

White Paper

### **Herbal Male Enhancement Products**

Samples Analysed Contained Hidden Synthetic Ingredients





### lgcgroup.com

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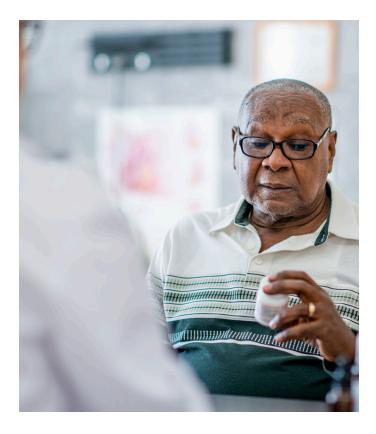
## Introduction

Do you really know what's in your supplements? Does a product labeled as 'herbal' truly mean all natural? No matter your goal with supplementation, it's crucial all supplement users are aware of the ingredients their products contain.

No matter your goal with supplementation, it's crucial all supplement users are aware of the ingredients their products contain. The U.S. Food and Drug Administration (FDA) has identified an emerging trend of non-prescription dietary supplements containing undisclosed active ingredients that could be harmful<sup>1</sup> when ingested. Although the supplement industry brings in nearly \$32 billion a year, the FDA doesn't require manufacturers to reveal their ingredients unless there is a complaint and investigation.<sup>2</sup>

Consumers may, therefore, unknowingly take products that are laced with potentially untested and unstudied prescription drugs and controlled substances. These "hidden" ingredients are increasingly becoming a problem in products that are promoted for sexual enhancement.<sup>3</sup>

In a 2011 study, the National Institute for Public Health in the Netherlands found illicit products, which were used to treat erectile dysfunction and marketed to improve libido and sexual performance, being illegally produced or distributed without the necessary licenses or prescriptions.<sup>4</sup> In this extensive survey, it was identified that these products contained the parent drugs such as sildenafil, tadalafil or vardenafil, as well as the similar drug compounds.<sup>5</sup> More recently, the FDA regularly finds hidden drug ingredients within male enhancement products. The ingredients, whether inadvertently added or not, pose health risks to those who ingest them.<sup>6</sup>



In this study conducted by LGC, products were obtained from the internet that claim to improve or enhance sexual performance with "all-natural" ingredients. The products were then analysed for the presence of the following synthetic pharmaceutical compounds and their analogs (structurally similar compounds):

- Sildenafil: an active ingredient in Viagra
- Tadalafil: an active ingredient in Cialis
- Vardenafil: an active ingredient in Levitra
- Avanafil: an active ingredient in Stendra
- Benzamidenafil

The purpose of this study is to educate consumers on the actual content of "natural" male enhancement products. Also, this study evaluates the risks of product contamination and inadvertent consumption in order to further shape the compound list utilised in supplements screening.



# Experiment

The majority of the commercially available samples were purchased online, except for four products that were purchased in-store. A total of 20 products were purchased, all of which claimed to contain ingredients that were from natural, herbal origin. The tested samples included capsules, tablets, liquid and softgel forms. The compounds in the samples were analysed by liquid chromatography coupled to high-resolution accurate mass spectrometry (HRAM LC-MS).

### Results

The products purchased all claimed to be comprised of entirely plant-based ingredients. The herbal nature of each product was revealed by compounds that are naturally present in plants. The compounds found in the samples are listed in Table 1.

| Table 1: Identified compounds in the herbal "male-enhancement" products that have been confirmed using various HRAM LC-MS experiments. |                                    |
|--|------------------------------------|
| Sample   | Identified Compounds               |
| 1  |                                    |
| 2  | caffeine; yohimbine, DHEA          |
| 3  | icariin; abietic acid              |
| 4  | ginsenoside Rb2, Rd, Rg1, Rg2, Rg3 |
| 5  |                                    |
| 6  | yohimbine                          |

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## Results

Table 1 (cont): Identified compounds in the herbal "male-enhancement" products that have been confirmed using various HRAM LC-MS experiments.

| Sample | Identified Compounds  |
|--------|---|
| 7      | yohimbine   |
| 8      |   |
| 9      | sildenafil; tadalafil   |
| 10     | sildenafil; tadalafil   |
| 11     | various flavones including dimethylflavone, trimethylflavone, tetramethylflavone and qercetin pentamethyl ether |
| 12     | sildenafil; tadalafil   |
| 13     | baohuoside I, caffeine, yohimbine, sinapine, icartin, icariin   |
| 14     | sucralose   |
| 15     | capsaicin   |
| 16     | caffeine  |
| 17     | capsaicin; piperine   |
| 18     | capsaicin; piperine   |
| 19     | baohuoside I, icaritin, icariin, epimedin A,B and C   |
| 20     | ginsenoside F1  |

## Results

Four of the samples tested contained **yohimbine**, originating from yohimbe extract as a listed ingredient. Due to possible health effects, yohimbe supplements are banned in Australia, Canada and the United Kingdom. Side effects include:

- Gastrointestinal distress
- Increased heart rate
- Anxiety
- High blood pressure<sup>7</sup>

#### Dehydroepiandrosterone (DHEA) is

banned for sport by the World Anti-Doping Agency. One of the samples tested contained this compound as a listed ingredient. All elite athletes and drug tested personnel utilising supplements should ensure that DHEA is not an ingredient and that their supplements have been tested and certified by a thirdparty programme. The side effects of DHEA include:

- Diarrhea
- Eye problems
- Fatigue
- Headache
- Low blood pressure
- Night sweats<sup>8</sup>

Although it was claimed that all products were made from herbal ingredients, three of the samples contained, **sildenafil** and **tadalafil**. Unknowingly ingesting these compounds can generate numerous unwanted side effects. However, when combined with certain medications, the effects can prove more dangerous. It is recommended to either not ingest sildenafil and tadalafil or closely monitor dosages if a supplement user has a history of:

- Cardiovascular disease
- Liver disease
- Lung disease
- Kidney failure
- Seizures
- Retinitis pigmentosa (also known as rod cone dystrophy)<sup>9,10</sup>

Also, the consumption of alcohol should be limited when using products containing sildenafil as it can lead to dizziness, lightheadedness, fainting, flushing, headache, and heart palpitations.<sup>11</sup>

Other non-herbal compounds were also detected in the samples. Sucralose, an artificial sweetener (brand name Splenda) was detected in sample 14. It was listed as an ingredient.

# What is Sildenafil?

Sildenafil is used to treat erectile dysfunction in men and is also used to treat pulmonary hypertension in both men and women. It's important to consult a doctor prior to taking sildenafil. There are various amount of side effects that may occur, including:

- Dizziness
- Indigestion
- Tenderness in the stomach area
- Burning feeling in the chest or stomach
- Anxiety

- Difficulty in concentrating
- Painful, swollen joints
- Restless sleep<sup>12</sup>

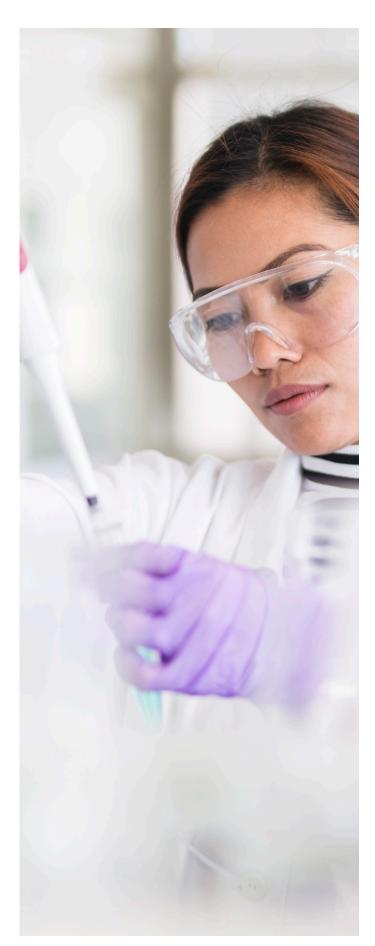
### What is Tadalafil?

Tadalafil is used to treat men with erectile dysfunction and pulmonary hypertension in both men and women. It's is used treat men who have signs and symptoms of benign prostatic hyperplasia (BPH) as well. Before taking a supplement containing tadalafil, a consultation with a doctor is necessary. A few side effects associated with tadalafil include:

- Blurred vision
- Chest pain or discomfort
- Hearing loss
- Nausea

- Unusual tiredness or weakness
- Pain or discomfort in the arms, jaw, back, or neck<sup>13</sup>

### Summary



The FDA states on its website: "[...] FDA cannot test all products on the market that contain potentially harmful hidden ingredients. Enforcement actions and consumer advisories for tainted products only cover a small fraction of the tainted over-the-counter products on the market."

Three of the four natural, herbal products that were purchased from an online retailer and readily available in the U.S. contained synthetic "maleenhancement" compounds. These findings underline the risks of buying not only male enhancement products, but any supplement online that claims to be of herbal, natural origin. The synthetic compounds found in these products could potentially pose a health risk to consumers and stresses the need for supplements to be tested and certified by a reputable, third-party programme.

Even though a product may be comprised of plant-based ingredients, it doesn't necessarily mean all ingredients are safe for use. Products can be contaminated by ingredients, during the production process and within the supply chain.

Based on the findings of this study, it's essential that all supplement users research ingredients in all of their supplement products prior to ingesting them.

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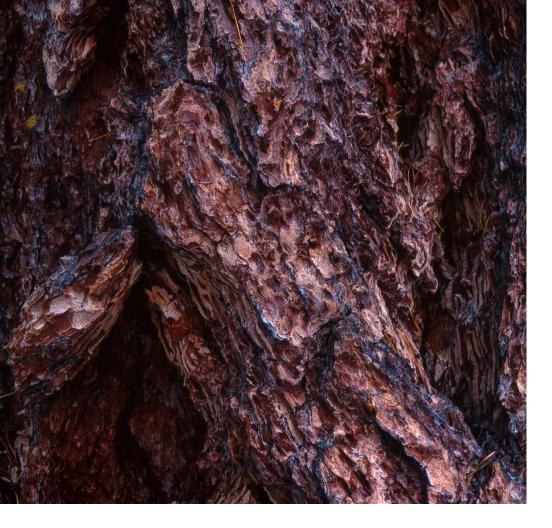
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