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Saw Palmetto

DEFINITION

Saw Palmetto consists of partially dried, ripe fruit of *Serenoa repens* (W. Bartram) Small (Fam. Arecaceae) [*Serenoa serrulatum* Schult.; *Sabal serrulata* (Michx.) Nutt. ex Schult. & Schult. f.]. It contains NLT 2% (v/w) of volatile oil, NLT 7% of lipophilic extract, and NLT 9.0% of total fatty acids, determined on the dried basis.

IDENTIFICATION

• A. [THIN-LAYER CHROMATOGRAPHY](#)

[NOTE—Perform the following test under subdued light.]

Reagent solution: 3.7 mg/mL of 4-bromomethyl-7-methoxycoumarin in acetone. Store this solution in a dark place.

Standard solution: 5.0 g of magnesium stearate in a 100-mL round-bottom flask fitted with a reflux condenser. Add 50 mL of ether, 20 mL of 12.5% nitric acid, and 20 mL of water, and heat until dissolution is complete. Cool, transfer the contents of the flask to a separatory funnel, withdraw, and retain the lower aqueous phase. Extract the ether phase twice, each time using 4 mL of water, separating the aqueous phases. Extract the combined aqueous phases with 15 mL of ether, combining the ether extracts. Evaporate to dryness, and dry the residue at 105°. Transfer 1 mg of the residue to an amber glass vial fitted with a metal-clamped rubber cap. Add 10 mg of lithium carbonate, 3 µL of tris-[2-(2-methoxyethoxy)ethyl]amine, and 1.0 mg of the *Reagent solution*. Seal the metal-clamped rubber cap, incubate at 105° for 2 h, and cool.

Sample solution: 10.0 g of finely powdered Saw Palmetto in a 250-mL round-bottom flask fitted with a reflux condenser. Add 150 mL of alcohol, and reflux for 1 h. Cool, filter, wash the residue with alcohol, and dilute the combined washings and filtrate with alcohol to 200.0 mL. Transfer 0.6 mL of this solution to a suitable flask, and evaporate to dryness. To the residue add 1.0 mL of the *Reagent solution*. Transfer this solution with the aid of a pipet to an amber glass vial fitted with a metal-clamped rubber cap. Add 3 µL of tris-[2-(2-methoxyethoxy)ethyl]amine and 10 mg of lithium carbonate to the vial. Seal the metal-clamped rubber cap, incubate at 105° for 2 h, and cool.

Blank solution: To 10 mg of lithium carbonate in an amber glass vial fitted with a metal-clamped rubber cap, add 3 µL of tris-[2-(2-methoxyethoxy)ethyl]amine and 1.0 mL of the *Reagent solution*. Seal the metal-clamped rubber cap, incubate at 105° for 2 h, and cool.

Chromatographic system

(See [Chromatography \(621\)](#), [Thin-Layer Chromatography](#).)

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture, typically 20 cm in length (TLC plates)

Application volume: 2 µL

Developing solvent system: Cyclohexane, ethyl acetate, and acetic acid (70:30:1)

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank solution*

Develop the chromatograms in the solvent system until the solvent front has moved three-fourths of the length of the plate. Remove the plate from the chromatographic chamber, mark the solvent front, and allow the plate to air-dry. Examine the plate under long-wave UV light (365 nm).

Acceptance criteria: The chromatogram of the *Sample solution* exhibits at least two blue fluorescent zones corresponding to similar zones in the *Standard solution*. The blue fluorescent zones in the *Sample solution* appear above the blue fluorescent zones in the *Blank solution*.

COMPOSITION

• [ARTICLES OF BOTANICAL ORIGIN](#), [Volatile Oil Determination\(561\)](#): NLT 2% (v/w) of oil that solidifies to a white solid at room temperature

• CONTENT OF LIPOPHILIC EXTRACT

Analysis: Transfer 10 g of pulverized Saw Palmetto to a 250-mL round-bottom flask fitted with a reflux condenser, and add 150 mL of alcohol. Maintain under reflux for 1 h. Cool, filter, and wash the residue with small portions of alcohol. Combine the filtrate and washings in a 200-mL volumetric flask, and dilute with alcohol to volume. Evaporate 100.0 mL of this solution to dryness in a rotary evaporator under vacuum. Add 40 mL of *n*-hexane to the residue, stir for 5 min, filter, and collect the filtrate in a round-bottom flask. Repeat the above operation of

washing with *n*-hexane two more times, and combine all of the filtrates in the same flask. Using a rotary evaporator, evaporate to dryness. Dry the residue at 105° for 2 h.

Acceptance criteria: The weight of the residue is NLT 0.35 g (NLT 7%).

• **CONTENT OF FATTY ACIDS**

Internal standard solution: 12 mg/mL of nonadecane in hexanes

Standard stock solution: Dissolve quantities of [USP Methyl Laurate RS](#), [USP Methyl Oleate RS](#), [USP Methyl Myristate RS](#), [USP Methyl Palmitate RS](#), [USP Methyl Linoleate RS](#), [USP Methyl Caproate RS](#), [USP Methyl Caprylate RS](#), [USP Methyl Caprate RS](#), [USP Methyl Palmitoleate RS](#), [USP Methyl Stearate RS](#), and [USP Methyl Linolenate RS](#) in hexanes to obtain concentrations of each methyl ester as given in [Table 1](#).

Table 1

Methyl Ester	Concentration (mg/mL)
Methyl laurate	5
Methyl oleate	5
Methyl myristate	2
Methyl palmitate	2
Methyl linoleate	1
Methyl caproate	0.4
Methyl caprylate	0.4
Methyl caprate	0.4
Methyl palmitoleate	0.4
Methyl stearate	0.4
Methyl linolenate	0.4

Standard solution: Combine 1.0 mL of *Internal standard solution* with 5.0 mL of the *Standard stock solution*.

Sample solution: Pulverize 50 g of dried Saw Palmetto to a moderately coarse powder. Transfer 1 g of powder, accurately weighed, to a 100-mL round-bottom flask fitted with a reflux condenser and a magnetic bar. Add 10 mL of 0.5 N methanolic sodium hydroxide solution (20 mg/mL of sodium hydroxide in methanol), and reflux, while stirring, for 15 min. Add 5 mL of a 140 mg/mL solution of boron trifluoride in methanol through the condenser into the flask, and reflux for 2 more min. Add 5.0 mL of hexanes through the condenser, and reflux for an additional 1 min. Cool the flask, remove the condenser, add 15 mL of saturated sodium chloride solution, and 1.0 mL of the *Internal standard solution*. While the solution is still tepid, stopper the flask and shake vigorously. Pipet 1.0 mL of the upper hexanes layer into a glass-stoppered test tube containing a small quantity of anhydrous sodium sulfate. Filter the solution, and, if necessary, dilute a volume of the filtrate with hexanes to obtain a known volume. [NOTE—Store this solution in a refrigerator until just before use.]

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: GC

Detector: Flame ionization

Column: 0.25-mm × 30-m fused silica capillary; 0.25-μm film of phase G16 coating

Temperatures

Injector: 250°

Detector: 300°

Column: See [Table 2](#).

Table 2