

# Undeclared Chemicals in Slimming Herbal Medicines, Dietary Supplements and their Associated Risks

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## Abstract

According to WHO projections, there will be over 2.3 billion overweight adults and 700 million obese by 2019, a survey of around 150 herbal weight loss drugs and dietary supplements in UAE with special reference to Abu Dhabi market, as well as from samples received from DOH, and other government organizations, VIP's and various other sources revealed the presence of adulteration in more than one fifth herbal medicinal products. These findings of Zayed Herbal Research laboratory will help consumers, health care practitioners, and the general public understands ZCHRTM's action regarding weight loss products contaminated with various prescription drugs and chemicals.

FDA has identified an emerging trend where over-the-counter products, frequently represented as dietary supplements, contain hidden active ingredients that could be harmful. Consumers may unknowingly take products laced with varying quantities of approved prescription drug ingredients, controlled substances, and untested and unstudied pharmaceutically active ingredients. These deceptive products can harm. Hidden ingredients are increasingly becoming a problem in products promoted for weight loss [1].

There is a growing trend where herbal medicines, dietary supplements and conventional foods are adulterated with hidden drugs and chemicals. These products are typically promoted for weight loss, sexual enhancement, and bodybuilding and are often represented as being "Natural." Consumers should exercise caution before purchasing any product in the above categories.

We have identified an emerging trend where over-the-counter weight loss herbal products, frequently represented as dietary supplements, contain hidden active ingredients that could be harmful. Consumers may unknowingly take products laced with varying quantities of approved prescription drug ingredients, controlled substances, and untested and unstudied pharmaceutically active ingredients.

In continuation of our earlier studies [2,3], the main objective of the present study is to check pharmaceutical medicine adulteration of nonprescription and even prescription slimming medicines in the laboratory using chromatographic and spectrometric techniques and to discuss its side effects in the best interest of consumers and public health safety (Chart -1). This paper also gives an overview of health-related risks after consuming such spurious products and challenges for future perspectives to control such type of malpractices.

## Introduction

Traditional herbal medicines are gaining popularity worldwide as an alternative approach to prescription drugs for many reasons including a general perception that they are safe. Recently there have been number of reported studies that reveal adulteration of herbal

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medicines with undeclared synthetic drugs, which may potentially cause serious toxic adverse effects. This paper reviews the various classes of synthetic drugs that were found to be adulterated in herbal slimming medicines. The focus is to highlight newer analytical tools used to detect adulteration. Due to the advanced chromatographic and spectrometric techniques and other conventional tools, it has become possible to detect synthetic drugs and their analogues as adulterants even if they are present in small quantities.

The Food and Drug Administration (FDA) is advising consumers to stop using multiple weight-loss products that contain the undeclared drug ingredients e.g. sibutramine, which was removed from the market in 2010 for safety Reasons and may present significant risks for those with coronary artery disease and other heart issues increasing global interest in herbal medicines creates a serious need for truly objective data, on not only their efficacy, but also their side effects and interactions. In the interests of public health safety and looking into severity of this epidemic, an emphasis for the regular laboratory checking of herbal medicines for their safety & quality is a need of the day. Since intentional adulteration of "natural herbal medicines" with unknown synthetic drugs or chemicals is a common and dangerous phenomenon of alternative medicine, it is important to modify and validate analytical tools to monitor and evaluate these herbal drugs.

## Method

### Chemicals

Alverine (A) Fluoxetine (B) Tripropyl amine (C) Sibutramine hydrochloride (D) Atenolol (E) Duocolax (F) Hydroxyzine (G) were received from the Sigma Aldrich and other recognized agencies. HPLC grade methanol was obtained from Merck, USA. High purity water was prepared by a Waters Milli Q plus purification system.

## Equipment

Gas Chromatography-Mass Spectrometer QP-2010 (GC-MS) analysis for all samples and standards were performed.

## Sample preparation

Approx. 1.0 mg of sample was weighed and mixed with 5.0 mL of methanol. The samples were ultra-sonicated for 30.0 minutes and filtered using a 0.45 µm membrane. The volume of the filtered supernatant was completed to 10.0 mL with methanol.

## Gas Chromatographic - Mass Spectrometric (GC-MS) Studies

Different mobile phases were used to develop the thin layer chromatograms using petrol/acetone, methanol extracts. Compounds are identified in the sample taken in above solvents and on comparison with reference standards on Chromatographic studies and Mass spectrometric analysis:

## Results and Discussion

Research analyses on 5 Herbal Medicinal Products (HMPs) purchased from Thailand, it has been found that the undeclared active pharmaceutical ingredients are present in all five of these products and a couple of them contained more than one including either sibutramine (a controlled substance), alverine (adruq for functional gastrointestinal disorders), tripropyl amine (a laboratory chemical not advised for food, drug), atenolol (used with or without other medications to treat high blood pressure (hypertension).), Docolax (a stimulant laxative drug), besides other ingredients. The tainted products are listed here (1-5 Unknown capsules/tablets), along with the undeclared drugs and/or chemical ingredients along with their side effects, analyzed using chromatographic & mass spectrometric technique. Final recommendation is given in each case for not using these medicines for public health safety.

Starting with five (5) unknown herbal medicines, purchased from Thailand for weight reduction. These unknown medicines were subjected to chromatographic and spectrometric analysis (GC-MS) to find out their ingredients and chemical compounds.



Figure a: Photographs of five (5) Herbal medicines, purchased from Thailand.

Unknown white blue capsules:

The white Blue Capsules purchased for weight reduction contains:

- Alverine
- Fluoxetine
- Tripropylamine
- Ethylphthalate
- Propenyl propylether
- Pyridine-2, 6-dioldiacetate
- 2-Tertiarybutyl-3-methyl-2-cyclopentendione
- Valeraldehyde 2-methylene, isopropyl hydrazine
- Androsta-2, 4-dien-3-ol, heptafluorobutanoat

Fluoxetine: (An anti-depressant medicine) present in a major concentration,

Alverine: (A drug for functional gastrointestinal disorders),

Tripropyl amine: (A laboratory chemical not advised for food, drug, pesticide or biocidal product use (The 2012 OSHAD Hazard Communication Standard considers this chemical hazardous).

Based on above lab. studies 'Unknown white Blue Capsules' are not at all safe to use.

### Unknown white tablet:

The following compounds are identified in the powder content of 'Unknown white Tablets on Chromatographic studies and Mass spectrometric analysis:

- Preg-5-en-20-3, 16-bis[(TMS)oxy]-o-methyloxime
- Triacontane
- Nonanoic acid
- Atenolol (Very very high concentration)

Atenolol is present in a very very high concentration in the tested white tablets for weight reduction. Due to the presence of Atenolol (Tenormin) in a very high concentration, the 'Unknown white Tablets' does not at all safe to use.

### Unknown white and green capsules:

The following compounds are identified in the powder content of 'Unknown white Green Capsules' on Chromatographic studies and Mass spectrometric analysis:

- Triacontane
- Nonanoic acid
- Sibutramine HCl
- Ceanothamine A /Frangulanine
- Tripropyl amine/1-PropanamineN-N-dipropyl (Very high concentration)
- Phthiodiolone-A
- Alpha L-Galactopyranoside, methyl6-deoxy

Due to the presence of Sibutramine HCl and Tripropyl amine the 'Unknown white and green Capsules' does not at all safe to use.

### Unknown pink and blue capsules

The following compounds are identified in the powder content of

‘Unknown pink Blue Capsules ‘on comparison with reference standards on Chromatographic studies and Mass spectrometric analysis:

- Caprylic ether
- Ducolax (Bisacodyl)
- 2-Bromooctane
- Bis (2-ethyl hexyl) fumarate
- 2-Butyl isopentylidene amine
- Acrylic acid, 2-ethyl hexylester
- Bis (2-amino,5-pyridyl phenyl methane)
- 2-(alpha-(4-hydroxy phenyl)-4-hydroxy benzyl)pyridine
- Benzothiazole,2-(4-butyl-3,5-dimethyl-1Hpyrazol-1-yl)-6-chloro

The Unknown pink and blue capsules contain Ducolax (Bisacodyl), a stimulant laxative drug in a high concentration besides other unsafe compounds.

Looking into above studies ‘Unknown Pink and Blue capsules’ does not seem safe to use.

### Unknown blue tablets

The following compounds are identified in the powder content of ‘Unknown blue tablets ‘on Chromatographic studies and Mass spectrometric analysis:

- Oleic acid
- Hydroxyzine
- Trimethyl silyl derivative of 1-monolinolein
- 9,12-Octadecadienoic acid
- Triacontanoic acid, methylester
- n-pentadecanoic acid
- Hydroxyzine (Atarox; Vistaril, Fenorol)

The Unknown Blue Tablets contain an undeclared compound Hydroxyzine (Atarox; Vistaril, Fenorol) in a major concentration Based on above studies ‘Unknown blue Tablet ‘seems not safe to use.

Besides the above-unknown medicines, quite a large number of herbal medicines have been tested in laboratory and were found adulterated with pharmaceutical medicines (Chart-1).

Some of the above herbal medicines from the above-mentioned chart are described here:

### Miaomiao slimming capsules:

Manufacturer : Hong Kong Tian Lun pharmacytech.co.Ltd.  
 Description : Light green/dark green colored capsules having light brown powder.

The following compounds were identified in the content of the capsule taken in above solvents and on comparison with reference standards on TLC studies and GCMS analysis:

2-Aminopropanol	Propylene diamine
Sibutramine HCl	Isoamyl acetate
Momeinositol	1,3-Propane diamineN-(2-aminoethyl)
L-Alanine ethylester	2,3-Dimethylhexahydro-6H-pyrazolo-[1,2,a][1,2,4,5] tetraazine

Discussion : Since Miaomiao Slimming Capsules contain Sibutramine Hydrochloride as an undeclared ingredient which is a banned chemical medicine.

S.No	Herbal Medicine	Laboratory Test Results- Undeclared drugs and/or chemical ingredients (other than herbal ingredients)
1	Fashion Slimming Coffee	Sibutramine Hydrochloride
2	Majestic Slimming Capsules	Sibutramine Hydrochloride
3	Slimming Bomb	Sibutramine hydrochloride & Phenolphthalein
4	Hoodia gordonii capsules	Sibutramine hydrochloride
5	Slim Body Capsules	Sibutramine hydrochloride
6	AlMalaka Capsules	Sibutramine hydrochloride
7	Blue Tablets	Hydroxyzine (Atarox)
8	Pink Blue Capsules	Duolax (Bisacodyl)
9	White green capsules	Sibutramine hydrochloride & Tripropyl Amine
10	White tablets	Atenolol
11	White blue capsules	Fluoxetine, Alverine & Tripropyl Amine
12	Novac capsules	Raspberry ketone
14	Smart Diet	Chromium picotenate
15	Acai Power Dietary Supplement	
16	Makkah Shape Dietary Supplement	Chromium picotenate
17	Hoodia Gordonii Gold Capsules	Phenolphthalein Sibutramine hydrochloride
18	Green Cofee Bean Extract	
19	Miaomiao Slimming Capsule	Sibutramine Hydrochloride
20	Unknown Weight Gain Herbal Product	Cyproheptadiene (Periactin)
21	Natural Max Slimming Capsules	Fluoxetine & Phenolphthalein Sibutramine hydrochloride
22	Super Power Fating 007	Cyproheptadiene
23	Diet Capsules1-Day	Phenolphthalein Sibutramine hydrochloride
24	Magrim Capsule	Sibutramine hydrochloride
25	Natural Unknown Sample for increasing weight	Cyproheptadiene
26	Super Slim Capsule	Phenolphthalein Sibutramine hydrochloride
27	Fat Burner Tablets	Sibutramine Hydrochloride
28	Unknown Weight Gain Herbal Product	Cyproheptadiene
29	Mega T Green Tea Caplets (Fat Burner Supplement)	Pyrogallol & Caffeine (V.H.Conc.)
30	Sabr Plus Capsules	Phenolphthalein Sibutramine hydrochloride
31	Quick Acting Slimming Capsule Zein	Sibutramine hydrochloride Phenolphthalein
32	Seven Slim Capsules	Sibutramine hydrochloride
33	Phyto Shape	Sibutramine hydrochloride
34	Slimming Capsules	Sibutramine hydrochloride Phenolphthalein
35	Super Slim	Sibutramine hydrochloride Phenolphthalein
36	AB Slim	Sibutramine hydrochloride
37	Fat Burning Capsules	Sibutramine hydrochloride Phenolphthalein

Chart 1: Intentional adulteration found in Slimming Herbal Medicines.

It is, therefore, recommended that this product should be taken off from the market.

### Hoodia gordonii gold capsules:

Batch Number : CF9550TE671  
 Description : Pink /Red capsules

Chromatographic Studies: Different mobile phases were used to develop the thin layer chromatograms using petrol /acetone, methanol extracts. The following plants & compounds are identified in the

'Hoodia Gordonii Gold Capsules' taken in above solvents and on comprison with reference standards on TLC studies and GCMS analysis.

- Caffeine                    Cyclo octacoasane
- Phenolphthalein        Sibutramine Hydrochloride
- DisalylAldehyde        Cyclo hexane(1-hexa decyl heptadecyl)
- Glyceryl triaureate     Cis-2,3-dihydroxy diphenyl methyl bicycle [2.2.1] hepta-5-ene
- Transcrotlylcohol      p-Phenyl azobenzoicacid

Discussion : Phenolphthalein and Sibutramine hydrochloride are found as an undeclared and banned compounds.

Recommendation : On the basis of above two undeclared and banned chemicals 'Hoodia Gordonii Gold Capsules' is not at all safe to use.

**Nature max slimming capsule**

Chemical compounds: Isopentyl acetate; Trans-2-Dodecan-1-ol; Momeinositol; Benzoic acid; Sibutramine HCl; Phenolphthalein; 4-Octen-3-one ; 4,7,9-Decatrien-2-amineN-butyl (Bottle2) X anthosine; Cytosine riboside; Sibutramine HCl; Phenolphthalein; Fluoxetine; Farnesol; Caffeine ; Alpha, alpha, alpha-Trifluoro- p-cresol

**Super power fattig 007**

Chemical compounds isolated: Honey; Oleic acid; Behenic acid; Cypproheptadine; DL-Arabinose; 4-Methyl-1, 3-dioxane; 3-Acetoxy dodecane; Sugar; Hexanoic acid, 3-OH-methyl ester; Zingiberene; Levo Alpha Cedrene; Cuparene; Caryophyllene oxide; Alpha Bisabolol; Tumerone; Alpha Atlantone; 4-Ethylguaicol; Elaidic acid, methyl ester; Beta Himachalene; Longifolene-(V4) Alpha & beta -D-glucopyranose; Hydroxymethylfurfural 3- Deoxy-d-mannoic acid.

**Mega T green tea caplets:**

- Product Type : Fat Burner Supplement
- Manufacturer : USA
- Lot Number : #0176-03-1
- Description : Orange colour capsule with yellow powder

The following plants & compounds are identified in the 'Mega T Green Tea Caplets':

- Caffeine (Very high Conc.)
- Pyrogallol (High Conc.)
- Quinic acid
- Capric acid
- Myristic acid
- Propylene glycol
- Nitrosomethane
- 3-Methoxy pyrocatechin
- Pentadecanoic acid
- Propyl hexacosanoate
- Octamethyl cyclotetrasiloxane

Discussion : It won't contain sibutramine or phenolphthalein but Mega T Green Tea contains high level of Caffeine, which may cause anxiety and insomnia. Pyrogallolis also present in high concentration and does not seems from a plant origin. The expiry date of the dietary supplement is 3/14, hence expired 4 years before.

Recommendation: Based on above facts 'Mega T Green Tea Caplets' is not advisable to use.



Figure b: Novac Capsules

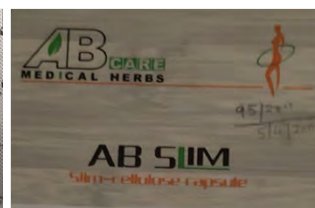


Figure c: AB Slim Capsules



Figure d: Super Slim Capsules



Figure e: Maca Capsules



Figure f: Acai Capsules



Figure g: Smart Diet Capsules

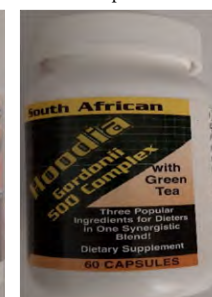


Figure h: Hoodia Gordonii Capsul



Figure i: Seven Slim Capsules



Figure j: Seven Slim Capsules



Figure k: Miaomiao Slimming Capsules



Figure l: Phyto Shape Capsules



Figure m: Zein Slimming Capsules



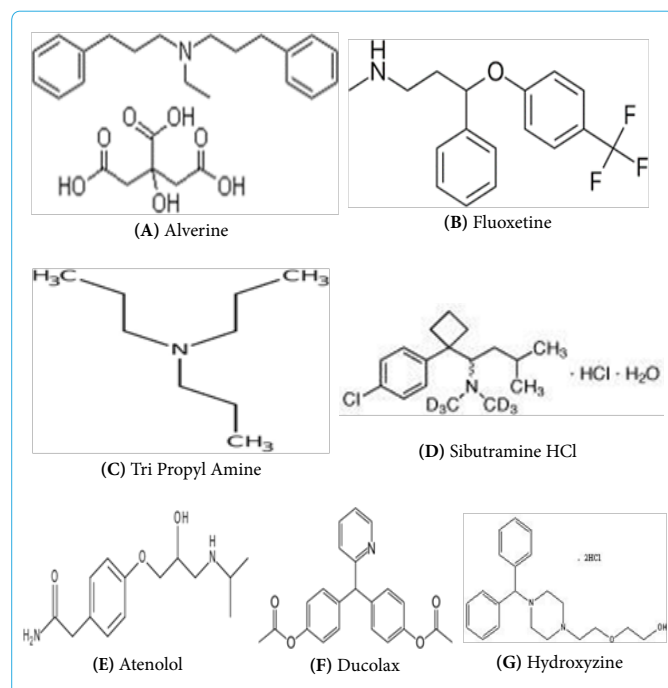
Figure n: Slimming Capsule



Figure o: Fat Burning Capsules

## Photographs of some adulterated Herbal Medicines

### Structures of the Detected Compounds (Adulterated)



### Associated Risk And Side Effects Of These Adulterated Pharmaceuticals

#### Sibutramine and associated risk:

Sibutramine is in a class of medications called appetite suppressants and is used to help people lose weight. It is a controlled substance and the active pharmaceutical ingredient in Meridia / Reductil, previously an approved prescription drug to treat obesity.

Populations who would be at increased risk of serious adverse health effects from consuming a standard dose of sibutramine include:

Patients with a history of hypertension, coronary artery disease, congestive heart failure, arrhythmias, or stroke, narrow angle glaucoma, history of seizure, predisposed to bleeding events and those taking concomitant medications known to affect hemostasis or platelet function, severe hepatic dysfunction. and those concurrently taking the following medications: Sumatriptan, Dihydroergotamine, Dextromethorphan, Meperidine, Pentazocine, Fentanyl, Lithium, Tryptophan, MAO inhibitors.

Looking into its risk many countries have banned Sibutramine HCl. In Jan'2010 Health Authority Abu Dhabi, decided to suspend Sibutramine from Abu Dhabi Market. The UAE Health Ministry asked hospitals and pharmacies to recall all products containing the substance sibutramine in accordance with the recommendations of the US Drug and Food Administration and European Association for Medicine. Clinical trials have found that the substance may cause heart attacks and cardiac arrests.

#### Phenolphthalein and associated risk:

Phenolphthalein was an ingredient in some Over-the-Counter laxative products until 1999 when the FDA reclassified the drug as "not generally recognized as safe and effective" after studies indicated that phenolphthalein presented a potential carcinogenic risk. Phenolphthalein has also been found to be genotoxic in that it can damage or cause mutations to DNA.

#### Hydroxyzine (Atarox; Vistaril, Fenorol):

**SIDE EFFECTS:** Hydroxyzine reduces activity in the central nervous system. A new study shows that the antihistamine hydroxyzine is an effective treatment for restoring normal sleep patterns when liver damage causes chemical pathways in the brain to be disrupted. "In patients with cirrhosis of the liver, histamine levels in the brain can be altered," says study author Dr. Laurent Spahr. Hydroxyzine should be used with caution (if at all) in persons with narrow-angle glaucoma, prostatic hypertrophy (enlarged prostate gland), hyperthyroidism, cardiovascular disease, hypertension, and asthma.

#### Drugs or supplements interact with hydroxyzine:

- diazepam (Valium),
- lorazepam (Ativan),
- clonazepam (Klonopin), and
- alprazolam (Xanax).

#### Tripropyl amine and associated risks:

Tripropyl amine, which is a laboratory chemical, not advised for food and drug. It is toxic if swallowed; toxic in contact with skin; causes severe skin burns and eye damage; moreover, may cause respiratory irritation.

#### Atenolol and associated risks:

Atenolol is available under the brand name Tenormin. Atenolol is used with or without other medications to treat high blood pressure (hypertension). Lowering high blood pressure helps prevent strokes, heart attacks, and kidney problems. This medication is also used to treat chest pain (angina) and to improve survival after a heart attack. Atenolol belongs to a class of drugs known as beta-blockers. It works by blocking the action of certain natural chemicals in your body, such as epinephrine, on the heart and blood vessels. This effect lowers the heart rate, blood pressure, and strain on the heart. Atenolol may also be used to treat irregular heartbeat, heart failure, alcohol withdrawal symptoms, and to prevent migraine headaches.

#### Side effects of atenolol include:

Low blood pressure (hypotension); Slow heart rate; Cold extremities; Dizziness upon standing; Depression; Nausea; Fatigue; Leg pain; Lethargy; Lightheadedness; Spinning sensation (vertigo); Shortness of breath; 2°/3° atrioventricular (AV) block. Other side effects of atenolol include severe congestive heart failure (CHF); Sick sinus syndrome; Catatonia.

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