

ameter and 15 to 25 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 to 10 μm in particle diameter).

Column temperature: A constant temperature of about 40°C.

Mobile phase: Dissolve 3.4 g of potassium dihydrogenphosphate and 1.7 g of sodium lauryl sulfate in 1000 mL of a mixture of water and acetonitrile (1:1).

Flow rate: Adjust the flow rate so that the retention time of berberine is about 10 minutes.

Selection of column: Dissolve 1 mg each of Berberine Chloride Reference Standard and palmatine chloride in 10 mL of methanol. Proceed with 20 μL of this solution under the above operating conditions. Use a column giving elution of palmatine and berberine in this order, and clearly dividing each peak.

System repeatability: When repeat the test 5 times with the standard solution under the above operating conditions, the relative standard deviation of the peak area of berberine is not more than 1.5%.

Compound Phellodendron Powder for Cataplasm

パップ用複方オウバク散

Method of preparation

| | |
|----------------------------------|--------|
| Powdered Phellodendron Bark | 660 g |
| Powdered Gardenia Fruit | 325 g |
| <i>d</i> - or <i>dl</i> -Camphor | 10 g |
| <i>dl</i> - or <i>l</i> -Menthol | 5 g |
| To make | 1000 g |

Prepare as directed under Powders, with the above ingredients.

Description Compound Phellodendron Powder for Cataplasm occurs as a yellow-brown powder, having a characteristic odor.

Identification Shake thoroughly 0.2 g of Compound Phellodendron Powder for Cataplasm with 5 mL of methanol, filter, and use the filtrate as the sample solution. Dissolve 0.01 g of berberine chloride in 10 mL of methanol, and use the solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 5 μL each of the sample solution and the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of 1-butanol, water and acetic acid (100) (7:2:1) to a distance of about 10 cm, air-dry the plate, and examine under ultraviolet light (main wavelength: 365 nm): the spots from the sample solution and the standard solution reveal a yellow color, and show the same *R_f* value (berberine).

Containers and storage Containers—Tight containers.

Phellodendron, Albumin Tannate and Bismuth Subnitrate Powder

オウバク・タンナルビン・ビスマス散

Phellodendron, Albumin Tannate and Bismuth Subnitrate Powder contains not less than 12.9% and not more than 16.3% of bismuth (Bi: 208.98).

Method of preparation

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|--|--------|
| Powdered Phellodendron Bark | 300 g |
| Albumin Tannate | 300 g |
| Bismuth Subnitrate | 200 g |
| Scopolia Extract | 10 g |
| Starch, Lactose or their mixture a sufficient quantity | |
| To make | 1000 g |

Prepare as directed under Powders, with the above ingredients. Scopolia Extract Powder may be used in place of Scopolia Extract.

Description Phellodendron, Albumin Tannate and Bismuth Subnitrate Powder is brownish yellow in color, and has a bitter taste.

Identification (1) Shake thoroughly 0.1 g of Phellodendron, Albumin Tannate and Bismuth Subnitrate Powder with 5 mL of methanol, filter, and use the filtrate as the sample solution. Dissolve 0.01 g of berberine chloride in 10 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 5 μL each of the sample solution and the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of 1-butanol, water and acetic acid (100) (7:2:1) to a distance of about 10 cm, air-dry the plate, and examine under ultraviolet light (main wavelength: 365 nm): the spot of berberine chloride reveals a yellow color, and the spots from the sample solution and the standard solution show the same *R_f* value (berberine).

(2) To 0.3 g of Phellodendron, Albumin Tannate and Bismuth Subnitrate Powder add 20 mL of ethanol (95), heat in a water bath for 3 minutes with shaking, cool, and filter. To 10 mL of the filtrate add 1 drop of iron (III) chloride TS: a blue-green color is produced. Allow to stand: a bluish black precipitate is produced (albumin tannate).

(3) To 0.3 g of Phellodendron, Albumin Tannate and Bismuth Subnitrate Powder add 10 mL of diluted pyridine (1 in 5), warm in a water bath for 3 minutes with shaking, cool, and filter. Add 1 mL of ninhydrin-ascorbic acid TS to the filtrate, and heat in a water bath: a blue color is produced (albumin tannate).

(4) To 0.5 g of Phellodendron, Albumin Tannate and Bismuth Subnitrate Powder add 5 mL of dilute hydrochloric acid and 10 mL of water, warm, shake thoroughly, and filter. The filtrate responds to the Qualitative Tests for bismuth salt.

Assay Weigh accurately about 0.7 g of Phellodendron, Albumin Tannate and Bismuth Subnitrate Powder, shake well with 10 mL of water and 20 mL of diluted nitric acid (1 in 3), add water to make exactly 100 mL, and filter. Discard the