

OUBAKU Liquid B

This product is obtained by extracting with 1,3-butylene glycol solution from the bark, from which the periderm has been removed, of *Phellodendron amurense* Ruprecht (Rutaceae). It contains not less than 0.13 w/v% and not more than 0.23 w/v% of berberine as berberine chloride (C₂₀H₁₈ClNO₄: 371.82).

Manufacturing method

Add 1,3-butylene glycol solution to the bark, from which the periderm has been removed, of *Phellodendron amurense* Ruprecht (Rutaceae), and extract. Allow it to stand in a freezer for a while, and filter to obtain the product.

Description

This product is a yellowish brown transparent liquid. It has a characteristic odor.

Identification

Berberine

To 2 to 3 drops of this product add 1mL of hydrochloric acid, then shake with 1 to 2 drops of hydrogen peroxide TS: a reddish purple color develops.

Berberine

Dissolve 0.1g of berberine chloride(*1) in 50mL of methanol, and use this solution as the standard solution. Spot 1 μ L each of this product and the standard solution on a thin-layer plate (containing a fluorescent substance), and perform the test as directed under Thin-layer Chromatography, with a mixture of n-butanol, glacial acetic acid and water (7:1:2) as a developing solvent. Dry the plate in air: the spot from this product and the standard solution show yellow color and the same R_f value (about 0.36). Examine under ultraviolet light (the dominant wavelength: 365nm): a yellowish green fluorescence develops.

Phenolic compounds

To 5mL of this product add water to make 50mL, and stir with 5mL of a solution of potassium iodide (1 \rightarrow 5). Allow to stand for 10 minutes, and filter: a yellow precipitate (berberine) is produced on the filter paper. Then add 1 drop of ferric chloride TS to 2mL of the filtrate: a yellowish brown to reddish brown color develops.

Specific gravity d_{20}^{20} : 1.010 to 1.050 (Method 1, C)

Purity

Heavy metals

Proceed with 1.0g of this product according to Method 3, and perform the test: the limit is not more than 20ppm. Prepare the control solution with 2.0mL of Standard Lead Solution.

Arsenic

Prepare the test solution with 1.0g of this product according to Method 3, and perform the test: the limit is not more than 2ppm.

Residue on evaporation: 0.70 to 1.80 w/v% (10mL, 105°C, 6 hours)

The residue is dried according to the above specified conditions after evaporating to dryness on a water bath.

Assay

Berberine

Measure accurately 2mL of this product, dissolve in methanol to make exactly 20mL, and use this solution as the test solution. Separately, weigh accurately about 0.1g of berberine chloride(*1), dissolve in methanol to make 100mL. Measure accurately 2mL, 3mL, 5mL, 6mL and 7mL of this solution, add methanol to each make exactly 25mL, and use these solutions as the standard solutions for provide the calibration curve.

Filter the test solution and those standard solutions with membrane-filter (0.45 μ m), and perform the test with 5 μ L each of the test solution and those standard solutions as directed under Liquid chromatography according to the following operating conditions. Prepare a calibration curve, and calculate the amount of the berberine with using the calibration curve.

Operating condition:

Detector: An ultraviolet absorption photometer. (wavelength: 345nm)

Column: A stainless tube 4mm in inside diameter and 15 to 25cm in length, packed with octadecylsilanized silicagel (5 to 10 μ m in particle diameter) for Liquid chromatography.

Column temperature: 55° C

Mobile phase: Add 0.5% of sodium lauryl sulfate for ion pair chromatography to a mixture of methanol and water (65:35).

Flow rate: 1.0mL/min.

*1...Use Berberine chloride(*1) or use more than the same class of berberine chloride(*1), and the purity is identified.

These standards and test method are referred to General Notices and General Tests, Processes and Apparatus of The Japanese Standards of Quasi-Drug Ingredients, unless otherwise specified.

Trade Name : OUBAKU Liquid B Manufacturer : ICHIMARU PHARCOS CO., LTD. 318-1 Asagi, Motosu-shi, Gifu 501-0475 JAPAN

Remarks :

*1...The Pharmacopoeia of Japan

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