

# ADULTERATED & FAKE SAW PALMETTO EXTRACTS

## REVEALED BY VALENSA INTERNATIONAL

Valensa's USPlus® brand Supercritical Saw Palmetto extract is well-established as the industry standard for quality. Every lot of our extract is scrupulously tested in our own laboratory to confirm compliance with the current U.S. Pharmacopeia (USP) monograph and the strict internal requirements of Valensa International.

**Table 1**

<b>Current USP 40 Monograph</b>	
Content of Total Fatty Acids	≥ 80.0%
Fatty Acid Profile	Meets individual ratio ranges
Phytosterols	≥ 0.2%
Beta-Sitosterol	≥ 0.1%
Long-chain Alcohols	0.15 – 0.35%
Iodine Value	40 – 50
Saponification Value	210 – 250
<b>Extended Valensa Identity and Quality Parameters</b>	
Content of Free Fatty Acids	60 – 90%
Acid Value Matching Coefficient	90 – 110
Fatty Acid Matching Coefficient	90 – 110 ; 80 – 110 (Myristic)
Acid Value	100 – 230 mg KOH/g
Water Content	≤ 1.5%
Peroxide Value	< 5.0 meqO <sub>2</sub> /kg

Valensa applies a unique approach<sup>a,b</sup> to verify product quality and authenticity. This approach is based on empirical rule that in the high-quality, genuine saw palmetto extract, the profiles of free fatty acids (FFA) and total fatty acids (TFA) are nearly identical for major fatty acids (namely lauric, myristic, palmitic and oleic). This observation, along with our simple method for free fatty acids determination, allows for easy identification of low quality and/or adulterated saw palmetto extract by comparing the relative contents of FFA and TFA. Valensa is working with both the USP and American Botanical Council (ABC) to strengthen standard monographs with FFA testing to help prevent adulterated or substandard products from entering the market.

<sup>a</sup> G. Mikaelian, M. Sojka, **Authenticating saw palmetto extract: a new approach**, *Nutraceutical Business & Technology*, 2009; **5**: 24-27.

<sup>b</sup> G. Mikaelian, M. Sojka, J. Minatelli, **The ultimate way to win the fight against saw palmetto extract adulteration**, *Nutraceutical Business & Technology*, 2009; **1**: 46-49.

In recent years, we have received alarming signals from our customers about very inexpensive saw palmetto extracts offered in the market. We were able to test some of these suspicious products and found that all of them were adulterated or fake (out-of-spec test results below are shown in *red*). Assessment

Results of our testing are presented in reports 1-7 below. For comparison purpose, Report #1 shows typical results of Valensa's USPlus® Saw Palmetto extract made from the berries harvested in 2016. Our data indicates that imitation saw palmetto extracts typically fail by not meeting standards for parameters such as levels of long-chain alcohols, phytosterols or meeting USP fatty acid profile. More sophisticated or diluted "extracts" can be more difficult to detect with existing monograph tests, which underscores the need for deeper testing in free fatty acids.

**For confidentiality reasons the names of irresponsible manufacturers are not disclosed at this time.**

## List of Abbreviations

**U – USP**

**V – Valensa International**

**TFA – Total Fatty Acid:** Measured absolute content (in %) of the particular fatty acid, which is represented in the extract both in free and glyceride form.

**FFA – Free Fatty Acid:** Measured absolute content (in %) of the particular fatty acid, which is represented in the extract in free form only.

**TFAR – Total Fatty Acid Ratio:** The ratio of the total content of lauric acid to the total content of the respective fatty acid. It is required by USP for product identification.

**TFA<sub>p</sub> – Total Fatty Acid in profile:** Calculated relative content (in %) of the individual fatty acid (TFA<sub>i</sub>) in both free and glyceride form to the sum of all fatty acids ( $\sum$ TFA<sub>i</sub>):

$$\text{TFA}_p = \frac{\text{TFA}_i}{\sum \text{TFA}_i} \times 100\%; \quad \text{Example (see: Report \#1; myristic acid): } \text{TFA}_p = \frac{10.8\%}{89.9\%} \times 100\% = 12.0\%$$

**FFA<sub>p</sub> – Free Fatty Acid in profile:** Calculated relative content (in %) of the individual fatty acid (FFA<sub>i</sub>), represented in the extract in free form only, to the sum of all free fatty acids ( $\sum$ FFA<sub>i</sub>):

$$\text{FFA}_p = \frac{\text{FFA}_i}{\sum \text{FFA}_i} \times 100\%; \quad \text{Example (see: Report \#1; myristic acid): } \text{FFA}_p = \frac{9.1\%}{71.8\%} \times 100\% = 12.7\%$$

**FAMC – Fatty Acid Matching Coefficient.** This coefficient is calculated for Lauric, Myristic, Palmitic and Oleic acids in Saw Palmetto Extract. It shows how close the content of each of these acids in the Total Fatty Acid Profile (TFA<sub>p</sub>) is to that in the Free Fatty Acid Profile (FFA<sub>p</sub>). FAMC is calculated by the following formula:

$$\text{FAMC} = \frac{\text{TFA}_p}{\text{FFA}_p} \times 100\%; \quad \text{Example (see: Report \#1; myristic acid): } \text{FAMC} = \frac{12.0\%}{12.7\%} \times 100\% = 94\%$$

**AVMC – Acid Value Matching Coefficient:** This coefficient shows how close the measured Acid Value (AV<sub>m</sub>) and the Acid Value calculated are based on Free Fatty Acids content (AV<sub>c</sub>). AVMC is calculated by the following formula:

$$\text{AVMC} = \frac{\text{AV}_m}{\text{AV}_c} \times 100\%; \quad \text{Example (see: Report \#2):} \quad \text{AVMC} = \frac{141}{132} \times 100\% = 107\%$$

## REPORT #1

Sample Name	USPlus® Supercritical Saw Palmetto Extract
Sample Source	Valensa International
Sample Lab ID	U4463-1
Sample Lot Number	170304
Report Date	March 16, 2017

### Summary

Test	Unit	Specification	Found
USP Identification (TFAR)	n/a	Pass (USP)	Pass
Total Fatty Acids	%	≥80.0 (USP)	89.9
Free Fatty Acids		60.0 – 90.0 (Valensa)	71.8
Long-Chain Alcohols		0.01 – 0.35 (USP)	0.30
Sterols		≥0.2 (USP)	0.32
β-Sitosterol		≥0.1 (USP)	0.22
Measured Acid Value (AV <sub>m</sub> )	mgKOH/g	100 – 230 (Valensa)	177
Calculated Acid Value (AV <sub>c</sub> )			177
AVMC	%	90 – 110 (Valensa)	100

### Fatty Acids

FA	Unit	TFA	FFA	TFA <sub>p</sub>	FFA <sub>p</sub>	FAMC/Specs (V)	TFAR	TFAR Specs (U)	ID	
Caproic	%	1.4	1.2	1.6	1.7	n/a	17.5	8.5 – 24	Pass	
Caprylic		2.3	1.8	2.5	2.5		9.7	8.5 – 17.5	Pass	
Capric		2.8	2.0	3.1	2.8		13.9	9.0 – 16	Pass	
Lauric		29.2	23.7	32.5	33.0	98 / 90 - 110	n/a			
Myristic		10.8	9.1	12.0	12.7	94 / 80 – 110	2.5	2.2 – 2.8	Pass	
Palmitic		8.4	6.8	9.3	9.5	98 / 90 – 110	3.3	2.8 – 3.9	Pass	
Palmitoleic		0.2	n/a		n/a		n/a			
Stearic		1.7	1.2	1.8	1.7	n/a	19	13 – 20	Pass	
Oleic		27.7	21.9	30.8	30.5	101 / 90 – 110	1.08	0.60 – 1.15	Pass	
Linoleic		4.8	3.3	5.4	4.6	n/a	7.1	5.0 – 16	Pass	
Linolenic		0.7	0.6	0.8	0.8		53	35 – 60	Pass	
Total			89.9	71.8						

### Test conclusion

Parameter	Result	Reason
Authenticity	Pass	1. FAMC for all major fatty acids are within the specified limits 2. AVMC is within the specified limits
USP Compliance	Complies	All USP requirements are met
<b>Extract meets all USP and Valensa specs; this is a genuine and high quality product.</b>		

## REPORT #2

Sample Name	SPE Extract
Sample Source	Manufactured by A. Submitted by customer for QC
Sample Lab ID	U4154-1
Sample Lot Number	160620
Report Date	June 29, 2016

### Summary

Test	Unit	Specification	Found
USP Identification (TFAR)	n/a	Pass (USP)	Pass
Total Fatty Acids	%	≥80.0 (USP)	90.4
Free Fatty Acids		60.0 – 90.0 (Valensa)	56.5
Long-Chain Alcohols		0.01 – 0.35 (USP)	0.001
Sterols		≥0.2 (USP)	0.39
β-Sitosterol		≥0.1 (USP)	0.20
Measured Acid Value (AV <sub>m</sub> )	mgKOH/g	100 – 230 (Valensa)	141
Calculated Acid Value (AV <sub>c</sub> )			132
AVMC	%	90 – 110 (Valensa)	107

### Fatty Acids

FA	Unit	TFA	FFA	TFA <sub>p</sub>	FFA <sub>p</sub>	FAMC/Specs (V)	TFAR	TFAR Specs (U)	ID
Caproic	%	1.7	1.5	1.9	2.6	n/a	17.5	8.5 – 24	Pass
Caprylic		3.0	0.2	3.3	0.3		9.7	8.5 – 17.5	Pass
Capric		2.1	0.1	2.3	0.1		13.9	9.0 – 16	Pass
Lauric		29.3	14.1	32.4	25.0	130 / 90 - 110	n/a		
Myristic		11.8	6.1	13.1	10.8	121 / 80 – 110	2.5	2.2 – 2.8	Pass
Palmitic		8.9	5.9	9.9	10.4	95 / 90 – 110	3.3	2.8 – 3.9	Pass
Palmitoleic		0.0	n/a		n/a		n/a		
Stearic		1.6	0.6	1.7	1.1	n/a	19	13 – 20	Pass
Oleic		27.2	24.6	30.1	43.5	69 / 90 – 110	1.08	0.60 – 1.15	Pass
Linoleic		4.2	3.5	4.6	6.1	n/a	7.1	5.0 – 16	Pass
Linolenic		0.6	0.0	0.6	n/a		53	35 – 60	Pass
Total			90.4	56.5					

### Test conclusion

Parameter	Result	Reason
Authenticity	Fail	1. Out-of-spec FAMC for three major fatty acids 2. Out-of-spec for free fatty acids
USP Compliance	Not complying	Out-of-spec long-chain alcohols content
<b>Extract doesn't meet some USP and Valensa specs; this is probably an adulterated/engineered product.</b>		

## REPORT #3

Sample Name	Saw Palmetto Oil 90%
Sample Source	Manufactured by B. Submitted by customer for QC
Sample Lab ID	101116
Sample Lot Number	U4356-1
Report Date	November 30, 2016

### Summary

Test	Unit	Specification	Found
USP Identification (TFAR)	n/a	Pass (USP)	Fail
Total Fatty Acids	%	≥80.0 (USP)	90.5
Free Fatty Acids		60.0 – 90.0 (Valensa)	1.25
Long-Chain Alcohols		0.01 – 0.35 (USP)	0.002
Sterols		≥0.2 (USP)	0.17
β-Sitosterol		≥0.1 (USP)	0.10
Measured Acid Value (AV <sub>m</sub> )		mgKOH/g	100 – 230 (Valensa)
Calculated Acid Value (AV <sub>c</sub> )	3.8		
AVMC	%	90 – 110 (Valensa)	5

### Fatty Acids

FA	Unit	TFA	FFA	TFA <sub>p</sub>	FFA <sub>p</sub>	FAMC/Specs (V)	TFAR	TFAR Specs (U)	ID
Caproic	%	0.5	0.07	0.6	5.6	n/a	62.6	8.5 – 24	Fail
Caprylic		5.4	0.16	6.0	12.6		5.6	8.5 – 17.5	Fail
Capric		4.1	0.12	4.5	9.9		7.4	9.0 – 16	Fail
Lauric		29.9	0.72	33.0	58.0	57 / 90 - 110	n/a		
Myristic		11.4	0.10	12.6	7.9	160 / 80 – 110	2.6	2.2 – 2.8	Pass
Palmitic		8.8	0.07	9.7	5.4	180 / 90 – 110	3.4	2.8 – 3.9	Pass
Palmitoleic		0.03	n/a		n/a		n/a		
Stearic		2.9	0.01	3.2	0.9	n/a / 90 – 110	10.1	13 – 20	Fail
Oleic		10.3	0.00	11.4	n/a		2.90	0.60 – 1.15	Fail
Linoleic		15.3	0.00	16.9	n/a	n/a	1.9	5.0 – 16	Fail
Linolenic		2.0	0.00	2.2	n/a		15.1	35 – 60	Fail
Total			90.5	1.25					

### Test conclusion

Parameter	Result	Reason
Authenticity	Fail	1. Out-of-spec FAMC for all major fatty acids 2. Out-of-spec AVMC
USP compliance	Not complying	1. USP Identification fail 2. Out-of-spec sterols 3. Out-of-spec long-chain alcohols
<b>Extract doesn't meet practically all USP and Valensa specs; this is surely a fake product.</b>		

## REPORT #4

Sample Name	Saw Palmetto Extract
Sample Source	Manufactured by C. Submitted by customer for QC
Sample Lab ID	161011
Sample Lot Number	U4408-1
Report Date	January 10, 2017

### Summary

Test	Unit	Specification	Found
USP Identification (TFAR)	n/a	Pass (USP)	Passed
Total Fatty Acids	%	≥80.0 (USP)	93.5
Free Fatty Acids		60.0 – 90.0 (Valensa)	60.4
Long-Chain Alcohols		0.01 – 0.35 (USP)	0.005
Sterols		≥0.2 (USP)	0.60
β-Sitosterol		≥0.1 (USP)	0.26
Measured Acid Value (AV <sub>m</sub> )		mgKOH/g	100 – 230 (Valensa)
Calculated Acid Value (AV <sub>c</sub> )	141		
AVMC	%	90 – 110 (Valensa)	99

### Fatty Acids

FA	Unit	TFA	FFA	TFA <sub>p</sub>	FFA <sub>p</sub>	FAMC/Specs (V)	TFAR	TFAR Specs (U)	ID	
Caproic	%	1.5	1.4	1.7	2.3	n/a	19.1	8.5 – 24	Pass	
Caprylic		2.7	0.3	2.9	0.4		10.9	8.5 – 17.5	Pass	
Capric		2.1	0.2	2.2	0.3		14.4	9.0 – 16	Pass	
Lauric		29.8	15.3	31.9	25.3	126 / 90 – 110	n/a			
Myristic		11.8	6.1	12.6	10.1	125 / 80 – 110	2.5	2.2 – 2.8	Pass	
Palmitic		9.9	6.3	10.6	10.4	102 / 90 - 110	3.0	2.8 – 3.9	Pass	
Palmitoleic		0.1	n/a		n/a		n/a			
Stearic		1.9	0.9	2.0	1.4	n/a		16	13 – 20	Pass
Oleic		28.6	26.2	30.7	43.5	71 / 90 – 110	1.04	0.60 – 1.15	Pass	
Linoleic		4.5	3.7	4.8	6.1	n/a	6.7	5.0 – 16	Pass	
Linolenic		0.6	0.0	0.6	0.0		53	35 – 60	Pass	
Total			93.5	60.4						

### Test conclusion

Parameter	Result	Reason
Authenticity	Fail	Out-of-spec FAMC for three major fatty acids
USP compliance	Not complying	Out-of-spec long-chain alcohols
<b>Extract doesn't meet some USP and Valensa specs; this is probably an adulterated/engineered product.</b>		

## REPORT #5

Sample Name	Saw Palmetto Extract
Sample Source	Manufactured by D. Submitted by customer for QC
Sample Lab ID	SVA161016
Sample Lot Number	U4507-1
Report Date	April 21, 2017

### Summary

Test	Unit	Specification	Found
USP Identification (TFAR)	n/a	Pass (USP)	Fail
Total Fatty Acids	%	≥80.0 (USP)	89.4
Free Fatty Acids		60.0 – 90.0 (Valensa)	2.2
Long-Chain Alcohols		0.01 – 0.35 (USP)	0.003
Sterols		≥0.2 (USP)	0.16
β-Sitosterol		≥0.1 (USP)	0.09
Measured Acid Value (AV <sub>m</sub> )	mgKOH/g	100 – 230 (Valensa)	0.4
Calculated Acid Value (AV <sub>c</sub> )			4.3
AVMC	%	90 – 110 (Valensa)	9

### Fatty Acids

FA	Unit	TFA	FFA	TFA <sub>p</sub>	FFA <sub>p</sub>	FAMC/Specs (V)	TFAR	TFAR Specs (U)	ID	
Caproic	%	0.5	0.1	0.5	4.6	n/a	19.1	8.5 – 24	Pass	
Caprylic		5.5	0.4	6.2	18.2		10.9	8.5 – 17.5	Pass	
Capric		3.9	0.2	4.3	9.1		14.4	9.0 – 16	Pass	
Lauric		29.7	1.3	33.2	59.1	56 / 90 – 110	n/a			
Myristic		11.4	0.2	12.8	9.1	141 / 80 – 110	2.5	2.2 – 2.8	Pass	
Palmitic		7.3	0.0	8.2	n/a	n/a / 90 - 110	3.0	2.8 – 3.9	Pass	
Palmitoleic		0.0	n/a		n/a		n/a			
Stearic		2.6	0.0	2.9	n/a	n/a		16	13 – 20	Pass
Oleic		9.7	0.0	10.9	n/a	n/a / 90 – 110	1.04	0.60 – 1.15	Pass	
Linoleic		5.1	0.0	5.8	n/a	n/a	6.7	5.0 – 16	Pass	
Linolenic		13.7	0.0	15.3	n/a		53	35 – 60	Pass	
Total			89.4	2.2						

### Test conclusion

Parameter	Result	Reason
Authenticity	Fail	1. Out-of-spec FAMC for all major fatty acids 2. Out-of-spec AVMC
USP compliance	Not complying	1. Fail USP Identification 2. Out-of-spec sterols 3. Out-of-spec long-chain alcohols
<b>Extract doesn't meet practically all USP and Valensa specs; this is surely a fake product.</b>		



## REPORT #6

Sample Name	Saw Palmetto Extract
Sample Source	Manufactured by E. Submitted by customer for QC
Sample Lab ID	0114929516
Sample Lot Number	U4507-2
Report Date	April 21, 2017

### Summary

Test	Unit	Specification	Found
USP Identification (TFAR)	n/a	Pass (USP)	Pass
Total Fatty Acids	%	≥80.0 (USP)	93.6
Free Fatty Acids		60.0 – 90.0 (Valensa)	63.7
Long-Chain Alcohols		0.01 – 0.35 (USP)	Not detected
Sterols		≥0.2 (USP)	0.62
β-Sitosterol		≥0.1 (USP)	0.28
Measured Acid Value (AV <sub>m</sub> )	mgKOH/g	100 – 230 (Valensa)	138
Calculated Acid Value (AV <sub>c</sub> )			150
AVMC	%	90 – 110 (Valensa)	92

### Fatty Acids

FA	Unit	TFA	FFA	TFA <sub>p</sub>	FFA <sub>p</sub>	FAMC/Specs (V)	TFAR	TFAR Specs (U)	ID	
Caproic	%	1.6	1.5	1.8	2.3	n/a	19.1	8.5 – 24	Pass	
Caprylic		3.0	0.6	3.2	1.0		10.9	8.5 – 17.5	Pass	
Capric		2.1	0.4	2.3	0.7		14.4	9.0 – 16	Pass	
Lauric		30.0	16.6	32.1	26.0	123 / 90 – 110	n/a			
Myristic		12.0	7.0	12.9	11.0	117 / 80 – 110	2.5	2.2 – 2.8	Pass	
Palmitic		7.9	5.2	8.5	8.2	103 / 90 - 110	3.0	2.8 – 3.9	Pass	
Palmitoleic		0.0	n/a		n/a		n/a			
Stearic		1.5	0.7	1.6	1.1	n/a		16	13 – 20	Pass
Oleic		30.1	27.6	32.1	43.4	74 / 90 – 110	1.04	0.60 – 1.15	Pass	
Linoleic		4.7	3.9	5.0	6.2	n/a	6.7	5.0 – 16	Pass	
Linolenic		0.6	0.1	0.6	0.1		53	35 – 60	Pass	
Total			93.6	63.7						

### Test conclusion

Parameter	Result	Reason
Authenticity	Fail	Out-of-spec FAMC for three major fatty acids
USP compliance	Not complying	Out-of-spec long-chain alcohols
<b>Extract doesn't meet some USP and Valensa specs; this is probably an adulterated/engineered product.</b>		

## REPORT #7

Sample Name	Saw Palmetto Extract
Sample Source	Manufactured by F. Submitted by customer for QC
Sample Lab ID	290402
Sample Lot Number	U4507-3
Report Date	April 21, 2017

### Summary

Test	Unit	Specification	Found
USP Identification (TFAR)	n/a	Pass (USP)	Pass
Total Fatty Acids	%	≥80.0 (USP)	93.6
Free Fatty Acids		60.0 – 90.0 (Valensa)	64.2
Long-Chain Alcohols		0.01 – 0.35 (USP)	Not detected
Sterols		≥0.2 (USP)	0.59
β-Sitosterol		≥0.1 (USP)	0.27
Measured Acid Value (AV <sub>m</sub> )	mgKOH/g	100 – 230 (Valensa)	137
Calculated Acid Value (AV <sub>c</sub> )			152
AVMC	%	90 – 110 (Valensa)	90

### Fatty Acids

FA	Unit	TFA	FFA	TFA <sub>p</sub>	FFA <sub>p</sub>	FAMC/Specs (V)	TFAR	TFAR Specs (U)	ID
Caproic	%	1.6	1.4	1.7	2.2	n/a	19.1	8.5 – 24	Pass
Caprylic		3.0	0.7	3.2	1.2		10.9	8.5 – 17.5	Pass
Capric		2.1	0.5	2.2	0.7		14.4	9.0 – 16	Pass
Lauric		30.0	16.9	32.1	26.3	122 / 90 – 110	n/a		
Myristic		12.6	7.5	13.5	11.7	115 / 80 – 110	2.5	2.2 – 2.8	Pass
Palmitic		9.6	6.9	10.3	10.8	103 / 90 - 110	3.0	2.8 – 3.9	Pass
Palmitoleic		0.0	n/a			n/a	n/a		
Stearic		1.7	0.8	1.8	1.3		16	13 – 20	Pass
Oleic		28.0	25.6	29.9	39.9	75 / 90 – 110	1.04	0.60 – 1.15	Pass
Linoleic		4.4	3.7	4.8	5.7	n/a	6.7	5.0 – 16	Pass
Linolenic		0.6	0.1	0.6	0.1		53	35 – 60	Pass
Total			93.6	64.2					

### Test conclusion

Parameter	Result	Reason
Authenticity	Fail	Out-of-spec FAMC for three major fatty acids
USP compliance	Not complying	Out-of-spec long-chain alcohols
<b>Extract doesn't meet some USP and Valensa specs; this is probably an adulterated/engineered product.</b>		