



Article Info

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¹Department of Pharmaceutical and Medicinal Chemistry, Faculty of Pharmaceutical Sciences, Usmanu Danfodiyo University, Sokoto, Nigeria

²Department of Community Health, Faculty of Clinical Sciences, College of Health Sciences, Usmanu Danfodiyo University, Sokoto, Nigeria

³Department of Pharmacognosy and Ethnopharmacy, Faculty of Pharmaceutical Sciences, Usmanu Danfodiyo University, Sokoto, Nigeria

*Corresponding author's email:

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Analysis of sildenafil citrate in herbal aphrodisiac preparations marketed in Sokoto metropolis and its public health implications

Alhassan M. Alhassan^{1*}, Badaru Abdulkarim¹, Magaji B. Arkilla² and Ibrahim Malami³

Aphrodisiacs are among the most widely marketed and consumed herbal products in North-Western Nigeria. There are speculations that these products are being adulterated with orthodox medicines in order to boost their effects and sales. The objective of current research was to analyse the presence of adulterated sildenafil citrate in some herbal aphrodisiacs commonly sold and consumed in Sokoto metropolis. Ten different liquid herbal aphrodisiac preparations marketed in Sokoto metropolis were collected from different areas of the city. Each of the preparation was analysed for adulteration with sildenafil citrate using thin layer chromatography and UV spectroscopy. Five of the preparations were found to contain sildenafil citrate in the range of 34 – 291 mg per daily dose. The findings from this study indicate that some of the herbal aphrodisiac preparations marketed in Sokoto metropolis are being adulterated with substantial amount of undeclared sildenafil citrate, a practice that poses serious public health hazard to its consumers. Consequences of which ranges from nausea, dyspepsia, pain, dizziness, abnormal vision, and headache and potentially heart attack especially among adults with underlying chronic diseases such as hypertension among others.

Keywords: Sildenafil citrate, herbal-aphrodisiac, adulteration, undeclared, TLC.

1. Introduction

Traditional medicine is an important contributor to the health care delivery in Nigeria and the entire West African sub-region (James *et al.*, 2018, p.1). The WHO reported that most of the population living in developing countries make use of traditional medicine for their therapy (WHO, 2019, p.1).

The traditional medicine practice besides being a major contributor to health care and general well-being of citizens, is capable of generating a lot of economic benefits. Currently, the global herbal medicine market stands at about 50 billion United States Dollars, with most of the revenue accruing to Asian countries and the United States (Prabhakar & Mamoni, 2021, p.214). While other countries are reaping enormous health and economic benefit from their traditional medicine system, we are yet to organize our system in Nigeria to properly harness these benefits.

The current practice as it is today is not well standardized. There is no proper regulation of the herbal medicine production, marketing and consumption in Nigeria. This gives room for

fraudulent practices that often endanger the lives of people taking these medicines. One of which is the addition of undeclared orthodox drugs in the herbal preparations. Adulteration of herbal medicines with synthetic pharmaceuticals has been reported by several researchers as one of the major challenges in the global herbal product market (Ernst, 2002, p.107; Haneef *et al.*, 2013, p.608; Foroughi *et al.*, 2017, p.720; Ching *et al.*, 2018, p.175).

Aphrodisiacs are among most widely marketed and consumed herbal products in North-Western Nigeria. Aphrodisiacs are drugs that are used for enhancing libido and treatment of erectile dysfunction. Erectile dysfunction often occur in men due to old age, chronic stress and disorders such as hypertension and diabetes (Glina *et al.*, 2013, p.115). Men suffering from erectile dysfunction experience a feeling of guilt and shame due to difficulty in initiating sexual contact and intimacy which results in psychological stress that impact negatively on their general wellbeing (Srivatsav *et al.*, 2020, p. 431). This perhaps has contributed significantly to the widespread use of

aphrodisiacs. Sildenafil citrate is a synthetic phosphodiesterase-5 inhibitor that was developed for the treatment of erectile dysfunction (Boyce & Umland, 2001, p.2). Despite the availability of this drug and its analogues, several men prefer the use of herbal aphrodisiacs. This is, in part, due to their perceived effectiveness and safety (Agrawal & Mishra, 2016, p.153).

The producers of herbal aphrodisiacs in an effort to promote the sales of their products, may perhaps involve in unethical practice of adulterating their preparations with synthetic drugs such as sildenafil citrate. Such practice constitutes a serious threat to public health because most of the products do not have clear direction for use, hence consumers may likely take an overdose of these substances in the quest for enhancing their sexual performance. Therefore, the objective of current research was to analyse the presence of undeclared sildenafil citrate in some herbal aphrodisiacs commonly sold and consumed in Sokoto metropolis.

2. Materials and Methods

2.1 Materials

Standard sildenafil citrate powdered was purchased from Sigma Aldrich (Germany). All solvents were analytical grade bought from Lobal Chemie Laboratory (India). Thin Layer Chromatographic (TLC) plates pre-coated with silica gel F₂₅₄ was obtained from Sigma Aldrich (Germany).

2.2 Sample Collection

Ten different samples of liquid aphrodisiac herbal preparations marketed in Sokoto metropolis were randomly sourced from different parts of the city which include, Old Market (Tsohuwar kasuwa), Hubbare area (Masallacin Shehu), Kano road, Old Airport Junction, kalambaina Street and Manniru road. The label on the products were removed and each of the sample assigned a code (BS 001 to BS 010) to avoid bias during the analysis.

2.3 Thin Layer Chromatography

The samples of 5 mL each was collected and filtered using Watman filter paper. The standard sildenafil citrate 2 mg was dissolved in 5 mL of methanol. The samples and standard were spotted on the TLC plates and allowed to dry off. The plates were developed in a TLC chamber using methanol/ethyl acetate 1:2 as solvent system. The chromatogram was viewed under normal daylight as well as UV at 254 nm and the appearance and position of sample spots in relation to that of the standard sildenafil citrate was noted. The value of the retention factor (RF)

for each sample was calculated and compared with that of the standard drug.

2.4 UV Analysis

The analysis was carried following a protocol described by (Soubra *et al.*, 2020, p.59). The UV spectroscopic analysis of the standard and herbal samples were carried out using Double beam spectrophotometer Atico-ATE 4331 (India). The absorbances were obtained at a wavelength of 298 nm using methanol as blank and 1 cm cuvette. Solutions of standard drug of different concentration were prepared and used for calibration. The calibration curve was prepared by plotting the absorbances obtained against the corresponding concentrations in Microsoft excel 2019. Thereafter the herbal samples were analysed. The assay was performed in triplicate and average absorbance was determined for each sample. The concentration of sildenafil in each sample was extrapolated from the calibration curve.

3. Results and Discussion

3.1 Sample collection

A total of ten herbal aphrodisiacs samples were purchased from eight different locations within Sokoto metropolis. All the products were liquid preparation. Table 1 shows the information available on the label of each product and the code given to it. It was observed that only two of the products have NAFDAC registration number while three of the products have manufacture and expiry dates written on their labels. However, all the 10 products have written indication for their use in enhancing sexual performance.

3.2 Thin Layer Chromatographic analysis

Sildenafil adulteration in the herbal preparations were determined qualitatively using TLC. The TLC chromatogram of sildenafil citrate developed with the solvent system; methanol-ethyl acetate (1:2) showed that the standard drug has a R_f value of 0.61. The TLC chromatogram of five out of the 10 herbal samples (50%) showed a single prominent spot with R_f values 6.1 in methanol-ethyl acetate (1:2) solvent system. This indicates the presence of sildenafil citrate as the major constituent in the preparations. The R_f values of the standard sildenafil and the five samples that were positive are shown in Table 2.

3.3 UV Spectroscopic Analysis

After herbal products tested were found to be adulterated with sildenafil citrate using TLC. The positive samples were further analyzed in order to quantify the sildenafil present. The UV analysis of the standard sildenafil citrate solution produced absorbance at wavelength 298 nm and the calibration curve constructed by plotting

absorbance against the serial dilutions exhibit linearity with R^2 of 0.9939 as depicted by Fig.1. This is in line with Beer-Lambert law that holds that the higher the absorption of the radiation, the more the concentration of the analyte present.

Then, the absorbance obtained from the UV analysis of the tested samples were used to extrapolate the corresponding concentration of the sildenafil in the samples; BS004, BS006, BS008, BS009 and BS010 respectively. The result is shown presented in Tablet 3.

Table 1: Information on collected herbal aphrodisiacs

S/No	Sample codes	Medicinal Claims on the Label	Location	Direction of Use	Quantity	Date of manufacture	Expiry Date	NAFDAC number
1	BSO1	Manpower, increase sexual desire, increase sperm count, and tightening of woman's cervix	Hubbare (Masallac in shehu)	To be taken in the morning and evening	NI	NI	NI	NI
2	BS002	Sexual energy and stamina, improves sexual drive, increases satisfaction, enhances strong erection, and promotes fertility and libido stimulation	Tsohuwa r kasuwa	Half of the bottle to be taken in the morning and evening	NI	October, 2020	December ,2024	NI
3	BS003	Man power, penis enlargement, strong erection, delay ejaculation and enhances sexual energy	Tsohuwa r kasuwa	Shake well before use. Half of the medicine should be taken in the first day and the remaining in the next day	250ml	2021	2024	NI
4	BS004	Man power, and provides extreme desire for sex	Kalambai na Street	To be taken twice daily, half bottle in the morning and evening	NI	NI	NI	NI
5	BS005	Sexual improvement	Kalambai na Street	NI	NI	NI	NI	NI
6	BS006	Original man power preparation	Kalambai na Street	Complete content of the bottle should be taken 15 minutes before intercourse	NI	NI	NI	NI
7	BS007	Makes a person sexually active, improves quality of sperm, inhibits premature ejaculation Cures STIs	Tsohuwa r kasuwa	Half of the bottle to be taken 30 minutes before sex	100ml	2020	2023	NI

8	BS008	Manpower and delay ejaculation	Kano road	Half of the preparation to be taken morning and evening	250 ml	NI	NI	Available
9	BS009	Cures male sexual weakness, premature ejaculation, squeeze of the penis, and returns the lost sexual agitation.	Manniru road	30 ml to be taken daily at least 4 hours before sex	500 ml	NI	NI	Available
10	BS010	Remedy for weak erection and premature ejaculation.	Old Airport junction	One bottle to be taken an hour before sex	100 ml	NI	NI	NI

NI = not indicated

Table 2: TLC of the reference standard sildenafil citrate and the sample preparations

Sample	Spot	Retardation factor
Standard sildenafil citrate	+	0.61
BS001	-	-
BS002	-	-
BS003	-	-
BS004	+	0.61
BS005	-	-
BS006	+	0.61
BS007	-	-
BS008	+	0.61
BS009	+	0.61
BS0010	+	0.61

+ Indicates the presence of sildenafil citrate, - indicates the absence of sildenafil citrate

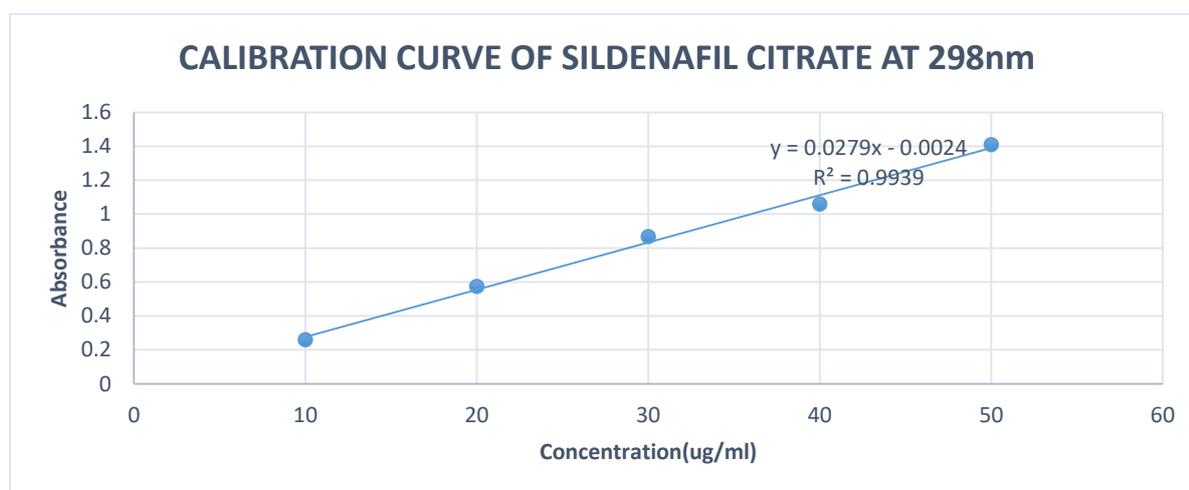


Figure 1: Calibration curve for standard

Table 3: Analysis of UV results

Sample code	Adulterant detected	Mean Conc. (mg/ml)	Mean Amount in the container (mg) \pm SD	Daily dose (mg)
BS004	Sildenafil citrate	0.27	68 \pm 0.31	34
BS006	Sildenafil citrate	0.49	49 \pm 0.86	49
BS008	Sildenafil citrate	0.18	45 \pm 0.54	45
BS009	Sildenafil citrate	1.01	505 \pm 3.62	168
BS010	Sildenafil citrate	2.91	291 \pm 3.29	291

SD = standard deviation, Conc = concentration

The sildenafil detected in five samples was quantified to be at daily doses ranging from 34 mg to 291 mg while the daily therapeutic dose being 100 mg. Although the sample size is small, the results show that 50% of the samples tested were adulterated with sildenafil citrate, some of which are in very high amount. Consumers who purchase those sex enhancing herbal products often believed that they are taking natural products which are believed to be safer than the synthetic ones but they are unaware that they are in fact, consuming undeclared synthetic drugs at either suboptimal or high dose. Thus, there is an urgent need for more investigation and better regulation in this area for the public health and well-being of the populace.

4. Conclusion

Sildenafil citrate (Viagra) is a phosphodiesterase inhibitor (PDE-5 inhibitor) used to treat impotence. This drug prevents phosphodiesterase-5 enzyme from destroying cGMP so erection is maintained for a longer period than usual (Kukreja *et al.*, 2005, p.221). Sildenafil has several mild to severe side effects affecting several organs. Notable ones include, flushy face, headache, stomach pain, nasal congestion, low blood pressure, abnormal ejaculation and priapism. In addition, in patient with high blood pressure, sildenafil may interact with anti-hypertensive drugs especially those containing nitrates to potentiate their effect and thereby led to severe hypotension (Moreira *et al.*, 2000, p.474). The impact and severity of the side effects and adverse events differs among people and is worse among those with underling risk factors. For example, myocardial infarction has been reported following use of sildenafil among people with cardio-vascular risk factors (Krenzelok & Krenzelok, 2000, p.645).

The public health implication of the findings of the above research is that people are consuming undeclared sildenafil of different degrees of dosages ranging from suboptimal dose (30 mg) to high dose of over 290 mg. At this level of dosages, victims are likely to experience sides effects, though they may get some effect of the sildenafil which will be ascribed wrongly to the herbal

concussion. Most of the people are using these herbal products as a remedy for erectile dysfunction. The erectile dysfunction of which is commonly caused by an underlying medical condition (either known or unknown to the users). Unfortunately, the patient may delay seeking for medical attention with regards to the actual cause of the erectile dysfunction.

With the paucity of data, the extent to which these adults experience side effects of the undeclared sildenafil in herbal aphrodisiac are not known. Further study is needed to understand the experiences of the consumers.

Furthermore, eight out of ten products analyzed were not registered with NAFDAC. Unfortunately, only two products were duly registered with NAFDAC and were also found to have adulterated their products with sildenafil. This finding questioned the authenticity of post registration quality assessment by the regulatory bodies.

However, Further research with a large sample of the herbal products and more in-dept analysis will allow understanding in details the extend and potential impact of the adulteration of herbal drugs with orthodox medicines in this part of the country.

Conflict of Interest

The author declares that there is no conflict of interest.

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