HPLC Quantification and Impurity Profiling of Counterfeit Sildenafil Tablets from the African Market

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Counterfeit medicines represent a major public health concern, as they may contain toxic substances, inappropriate excipients, or incorrect amounts of the active pharmaceutical ingredient (API), including cases with no API at all, despite being marketed as authentic. This study aimed to quantify sildenafil citrate and identify impurities in illegally distributed products. Nine counterfeit sildenafil citrate tablets (labeled 100 mg) were analyzed by high-performance liquid chromatography (HPLC). Separation was achieved on a Lycospher C18 column (15 cm × 4.6 mm, 5 µm) using 0.2 M ammonium acetate buffer (pH 7.0) and acetonitrile (50:50, v/v) as the mobile phase, at a flow rate of 1 mL/min, injection volume 20 µL, and UV detection at 240 nm. The method provided reliable separation of sildenafil and related substances within a 7-minute run and was validated for linearity, recovery, precision, and limits of detection (LOD) and quantification (LOQ). Analysis showed that 44 % and 77 % of samples contained sildenafil citrate levels below USP and EP specifications, respectively. Four samples exceeded the pharmacopoeial limits for impurity B, and two exceeded the limits for impurity C. These results highlight the poor quality of counterfeit sildenafil citrate products available outside official distribution channels and underline their potential risks to patient health.

Keywords: counterfeit medicines, sildenafil, falsification, USP, HPLC

Introduction

The discovery of sildenafil, marketed under the brand name Viagra®, marked a major breakthrough in the treatment of erectile dysfunction [1]. Since its launch on the global market by Pfizer in 1998 [2], this drug has provided an effective and well-recognized therapy for a condition that can significantly impair quality of life, thereby transforming the lives of millions of men worldwide. However, the continuing demand and growing popularity of sildenafil have also led to a serious threat: the counterfeiting of this drug [3].

According to the World Health Organization (WHO), a counterfeit medication is one that is deliberately and fraudulently mislabeled with respect to its identity and/or source [4]. In 2006, the WHO established the International Medical Products Anti-Counterfeiting Taskforce (IMPACT), a global coalition of stakeholders, to address this issue [5].

Drug counterfeiting has become an increasing challenge for the pharmaceutical industry, affecting a wide range of therapeutic categories, including type 5 phosphodiesterase (PDE5) inhibitors such as sildenafil [6]. Counterfeit medications endanger public health, compromise patient safety, and undermine confidence in legitimate medical treatments. To mitigate these risks, the European Union (EU) has implemented Regulation (EU) 2016/161, which requires most prescription and certain over-the-counter medicines to include safety features on their packaging, such as unique identifiers and tamper-evident devices [7].

The problem is particularly acute in emerging economies across Asia, Africa, and Latin America, where multiple factors, such as a high proportion of low-income populations with unmet healthcare needs, contribute to the circulation of counterfeit products. In some of these regions, more than 30 % of medicines sold are either falsified or of substandard quality, with prevalence exceeding 50 % in certain areas [8]. China and India are among the primary sources of counterfeit medicines, and according to the European Commission, India alone is responsible for 75 % of all counterfeit drugs distributed globally [9].

The composition of counterfeit medicines is often directly linked to their falsification. These products may contain harmful substances, incorrect amounts of pharmacologically active ingredients, or no active

ingredient at all, making them illegal and posing serious health risks [10]. For example, in 2017, 13 counterfeit tablets falsely labeled as “Viagra” and sold in Brazil were examined using infrared spectroscopy. Five tablets contained reduced amounts of sildenafil, while eight contained starch and six contained calcium sulfate as undesirable excipients [11].

Consequently, the development of reliable analytical methods for the detection of counterfeit medicines is essential. Such methods must be able to identify both the targeted analytes and possible degradation products. Physical and chemical tests have been widely applied to verify the quality of counterfeit drugs. Techniques include high-performance liquid chromatography with ultraviolet detection (HPLC-UV) [12–16], ultra-high-performance liquid chromatography (UHPLC-UV) [17, 18], nuclear magnetic resonance (NMR) spectroscopy, gas chromatography–mass spectrometry (GC-MS) [19], Raman spectroscopy, and near-infrared spectroscopy [20, 21] to determine the chemical identity of the product, as well as X-ray powder diffraction for compositional analysis. Among these, liquid chromatography coupled with different detectors has been the most commonly employed approach for characterizing counterfeit pharmaceutical products [22–24].

Morocco has also rejoined the Council of Europe’s “Medicrime” Convention, which came into force on January 1, 2016 [25]. This treaty addresses the counterfeiting of medicines and medical devices and aims to protect public health by safeguarding the integrity of healthcare product distribution systems. The Gendarmerie Royale is tasked with monitoring the market for sildenafil-containing products, although comprehensive data on the actual quantities of sildenafil in circulation remain unavailable.

The objective of this study was to evaluate the quality of eleven sildenafil-based drug products purchased from legitimate suppliers. Specifically, the active ingredient was identified, the dosage was compared with the amount stated on the label, degradation products were quantified according to USP requirements, and the results were compared to the product specifications.

Materials and Methods

Instrumentation. Chromatographic analyses were performed using a Waters 2695 HPLC separation system equipped with a quaternary pump, autosampler with a circulating needle, column oven, and UV/Vis detector. Data acquisition and processing were carried out using Empower 3 software (Waters, USA).

Chromatographic conditions. The chromatographic separation was achieved on a Lycospher C18 column (150 mm × 4.6 mm, 5 µm) maintained at 40 °C. The mobile phase consisted of a 50:50 (v/v) mixture of acetonitrile and 0.2 M ammonium acetate buffer (pH 7.0), filtered and degassed prior to use. The flow rate was 1.0 mL/min, the injection volume was 20 µL, and UV detection was performed at 240 nm.

Standards, reagents, and samples. Sildenafil citrate reference standard (USP grade, 98.8 % purity) was used for calibration. HPLC-grade acetonitrile was obtained from Carlo Erba (France), ammonium acetate from Honeywell (Netherlands), and purified water from a Milli-Q Plus® system (Millipore, Merck, France).

Impurities and degradation products of sildenafil were obtained from Clearsynth (Canada), including 1-methyl-4-nitro-3-n-propyl-5-pyrazole carboxamide (impurity A), 1-{[3-(6,7-dihydro-1-methyl-7-oxo-3-propyl-1H-pyrazolo[4,3-d]pyrimidin-5-yl)-4-ethoxyphenyl]sulfonyl}-4-methylpiperazine N4-oxide (impurity B), 4-(2-ethoxybenzoylamino)-1-methyl-3-n-propyl-5-pyrazole carboxamide (impurity C), and 5-(2-ethoxyphenyl)-1-methyl-3-n-propyl-pyrazolo[4,3-d]pyrimidin-7-1 (impurity D).

Nine batches of counterfeit sildenafil products were collected from street vendors in Rabat and Casablanca between December 2023 and January 2024. For comparison, brand-name Viagra® (Pfizer) and a locally manufactured generic product were purchased from authorized pharmacies. Characteristics of sildenafil tablet samples are shown in Table S1.

Solution preparation. For each sample, ten tablets were weighed, finely powdered, and an amount equivalent to 100 mg of sildenafil citrate was transferred to a 100 mL volumetric flask. The volume was adjusted with mobile phase to obtain a concentration of 1 mg/mL. All solutions were filtered through 0.45 µm nylon filters before injection.

The reference standard solution was prepared by dissolving 25 mg of sildenafil citrate in a 50 mL volumetric flask with mobile phase. Impurity stock solutions (A–D) were prepared by dissolving 1 mg of each compound in 100 mL of mobile phase and sonicated to ensure complete dissolution.

The system suitability solution was prepared by dissolving 50 mg of sildenafil citrate standard and 10 mg of each impurity (A–D) in 100 mL of mobile phase. A 1 mL aliquot of this solution was further diluted to 10 mL to yield final concentrations of 0.05 mg/mL sildenafil citrate and 0.01 mg/mL of each impurity.

Analytical method. The HPLC method was based on the procedure described in the United States Pharmacopeia (USP) for the assay and quantification of sildenafil and its related impurities. Although the pharmacopoeial method involves higher reagent consumption and may lead to variability at very low analyte concentrations (coefficient of variation > 5 %), it remains the reference method.

Quantification of active ingredients and impurities. Each analytical run included a blank, a limit of quantification solution, a system suitability solution, a reference standard, and sample solutions. The content of sildenafil and each impurity was determined by comparing the peak areas of the samples with those of the standards. All analyses were performed

in triplicate, and results are reported as mean values.

Acceptance criteria. Acceptance criteria followed the European Pharmacopoeia (± 5 %) and USP (± 10 %) limits for the assay of active ingredients. Considering a maximum daily dose of 100 mg of sildenafil, the qualification threshold for each impurity was set at 0.2 %, and the total amount of impurities was not to exceed 0.5 % of the daily dose, in accordance with USP guidelines.

Results and discussion

Method development

To ensure clear resolution of sildenafil and its related impurities, the HPLC method was adapted from the United States Pharmacopeia (USP) procedure. The main modification concerned the detection wavelength: based on the UV spectra of sildenafil and its impurities (Figure S1), 240 nm was selected to allow reliable quantification of all components. The optimized method was then fully validated to confirm its suitability for routine analysis.

Analytical method validation

Method validation was carried out according to ICH Q2(R1) guidelines for simultaneous determination of sildenafil and its related substances. Parameters assessed included system suitability, specificity, linearity, precision, accuracy, and limits of detection (LOD) and quantification (LOQ).

System suitability. System suitability testing was performed prior to validation by injecting the sildenafil standard six times. Results (Table S2) demonstrated negligible variation in retention times, %RSD of peak areas below 1 %, symmetry factor < 2, and more than 2000 theoretical plates, indicating excellent chromatographic performance.

Specificity. The specificity of the developed HPLC method was evaluated by comparing representative chromatograms of a blank solution (mobile phase), a placebo solution, and a mixture containing sildenafil citrate and its related impurities. The placebo matrix consisted of the commonly used excipients lactose, corn starch, crospovidone, magnesium stearate, talc, cellulose, hydroxypropyl methylcellulose, titanium dioxide, and isopropyl alcohol.

As illustrated in Figure S3, no peaks or interfering signals were observed at the retention times corresponding to sildenafil citrate or its known impurities (A, B, C, and D) in either the blank or placebo chromatograms. This confirms the absence of co-eluting components from the mobile phase or excipients that could compromise analyte detection. The chromatogram of the spiked mixture demonstrated well-resolved, baseline-separated peaks for sildenafil citrate and all related compounds at concentrations of approximately 15 mg/mL, further supporting the method's specificity.

Linearity. The linearity of the calibration curve for sildenafil citrate was evaluated over the concentration range of 14–42 µg/mL. The resulting calibration plot exhibited an excellent linear response, described by the regression equation Y = 25213.174X – 33608.001, where X represents concentration and Y the corresponding peak area. The correlation coefficient (R^2) was 0.9998, confirming the strong linearity of the method across the tested range. Similarly, the linearity of the calibration curves for the sildenafil-related impurities (A, B, C, and D) was assessed. Impurities B, C, and D demonstrated linear responses over the range of 0.10–1.58 µg/mL, while impurity A was linear between 0.10–3.00 µg/mL. In all cases, the correlation coefficients (R^2) exceeded 0.9995, indicating excellent linearity and suitability of the method for quantitative analysis of trace levels of related substances. Table 1 summarizes the regression parameters and statistical data for sildenafil citrate and its related impurities

Precision. Method precision was evaluated at two levels: repeatability (intra-day precision) and intermediate precision (inter-day precision). Six replicate determinations of sildenafil citrate and its related impurities were performed under the same operating conditions for repeatability, while intermediate precision was assessed on different days by a different analyst using freshly prepared solutions. As summarized in Table 3, the coefficients of variation (CV) for sildenafil citrate were consistently below 2%, confirming the excellent repeatability of the method. For the four related impurities (A, B, C, and D), CV values were below 5%, which is within the acceptance criteria established by ICH Q2(R1). These results demonstrate that the method exhibits good precision and is suitable for routine quantitative analysis of sildenafil citrate and its related substances.

Accuracy. Accuracy is a key parameter in analytical method validation, as it reflects the degree of agreement between the measured value and the true value, thereby assessing potential systematic error. In this study, accuracy was determined through recovery experiments by analyzing sildenafil citrate and its related compounds at multiple concentration levels. The results were expressed as percentage recoveries for both sildenafil citrate and its impurities (Table 2). The mean recovery for sildenafil citrate was 99.9%, with a relative bias of less than 2%, demonstrating excellent accuracy of the method. For the related impurities, recovery values ranged from 99.6% to 100.6%, with relative bias below 5%, confirming that the method is accurate and reliable for quantifying sildenafil citrate and its related substances across the studied concentration range.

Limit of Detection (LOD) and Quantification (LOQ. The limits of detection (LOD) and quantification (LOQ) for sildenafil citrate and its related substances were determined using the graphical method, based on the calibration curve parameters (slope and intercept) and the standard deviation of the response. As summarized in Table 3, LOD and LOQ values were established for each impurity, demonstrating the high sensitivity of the method. The LOD values were as low as 0.003 µg/mL

Table 1. Validation results of the HPLC analytical method for sildenafil citrate and its related impurities.

Parameter	Sildenafil (Assay)	Impurity A	Impurity B	Impurity C	Impurity D
Linearity					
Slope	25 213.174	33 608.001	27 891.766	43 787.180	43 672.695
Intercept	98.460	−348.693	29.018	−523.633	113.801
R^2	0.9998	0.9996	0.9998	1.0000	0.9999
Range (μg/mL)	14–42	0.10–3.00	0.10–1.58	0.10–1.58	0.10–1.58
Precision (RSD, %)					
Repeatability	0.98	0.42	0.52	0.68	0.36
Intermediate precision	1.05	0.69	0.90	1.72	1.08
Accuracy					
Mean recovery (%)	99.9	99.6	100.1	100.6	99.8
RSD (%)	1.2	2.6	3.1	2.1	3.8
95% CI	99.4–101.3	98.7–100.4	98.8–101.3	99.4–101.2	99.3–101.2
Sensitivity					
LOQ (μg/mL)	NA	0.014	0.014	0.010	0.014
LOD (μg/mL)	NA	0.006	0.005	0.003	0.005

for impurity C and did not exceed 0.006 μg/mL for any impurity, while LOQ values ranged between 0.010 and 0.014 μg/mL. These results indicate that the method is capable of reliably detecting and quantifying even trace levels of impurities in sildenafil citrate formulations, thereby meeting the requirements for quality control and regulatory compliance.

Quantitative analysis of sildenafil in counterfeit medicines

The validated HPLC method was applied to the quantitative determination of sildenafil citrate content in samples of suspected counterfeit medicinal products. The results revealed that 7 out of 9 analyzed samples contained sildenafil at levels falling outside the acceptance criteria specified by the European Pharmacopoeia (95–105% of the labeled claim). Furthermore, 4 out of 9 samples were outside the broader acceptance limits defined by the United States Pharmacopeia (USP) (90–110%). These findings, summarized in Table 4, highlight significant variability in the content of sildenafil among counterfeit products, underscoring the potential risks associated with their use and the importance of employing validated analytical methods for quality control and regulatory surveillance.

Impurity profile of counterfeit medicines

According to the USP requirements, the level of each individual impurity in a finished product must not exceed 0.2%, while the total amount of impurities must remain below 0.5%. The impurity profiling performed using the validated HPLC method yielded the following results:

Impurity A was detected in all seven counterfeit drug samples, but its concentration did not exceed the USP limit of 0.2%.

Impurity B was present in all counterfeit drugs as well as in the reference (princeps) and generic formulations. In four counterfeit products (NIZARGA, BLACK COBRA, PURGREY, and YOGA 100), the percentage of impurity B exceeded the 0.2% limit, with the highest value observed for NIZARGA (1.3%).

Impurity C was absent from two samples (SIL FIX and VIAGRA), while in the remaining products its concentration was below 0.2%.

Impurity D was found in three counterfeit drugs (FAST4S, BLACK COBRA, and SUPERGRA), and exceeded 0.2% in two of them (BLACK COBRA, SUPERGRA), reaching a maximum value of 0.57% in BLACK COBRA.

Overall, the total impurity content exceeded 0.5% in five counterfeit products (NIZARGA, BLACK COBRA, SUPERGRA, PURGREY, and YOGA 100). With the exception of impurities B and D, all other analytes remained within USP limits across all tested samples. Notably, the reference and local generic samples did not contain detectable amounts of impurities A and D, supporting their superior quality profile relative to counterfeit products.

The quantitative results for all impurities (A, B, C, and D) in each analyzed sample are presented in Table 2.

Discussion

The presence of counterfeit medicines on the market, particularly counterfeit sildenafil citrate products marketed under names such as Viagra, represents a significant public health concern. These products may fail to provide the intended therapeutic effect and can expose consumers to harmful or undeclared ingredients.

In this study, a high-performance liquid chromatography (HPLC) method was developed and

Table 2. Assay of active pharmaceutical ingredient (API) and content of related impurities (%) in the analyzed sildenafil samples.

Product	Assay (% of label claim)	Impurity A (%)	Impurity B (%)	Impurity C (%)	Impurity D (%)	Total impurities (%)
FAST4S	**105.62**	0.01	0.03	0.01	0.01	0.06
NIZAGRA	**82.82**	0.01	**1.31**	0.06	–	**1.38**
BLACK COBRA	**89.10**	0.02	**0.31**	0.03	**0.57**	**0.93**
PUNERGY	94.29	0.02	0.02	0.02	–	0.06
PUREGREY	**91.29**	0.02	**1.05**	0.03	–	**1.10**
SIL FIX	95.81	0.01	0.03	–	–	0.04
SUPERGRA	**89.86**	0.03	0.18	0.04	**0.34**	**0.59**
VEGERA	99.13	–	0.05	0.05	–	0.10
YOGA 100	**88.37**	–	**0.82**	0.01	–	**0.83**
VIAGRA (princeps)	99.98	–	0.01	ND	–	0.01
VIGOREX (generic)	99.63	–	0.01	0.01	–	0.02

Notes: Bold values indicate results exceeding USP acceptance criteria (≥0.20% for any individual impurity or ≥0.50% for total impurities). ND = Not detected; – = Below the limit of detection.

validated for the quantification of sildenafil citrate and the determination of its related impurities in suspected counterfeit drug samples. The use of a Lycospher C18 column with an acetonitrile–ammonium acetate mobile phase allowed efficient separation of sildenafil and its impurities within approximately seven minutes, with selective detection at 240 nm. Validation parameters, including linearity, precision, accuracy, limit of detection (LOD), and limit of quantification (LOQ), confirmed the robustness and reliability of the method, making it suitable for regulatory surveillance and routine quality control.

The results obtained from nine counterfeit samples were concerning: 44 % did not comply with the United States Pharmacopeia (USP) assay requirements (90–110 % of label claim), and 77 % failed to meet the stricter European Pharmacopoeia (EP) criteria (95–105 %). Most products were underdosed, suggesting that they would likely be therapeutically ineffective and could jeopardize patient safety. Impurity profiling further revealed that impurity B (sildenafil N-oxide) exceeded the USP limit of 0.2 % in four counterfeit products (NIZARGA, BLACK COBRA, PURGREY, and YOGA 100), reaching a maximum of 1.3 % in NIZARGA. Impurity D exceeded the limit in two products (BLACK COBRA and SUPERGRA), whereas impurities A and C remained below 0.2 % in all samples. The total impurity content was greater than 0.5 % in five counterfeit products, indicating poor manufacturing control and possible use of substandard raw materials rather than degradation during storage, since sildenafil is known to be thermostable.

Our findings are consistent with international reports. Veronin et al. showed that 4 of 15 sildenafil tablets purchased online in the USA contained impurity B above ICH qualification thresholds, while Akmal Taher and Arini Setiawati reported that 64 % of 106 counterfeit tablets in Indonesia contained ≤ 50 mg of sildenafil per tablet. Studies conducted in Luxembourg, the UK, and the Netherlands also demonstrated high rates of underdosing and non-compliance with pharmacopeial standards. Taken together, these data confirm that substandard sildenafil products represent a persistent global issue.

The widespread availability of counterfeit sildenafil highlights the urgent need for tighter regulatory control, routine analytical monitoring, and enforcement of Good Manufacturing Practices (GMP) to protect consumers. Although this study did not include comparative dissolution or other pharmaceutical performance testing, and the sample set may not fully represent the entire market, particularly in regions where sildenafil-containing traditional preparations are used—its findings clearly demonstrate that counterfeit sildenafil products often contain subtherapeutic API levels and elevated impurities, posing a dual risk of treatment failure and exposure to potentially harmful substances.

Conclusion

This study examined eleven brands of sildenafil tablets obtained from informal street markets and assessed both the purity and concentration of the active pharmaceutical ingredient (API). The majority of the samples were found to be substandard, with low sildenafil content and elevated levels of impurity B exceeding USP limits. These findings underscore the potential health risks of consuming counterfeit sildenafil products, including therapeutic inefficacy, adverse reactions, and the possibility of misuse.

The results provide valuable insight into the quality of illicitly distributed and imported counterfeit medicines. However, the broader public health implications remain insufficiently characterized and require further investigation. The data emphasize the urgent need for stronger regulatory enforcement, comprehensive market surveillance, and public awareness campaigns to reduce the circulation and use of substandard and falsified medicines.

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