

Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Nov-2020
Document Type: Dietary Supplement Monographs
DocId: GUID-53E14A4F-6F17-4CF1-852C-C6547F5A79DB_5_en-US
DOI: https://doi.org/10.31003/USPNF_M74425_05_01
DOI Ref: j51w3

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Saw Palmetto Extract

DEFINITION
Saw Palmetto Extract is obtained from comminuted Saw Palmetto by extraction with hydroalcoholic mixtures or with solvent hexane or by supercritical extraction with carbon dioxide. The ratio of starting crude plant material to Extract is from 8.0 :1 to 14.3 :1. The Extract contains NLT 80.0% of fatty acids, NLT 0.2% of sterols, and NLT 0.1% of β-sitosterol, all on the anhydrous basis. The lipophilic Extract contains NLT 0.15% and NMT 0.35% of long-chain alcohols. The hydroalcoholic Extract contains NLT 0.01% and NMT 0.15% of long-chain alcohols on the anhydrous basis. It contains no added substances.

IDENTIFICATION
• **A. Gas Chromatography**
Analysis: Proceed as directed in *Content of Fatty Acids*.
Acceptance criteria: The retention times of the 11 major peaks of the *Sample solution* correspond to those of the *Standard solution*. The ranges for ratios of the concentration of lauric acid to the concentration of the respective fatty acid in Extract prepared using hydroalcoholic mixtures or solvent hexane are in [Table 1](#). The ranges for ratios of the concentration of lauric acid to the concentration of the respective fatty acid in Extract prepared by supercritical extraction with carbon dioxide are in [Table 2](#).

Table 1

Fatty Acid	Minimum Ratio	Maximum Ratio
Capric	9.0	16
Caproic	8.5	24
Caprylic	8.5	17.5
Linoleic	5.0	16
Linolenic	31.5	55
Myristic	2.2	2.8
Oleic	0.60	1.15
Palmitic	2.8	3.9
Stearic	14	26

Table 2

Fatty Acid	Minimum Ratio	Maximum Ratio
Capric	9.0	16
Caproic	9.0	40

Fatty Acid	Minimum Ratio	Maximum Ratio
Caprylic	8.5	17.5
Linoleic	4.0	8.0
Linolenic	35	60
Myristic	2.2	2.8
Oleic	0.60	1.15
Palmitic	2.8	3.9
Stearic	13	20

COMPOSITION

• 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 3](#).

Table 3

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: Transfer 1.0 mL of the *Internal standard solution* to 5.0 mL of the *Standard stock solution*.

Sample solution: Transfer 100 mg of Extract to a pressure-proof, screw-capped vial, and add 3.0 mL of a solution of sulfuric acid in methanol (5 in 100). Heat at 100° in an oil bath for 2 h, shaking intermittently. Allow to cool, and add 1.0 mL of the *Internal standard solution*, 10.0 mL of water, 1 g of sodium chloride, and 5 mL of hexanes. Shake well, allow the layers to separate completely, and use the hexanes layer. [NOTE—Store in a refrigerator until ready to use.]

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)**Mode:** GC**Detector:** Flame ionization**Column:** 0.25-mm × 30-m fused silica capillary; coated with a 0.25-μm film of phase G16**Temperatures****Injection port:** 250°**Detector:** 300°**Column:** See [Table 4](#).**Table 4**

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
120	0	120	3
120	50	220	12

Carrier gas: Helium**Flow rate:** 1 mL/min**Injection volume:** 1 μL**System suitability****Sample:** *Standard solution*[NOTE—See [Table 5](#) for the relative retention times.]**Table 5**

Methyl Ester	Relative Retention Time
Methyl caproate	0.39
Methyl caprylate	0.56
Methyl caprate	0.76
Methyl laurate	0.94
Nonadecane (internal standard)	1.0
Methyl myristate	1.1
Methyl palmitate	1.3
Methyl palmitoleate	1.35
Methyl stearate	1.65
Methyl oleate	1.7
Methyl linoleate	1.8
Methyl linolenate	2.0

Suitability requirements**Resolution:** NLT 1.5 between methyl stearate and methyl oleate