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2751 Nutra Lane Eustis, FL 32726 main: 352.357.2004 toll free: 877.876.8872 fax: 352.483.2095 www.valensa.com

USPlus®
Pure Lipidosterolic Extract

USPlus® Pure Lipidosterolic Extract of Saw Palmetto is well-established as the industry standard for quality. It is the first and only USP-Verified Saw Palmetto extract manufactured using a pure Supercritical CO_2 process enabled by our GEMS™ Supply Chain Excellence Program. Saw palmetto grows only in the coastal Southeast United States and the wildcraft saw palmetto berry harvest supplies the worldwide dietary supplement and herbal medicine extract demand. Economically motivated adulteration exists in the marketplace with unscrupulous suppliers wholly or partially substituting valuable saw palmetto extract with unlabeled vegetable and animal fats.

The extra virgin olive oil market also experiences adulteration, and publication of recognized analytical methods for detecting fraud and ensuring quality can help ensure that authentic, effective products can be confidently used.

The U.S. Pharmacopeia (USP) is an independent organization which sets standards for pharmaceuticals, food and dietary ingredients. The USP monograph for saw palmetto extract establishes limits for marker compounds and contaminants. As pure saw palmetto extract has a unique fatty acid profile, the monograph sets limits for the ratio of each fatty acid to lauric acid as a reliable identity test. Every batch of our extract is tested in our USP Verified laboratory to confirm compliance with the current U.S. Pharmacopeia (USP) monograph and our strict internal requirements. The Table below highlights our specifications for a quality extract.

Table 1

USP Saw Palmetto Extract Monograph	
Content of Total Fatty Acids	NLT 80.0%
Identity	Meets individual Lauric acid ratio ranges
Caproic acid	9.0 – 40
Caprylic acid	8.5 – 17.5
Capric acid	9.0 – 16
Myristic acid	2.2 – 2.8
Palmitic acid	2.8 – 3.9
Stearic acid	13 – 20
Oleic acid	0.60 – 1.15
Linoleic acid	4.0 – 8.0
Linolenic acid	35 – 60
Phytosterols	NLT 0.2%
Beta-Sitosterol	NLT 0.1%
Long-chain alcohols	0.15 – 0.35%

In recent years, we have received concerning information from our customers about very inexpensive saw

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palmetto extracts offered in the market. The pricing for these "saw palmetto" extracts were inconsistent with market pricing of authentic berries, which can be sourced only from the southeast United States. We have tested some of the suspicious products and found that all were adulterated or fraudulent. Results from recent samples are presented below. For comparison, the first report shows typical results of Valensa's USPlus® Pure Lipidosterolic Extract of Saw Palmetto.

Our data indicates that imitation saw palmetto extracts typically fail not only in chemical markers, but also color and odor. Valensa is working with both the USP and American Botanical Council (ABC) to strengthen standard monographs with advanced testing methods to help prevent adulterated or substandard products from entering the market.

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Sample Name	USPlus® Pure Lipidosterolic Extract of Saw Palmetto
Product Lot Number	201028
Sample Lab ID	U5739-1
Date Submitted	Nov-10-2020

Component	Measured Amount (% w/w)	Lauric Acid Ratio	USP Monograph
Caproic acid	1.4	20	9.0 - 40
Caprylic acid	2.2	13	8.5 - 17.5
Capric acid	2.7	11	9.0 - 16
Lauric acid	28.9	-	-
Myristic acid	11.1	2.6	2.2 - 2.8
Palmitic acid	8.1	3.6	2.8 - 3.9
Stearic acid	1.7	17	13 - 20
Oleic acid	28.2	1.03	0.60 - 1.15
Linoleic acid	4.7	6.1	4.0 - 8.0
Linolenic acid	0.5	54	35 - 60
Total Fatty Acids	89.6	-	> 80%
Unbound (Free) Fatty Acids	74.5	-	-
Tetracosanol	0.004		-
Hexacosanol	0.019		-
Octacosanol	0.176		-
Triacontanol	0.034		-
Total Long-Chain Alcohols	0.233		0.15 – 0.35%
Campesterol	0.058		-
Stigmasterol	0.026		-
β-Sitosterol	0.190		> 0.1%
Stigmastanol	0.011		-
Total Sterols	0.286		> 0.2%

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Sample Name	Saw Palmetto Extract
Product Lot Number	J
Sample Lab ID	U5574-2
Date Submitted	Mar-26-2020

Component	Measured Amount (% w/w)	Lauric Acid Ratio	USP Monograph
Caproic acid	1.7	18.9	9.0 - 40
Caprylic acid	3.0	10.5	8.5 - 17.5
Capric acid	2.2	14.3	9.0 - 16
Lauric acid	31.6	-	-
Myristic acid	11.9	2.7	2.2 - 2.8
Palmitic acid	7.1	4.4	2.8 - 3.9
Stearic acid	1.5	21	13 - 20
Oleic acid	30.3	1.04	0.60 - 1.15
Linoleic acid	5.7	5.6	4.0 - 8.0
Linolenic acid	0.5	59	35 - 60
Total Fatty Acids	95.5	-	> 80%
Unbound (Free) Fatty Acids	61.1	-	-
Tetracosanol	0.001		-
Hexacosanol	0.000		-
Octacosanol	0.000		-
Triacontanol	0.000		-
Total Long-Chain Alcohols	0.001		0.15 – 0.35%
Campesterol	0.144		-
Stigmasterol	0.166		-
β-Sitosterol	0.262		> 0.1%
Stigmastanol	0.012		-
Total Sterols	0.585		> 0.2%

Results Summary

- USP Sample does not meet USP monograph
- Spec Off spec for expected levels of key sterols and long-chain alcohols
- Odor Sample has an uncharacteristic rancid odor

Product contains only a trace amount of long-chain alcohols (0.001%) compared to the USP lower limit of 0.15%. Total sterols are over 2x typical levels in authentic extracts. Most remarkable is the level of Stigmasterol which are found at 6x compared to normal levels. Potential addition of coconut sterol fractions which can contain high proportions of Stigmasterol.

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Sample Name	Saw Palmetto Extract
Product Lot Number	G
Sample Lab ID	U5574-3
Date Submitted	Mar-26-2020

Component	Measured Amount (% w/w)	Lauric Acid Ratio	USP Monograph
Caproic acid	1.4	21.4	9.0 - 40
Caprylic acid	2.8	10.5	8.5 - 17.5
Capric acid	1.9	15.3	9.0 - 16
Lauric acid	29.6	-	-
Myristic acid	11.5	2.6	2.2 - 2.8
Palmitic acid	9.0	3.3	2.8 - 3.9
Stearic acid	1.7	17	13 - 20
Oleic acid	27.9	1.06	0.60 - 1.15
Linoleic acid	5.0	5.9	4.0 - 8.0
Linolenic acid	0.6	54	35 - 60
Total Fatty Acids	91.3	-	> 80%
Unbound (Free) Fatty Acids	36.5	-	-
Tetracosanol	0.012		-
Hexacosanol	0.010		-
Octacosanol	0.016		-
Triacontanol	0.039		-
Total Long-Chain Alcohols	0.076		0.15 – 0.35%
Campesterol	0.057		-
Stigmasterol	0.081		-
β-Sitosterol	0.271		> 0.1%
Stigmastanol	0.010		-
Total Sterols	0.420		> 0.2%

Results Summary

- USP — Sample does not fully meet USP monograph
- Spec — Off spec for expected free fatty acid levels and long-chain alcohols
- Color and Odor — Fruity odor, pale yellow and cloudy - uncharacteristic of an authentic saw palmetto extract

Sample meets the USP monograph fatty acid identity profile. However, the free fatty level of 36% is very low compared to reference extracts which are found to have 50 - 80% free fatty acids.

Product contains only ~ 1/2 the amount of total long-chain alcohols required by the monograph, while the Tetracosanol is 3x the amount found in an authentic extract. Total sterols are slightly higher than typical level, but most notable is the 3x higher concentration of Stigmasterol, indicating potential addition with other plant phytosterols.

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Sample Name	Saw Palmetto Extract
Product Lot Number	C
Sample Lab ID	U5574-1
Date Submitted	Mar-26-2020

Component	Measured Amount (% w/w)	Lauric Acid Ratio	USP Monograph
Caproic acid	1.6	19.1	9.0 - 40
Caprylic acid	2.8	10.9	8.5 - 17.5
Capric acid	2.3	13.5	9.0 - 16
Lauric acid	30.7	-	-
Myristic acid	12.1	2.5	2.2 - 2.8
Palmitic acid	8.9	3.4	2.8 - 3.9
Stearic acid	1.6	19	13 - 20
Oleic acid	29.1	1.06	0.60 - 1.15
Linoleic acid	5.3	5.8	4.0 - 8.0
Linolenic acid	0.6	56	35 - 60
Total Fatty Acids	95.0	-	> 80%
Unbound (Free) Fatty Acids	67.4	-	-
Tetracosanol	0.001		-
Hexacosanol	0.003		-
Octacosanol	0.024		-
Triacontanol	0.004		-
Total Long-Chain Alcohols	0.033		0.15 – 0.35%
Campesterol	0.128		-
Stigmasterol	0.135		-
β-Sitosterol	0.260		> 0.1%
Stigmastanol	0.013		-
Total Sterols	0.536		> 0.2%

Results Summary

- USP Sample does not meet USP monograph
- Spec Off spec on total long chain alcohols
- Color and Odor Faint characteristic saw palmetto odor

Sample meets the USP monograph fatty acid identity profile, but the total fatty acid level of 95% is abnormal, as most saw palmetto extracts contain ~ 90%. Product contains a typical level of total long-chain alcohols, however there are only trace amounts of Tetracosanol, Hexacosanol and Triacontanol which are found at higher concentrations in true saw palmetto extract.
Total sterols are within USP monograph, but much higher than the typical ~0.34% in authentic extracts. Campesterol and Stigmasterol are 2x and 5x the amount typically found, suggesting addition of exogenous plant phytosterols. Faint characteristic saw palmetto odor, indicating at least partial presence of authentic extract. Good example showing that more than one marker should be examined when testing new saw palmetto extract supplies.