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Research Article

An Investigation into Microbial Contamination of Herbal Medicine Used for the Treatment of Erectile Dysfunction in Nairobi County, Kenya

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Abstract

Evaluation of quality of herbal medicine is crucial for their safe use. WHO has recommended that quality of herbal medicinal products should be evaluated with respect to adulterants and contaminants mainly heavy metals, pesticide residues and microbial contamination. This study focused on microbial contamination of herbal medicine used for treatment of erectile dysfunction (ED) in Nairobi County, Kenya. The samples were purchased from health stores in Nairobi County and evaluated for microbial contamination by MLT method and specific pathogenic microbes. 84 samples were subjected to Microbial Limit Test (MLT) and specific pathogenic microbes against European Pharmacopeia and USP 31. 46.43% of samples did not comply with TAMC while 31.14% of samples did not comply with TYMC requirements. 8.33% of samples did not comply with requirements for pathogenic microbes. Locally manufactured and samples from Tanzania were majorly contaminated while imported samples were less contaminated. These findings were in agreement with previous studies. The study revealed that herbal medicines used for treatment of ED in Nairobi County were contaminated with microbes. There is need to put a policy in place to evaluate herbal medicine for contamination with microbes before grand of market authorization.

Keywords: Herbal Medicines; Erectile Dysfunction; Microbial Contamination; MLT; Pathogenic Microbes

Introduction

Herbal medicinal products (HMPs) are prone to microbial contamination from many sources. The main source of microbial contamination may come from the soil. The HMPs are derived from plant parts such as roots, the bark, leaves, fruits etc. These can contaminate HMPs if not properly handled. HMPs are prepared from plant parts through process of washing and drying which can lead to microbial contamination if the moisture content is high enough to support microbial growth.

Contamination can also occur from the water used in processing and manufacturing. Manufacturing equipment if not properly sanitized can lead to microbial contamination.

World Health Organization (WHO) has issued guidelines to control and avoid contamination through quality assurance measures such as Good Agricultural and Collection Practice (GACP) for medicinal plants and Good Manufacturing Practice (GMP) for herbal medicinal products (HMPs) [1-4]. Microbial limits or absence of specific pathogenic microbes in HMPs have been published in monographs [5-7].

There are no known studies on microbial contamination of herbal medicine used for the treatment of erectile dysfunction in Nairobi County, Kenya. The current study reports the level of microbial contamination of herbal medicine used for the treatment of erectile dysfunction in Nairobi County, Kenya.

Materials and Methods

Study area and sampling

The survey was conducted in the administrative regions of Nairobi County, which is divided into nine (9) administrative regions namely Starehe, Westlands, Langata, Makadara, Embakasi, Kasarani, Dagoreti, Kamukunji and Njiiru. The administrative areas were used as sampling blocks. Nairobi County has the highest concentration of outlets and purchasing power is high. Consequently, Nairobi was deemed as representative of the whole Country (MOH and PPB 2015 data).

Randomly selected outlets stocking herbal products for treatment of erectile dysfunction were visited. Outlets were categorized broadly into wholesale pharmacies, retail pharmacies, health stores and herbal kiosks, clinics and hawkers. The samples collected were all inclusive i.e. tablets, hard and soft gelatin capsules, gels, liquids and powders. The samples collected only included intact packs, broken/loose packs were not sampled as the products had been exposed to the environment and the quality may have been affected. Ninety-nine (99) samples were purchased and the following information was tabulated; Name of the product, Manufacturer details (Physical address/postal address, email address, phone number and any other information), Country of origin, Ingredients, dosage form, indications/dose, Date of manufacture/date of expiry/Batch number, Pack size, Registration status and Patient information leaflet (PIL). The samples were analyzed for microbial contamination and presence of selected pathogenic microbes in Geochem laboratories, Mumbai, India.

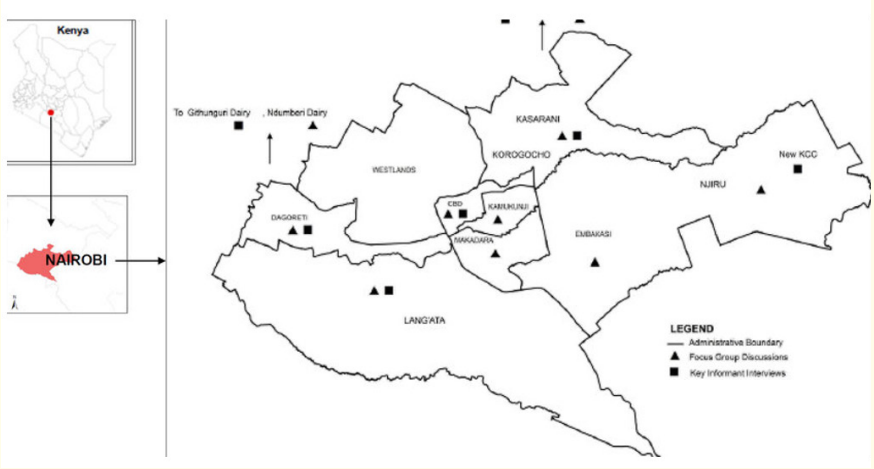

Figure 1: Map of Nairobi City County showing study site.

Inclusion and Exclusion criteria

Liquid, semisolid and solid preparations of herbal medicinal products administered orally or topically stored in their original container were included in the study. Products, which were commercially packed locally or imported, were included in the study while products, which were extemporaneously prepared, were excluded. Herbal medicines with other routes of administration and/or those that were delivered in unsuitable bottles (non-sterile or different from the original) and whose original pack was broken were excluded from the study.

Microbial analysis

This was done for total aerobic microbial count (TAMC), total yeast microbial count (TYMC) and for selected pathogens. Negative control was done by use of diluent (sterile buffered Sodium chloride peptone solution PH 7.0). Positive control was done by use of known microbial cultures.

Materials and Methods

All samples were analyzed at Geochem laboratories, Mumbai, India. General-purpose nutrient media, enrichment media and other appropriate selective media (all obtained from Hi-media private

limited, Mumbai, India) were employed in the culturing and isolation of selected pathogenic bacteria in the study [8]. Bacteriological and fungal media were supplied by Hi-media Laboratories Pvt ltd (Mumbai, India). The following media were used: Nutrient Agar, Sabouraud Dextrose Agar (SDA), MacConkey Agar, Eosin-Methylene Blue (EMB) Agar, Salmonella Shigella Agar (SSA), Xylose-Lysine Deoxycholate (XLD) Agar and Mannitol Salt Agar. All media were tested for viability using Bacillus pumilus NC08241, Staphylococcus aureus NC07447, Pseudomonas aeruginosa NC12924, Saccharomyces cerevisiae NC010716, Candida albicans NC10400, and Aspergillus niger NCPF3179. All standard strains of microorganisms were obtained from American Type Culture Collection (ATCC), USA. Counting of the bacterial/Fungal colonies was done using the Stuart Digital colony counter (Cole-Parmer, Vernon Hills, IL, USA). An autoclave (LTE J7090 model, LTE Scientific Ltd, England) was used for sterilizing the media.

Media preparation

All dehydrated media were prepared according to manufacturer's instructions. Media in powder form were weighed, reconstituted with distilled water, heated to completely dissolve. The media were then sterilized in an autoclave (LTE J7090 model, LTE Scientific Ltd, England) at 115 KPa, 121°C for 15 minutes. The sterile media were dispensed or poured into sterilized Petri dishes and allowed to cool. The sterility of the prepared media was checked by incubation of blindly selected plates at 37°C for 24hrs.

Sample preparation

1g of sample was dissolved in 9ml of Buffered Sodium Chloride Peptone (BSCP) solution of PH 7.0. The volume was adjusted to 100ml with same diluent to give 1:10 dilution. Surfactant 1g/liter Polysorbate 80 was added for samples that were fatty to help solubilize the sample.

Inoculation

1ml of sample was inoculated into 15ml of Soya Casein Digest Broth/Media (SCDB/A) in duplicate and incubated at 37° C for 2-5days. The average number of CFUs counted on the plates was considered total aerobic count per gram (cfu/g). 1ml of sample was inoculated into 15ml of Sabouraud Dextrose Agar (SDA) in duplicate and incubated at 25° C for 2-5days. The average number of CFUs counted on the plates was considered total yeast count per gram (cfu/g). Counting of the bacterial/Fungal colonies was done using the Stuart Digital colony counter. The number of CFU/g was compared by the BP 2018 guidelines for oral non-sterile products.

Isolation of pure colonies

Colonies were isolated based on morphologic differences from their axenic cultures. Colony form, elevation, pigmentation and size were the major distinguishing characteristics. Petri dishes were divided to quadrants and sub-culturing done by the streak plate technique [9].

Test for specific microbes using differential and selective media

The method of BP 2018, 14th edition was modified and used. 1g of sample was dissolved in 9ml of SCDM (1ml = 1g) solution A. The solution was kept at 32° C for 24 hours. 1ml of this solution was diluted with 9ml of SCDM (1ml = 0.1g) to give solution B.

Test for *E. coli*

1ml of solution B was kept for 24 hours at 32° C, then 1ml was diluted with 9ml Mac broth (MB) and kept at 42° C for 24- 48 hours. 1ml of the preparation was streaked on to Mac Agar and incubated for 72 hours at 32° C. The pathogens should be absent. If growth is obtained E. coli was present.

Test for *Salmonella typhii*

1g of sample was dissolved into 9ml SCDM kept for 24 hours at 32° C. 1ml of solution was diluted to 10ml with Rappaport Vassiliadis Salmonella Broth (RV) and kept for 18 hours at 32° C. This was then streaked on plates of Xylose Lysine Deoxycholate (XLD) and observed. No growth obtained means Salmonella was absent. Salmonella was present if growth was observed.

Test for *Pseudomonas aureginosa*

1g of sample was dissolved in 9ml of SCDM and diluted to 100ml with SCDM. This was kept for 24 hours at 32° C. This was sub cultured for 72hours at 32° C on Centrimide Agar (CA) and observed for growth. Presence of growth of greenish colonies indicated Pseudomonas present.

Test for *Staphylococcus aureus*

1g of sample was dissolved in 9ml SCDM then 1ml diluted with SCDM to give 10ml. This was kept for 24hours at 32° C then plated

on Mannitol Salt Agar (MSA) and incubated at 32° C for 72hours. Growth of yellow colonies indicated *S aureus* was present.

Test for Candida spp

A pure culture isolated in Sabouraud Dextrose Broth was inoculated into Sabouraud Dextrose Agar. It was incubated at 25 °C for 5 days. Growth of small round moist, white to colorless colonies with even edges was considered to be the presence of Candida spp. further microscopic studies were done for confirmation.

Test for Shigella spp

10g of the sample was dissolved into sterile nutrient broth with pH adjusted to 8.0 and incubated for 18 hours at 37°C. The pre-enriched culture was then streaked onto the freshly prepared selective differential agar plates of *Salmonella-Shigella* agar. Incubation was done at 37°C for 48 hours. Non- lactose fermenters that grew as colorless colonies were identified with suitable biochemical test such as Triple Sugar Iron (TSI) agar test. Confirmation of *Shigella* isolates was by serological tests.

Results and Discussion

Results

Eighty-four (84) samples were subjected to microbial limit test (MLT) against the acceptance criteria for microbiological quality of nonsterile dosage forms shown in table 1 below.

Dose form	TAC (CFU/g)	TYC (CFU/g)	SPECIFIED PATHOGEN (g or ml)
Non-aqueous preps for oral use	10^3	10^2	*E. coli* absent
Aqueous preps for oral use	10^2	10^1	*E. coli* absent
Rectal use	10^3	10^2	Pathogens absent
Oral/mucosal	10^2	10^1	*Staphylococcus aureus* absent
Vaginal use	10^2	10^1	*S aureus, P aureginosa*, *C albicans* absent
Inhalation (special requirement applies to liquid preps for nebulization)	10^2	10^1	*S aureus, P aureginosa,* Bile tolerant gram- negative bacteria absent
Transdermal patches (limits for one patch including adhesive layers and backing)	10^2	10^1	*S aureus, P aureginosa* absent

Table 1: Acceptance criteria for microbiological quality of nonsterile Pharmaceutical dosage forms (EP and USP Limits).

Source: BP 2018, 14TH Edition.

Tabulated below is the microbial limit test results of 84 samples used for treatment of ED surveyed in Nairobi County.

S/NO	Sample code	Country of origin	TAMC (CFU/g)	TYMC (CFU/g)	Pathogen/s Should be absent
1	BGS	USA	$5x10^1$	<10	Absent
2	MTC	USA	$1x10^1$	<10	Absent
3	SL	USA	<10	<10	Absent
4	NHC	India	<10	>10	Absent
5	VLSC	USA	$3x10^1$	<10	Absent
6	NAM	UK	$1x10^1$	<10	Absent
7	NHGE	USA	$6x10^1$	<10	Absent
8	PACP	South Africa	<10	<10	Absent
9	GSP	Kenya	Too numerous to count	$39x10^2$	Absent
10	AaEF	Kenya	$44x10^2$	$25x10^2$	Absent
11	MNP	USA	$1x10^1$	<10	Absent
12	ZMP	Kenya	$68x10^2$	$25x10^1$	Absent
13	NMVPC	USA	<10	<10	Absent

14	MLZT	USA	<10	<10	Absent
15	GH	USA	<10	<10	Absent
16	GA	China	<10	<10	Absent
17	HV	China	<10	<10	Absent
18	LMR	USA	<10	<10	Absent
19	MC	India	$228x10^3$	$43x10^2$	Absent
20	MRC	USA	$8x10^1$	<10	Absent
21	MEPC	Spain	<10	<10	Absent
22	MTr C	Spain	<10	<10	Absent
23	MNFL- 7	USA	<10	<10	Absent
24	MPPL	Kenya	$113x10^1$	$11x10^2$	E coli present
25	MPPD	Kenya	$214x10^2$	$4x10^3$	Absent
26	MVIPI	China	<10	<10	Absent
27	MSO	Kenya	$119x10^3$	$116x10^3$	E coli present
28	OHBMVC	India	$7x10^3$	1x10	Absent
29	PAC	South Africa	<10	<10	Absent
30	RMG	Thailand	<10	<10	Absent
31	MPRS	Kenya	$188x10^1$	$19x10^1$	E coli present
32	BGPFC	USA	$9x10^1$	<10	Absent
33	VG800	China	<10	<10	Absent
34	VFM	China	$2x10^3$	<10	Absent
35	MxC	China	$182x10^2$	<10	Absent
36	VegV	China	<10	<10	Absent
37	ProT	India	$25x10^3$	$11x10^2$	Absent
38	SaPC	China	<10	<10	Absent
39	TBC	USA	<10	<10	Absent
40	ViaHS	Canada	$194x10^4$	$22x10^3$	Absent
41	TriC	USA	$5x10^1$	<10	Absent
42	VitAL	Kenya	<10	<10	Absent
43	TAl	USA	<10	<10	Absent
44	Thu M	India	$4x10^1$	<10	Absent
45	Vig G	India	$1x10^3$	<10	Absent
46	ThuBL	Kenya	$2x10^1$	<10	Absent
47	Max co	China	$4x10^1$	<10	Absent
48	EUC	Poland	<10	<10	Absent
49	FT253	China	<10	<10	Absent
50	SaK	USA	$2x10^1$	<10	Absent
51	Veg H	USA	$2x10^1$	<10	Absent
52	Vig P+B	USA	$1x10^1$	<10	Absent
53	MkoI	Tanzania	$15x10^4$	$19x10^2$	Absent

54	ViaSCo	Canada	$130x10^2$	<10	Absent
55	MucDC	USA	10	<10	Absent
56	BGBioHC	USA	$11x10^1$	$1x10^1$	Absent
57	SNMNP	USA	$1x10^1$	<10	Absent
58	SLSG	USA	<10	<10	Absent
59	NHGWE	USA	$6x10^1$	<10	Absent
60	MurLP	Kenya	Too numerous to count	$2x10^2$	Absent
61	MeSF	Kenya	$5x10^3$	$10x10^3$	E coli present
62	C O and P	Tanzania	$5x10^4$	$4x10^4$	Absent
63	NgoE	Tanzania	$2x10^3$	$3x10^3$	Absent
64	MakoS	Tanzania	Too numerous to count	$3x10^3$	Absent
65	Sen 5	Tanzania	$2x10^3$	Too numerous to count	Absent
66	NjiT	Tanzania	$6x10^4$	$1x10^4$	Salmonella present
67	StimB	Kenya	$1x10^3$	$1x10^1$	Absent
68	AHMK	Kenya	$30x10^4$	$2x10^4$	Absent
69	SuPM (PoMS)	Kenya	$2x10^4$	$1x10^4$	E coli present
70	MapeC	Kenya	Too numerous to count	<10	Absent
71	AlpM (TesB)	Kenya	$17x10^4$	$6x10^2$	Absent
72	MorP	Kenya	$2x10^4$	$2x10^4$	Absent
73	Me P	Kenya	$4X10^4$	$2X10^4$	Absent
74	VigoF	India	$1x10^4$	<10	Absent
75	ShilCap	India	$3x10^4$	$10x10^1$	Absent
76	PlaVig	China	$1x10^3$	$3x10^1$	Absent
77	JMS	China	$7x10^3$	<10	Absent
78	OIVitaC	India	$3x10^4$	<10	Absent
79	MaxVC	Kenya	$2x10^4$	$2x10^2$	Absent
80	MaxEG	Thailand	$9x10^4$	$23x10^4$	Absent
81	NS-8P	Tanzania	$1x10^3$	Too numerous to count	Absent
82	GdmP	China	$34x10^3$	$13x10^3$	Absent
83	SerP	Kenya	Too numerous to count	$6x10^4$	E coli present
84	SaPCap	China	$2x10^4$	$1x10^2$	Absent

Table 2: Result of MLT of 84 samples used for the treatment of ED surveyed in Nairobi County.

Source: Created for this research.

S/N	Country	Total number of samples analyzed	TAMC Non Compliant Samples	TYMC Non-Compliant Samples	Pathogen Present/Organism Present
1	China	14	6	2	0
2	USA	24	0	0	0
3	UK	1	0	0	0
4	India	8	6	2	0
5	Poland	1	0	0	0

6	South Africa	2	0	0	0
7	Spain	1	0	0	0
8	Canada	2	1	0	0
9	Tanzania	7	7	7	1 (*Salmonella* present)
10	Kenya	20	18	15	6 (*E coli* present)
11	Thailand	2	1	1	0

Table 3: Summary of MLT analysis.

Source: Created for this study

TAMC- Total Aerobic Microbial Count

TYMC- Total Yeast Microbial Count.

MLT was conducted as per European and US Pharmacopoeia limits for oral dose forms, which proscribes limit of NMT 100 CFU/g or 1ml [10-12]. Samples were analyzed for total bacteria and yeast/mold count and presence of pathogens. Results of MLT is presented in table (i) above, 39 (46.43%) samples out of 84 samples did not comply with TAMC, out of these 4 (4.76%) samples from Kenya and 1 (1.19%) sample from Tanzania were contaminated with too numerous to count TAMC. 27 (32.14%) of the samples did not comply with TYMC out of which 2 (2.38%) samples from Tanzania were contaminated with too numerous to count TYMC. 7 (8.33%) of the samples did not comply with the requirements of pathogens in the samples, out of which 1 sample from Tanzania was contaminated with *Salmonella* while 6 samples from Kenya were contaminated with *Eschericha coli*. 14 (16.67%) samples analyzed for MLT were from china, out of which 6 (7.14%) was non-compliant with respect to TAMC while 2 (2.38%) did not comply to TYMC. All the samples from China complied to the requirements of pathogens. 24 (40%) of the samples analyzed were from USA all of which complied with the requirement of TAMC, TYMC and pathogens respectively. 8 (9.52%) samples analyzed were from India out of which 6 (7.14%) samples did not comply with TAMC, 2 (2.38%) samples did not comply with TYMC while all of them complied with pathogen requirement. There was only 1 (1.19%) sample from UK, Spain and Poland respectively which complied with requirements of TAMC, TYMC and pathogens respectively. There were 2 (2.38%) samples from South Africa, which complied with the requirements of TAMC, TYMC and pathogens. There were 2 (2.38%) samples analyzed from Canada, the two complied with TAMC and pathogens while 1 (1.19%) sample did not comply with requirement of TYMC. 20 (23.81%) samples analyzed were from Kenya, out of which 18 (21.43%) did not comply with the requirements of TAMC while 15 (17.86%) did not comply with the requirements of TYMC. 6 (7.14%) samples did not comply with requirement for pathogens as they were contaminated with *E. coli.* This was the largest number of samples which were non- compliant with respect to TAMC, TYMC and pathogens. This was followed by Tanzania which had the following trend i.e. all the 7 (8.33%) samples analyzed, all of them were non-compliant with respect to TAMC and TYMC while 1(1.19%) sample was non-compliant with respect to pathogen requirement as it was contaminated with *Salmonella.* None of the samples tested was contaminated with *Shigella spp.*

Discussion

The study has revealed that local samples and those imported from Tanzania available in Nairobi County were contaminated with aerobic bacteria and yeast/molds. The samples were contaminated with aerobic bacteria more than yeast/molds. Samples from the rest of the world were contaminated to varying levels. A few samples were found contaminated with pathogenic E. coli and Salmonella. The samples therefore did not meet Pharmacopoeia specifications. WHO has set limits for TAMC and TYMC in herbal preparations as NMT 10^5 CFU/g and NMT 10^3 CFU/g respectively and pathogenic microbes should be absent in the sample [2]. In accordance with these limits, there were some samples that exceeded limit like Ginseng super that had too numerous to count (TNTC) microbial contamination. Some samples were also contaminated with pathogens. Therefore, the trend of microbial contamination with respect to EP and USP limits in the samples studied were similar to WHO limits trend.

Various studies have been conducted and the results show contamination above limits set out in the monographs, which poses

health risk to consumers. Contamination of herbal medicinal products with microbes and their products is a wide spread occurrence. An evaluation of risk associated with Aflatoxin in herbal medicinal products in Kenyan market showed that they were contaminated with Aflatoxin and Fumonisin. The results of the study are similar to studies conducted elsewhere. A study conducted by Onyambu., *et al*. showed that the samples did not meet Pharmacopoeia standards and contained pathogens. Registered products complied with requirements of monographs while unregistered products did not comply [13].

Dei- Tutuwa., *et al*. conducted a study on microbial contamination in Ghanaian herbal medicines by PCR. The study revealed that some samples had contamination levels above WHO limits for aerobic bacteria in herbal products [14]. In a study conducted by Walther., *et al*. on microbial contamination of traditional liquid herbal medicinal products marketed in Mwanza city, Tanzania, the study revealed that samples were highly contaminated. Contamination was attributed to either manufacturing process or equipment [15].

According to a study conducted on herbal medicine marketed in Kaduna Metropolis, products were contaminated and did not meet specifications in the monographs [16]. Souza Lima., *et al*. investigated microbial contamination of traditional medicinal products sold in the city of Macapa, Brazil. The study revealed that the products were contaminated with microbes and pathogens above limits set out in the monographs [17].

Research was conducted at Free Town, Sierra Leon on microbial quality of some herbal products revealed that 80% of the products were contaminated and did not meet the requirements of the monographs. Bacterial contaminants were majorly Gram-positive organisms. Fungal contaminants included Candida, Aspergillus and Cryptococcus species [18].

In a research study published in African journal of Biotechnology, Enayatifard., *et al*. investigated microbial quality of some herbal solid dosage forms, results showed that all the samples had microbial contaminants and they contained pathogenic *salmonella* that did not comply with USP 30 [19].

Contamination of herbal medicinal products (HMPs) could be attributed to several factors. In the study some samples were contaminated with aerobic bacteria while others were contaminated with fungi (yeast and molds) exceeding the limits set out in the monographs and WHO guideline. The contamination could be attributed to the source of raw materials, inadequate drying, poor processing and low standard of GMP of finished product. Contamination with *E. coli* is indicative of fecal contamination of water or raw materials. This can lead to infections to individuals using these products. According to WHO report [20]. *Salmonella* food poisoning is major problem worldwide and has increased in many countries in the recent past. In Blantyre, Malawi researchers conducted an investigation into bacterial contamination in selected commonly sold herbal medicine, which revealed that twenty out of the 29 samples (68.9%) were contaminated with enterobacteria. Out of 20 contaminated samples, most of them exceeded WHO regulatory limit (10^3 CFU/g for enterobacteria). Although liquid samples had the highest level of bacterial contaminants, the count was not statistically different from other formulations [21]. According to Hassan., *et al*. during an investigation of microbiological contamination of herbal medicinal products marketed in Kenya for chronic diseases in Nairobi Metropolis, out of 86 herbal samples twenty-eight (32.6%) products failed to comply with the British Pharmacopoeia (2019) specifications for microbial load. Twenty-six (30.2%) herbal products were contaminated with bile-tolerant Enterobacteria. Results of this study imply herbal medicines are heavily contaminated with pathogenic microbes [22].

In Dhaka, Bangladesh researchers investigated microbial contamination in herbal medicines available in the market. The results revealed that, the products were contaminated with bacteria, fungi and pathogens beyond limits set out in the monographs [23].

In another study, researchers investigated microbiological contamination of common oral herbal medicinal products within Dhaka metropolis. The results revealed that samples were contaminated with total viable bacteria, fungal and pathogens [23].

Temu-Justin and others conducted a study on microbiological quality of herbal drug products prepared locally in Dar es salaam, Tanzania. The study revealed high bacterial contamination in both liquid and powder drug samples. Contamination with fungi was higher in powder than liquid samples [24].

A study of bacterial contamination of herbal medicinal products sold in Nairobi, Kenya isolated multi-drug resistant bacteria

[25,26]. An evaluation of microbial contamination of herbal medicine was conducted around Riyadh, Saudi Arabia and Kaduna metropolis in Nigeria. The results showed that samples contained fungal, coliform bacteria and heavy metal contaminants [27]. The results of an investigation on contamination of HMPs with selected pathogenic bacteria in Kaduna Metropolis indicated that samples were contaminated with enterobacteria and other pathogens [16].

A study conducted in Malaysia to evaluate the level of microbial contamination in herbal medicine indicated that samples were generally contaminated with microbes and heavy metals [28]. Zhang., *et al*. evaluated microbiological quality of herbal medicine, which revealed that samples were contaminated with bacteria and fungi above the allowable limits [29]. A study was conducted on the important bacteria isolates from commercial herbal medicines in Africa from 2000 to 2021. The study showed that herbal medicines in Africa were contaminated with bacteria that are highly resistant to allopathic/prescription medicine [30].

Dike., *et al*. carried out an evaluation of microbial quality of some herbal bitters sold in Southwest Nigeria. The study indicated that samples were contaminated with various bacteria and fungi. All the drinks were contaminated with Staphylococcus aureus [31]. Matotoka and Masoko conducted an investigation into microbial contamination of herbal concoctions sold in Ga Maja, Limpopo province in South Africa. The study revealed presence of bacterial contaminants in some samples [32]. A systematic review was conducted on contamination and adulteration of herbal Medicinal Products (HMPs) using common search engines. The review revealed that HMPs were contaminated with bacteria, fungi, toxins, heavy metals and adulterated with prescription medicine [33].

Okunlola., *et al*. investigated the microbial qualities of 21 different herbal medicinal products (HMPs) sourced from traditional medicine sales and retail Pharmacy outlets in South West Nigeria. Results indicated that some samples were contaminated with pathogenic bacteria and Fungi [34].

Researchers at the University of Nairobi conducted a study on microbiological contamination of herbal medicinal products marketed in Kenya for chronic diseases. The study revealed that some samples failed microbial load requirements set out in British Pharmacopoeia (2019) and some were contaminated with pathogens [22].

Archibong., *et al*. conducted microbiological Assessment of Some Liquid Herbal Medications Sold in Awka Metropolis, Anambra State, Nigeria. The result showed most of the registered drugs met the WHO standard for liquid herbal drugs while few of unregistered ones met the standard. This study showed that the microbial quality of these herbal drugs is low compared as referenced to World Health Organization and could pose a great health risk to public health [35].

A study on microbiological quality of some herbal medicinal products sold in Accra, Ghana showed that samples were contaminated and microbial load varied considerably. Fungal contamination was at low level as only one sample had fungal isolates [36]. Osei-Adjei., *et al*. conducted Quality Assessment Of Aqueous Herbal/Medicinal Products Sold On The Ghanaian Market. The results indicated that, most of the decoctions were contaminated with aerobic bacteria and/or fungi and a few samples were free from fungal contamination [37].

Occurrence of potential bacterial pathogens and their Antimicrobial susceptibility patterns isolated from Herbal Medicinal Products sold in different Markets of Gondar Town, northwest Ethiopia was investigated by Yesuf., *et al*. In the study the total aerobic bacterial count did not meet the requirements in the monographs. Contamination was mainly by *Bacillus* spp., *Enterobacter* spp., *Shigella dysenteriae* and *Salmonella* spp [38].

An assessment of bacterial contamination in HMPs vended in Morogoro Municipality, Tanzania revealed that 88% of the tested HMPs did not meet WHO requirements. Most of the samples were contaminated with *E. coli* and *Staphylococcus aureus* [39]. In another study conducted in Mwanza City, Tanzania by Walther., *et al*. most of the samples were contaminated with fecal coliforms *(Klebsiella* and *Enterobacter* spp) [17].

Conclusion

The study found that herbal products used for treatment of erectile dysfunction available in Nairobi County, Kenya are contaminated with microbes (bacteria and fungi/molds) and that some of them are contaminated with pathogens (*E. coli* and Salmonella). These results could be extrapolated to other herbal medicinal products in the Kenyan market. Locally manufactured samples and those imported from Tanzania had the highest percentage of

contamination. A few samples had too numerous to count (TNTC) microbial contamination. Samples imported from the rest of the world (China/Hong Kong, USA, Europe etc.) were not contaminated with microorganisms. The contamination in the samples could be attributed to poor harvesting, drying and manufacturing practices. Poor sanitization of manufacturing equipment can lead to microbial contamination [40]. The use of water for processing that do not meet specifications in the monographs can lead to contamination with coliforms [41]. Therefore, manufacturers should assure the highest levels of hygiene during manufacturing. These bacteria constitute the intestinal flora of humans and other animals, and are therefore used as indicator organisms and as an index of possible contamination by human pathogens [40]. The significance of faecal bacteria is that if these specific bacteria are present then other harmful microorganisms may also be present, such as *Salmonella* [41]. Therefore, the high recovery rates of these suspected pathogenic bacteria from indigenous orally consumed herbal medications could be of public health relevance.

Recommendations

In the perspectives of the present study, where microbial contamination of herbal medicine used for the treatment of ED was evident, the assessment of microbial contamination in herbal medicines is urgently required. Based on the suggestive data in this study and considering previously reported microbial contamination in herbal medicine [13-15,17] it is recommended that there is an urgent need for constant monitoring and control of the microbiological standards of herbal medicines available in the local markets. The regulatory authority (PPB) should put in place a policy to evaluate microbial contamination in herbal products before granting marketing authorization (MA).

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Availability of Data and Materials

The datasets used and/or analyzed during the current study are available from the corresponding author on request.

Conflict of Interest

The authors declare no conflict of interest.

Ethics Approval

The ethical approval was obtained from Institutional Review Committee of University of Nairobi/ Kenyatta National Hospital.

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