Zagazig J. Pharm. Sci., December 2007
Vol. 16, No. 2, pp. 45-52

ISSN 1110-5089

QUALITY CONTROL OF TEN HERBAL PRODUCES USEFUL IN BENIGN PROSTATIC HYPERPLASIA MARKEDTED IN KSA

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ABSTRACT

Ten herbal drug products useful for the treatment of BPH have been chosen from the Saudi market to ensure their efficacy and safety. These products are reported previously to contain fatty acids and sterols as the active principles. Organoleptic evaluation, weight variation , ash values, moisture content, extractive values, microbiological examination, fatty acids and sterol analysis using GLC, have been undertaken. Interpretation of the results indicated that all the studied products are compatible with the standard values stated in the BP or USP.

INTRODUCTION

Benign Prostatic Hyperplasia (BPH) is a non-neoplastic enlargement of the prostate gland which occurs commonly after the age of 40-50 years. About 65% of men aged 45-55 years are affected and develop variable symptoms of urinary tract obstruction This disease is thought to be related to a hormonal imbalance; the androgen levels fall, with a relative rise in estrogens[1, 2].

Obviously, treatment of BPH is managed by one, or two strategies: prostatic α_1. adrenoceptors antagonists, surgery and/or plant products[3, 4, 5, 6]. This attitude is a result of dissatisfaction with the effectiveness and the cost of modern synthetic medicine in the treatment of chronic diseases[7, 8].

At present, specialists treat BPH patients with the herbal drug for a significant length of time before surgery[9]. In this connection, plant extracts commonly used for treatment of BPH[10] are: *Hypoxis rooperi L*, *Urtica dioica*, *Serenoa repens*, *Cucurbita pepo*, *Prunus africana*, *Populus tremula L*, *Echinacea purpura*, and *Secale cereale*.

Concerning the chemical constituents, it has been reported that the active constituents of plant extracts used in the treatment of BPH are compounds related to steroids, such as phytosterols of which β-sitosterol as well as fatty acids are supposed to be the important active constituents concerned with the activity[11, 12, 13, 14]. Mechanistically, most of these extracts exert their effects through reduction in plasma cholesterol , anti-inflammatory effect, direct cytotoxic effect and anti- prostaglandin activity[10, 13]. In the present study, ten products widely marketed in KSA, derived from four reputed plants were subjected to analytical investigation in order to quality control their efficacy and safety.

MATERIALS AND METHODS

A- Materials:

Ten selected products (of different expiry dates) of *Serenoa repens*, *Prunus africana*, *Urtica dioica* and *Cucurbita pepo* seed oil were purchased from different private pharmacies in Riyadh. These products belong to several herbal medicine companies, originate from USA. Description and details of each sample are given in table 1.

1- **Samples:** Several products were collected from different public pharmacy in greater Riyadh area, and subjected to the present study.

2- **Solvents and chemicals:** The solvents used: 95% ethanol, dichloromethane, n-hexane, acetonitrile, acetone, toluene, diethyl ether, petroleum ether 40-60°C, chloroform, methanol and ethyl acetate were analytically pure BDH. The chemicals used: diazald (Aldrich co.), pyridine, hexamethyldisilazane (HMDS), trimethylchlorosilane (Aldrich co.), phosphoric acid, sulphuric acid, glacial acetic acid, iodine bromide solution, potassium iodide, sodium thiosulphate, anhydrous sodium sulphate, diazomethane, BF_3- MeOH (14%), KOH, HCL, phenolphthalein solution, starch solution were analytical grade.

3- **For microbiology investigation:** Media used for microbiological study were prepared as directed by Oxoid Limited, Basingstoke, Hampshire, England:

i- Soybean-Casein digest agar medium.
ii- Fluid soybean- casein digest.
iii- Mannitol salt agar medium.
iv- Cetrimide ager medium.
v- Fluid Lactose broth.
vi- Tetrathionate medium.
vii- Macconkey agar medium.
viii-Potato agar medium.

Organisms used for testing are ATCC:

i-	*Staph. auresus*	ATCC 25923
ii-	*E. coli*	ATCC 25922
iii-	*Ps. aeruginosa*	ATCC 27853
iv-	*Candida albicans*	ATCC 10231
v-	*Salmonella Typhi*	ATCC 3311

4- **Standards and references:**

- Reference fatty acids were analytical grade 99.9%; supplied by carl-Roth company (Karlsruh, Germany).
- Reference methyl esters of fatty acids were kindly supplied by Dr. Ezzat A. Moety (Department of Pharmaceutical Chemistry. College of Pharmacy, KSU,Riyadh).
- Standards sterol compounds were supplied by phytolab Gmbh & CO-KG, Labor, Addipharma, Wandalenweg, Germany.

- The reference herbs were supplied by Red Mill Company (Natural Foods, Inc.) Milwaukie, Oregon, USA, were examined microscopically, *Serenoa repens* berries, *Prunus africana* bark, *Urtica dioica* herb, *Cucurbita pepo* seeds.

5- **Equipments and techniques:** Hot air oven (Gallenkamp, Model OV-160, England); Muffle furnace: Size 2, Gallenkamp,England; Polarimeter: Model 241 mc, Perkin Elmer, USA; Refractometer: Model: A 80026, Tafesa Hannover, W. Germany; Karl-Fischer apparatuswas used for determination of moisture content.

Soxhlet apparatus: Different sizes (50,100g); Rotary evaporator: Buchi, Model R110; Picnometer: $3cm^3$, UK, for specific gravity of pumpkin seed oil reference and sample; Atomic absorption spectrophotometer: Varian AA- 775 series, for determination zn, Lamp current: 5 mA, Fuel: acetylene, support: air, wavelength: 213.9 nm; Freeze dryer: super Modulyo piranitto 1001, USA; GLC (Gas Liquid Chromatography): Perkin Elmer autosystem XL Gas Chromatograph was used for analysis of sterols and fatty acids under the following conditions:

Column: PE- 225, Length: 30 meter, Internal Diameter: 0.25 mm, Film: 0.25 um, Flow rate: 0.5 ml/ min, Detector: FID, Detector temperature: 250° C, Gases: He, air, Injector temperature: 230° C; Initial Temperature: 50° C for 20 minutes then 10°/ minute to 280°, held for 2 minutes, carrier gas: Helium.

B- Methods:

1- ***Sampling:***

It was necessary to ensure that the composition of the products samples used be representative of the three different batches of preparations being examined.

2- ***Uniformity of weight (mass):***

Twenty units (capsules, tea-bags) taken at random were weighed individually according to the B.P.[15].

3- ***Moisture content:***

Moisture was determined according to BP[15] or the USP[16].

4- ***Extractive values:***

It was carried out by taking 20 g of the powdered samples and successively extracted with petroleum ether (100 ml) then chloroform, ethyl acetate. and finally by ethanol (96%) till exhaustion, and thr resulting extracts were separately weighed[16].

5- ***Ash values:***

Ash values were carried out according to USP[16].

6- ***Microbiological tests:***

All samples were tested for the presence or the absence of pathagenic microorganisms according to official standard protocols[16].

Test for *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Salmonella species* and *Escherichia coli* as well as for mold and yeast were conducted.

7- ***Preparation of fatty acids of the different products:***

i- ***Hydrolysis (specification)*** was conducted by one of the following methods[17, 18]:

a- ***In case of extract samples***, ten grams (specific number of capsules) were resolubilized into aqueous ethanol (1:1, 50 ml) then extracted with petroleum ether (3x15 ml). The ethereal extract was dried (Na_2SO_4), evaporated and the residue was weighed then subjected to hydrolysis (as under C).

b- ***In case of powders***, ten g powdered herbal products were extracted by Soxhlet apparatus using petroleum ether as a solvent then collecting the petroleum ether extract. Afterwards the following procedure was applied (under C).

c- ***In case of oil sample***[17, 18], one g oil or petroleum ether extract was dissolved in a solution of 1 M potassium hydroxide in 95% ethanol (20 ml), and the solution was refluxed for 1 hour . After cooling, water (5 ml) was added, and the solution was extracted with diethyl ether (10 ml x 3). The combined ethereal extract was dried (anhydrous Na_2SO_4) and evaporated to leave the non-saponifiable material (USM). The aqueous layer was acidified with 5% dilute hydrochloric acid to (pH=1-2 using pH paper) and extracted with diethyl ether (3x10 ml).The combined ether extract was washed with water (3x10 ml), and then dried over anhydrous sodium sulphate and finally evaporated to yield the free fatty acids.

The resulting fatty acids were methylated by one of the following methods:

ii- ***Methylation of the fatty acids using BF_3-MeOH (14%)***[18]: To 100 mg fatty acids, 3 ml BF_3-Methanol (14%) in a sealed vial was added, heated to 60 °C for 5-9 minutes, cooled and transferred to a separatory funnel containing 20 ml water and extracted with 30 ml hexane, washed (2 times) with saturated Na Cl solution and the aqueous layer was discarded. The hexane extract was dried (over $Na_2 SO_4$) and evaporated under nitrogen. The sample then was ready for GC analysis.

iii- ***Methylation of the fatty acids using diazomethane***[18]***:*** Diazomethane was prepared in a fume cupboard according to a previously reported procedure.

8- ***Preparation and extraction of sterols:***

After saponification of the oil, extraction by ether (10 ml x 3), washing and drying (anhydrous Na_2SO_4) afforded the unsaponifable matter (USM). For GLC analysis: Five to 50 mg of USM sample in a sealed vial was treated with 1 ml of anhydrous pyridine, 0.1 ml of hexamethyldisilazane (HMDS) and 0.2 ml trimethylchlorosilane (TMCS), shaken vigorously for about 30 seconds and allowed to stand at room temperature until silylation was complete. The reaction product was filtered and solution completed by dry ether to 2 ml in volumetric flask, then 10 ul of this solution was subjected to GLC against standard silylated β-sitosterol (prepared in the same manner) and

ISSN 1110-5089

the area under curve is measured, calculated to determine the % in each sample[18].

9- ***Pharmacopoeial tests for oil samples:***

i- Physical constants:

Specific gravity, refractive index, optical rotation were determined in the central Research lab at the College of Pharmacy, KSU.

ii- Acid value:

The acid value was measured according to the B.P. [15].

iii- Saponification value:

The saponification value was determined according to B.P.[15].

iv- Iodine value:

The iodine value of the oil was determined by BP bromide method[15].

Table (1): Description of the selected products.

Trade name	Dosage form	Composition	Agent saudi arabia	Manufactured by	Production date	Batch number	Expire period
Saw palnetto	Hard gelatin capsule	Each capsule contains 500 mg of saw palmetto powder	Armal EST	G.N.C	6.2002	88110	2 years
Saw palmetto Berries Tea Bags	Tea bags	Each tea bag contains 2.5g of saw palmetto powder	Twinlab	Alvita company	10/2001	89321	3 years
Saw palmetto	Hard gelatin capsule	Each capsule 500 mg of saw palmetto powder	Armal Est	Basic Nutrition company	6/2000	88283	4 years
Saw palmetto Berries	Hard gelatin capsule	Each capsule contains 600 mg of saw palmetto powder	Twinlab	Natures herbs company	1/2001	591080	3 years
Standardized saw palmetto Extract	Softgel capsule	Each capsule contains 160 mg(85- 95)% fatty acids	Twinlab	Natures way	5/2001	920892	3 years
Standardized pygeum extract	Softgel capsules	Each capsule contains 100 mg of pygeum extract (13% sterols)	TwinLab	Natures hervbs	1/2002	920396	2 years
Fingerprinted pygeum	Hard gelatine capsule	Each capsule contains 500 mg of pygeum powder	Armal EST	G.S.A	12/2001	83634	2 years
Nettle Herb	Hard gelatine capsule	Each capsule contains 435 mg of nettle powder	Twinlab	Natures way	11/2002	911688	2 years
Nettle Leaf	Hard gelatine capsule	Each capsule contains 435 mg of nettle powder	Twin Lab	Natures way	9/2002	67432	2 years
Pumpkin seed oil 1000	Softgel capsule of seed oil	Each capsule contains l g of pumpkin seed oil	Armal EST	G.N.C	05/2002	68593	2 years

RESULTS AND DISCUSSION

A) Analytical results of saw palmetto products:

Five products of SP were investigated and, results were compared with available SP reference as well as reported values. The following were obtained:

i- *Weight variation of saw palmetto products:*

All examined products of saw palmetto were found to show no weight variations according to BP[15].

ii- *Authentication:*

This was carried out microscopically by examining the features of the products in comparison to the reference berries. This showed full identity and freedom from adulterants and foreign matters[19].

iii- *Pharmacopeial standards:*

The pharmacopeial reference of these berries were measured and the results are recorded (tables 2 and 3). Results showed some differences between too high (FP products) values compared with too low (BN products) values; while the other values for the rest of products are in agreement with reported USP and BHP. The differences may be attributed to different plant ecology, storage and preparation.

iv- *Microbiological examination:*

Testing of microbial contamination of 5 saw palmetto products indicated absence of any microorganism.

v- *Relative percentage of fatty acids and sterols in saw palemetto products:*

Saponification of 2 g oil (as petroleum ether extract) afforded free fatty acids and sterols (USM) calculated as β-sitosterol. Results are shown in table 3.

vi- *GLC analysis of fatty acid methyl esters:*

The retention time of fatty acids methyl esters were compared by those standard fatty acids methyl esters determined at the same conditions (table 2).

GLC analysis of the fatty acids methyl esters as a marker of saw palmetto indicated the presence of 11 fatty acids (table 2). Clearly, the relative of fatty acids were widely different from the purchased sample (as reference). The highest value of reference was myristic acid (49.95%) then lauric acid (12.88), while the highest acid content of products was stearic acid (52.35%) followed by lauric acid (42.21%). This is in agreement with previouely reported GLC analysis[87] of fatty acids of SP using two different extraction methods which indicated real difference in % of total fatty acids as shown in table 17; to give 88.7% (from EtOH ext.) and 92.2% (CO_2 extract). Also, there was a difference in the % of individual fatty acid as that the highest acid content was oleic acid (34.84%) using ethanolic extract of the berries while CO_2 extraction afforded 29.96% of the same acid.

Reported values: Extract was purchased from Indena (Milano, Italy)[19].

Relative percentages are mean of 2 injections.

vii- *GLC analysis of the USM for β-sitosterol:*

GLC analysis of β-sitosterol (marker of this plant) indicated that there is a small difference from the reference , but the majority of products are in good agreement with respect to the percentage of β-sitosterol. Interestingly, the percentage in the reference sample was the lowest (26.35%) relative to 41.14, 32.06. 35.83. 39.79 and 38.14%) of products (table 3).

Table (2): Relative% of fatty acid methyl esters in saw palmetto products

Products	Caproic	Caprylic	Capric	Lauric	Myristic	Palmitic	Stearic	Oleic	Linoleic	Lino-lenic	Arachi-dic	Saturated fatty acids	Unsat-urated fatty acids
1)Saw palmetto reference	3.72	3.13	3.04	12.88	49.95	3.93	6.48	6.73	2.38	5.38	2.38	83.13	16.87
2)Saw palmetto FP	-	1.14	3.06	32.09	11.80	9.68	25.24	6.37	5.89	4.73	-	83.01	16.99
3)Saw palmetto extract	-	2.20	4.57	42.21	12.67	8.45	20.04	5.63	4.23	-	-	90 14	9.86
4)Saw palmetto extract	-	0.84	1.28	15.38	5.99	9.84	52.35	6.84	2.35	5.13	-	85.68	14.32
5)Saw palmetto tea	-	-	1.54	28.57	11.74	9.18	21.43	6.63	6.63	4.60	9.69	72.45	27.55
6)Saw palmetto NH	-	1.69	3.44	28.02	11.31	8.85	25.56	7.87	6.88	-	6.38	78.87	21.13
7)Ethanolic extract*	2.15	2.06	1.78	30.20	13.39	9.84	1.48	34.84	3.36	0.90	-	60.90	39.10
8)Co_2 extract*	1.39	2.33	2.74	32.84	12.34	9.13	1.87	29.96	6.42	0.98	-	62.64	37.36

*Reported values; extract was purchased from Indena (Milano, Italy) [19]

*The relative percentages are the mean of 2 injections

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ISSN 1110-5089

Table (3): Results of pharmacopeial parameters in saw Palmetto products

	Total ash	Acid-insoluble ash	H_2O sol.ash	Moisture percentage		Extractive values				Relative % fatty acids	β -sitosterol (relative %)
				Oven	Karl-Fischer	Pet-ether	$CHCl_3$	Ethyl acetate	Ethanol (96%)		
Sp Ref.	4.32	1.85	2.37	6.48	7.17	12.5	3.50	1.50	8.00	45.50	26.35
Sp BN	2.67	0.92	1.57	6.19	6.61	12 00	2.92	3.28	7.57	60.15	41.14
SP FP	5.00	2.10	2.80	6.65	5.86	10.99	3.44	3.79	10.51	17.35	32.06
SP EX	-	-	-	-	5.50	17.49	2.50	1.50	12.21	80.00	35.83
SP tea	3.59	1.65	1.83	10.50	11.03	9.74	3.35	2.31	9.02	47.34	39.79
SP NII	4.22	1.70	2.45	6 93	7.69	16.36	4.13	2.95	13.39	67.04	38.14

B) Analytical results of Pygeum products:

i- *Weight variation of Pygeum products:*

All examined products of pygeum were found to show no weight variations according to BP allowances concerning product weight variations.

ii- *Authentication:*

This was carried out by examining the features of the products in comparison to the reference drug. This showed full identity and absence of adulterants and foreign matters[19].

iii- *Pharmacopeial standards:*

The pharmacopeial standards of Pygeum products were determined and the results are recorded in table 5.

iv- *Microbiological examination:*

Testing of the microbial contamination of the two pygeum products according to B.P protocols[15] indicated complete freedom from any microorganism.

v- *Preparation of fatty acids and USM in Pygeum products:*

Saponification of the petroleum ether extract and extraction of the USM and subsequent extraction of the fatty acids gave the reported values in table 4.

vi- *Relative GLC analysis of fatty acids:*

GLC analysis of the methyl esters of fatty acids as markers of pygeum preparations (table 4) indicated the presence of 6 fatty acids. The percentage of fatty acids are widely different from the purchased sample (as reference). Here, the highest value of reference was linoleic acid (38.88%) then stearic acid (27.78), while the highest acid content of products was oleic acid (50.16%) followed by palmitic acid (47.04%). On the other hand, the previously reported data on fatty acids of pygeum preparations showed that the highest acid content was linoleic acid (30.60%) followed by palmitic acid (28.30%)[19].

This diversity in fatty acid percentage may be due to different sources of same plant storage conditions and time of collection as well as different extraction methods.

vii- *GLC analysis of β-sitosterol:*

GLC analysis of sterols contents (marker of this plant) (table 5) showed that there is a small difference in respect to the percentage of reference β-sitosterol.

Table (4): Relative percentage of fatty acids (methyl esters) in the pygeum products

Fatty Acids	Retention Time	Pygeum reference	Pygeum powder	Pygeum extract	Reported data[20]
Lauric	6.99	1.39	5.89	-	0.38
Myristic	9.08	5.56	3.92	-	0.94
Palmitic	11.16	13.89	47.04	18.06	28.30
Stearic	13.05	27.78	23.52	30.22	10.58
Oleic	13.22	12.50	13.73	50.16	24.90
Linoleic	13.48	38.88	5.89	1.56	30.60

Table (5): Results of pharmacopeial parameters in Pygeum products

	Total ash	Acid-insoluble ash	H_2O sol. .ash	Moisture percentage		Extractive values				% fatty acids	% β-sitosterol
				Oven	Karl-Fischer	Pet-ether	$CHCl_3$	Ethyl acetate	Ethanol (96%)		
Pyeum reference	6.15	1.56	4.51	16.35	16.98	2.00	1.50	1.50	19.5	43.70	45.02
Pygeum powder	5.96	1.28	4.41	16.91	17.14	1.46	1.95	2.00	18.9	50.00	44.54
Pygeum extract	-	-	-	-	16.2	2.15	1.70	2.50	19.8	8.62	46.05

C) Analytical results of Nettle products:

i- ***Weight variation of Nettle products:***

All examined products of Nettle were found to show no weight variations according BP allowances concerning product weight variations.

ii- ***Authentication:***

This was carried out by examining the morphological and microscopical features of the powdered products in comparison to the reference herb. This showed full identity and freedom of adulterants and foreign matters[19].

iii- ***Pharmacopeial standards:***

The pharmacopeial standards of these products were measured and the results are recorded in table 6.

iv- ***Microbiological examination:***

Investigation of the microbial contamination of Nettle products indicated freedom from any microorganism.

v- ***Relative percentages of fatty acids and sterols in Nettle products:***

Saponification of the petroleum ether extract and extraction of the USM and subsequent extraction of the fatty acids gave the reported values in tables 6 and 7.

vi- ***GLC analysis of fatty acids:***

The fatty acids obtained from saponification were methylated and the methyl esters were analyzed by GLC. Thus, GLC analysis of the fatty acids as a marker of nettle preparations (table 6) indicated the presence of 5 fatty acids. The percentage of fatty acids are widely different from the purchased sample (as reference). The highest value of reference was palmitic acid (57.69%) then arachidic acid (23.08), while the highest acid content of products was linoleic acid (55.68%) followed by oleic acid (31.48%).

These diversity in fatty acid percentages may be due to different plant sources, storage conditions and time of collection as well as different extraction methods (table 6).

vii- ***GLC analysis of β-sitosterol:***

GLC analysis of the USM showed that there is a difference in respect to the percentage of β-sitosterol (table 7).

Table (6): Relative percentages of fatty acids in Nettle products

Fatty acids	Retention Time	Nettle reference	Nettle herb	Nettle leaf
Capric	4.99	1.92	-	5.56
Lauric	11.16	37.69	3.41	-
Oleic	13.22	3.85	27.27	31.48
Linoleic	13.48	13.46	55.68	40.73
Arachidic	14.55	23.08	13.64	22.23

Table (7): Results of pharmacopeial parameters in Nettle products

Products	Total ash	Acid-insoluble ash	Water-soluble ash	Moisture percentage		Extractive values				% fatty acids	% β-sitosterol
				Oven	Karl-Fischer	Pet-ether	$CHCl_3$	Ethyl acetate	Ethanol (96%)		
Nettle Reference	15.57	4.85	10.67	8.33	9.12	2.00	2.00	1.00	7.00	45.00	43.53
Nettle Herb	13.50	3.91	8.82	7.67	8.11	2.15	6.82	4.64	11.20	50.00	41.13
Nettle Leaf	19.89	4.76	15.05	9.59	10.32	3.71	9.79	5.39	18.40	40.00	47.49

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ISSN 1110-5089

D) Analytical results of Pumpkin products:

The available products of this plant marketed in KSA are only one (seed oil) produced by GNC co.

i- ***Weight variation of Pumpkin products:***

Examined product of pumpkin was found to show no weight variations according to BP allowances concerning product weight variations.

ii- ***Authentication:***

This was carried out by examining the features of the products in comparison to the reference seed. This showed the following results:

Table (8): Results of some parameters for pumpkin oil products

Value	Pumpkin reference	Pumpkin seed oil
Refractive index	1.467	1.476
Specific gravity	1.127	1.069
Optical rotation	(+)25	+27
Acid value	1.6	1.7
Iodine value	119	120
Saponification value	186	188

iii- ***Microbiological examination:***

Investigation of the microbial contamination of pumpkin products indicated freedom from any microorganism.

iv- ***Relative percentages of fatty acids and sterols in Pumpkin products:***

Saponification of 3 g of oil as petroleum ether extract afforded free fatty acids and sterols (table 9).

v- ***GLC analysis of sterol:***

GLC analysis of sterols (marker of this plant) showed that there is an interesting difference, where the product sitosterol is higher than the reference sample (table 9 and 10).

vi- ***GLC analysis of fatty acids:***

GLC analysis of the fatty acids as a marker of pumpkin seed oil (tables 9 and 10) indicated the presence of 5 fatty acids. The percentage of fatty acids are widely different from the purchased sample (as reference). The highest value of reference was stearic (30.77%) then arachidic acid (23.08%), while the highest acid content of products was oleic acid (52.82%) followed by stearic acid (25.92%). Under different conditions, the previously reported data on fatty acid showed that the highest acid content was linoleic acid (44.13%) followed by oleic acid (35.63%) and fatty acid percentage may be due to different plant sources, storage conditions and time of collection as well as different extraction methods.

Table (9): Results of pharmacopeial parameters in Pumpkin products

Products	Moisture percentage		Extractive values				% fatty acids	% USM	% β - sitosterol
	Oven	Karl-Fischer	Pet-ether	$CHCl_3$	Ethyl acetate	Ethanol (96%)			
pumpkin reference	-	9.7	80.00	7.00	0.63	0.15	65.45	30.25	40.27
pumpkin seed oil		9.5	75.00	6.50	0.75	0.27	68.75	28.13	47.96

Table (10): Relative percentages of fatty acids in the pumpkin products

Fatty Acids	Retention time	Pumpkin reference	Pumpkin seed oil	Reported date [19]
Palmitic	11.16	6.59	14.95	20.24
Stearic	13.05	30.77	25.92	-
Oleic	13.22	30.77	52.82	35.63
Linoleic	13.48	8.79	6.31	44.13
Arachidic	14.55	23.08	-	-

CONCLUSION

Herbs and herbal products are a vital source of therapy for many diseases. Yet, it requires intensive and collaborative analytical efforts to setup specific protocols and methods for standardization of markers and overall evaluation.

The investigation and analysis of products from Saudi market for the treatment of BPH showed that some of these products are in agreement with the B.P and USP; while some other products have shown disagreements in few pharmacopeial parameters . These results are logic enough, because the active constituents are well known to be very stable type of compounds (steroids and fatty acids). Thus, this study addresses the importance of evaluating various herbal medicines available in the Saudi market for the sake of patients.

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Received: July 26, 2007
Accepted: August 28, 2007

الرقابه النوعيه على عشرة مستحضرات صيدلية متداولة فى المملكة العربية السعودية وتستخدم فى علاج تضخم البروستاتا الحميد

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استخدمت الأعشاب الطبية منذ وجود الإنسان على الأرض فى علاج كثير من الإمراض ، وكان الصينيون و المصريون و الهنود قد استخدموا الإعشاب الطبية منذ فجر التاريخ.

والآن هناك ادلة علمية موثقة على فائدة الادوية العشبية ، وعزوف كثير من المرضى عن الأدوية المشيدة كيميائيا فى علاج الأمراض المزمنة لكثرة الأعراض الجانبية وكذلك ثمنها المرتفع، وفى هذا الشأن تستوى الدول الغنية والفقيرة. فقد وجد أن ما يقارب 60 مليون أمريكى أنفقوا 3,24 بليون دولار فى شراء مستحضرات عشبية للعلاج. وفى أوروبا،حاليا 30-40%من الأدوية الموجودة تحتوى على مادة فعالة واحدة أو أكثر مشتقة من اصل نباتى .

ولما كان مرض تضخم البروستاتا مرضا غير خبيث ويصيب عادة الرجال بعد سن 40-60 عاما ويكون مصحوبا بأعراض انسداد القناة البولية نتيجة تضخم البروستاتا . هذا المرض إذا لم يعالج فى حينه فانه قد يؤدى إلى التهابات مثانية متكررة واختلال وظيفة الكلية.

والأعشاب المستخدمة فى العلاج عموما حسب البحوث المرجعية هى: الباليتو المنشارى، البرونس الافريقى، القراص (بودرة العفريت) ، القرع ، حشيش جنوب أفريقيا ، شواشى الذرة ، الايكيناسيا.

لهذا كان تحليل وتقويم بعض المنتجات العشبية الموجودة فى السوق السعودى والمستخدمة فى علاج تضخم البرستاتا الحميدة لدراسة جودة المنتجات العشبية ملحا.

فى هذه الدراسة تم اختيار 10 مستحضرات صيدلانية من السوق السعودى مستخدمة فى علاج تضخم البروستاتا الحميد وكذلك تم اختيار أربعة نباتات مرجعية (من الولايات المتحدة الأمريكية) وذلك بتحليلها. وفى هذه الدراسة تم تحديد الثوابت الدستورية و تحديد نسب المواد الفعالة الرئيسية(المحتوى الدهنى) وتم جمع 10 مستحضرات صيدلية عشبية من السوق السعودى *و اجراء التجارب الآتية عليها:* الوصف المظهرى للأعشاب داخل هذة المستحضرات - اختيار أوزان المواد داخل الكبسولات-الوصف المجهرى للمستحضرات- تعيين قيم الرماد المتبقى- تعيين نسبة الرطوبة فى هذه المستحضرات- تحديد قيمة المستخلصات من الاثير البترولى ،الكلوروفورم،خلات الاثيل، الايثانول(96%)- الفحص الميكروبيولوجى للمستحضرات- تحليل المحتويات الكيميائية بواسطة كروماتوغرافيا الطبقة الرقيقة ومقارنتها بمواد قياسية- تحليل الأحماض الدهنية بواسطة كروماتوغرافيا الغاز السائل- تحليل الستيرولات(بيتاسايتوستيرول)باستخدام كروماتوغرافيا الغاز السائل.

بعد التحاليل كانت معظم النتائج فى هذه الدراسة لجميع المستحضرات مطابقة لمعايير الدستورين البريطانى والأمريكى.