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RESEARCH ARTICLE

COMPARATIVE STUDY OF THREE BRANDS OF SILDENAFIL CITRATE TABLETS IN SUDANESE MARKETS

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Abstract

Aim and Objectives: This study assessed the quality of Sildenafil citrate tablet products, whether locally produced or imported, available in the Sudanese market, aiming to determine their potential interchangeability in clinical use.
Methods: The quality evaluation of the drug products covered physical and organoleptic characteristics, along with tests for weight variation, friability, hardness, disintegration time, dissolution profile, and determination of Sildenafil content. The assay was performed using the standard HPLC method.
Results: Findings indicated that the similarity between brand E & F was noticed in color, shape, film coat and weight, brand E, friability and hardness results were acceptable, the dissolution result showed that the peak release of the drug is between 30-45 minutes, disintegration of the tablet was not faster than brand F but shorter than brand S. Brands E and S were found to be containing more that the assumed concentration of Sildenafil citrate (50 mg).
Conclusion: The finding of this research clearly notes that the range of the active ingredient content in two brands out of the three is obviously way above limits. USP states that the tablet assay range flouts between 90-110%. Sildenafil is now widely prescribed for pulmonary hypertension in children here in Sudan, and it has been used with a high success ratio in this field, so the dosing system should be carefully measured, and without a proper Q.A, Q.C testing of the brands itself, it could lead to a very dangerous consequences.
Keywords: Disintegration, dissolution profile, drug products, quality assessment, Sildenafil, Sudan.

INTRODUCTION

Sildenafil citrate is a highly potent and selective inhibitor of phosphodiesterase type 5 (PDE5)[1,2]. Chemically, it is designated as 1-[[3-(6,7-dihydro-1-methyl-7-oxo-3-propyl-1H-pyrazolo[4,3-d]pyrimidin-5-yl)-4-ethoxyphenyl]-sulfonyl]-4-methyl-piperazine citrate, with a molecular weight of 666.7 for the citrate salt and 474.6 for the base form. This amphoteric compound exhibits two pKa values: 9.84 for the NH-piperazine group and 7.10 for the NH-amide within the pyrazolopyrimidine ring[3].

Sildenafil influences nitric oxide (NO) and cyclic GMP pathways and is employed in managing various cardiovascular conditions. More recently, it has been approved for treating pulmonary arterial hypertension, where oral administration of 20 mg in adults or 1–5 mg/kg three times daily in pediatric patients has shown positive therapeutic outcomes[4,5].

On 27 March 1998, the U.S. Food and Drug Administration approved Sildenafil citrate for the treatment of male erectile dysfunction (ED). Its introduction to the global market was met with considerable media attention, marking a breakthrough for men affected by ED, a condition impacting an estimated 10% of the male population and up to 52% of men aged 40–70 years. Following its release, Sildenafil became the fastest selling pharmaceutical in history. The drug was first synthesized by a research team at Pfizer's Sandwich facility in Kent[6].

Phosphodiesterases (PDEs) are a group of isoenzymes that hydrolyze cAMP and cGMP. Selective inhibitors for specific PDE subtypes have been identified, enhancing the action of cyclic nucleotides on target tissues, such as human spermatozoa[7]. Sildenafil citrate,

a recently developed PDE5-specific inhibitor, prevents cGMP degradation and enhances NO- mediated relaxation of vascular smooth muscle, yielding notable clinical success in ED management[8]. Beyond erectile dysfunction, Sildenafil is widely used for pulmonary hypertension and angina, ranking among the most prescribed drugs globally[9]. In the first six months after launch, over six million prescriptions were issued. Contrary to common misconceptions, Sildenafil is not an aphrodisiac, does not induce effects without sexual stimulation, and does not increase potency in men without ED[10].

Over the past decade, more than twelve Sildenafil brands have been registered in Sudan, originating from manufacturers in India, Syria, Jordan, Europe, Egypt, and Sudan. Differences in source materials, excipients, coloring agents (often used for brand differentiation), quality control standards, and purity of the active ingredient as well as significant price variations exist among these products.

This study was conducted to perform organoleptic evaluations and comparative analysis of both official and non-official quality control parameters, including friability, hardness, drug content uniformity, weight variation, and in vitro dissolution profiles, for Sildenafil tablets available in the Sudanese market. The findings aim to aid pharmacists and healthcare professionals in assessing potential product interchangeability.

MATERIALS AND METHODS

Sildenafil reference material was generously supplied by Tabuk Pharmaceuticals, Sudan. Three commercially available brands of Sildenafil citrate tablets (50 mg) were obtained from community pharmacies in Khartoum, Sudan. Each sample was verified for stated dose, manufacturing license, batch number, and manufacturing and expiry dates, and was coded as F, S, and E. The chemicals used including ethanol, sodium hydroxide, distilled water, and acetonitrile along with all other solvents and reagents, were of analytical grade.

Pharmaceutical evaluation of Sildenafil citrate tablet formulations

The study included both official and non-official quality control tests conducted on various marketed brands of Sildenafil[11].

Weight variation test

For the weight variation test, twenty tablets were randomly selected, and their average weight was calculated. Each tablet was then individually weighed and compared with the mean value. As per USP (2016) specifications, the batch complies if no more than two tablets deviate from the average weight by ±5%, and none deviate by more than twice this percentage[9].

Hardness test

Tablet hardness, which reflects their resistance to breakage during storage, transport, and handling, was evaluated for each formulation using a Monsanto hardness tester. Measurements were expressed in kg/cm², and the procedure was carried out in accordance with USP (2016) guidelines[9].

Friability test

Friability, an indicator of tablet mechanical strength, was evaluated using an Erweka Friabilator. Twenty tablets were accurately weighed and placed in a rotating drum operating at 25 rpm, causing them to fall a distance of six inches with each turn. After 4 minutes, the tablets were reweighed and the percentage weight loss was calculated. According to USP (2016) standards, conventional compressed tablets are considered acceptable if the weight loss is below 0.5–1.0%[8].

Thickness test

Tablet thickness was measured using a vernier caliper. Ten tablets from each formulation were tested, and the mean values were determined. The procedure followed USP (2016) specifications[10].

Disintegration

Disintegration time was determined for six randomly selected tablets from each brand using an Erweka tablet disintegration tester (Type ZT3/1, Heusenstamm, Germany) in distilled water maintained at 37±0.5 °C. The endpoint was reached when no residue remained on the basket. The time taken for each tablet was recorded[10].

Dissolution

Dissolution testing was performed using the basket method in accordance with USP guidelines, operating at 100 rpm in a 100 ml water bath maintained under sink conditions at 37±0.5 °C. For the standard solution, 10 mg of pure Sildenafil was transferred to a 250 ml volumetric flask, dissolved in 200 ml of medium with the addition of 25 ml of 1 N sodium hydroxide, and then diluted to volume with the same medium[8].

Sample Solution

A portion of the test solution was filtered through a 0.45 mm pore size membrane. From the filtrate, 20 ml was transferred into a 25 ml volumetric flask, followed by the addition of 2.5 ml of 1 N NaOH solution, and dilution to volume with the medium. Absorbance was measured at 289 nm using a UV spectrophotometer, with the blank prepared by adding 2.5 ml of 1 N NaOH to a 25 ml volumetric flask and diluting to volume with the medium. Both the standard and test solutions were warmed to 50 ± 1 °C for 45 minutes, then immediately cooled to room temperature before determining absorbance. The actual Sildenafil concentration was calculated from the corresponding absorbance values.

Quantification of Sildenafil tablets by HPLC

The chromatographic system comprised a Model 616 pump, Model 996 diode-array detector, and Model 717+ auto-sampler (all from Waters, Milford, MA, USA). Separation was achieved on a Separon² SGX C18 octadecyl silica cartridge column (15.3 mm I.D., 7 µm particle size). The mobile phase consisted of acetonitrile and water (35:65, v/v) containing 0.1% TFA, delivered at a flow rate of 1.0 ml/min.

Infra-Red Identification

The IR identification is of importance in Q.C testing to first insure that the active ingredient is present in the sample in question. IR Spectrophotometer identifies groups that are related to the compound we need to analyze. The spectrum measurement was carried in two

different forms, the first one was the STD Sildenafil powder in its most pure form, the second was done using the solvent used in the analytical procedure (Methanol: Water 50:50) in the solution form for the standard material and the samples as well. The sample preparation was carried out in the same process and conditions of HPLC sample preparation.

Statistical Analysis

Results were reported as mean ± standard deviation, calculated using Microsoft Excel 2010. Statistical analyses were carried out with SPSS software, version 20.0 for Windows (SPSS Inc., September 2011).

RESULTS AND DISCUSSION

Brand E : Similarity between Brand E & F was noticed in color, shape, film coat and weight, brand E , friability and hardness results were acceptable, the dissolution result showed that the peak release of the drug is between 30-45 minutes, disintegration of the tablet was not faster than brand F but shorter than brand S. The content percent of the active ingredient of this brand was found (120.3%) to be high and also in the dissolution test. HPLC results it was found to be higher than the acceptable range of tablet assay.

Brand F: This Brand showed the best results in the physical and chemical testing, hardness was in a fair measure, dissolution showed the peak at the official rate 30-45 min. and the disintegration was very rapid. However, the content of the tablet in the HPLC method of assay were found (88.7%) to be beyond the assumed concentration.

Brand S: Had a small weight compared with the other two brands, this have positive effect on decreasing the amount of excipient patient should take but the back draws of it that it could affect the mixing, rendering, hardness, friability and formulation in the manufacturing process.

Also it showed a very small hardness value therefore this can negatively affect its packing, transforming and it could be easily chipped, capped or broken. Disintegration of the tablet was found to be in a very long period of time, this affects the release, bioavailability and absorption of the drug.

Table 1: Quality control evaluation of Sildenafil citrate marketed tablets.

Code	Weight Variation (%)	Friability (%)	Hardness	Disintegration time (Minutes)
F	0.309±0.003	0.095±0.25	11.17±1.44	3:01
E	0.347±0.03	0.051±0.55	4.30±1.32	4:33
S	0.2267±0.09	0.115±0.36	10±2.13	7:02

Table 2: Dissolution profile of marketed Sildenafil citrate tablets.

Code	Release %				
	5 minutes	10 minutes	15 minutes	30 minutes	45 minutes
F	58.34	59.02	69.26	112.11	102.12
S	58.98	59.27	74.62	132.7	131.90
E	57.76	57.08	67.80	104.21	97.34

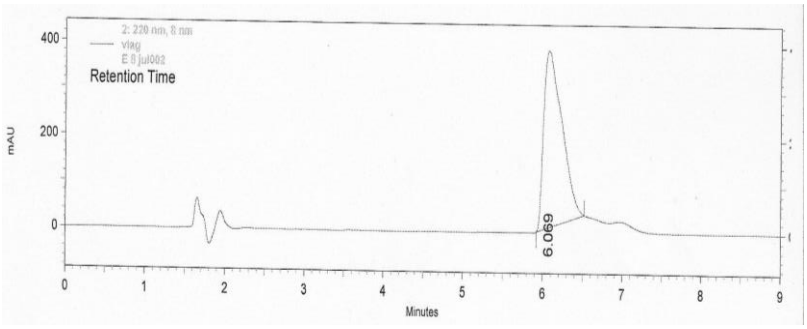

Figure 1: Characteristic chromatogram using HPLC-method of brand E.

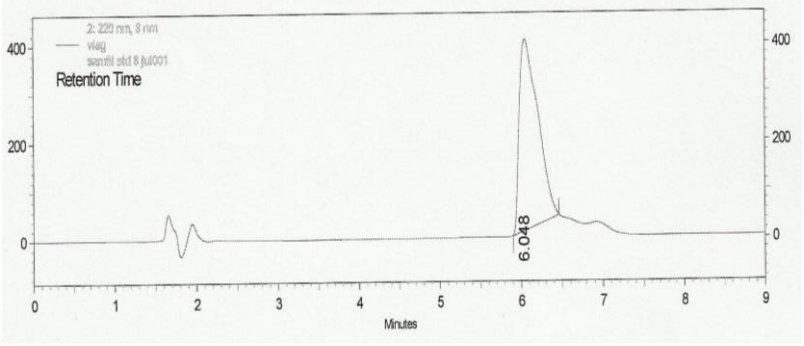

Figure 2: Characteristic chromatogram using HPLC-method of brand S.

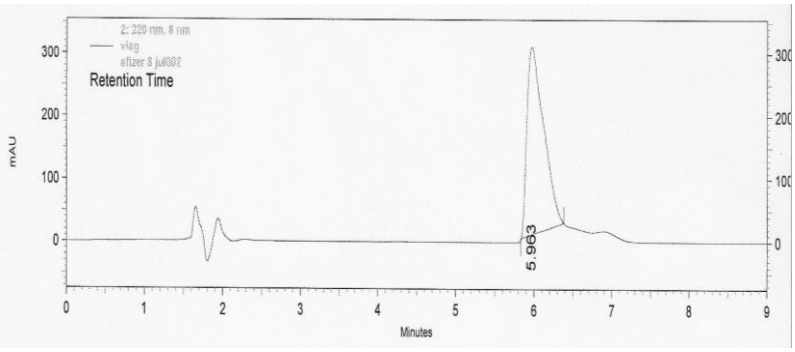

Figure 3: Characteristic chromatogram using HPLC-method of brand F.

The brand also showed a high content of the active ingredient (123.8%) in the method applied in this research along with the third application in the dissolution test significantly above the limits of assay.

Limitations of the study

The study should have covered all Sildenafil brands available in Sudan, from the practical aspect further test such as Kinetic analysis of the Sildenafil brands must be established and calculated.

CONCLUSIONS

Brands E & S were found to be containing more that the assumed concentration of Sildenafil citrate (50 mg) by an HPLC method which is more reliable and accurate. The finding of this research clearly notes that the range of the active ingredient content in two brands out of the three is obviously way above limits. USP states that the tablet assays range flouts between 90–110%. Sildenafil is now widely prescribed for pulmonary hypertension in children here in Sudan, and it has been used with a high success ratio in this field, so the dosing system should be carefully measured, and without a proper Q.A, Q.C testing of the brands itself, it could lead to a very dangerous consequences.

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AUTHORS' CONTRIBUTION

Magbool FF: conceived the research idea, experimental work. **Sami AA:** conceived the research idea, experimental work. **Osman Z:** drafting of manuscript. **Gami AM:** editing, review. **Ibrahim MA:** supervision. Final manuscript was checked and approved by all authors.

DATA AVAILABILITY

Data will be made available on request.

CONFLICT OF INTEREST

None to declare.

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