 0.86

Identification The solution obtained in the Assay has a red-purple color. Determine the absorption spectrum of the solution as directed under the Ultraviolet-visible Spectrophotometry: it exhibits a maximum between 520 nm and 535 nm (salicylic acid).

Alcohol number Not less than 8.8 (Method 2).

Assay Measure exactly 10 mL of Salicylic Acid Spirit, add 10 mL of ethanol (95) and water to make exactly 100 mL. Pipet 3 mL of this solution, and dilute with hydrochloric acid-potassium chloride buffer solution, pH 2.0, to make exactly 100 mL. Use this solution as the sample solution. Dissolve about 0.3 g of salicylic acid for assay, previously dried in a desiccator (silica gel) for 3 hours and accurately weighed, in 10 mL of alcohol and water to make exactly 100 mL. Pipet 3 mL of this solution, dilute with hydrochloric acid-potassium chloride buffer solution, pH 2.0, to make exactly 100 mL, and use this solution as the standard solution. Pipet 10 mL each of the sample solution and the standard solution, to each add 5 mL of a solution of iron (III) nitrate enneahydrate (1 in 200), dilute with hydrochloric acid-potassium chloride buffer solution, pH 2.0, to exactly 25 mL. Determine the absorbances, A_T and A_S , of both solutions at 530 nm, using a blank solution prepared in the same manner with water instead of the sample solution.

$$\begin{aligned} & \text{Amount (mg) of salicylic acid (C}_7\text{H}_6\text{O}_3\text{)} \\ & = \text{amount (mg) of salicylic acid for assay} \\ & \quad \times \frac{A_T}{A_S} \end{aligned}$$

Containers and storage Containers—Tight containers.

Compound Salicylic Acid Spirit

複方サリチル酸精

Compound Salicylic Acid Spirit contains not less than 1.8 w/v% and not more than 2.2 w/v% of salicylic acid ($C_7H_6O_3$: 138.12), and not less than 0.43 w/v% and not more than 0.53 w/v% of phenol (C_6H_6O : 94.11).

Method of preparation

Salicylic Acid	20 g
Liquefied Phenol	5 mL
Glycerin	40 mL
Ethanol	800 mL
Water or Purified Water	a sufficient quantity
To make 1000 mL	

Prepare as directed under Medicated Spirits, with the above ingredients.

Description Compound Salicylic Acid Spirit is a clear, colorless to light red liquid.

Specific gravity d_{20}^{20} : about 0.88

Identification (1) To 1 mL of Compound Salicylic Acid Spirit add hydrochloric acid-potassium chloride buffer solution, pH 2.0, to make 200 mL, and to 5 mL of this solution add 5 mL of a solution of iron (III) nitrate enneahydrate (1 in 200): a red-purple color is produced (salicylic acid).

(2) To 1 mL of Compound Salicylic Acid Spirit add 20 mL of water and 5 mL of dilute hydrochloric acid, and extract with 20 mL of diethyl ether. Wash the diethyl ether extract with two 5-mL portions of sodium hydrogen carbonate TS, and extract with 10 mL of dilute sodium hydroxide TS. Shake 1 mL of the extract with 1 mL of sodium nitrite TS and 1 mL of dilute hydrochloric acid, allow to stand for 10 minutes, and add 3 mL of sodium hydroxide TS: a yellow color is produced (phenol).

(3) To 0.5 mL of Compound Salicylic Acid Spirit add 5 mL of dilute hydrochloric acid, extract with 5 mL of chloroform, and use the extract as the sample solution (1). To 2 mL of Compound Salicylic Acid Spirit add 5 mL of dilute hydrochloric acid, extract with 5 mL of chloroform, wash the extract with two 5-mL portions of sodium hydrogen carbonate TS, and use the chloroform extract as the sample solution (2). Separately, dissolve 0.01 g each of salicylic acid and phenol in 5 mL each of chloroform, and use both solutions as the standard solution (1) and the standard solution (2). Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 5 μ L each of the sample solutions and the standard solutions on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of chloroform, acetone and acetic acid (100) (45:5:1) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): the spots from the sample solution (1) and the standard solution (1) show the same R_f value, and the spots from the sample solution (2) and the standard solution (2) show the same R_f value. Spray evenly iron (III) chloride TS upon the plate: the spot from the standard solution (1) and the corresponding spot from the sample solution (1)

reveal a purple color.

Alcohol number Not less than 7.5 (Method 2).

Assay Measure accurately 2 mL of Compound Salicylic Acid Spirit, add exactly 5 mL of the internal standard solution and diluted methanol (1 in 2) to make 100 mL, and use this solution as the sample solution. Weigh accurately about 0.2 g of salicylic acid for assay, previously dried in a desiccator (silica gel) for 3 hours, and about 0.05 g of phenol for assay, dissolve in diluted methanol (1 in 2) to make exactly 100 mL. Pipet 20 mL of this solution, add exactly 5 mL of the internal standard solution and diluted methanol (1 in 2) to make 100 mL, and use this solution as the standard solution. Perform the test with 15 μ L each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following conditions, and calculate the ratios, Q_{Ta} and Q_{Tb} , of the peak area of salicylic acid and phenol to that of the internal standard in the sample solution, and the ratios, Q_{Sa} and Q_{Sb} , of the peak area of salicylic acid and phenol to that of the internal standard in the standard solution.

$$\begin{aligned} & \text{Amount (mg) of salicylic acid (C}_7\text{H}_6\text{O}_3\text{)} \\ &= \text{amount (mg) of salicylic acid for assay} \\ & \times \frac{Q_{Ta}}{Q_{Sa}} \times \frac{1}{5} \end{aligned}$$

$$\begin{aligned} & \text{Amount (mg) of phenol (C}_6\text{H}_6\text{O)} \\ &= \text{amount (mg) of phenol for assay} \\ & \times \frac{Q_{Tb}}{Q_{Sb}} \times \frac{1}{5} \end{aligned}$$

Internal standard solution—A solution of theophylline in methanol (1 in 1250).

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 270 nm).

Column: A stainless steel column about 4 mm in inside diameter and 25 to 30 cm in length, packed with octadecylsilanized silica gel for liquid chromatography, 5 μ m in particle diameter.

Column temperature: Room temperature.

Mobile phase: A mixture of 0.1 mol/L phosphate buffer solution, pH 7.0, and methanol (3:1).

Flow rate: Adjust the flow rate so that the retention time of salicylic acid is about 6 minutes.

Selection of column: Dissolve 0.2 g of benzoic acid, 0.2 g of salicylic acid and 0.05 g of theophylline in 100 mL of diluted methanol (1 in 2). To 10 mL of this solution add 90 mL of diluted methanol (1 in 2). Proceed with 10 μ L of this solution under the above operating conditions. Use a column giving elution of benzoic acid, salicylic acid and theophylline in this order, and clearly dividing each peak.

Containers and storage Containers—Tight containers.

Saposhnikovia Root

Saposhnikovia Radix

ボウフウ

Saposhnikovia Root is the root and rhizome of

Saposhnikovia divaricata Schischkin (*Umbelliferae*).

Description Long and narrow, conical rhizome and root, 15–20 cm in length, 0.7–1.5 cm in diameter; externally light brown; rhizome reveals dense crosswise wrinkles like ring nodes, and sometimes reveals brown and hair-like remains of leaf sheath; the root reveals many longitudinal wrinkles and scars of rootlets; in a cross section, cortex is grayish brown in color and reveals many lacunae, and xylem is yellow in color. Odor, slight; taste, slightly sweet.

Purity Foreign matter—The amount of stems and other foreign matter contained in Saposhnikovia Root does not exceed 2.0%.

Total ash Not more than 7.0%.

Acid-insoluble ash Not more than 1.5%.

Extract content Dilute ethanol-soluble extract: not less than 20.0%.

Saussurea Root

Saussureae Radix

モッコウ

Saussurea Root is the root of *Saussurea lappa* Clarke (*Compositae*).

Description Nearly cylindrical roots, 5–20 cm in length, 1–6 cm in diameter; some of them slightly bent, and sometimes longitudinally cut; scar of stem dented on the top of the root with crown; externally yellow-brown to grayish brown, with coarse longitudinal wrinkles and fine reticulate furrows, and also with remains of lateral roots; sometimes root from which periderm has been removed; hard and dense in texture, and difficult to break. A cross section is yellow-brown to dark brown, and cambium part has a dark color. Under a magnifying glass, medullary rays distinct, here and there, large clefts, and brown oil sacs scattered; in old root, pith existing in the center, and often forming a hollow. Odor, characteristic; taste, bitter.

Identification Warm 0.5 g of pulverized Saussurea Root with 10 mL of ethanol (95) for 1 minute, cool, and filter. Shake 1 mL of the filtrate with 0.5 mL of hydrochloric acid: a purple color is produced.

Purity Foreign matter—Add iodine TS dropwise to a transverse section: no blue-purple color develops.

Total ash Not more than 4.0%.

Extract content Dilute ethanol-soluble extract: not less than 17.0%.