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IDENTIFICATION OF UNDECLARED SYNTHETIC DRUGS IN DIETARY HERBAL FORMULATIONS COMMERCIALIZED IN BRAZIL

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INTRODUCTION

In 2016, 1.9 billion adults were overweight and approximately 650 million were obese in the world[1]. Overweight and obesity are defined as abnormal or excessive fat accumulation that presents a risk to health. In 2016, about 18.9% of Brazilians were obese[2]. There is an increasing demand for slimming phytotherapeutic formulations in Brazil, regardless of registration. Though counterfeit anorectic preparations are declared to contain only medicinal herbs or extracts, their efficacy is, in fact, based on the presence of undeclared synthetic drugs, such as anorexigenic substances, resulting in a major risk to the health of consumers[3]. Phytotherapeutic medicines can only be manufactured by pharmaceutical establishments previously authorized by the Brazilian Health Surveillance Agency (ANVISA)[4]. This study aims to evaluate the occurrence of undeclared synthetic drugs in dietary herbal formulations by using chromatographic and spectroscopic methods.

MATERIAL AND METHODS

A total of three samples of plastic bottles containing capsules of dietary herbal formulations were provided by different sources. Each sample consisted of powder of plants usually employed in weight loss formulations. The content of the capsules of each product (the number varied according to the availability) was weighed and extracted with methanol (100mg:1mL) for 15 minutes. The extract was filtered and concentrated. The extracts were analyzed by thin layer chromatography (TLC), on silica gel F254 plates, using a proportion hexane/ethyl acetate (1:1) as eluent. Sibutramine drug (pharmaceutical grade) was used as the comparison substance. The TLC plates were observed under UV 254 and 366 nm and stained with iodine vapor. The retention factor values were calculated and compared. Nuclear Magnetic Resonance (NMR) spectra and GC-MS analyses were obtained for the total extracts of all samples.

RESULTS

Quantitative inadequacies and the presence of whitish powder were observed during the weighing of the contents present inside the capsules. Through the analysis by TLC, it was possible to compare the spots and retention factors between sibutramine and the extracts. The chromatographic analyses pointed to adulteration. 1H NMR spectrum showed chemical shifts characteristic of the drug sibutramine. All samples presented a pseudo-molecular ion $[M + H]^+$ at m/z 280.1830 relative formula mass of the compound sibutramine. The results obtained are in dissonance with the current legislation establish by ANVISA, in which phytotherapeutic products do not include isolated or highly purified active substances, whether synthetic, semi-synthetic or natural products[5].

Sibutramine was detected in all samples as an undeclared synthetic drug. These results point to the urgent need for more intensive surveillance by health authorities in herbal formulation products.

CONCLUSIONS

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REFERENCES

1.(WHO, 2018). 2.(MINISTERIO DA SAUDE, 2016).
3.ANDRIOLO, et al., 2012. Rev Inst Adolfo Lutz.
4.Consolidado de normas de registro e notificação de fitoterápicos. Brasília, DF. Out/2018.
5. (BRASIL, 2014).