

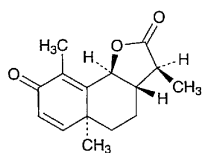
and titrate with 0.1 mol/L sodium hydroxide VS (indicator: 3 drops of phenolphthalein TS).

Each mL of 0.1 mol/L sodium hydroxide VS
= 13.812 mg of C₇H₆O₃

Containers and storage Containers—Well-closed containers.

Santonin

サントニン



C₁₅H₁₈O₃: 246.30
(3*S*,3*aS*,5*aS*,9*bS*)-3*a*,5,5*a*,9*b*-Tetrahydro-3,5*a*,9-trimethylnaphtho[1,2-*b*]furan-2,8(3*H*,4*H*)-dione
[481-06-1]

Santonin contains not less than 98.5% of C₁₅H₁₈O₃.

Description Santonin occurs as colorless crystals, or a white, crystalline powder. It is odorless, and tasteless at first, but afterward develops a slightly bitter taste.

It is freely soluble in boiling ethanol (95) and in chloroform, sparingly soluble in ethanol (95), slightly soluble in hot water and in diethyl ether, and practically insoluble in water.

It becomes yellow by light.

Identification (1) Dissolve 0.2 g of Santonin in 2 mL of potassium hydroxide-ethanol TS: a red color develops.

(2) Shake 0.01 g of powdered Santonin with 1 mL of diluted sulfuric acid (1 in 2), boil, and cool. Add 1 drop of dilute iron (III) chloride TS: a purple color develops.

Optical rotation $[\alpha]_D^{20}$: -170 - -175° (0.2 g, chloroform, 10 mL, 100 mm).

Melting point 172 - 175°C

Purity (1) Alkaloids—Boil 0.5 g of Santonin with 20 mL of diluted sulfuric acid (1 in 100), cool, and filter. Dilute 10 mL of the filtrate with water to 30 mL, add 3 drops of iodine TS, and allow to stand for 3 hours: no turbidity is produced.

(2) Artemisin—Dissolve 1.0 g of powdered Santonin in 2 mL of chloroform by slight warming: the solution is clear and colorless, or any yellow color produced is not darker than Matching Fluid A.

(3) Phenols—Boil 0.20 g of Santonin with 10 mL of water, cool, and filter. To the filtrate add bromine TS until the color of the solution becomes yellow: no turbidity is produced.

(4) Acid-coloring substances—Moisten 0.01 g of Santonin with nitric acid: no color develops immediately. Moisten Santonin with sulfuric acid, previously cooled to 0°C: no color is produced immediately.

Residue on ignition Not more than 0.25% (1 g).

Assay Weigh accurately about 0.25 g of Santonin, dissolve in 10 mL of ethanol (95) by warming, add exactly 20 mL of 0.1 mol/L sodium hydroxide VS, and heat on a water bath under a reflux condenser for 5 minutes. Cool quickly, and titrate the excess sodium hydroxide with 0.05 mol/L hydrochloric acid VS (indicator: 3 drops of phenolphthalein TS). Perform a blank determination.

Each mL of 0.1 mol/L sodium hydroxide VS
= 24.631 mg of C₁₅H₁₈O₃

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

Santonin Tablets

サントニン錠

Santonin Tablets contain not less than 92% and not more than 108% of the labeled amount of santonin (C₁₅H₁₈O₃: 246.30).

Method of preparation Prepare as directed under Tablets, with Santonin.

Identification To a portion of powdered Santonin Tablets, equivalent to 0.5 g of Santonin according to the labeled amount, add 50 mL of chloroform, shake, filter, and evaporate the filtrate to dryness. Proceed with this as directed in the Identification under Santonin.

Assay Weigh accurately, and powder not less than 20 Santonin Tablets. Weigh accurately a portion of the powder, equivalent to about 0.05 g of santonin (C₁₅H₁₈O₃), add 40 mL of methanol, shake for 10 minutes, and add methanol to make 50 mL. Centrifuge this solution, pipet 5 mL of the supernatant liquid, add exactly 3 mL of the internal solution, add methanol to make 10 mL, and use this solution as the sample solution. Separately, dissolve about 0.05 g of santonin for assay, accurately weighed, in methanol to make exactly 50 mL. Pipet 5 mL of this solution, add exactly 3 mL of the internal solution, add methanol to make 10 mL, and use this solution as the standard solution. Perform the test with 1 μL 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_T and Q_S , of the peak area of santonin to that of the internal standard.

$$\begin{aligned} & \text{Amount (mg) of santonin (C}_{15}\text{H}_{18}\text{O}_3) \\ &= \text{amount (mg) of Santonin Reference Standard} \\ & \quad \times \frac{Q_T}{Q_S} \end{aligned}$$

Internal standard solution—A solution of ethyl paraoxybenzoate in ethanol (95) (1 in 1000).

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 254 nm).

Column: A stainless steel column about 4 mm in inside diameter and about 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 25°C.