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Original Article

PHYSICOCHEMICAL ANALYSIS AND COST COMPARISON OF DIFFERENT LOCAL AND MULTINATIONAL BRANDS OF SITAGLIPTIN AVAILABLE IN PAKISTAN

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ABSTRACT:

The main objective of this study was to determine that various generic sitagliptin products from local and multinational brands competing in the local market are pharmaceutical equivalents. A physicochemical comparison was conducted on local and international brands of sitagliptin tablets gathered from local drug outlets of Hyderabad, Pakistan. A total of 5 sitagliptin brands were taken and globally accepted in-vitro tests were performed at Industrial pharmacy laboratory of Department of Pharmaceutics, Faculty of Pharmacy, University of Sindh, Jamshoro Pakistan, during period August 2021 to August 2022. All the sitagliptin products obtained from local market were fulfilling the quality standards required by BP for tests of weight uniformity, diameter, thickness, hardness, friability, disintegration, and World Health Organization (WHO) standards for tests of dissolution and content uniformity/assay. All sitagliptin generics from different local and multinational manufacturing companies are pharmaceutical equivalents and may be prescribed as an alternate to each other.

Keywords: Antidiabetics, Sitagliptin, Quality, Pharmaceutical Equivalents

INTRODUCTION

Diabetes mellitus (DM) is a metabolic disorder that affects the body's ability to regulate glucose levels. It is characterized by high glucose levels in the bloods caused by either inadequate insulin production or by the reduced body's response towards insulin at receptors (ie insulin resistance). It is mainly classified into two types type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM)(1). The global burden and incidence of diabetes mellitus are high, and it is estimated that the number of people affected will continue to rise. In Pakistan, it was reported that 7 million people confirmed to have DM in 2007, and this count is thought to increase to 14.5 million by 2025(2). The International Diabetes Federation predicts that by 2030, over 643 million people will have diabetes mellitus worldwide(3). Managing type 2 DM involves six classes of oral antidiabetic medications, such as sulfonylureas, meglitinides (Glinides), thiazolidinediones, biguanides, dipeptidyl peptidase IV (DPP-IV) inhibitors, and α-glucosidase inhibitors(4, 5).

Pharmaceutical manufacturer when design a drug, it is marketed under the brand name of the innovator company and protected by intellectual property rights for a period of about 12 years. After this period, Food and Drug Administration (FDA) requires generic brands to carry the active pharmaceutical ingredient (API), doses, dosage form, and its administering mode like the inventor's drug product. Generics must ascertain and show that their brand is equivalent to the original drug product of inventor. Each pharma company's packing and QC areas should meet the equal quality standards to the original product. Generic drugs are typically 80-85% less expensive than their innovator counterparts, making them more affordable for patients. However, this lower price should not come at the expense of quality. Multiple me too formulations increases the likelihood of issues in overall quality(6). Generic medicine brands carry risks bioequivalence results and may also show dissolution profiles, resulting in suboptimal effectiveness in patients(7). Therefore, most medical doctors in Pakistan choose international pharma products, but cost still remains a significant matter to consider. Many prescribers also affirm that prescribing patterns are influenced by pharma companies(8). This research aims to evaluate available brands of Sitagliptin tablets in the local pharmacies. Additionally, the research seeks to identify any low-quality brands. The study was conducted to do a qualitative comparison of OADs of local and international pharmaceutical industries.

METHODS

To determine the quality of sitagliptin by performing physicochemical tests such as test for physical appearance, weight uniformity, thickness and diameter of tablet, disintegration, dissolution and assay. British Pharmacopoeia and WHO criteria for acceptance of quality were used to compare the inferences. Foremost importance was given to all sitagliptin brands that is available in the local market and most frequently used as a treatment. Following were the sitagliptin drug products randomly obtained from the pharma market of Hyderabad, Sindh, Pakistan for the study. Data shown in research is of the drug products obtained and analyzed between August 2021 to July 2022 at Laboratory of Industrial pharmacy situated at Department of Pharmaceutics, University of Sindh, Jamshoro. Sitagliptin brand obtained from drug stores was from Multinational/innovator pharma named as; Sample 01, whereas four generics were of local pharma and coded as; Sample 02, Sample 03, Sample 04 and Sample 05.

Aesthetic test

The appearance of the tablet and existence of any contaminating particles in the drug product were examined by eye. For Tablets having film coat (also known as FCTs), perfectness of coating was also ascertained.

Weight Variation

The weight variation test for the tablets was conducted using a Shimadzu AY220 weighing balance. To perform the test, 20 tablets randomly selected from the commercial pack and individually weighed. Then average weight was taken. The maximum and minimum control limits were then calculated based on the allowed deviation. Only 2 out of 20 tablets were allowed to exceed the permitted range, and no tablet was allowed to exceed twice the allowed limit. Limit was ±10% for tablet weighing ≤80mg, ±7.5% for >80mg and <250 it was, and ±5% for >250mg.

Dimensions

To determine the thickness and diameter of the tablets, a Digital Vernier caliper was used as the equipment. Ten tablet samples were drawn from their blister packs, and the thickness and diameter of each tablet were measured individually. The tablets were placed in the jaws of the Digital caliper, and the obtained deviation from the average thickness of the ten tablets was within ±5%. For tablets, allowed limit was ±5% for diameter up to 12.5mm, while ±3% for diameter above 12.5mm.

Hardness

Not applicable to film coated tablets

Friability

Not applicable to film coated tablets

Disintegration test

USP Disintegration Apparatus was used to test the disintegration time of samples. 6 tablets/brand were drawn for testing. In case disintegration of all the tablets occur in the time specified, results were considered compliant, and if one tablet disintegration time exceeds the allowed limit of time, the test was repeated with 12 more tablets. If 16 out of 18 units completely disintegrated, it shows compliance. Distilled water as the test medium, and a 15minute disintegration time limit for uncoated, 30 minutes for film-coated, and one hour for sugar-coated tablets. The temperature of the medium was controlled at 37°C ±2°C during the test.

Dissolution test

Basket method/USP Dissolution apparatus type I was used for dissolution testing. Dissolution medium used was Water. Both beakers/vessels of dissolution assembly got filled with water to 900ml and maintained to 37°C (±0.5°C). One tablet was inserted to each of baskets and was stroked at 100rpm for 30 minutes. Post 30 minutes, 5ml solution was drawn from each of the two vessels and filtration was carried out through syringe filter 0.45µm. Simultaneously water equivalent to sample drawn was refilled in the vessels. Quantity of Sitagliptin in dissolution medium was then quantified. The acceptable criteria is eight percent of the drug should release within thirty minutes.

Preparation of Standard solution

Standard 10µg/mL solution was prepared by sonicating (10mg) Sitagliptin in 50mL of 0.1N HCl for 10 minutes and then volume made up to 100ml to give 100µg/ml concentration with 0.1N HCl. 1mL of aliquot were poured in 10mL volumetric flask and added with 0.1N HCl to yield 10µg per ml concentration. At the end, drug concentration was quantified by getting absorbance at 268nm. 0.1N HCl was used as blank.

Assay

Perkin Elmer UV/Visible Spectrophotometer ƛ25 was utilized for the content uniformity test. For determination of drug samples, 20 tablets were taken of each brand and was weighed and powdered. The powdered drug equal to

100mg Sitagliptin was taken in 100mL flask already containing 50mL 0.1N HCl. The mixture was then homogenized using sonicator for 15 minutes. Final volume was made using 0.1N HCl to 100µg/mL. At the end it was clarified via (0.45µm) disc filter. 1ml filtrate then transferred by A-grade pipettes in 10mL flasks. Final volume of the solutions were made with 0.1N HCl to produce concentration of 10µg/mL. The produce sample solution was then quantified for the sitagliptin(9). The process is summarized in Figure 1.

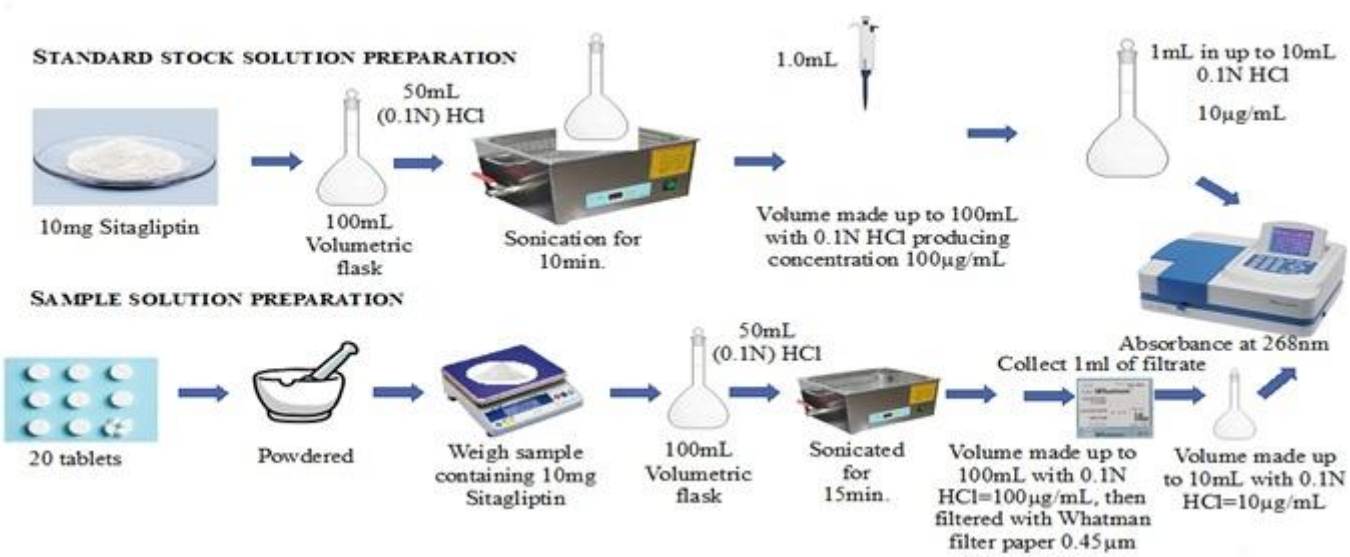


Figure 1. Protocol of Assay of Sitagliptin

Statistical methods

Statistical analysis was performed using statistical package for social science (SPSS) version 20.0. All the categorical variables were presented as frequencies and percentages.

RESULTS

The collected samples of sitagliptin were within their mentioned expiry date. The aesthetic test revealed that the dosage forms were in perfect condition, showing no signs of damage or cracks. The surface appeared smooth, and there were no visible contaminants present. During the test for weight variation, all twenty tablets demonstrated compliance with the allowed 5% limit in weight as specified in the test. Additionally, in the dimension assessment, all 10 tablets met the specified limits, with an allowed variation of 5%. For more detailed observations of weight variation and tablet dimensions, a summary is given in Table1.

During the test for disintegration, all 6 tablets eroded within half hour. Table 2 presents the average disintegration time. Dissolution test also showed compliance as mentioned in Table 2. Assay result also showed that drug products of all brands were within their specified limits. The results of the assay can be found in Table 2 and Figure 2.

Table 1. Results of weight uniformity and thickness and diameter of the tablets

Sample	Average Weight (mg)	SD	Allowed limit (±5%)	UCL	LCL	No. of samples complied
Weight variation						
Sample-01 (International)	413.73	±2.929	20.69	434.42	393.04	20/20
Sample-02 (Local)	394.93	±2.125	19.75	414.68	375.18	20/20
Sample-03 (Local)	306.89	±1.072	15.34	322.23	291.54	20/20
Sample-04 (Local)	434.68	±3.431	21.73	456.41	412.94	20/20
Sample-05 (Local)	325.92	±4.253	16.30	342.22	309.63	20/20
Thickness						
Sample-01 (International)	4.42	±0.035	0.22	4.64	4.20	10/10
Sample-02 (Local)	5.02	±0.048	0.25	5.27	4.77	10/10
Sample-03 (Local)	3.66	±0.043	0.18	3.84	3.48	10/10
Sample-04 (Local)	4.84	±0.060	0.24	5.08	4.60	10/10
Sample-05 (Local)	3.56	±0.077	0.18	3.74	3.38	10/10

Diameter						
Sample-01 (International)	10.02	±0.033	0.50	10.52	9.52	10/10
Sample-02 (Local)	9.07	±0.048	0.45	9.52	8.62	10/10
Sample-03 (Local)	10.13	±0.036	0.51	10.64	9.62	10/10
Sample-04 (Local)	10.17	±0.060	0.51	10.68	9.66	10/10
Sample-05 (Local)	9.90	±0.064	0.49	10.39	9.40	10/10

* SD=Standard Deviation, UCL=Upper Control Limit, LCL-Lower Control Limit

Table 2. Results (hardness, friability, disintegration, dissolution and assay test)

Sample	Average Hardness and Friability	Disintegration Test	Dissolution test (30 minutes)	Assay	Cost comparison of Local vs Multinational brands
Sample 01	N/A	8 minutes and 52.3 seconds	83%	102.19%	Local brands were 58-66% economical than multinational brands
Sample 02		7 minutes and 56.8 seconds	87%	97.33%	
Sample 03		9 minutes and 22.5 seconds	82%	92.80%	
Sample 04		9 minutes and 35 seconds	88%	101.14%	
Sample 05		7 minutes and 44.6 seconds	86%	96.10%	

DISCUSSION

The effectiveness of medications in treating patients depends on the quality and amount of the API contained in the drug product. To ensure that the medications meet the required standards, conventional quality assessment involves an examination and measurement approach in quality control. This process ensures that the medications adhere to predetermined standards of quality. Quality is essentially the degree to which a particular substance conforms to a reference or standard. In the context of pharmaceutical manufacturing and quality assurance, the concept of quality has significantly evolved from a narrow perspective. Presently, the accepted definition of quality emphasizes "fitness for purpose," indicating that the focus is on ensuring the product's suitability for its intended use(10).

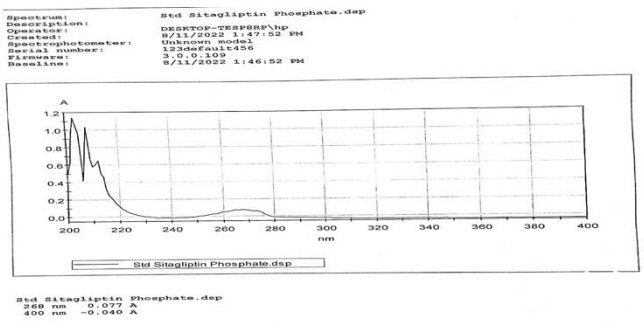
This research aimed to assess the quality of various products of sitagliptin. The findings concerning appearance and dimensions fell within the acceptable limits, aligning with the results of previous research done on sitgliptin in Pakistan and Yemen(11, 12). Nebal and Haider in 2014 in a study showed Sitagliptin generic products quality against Innovator's Sitagliptin. Hence, 5 different products were taken from Middle East drug stores. The physicochemical tests' results were juxtaposed to specifications laid down by USP31.Finally proved that generic brands were equivalent to innovator(12).

Moreover, in a study conducted by Tarkase, K., et. al. (2014) on sitagliptin tablets shown that the method developed for qualitative and quantitative assessment of sitagliptin was effective for cheaper analysis of sitagliptin brands and estimation of sitagliptin in its supplied form was efficiently done. Hence, with these assay test methods, the brands tested in this study also complied to allowed limits of content uniformity test(9).

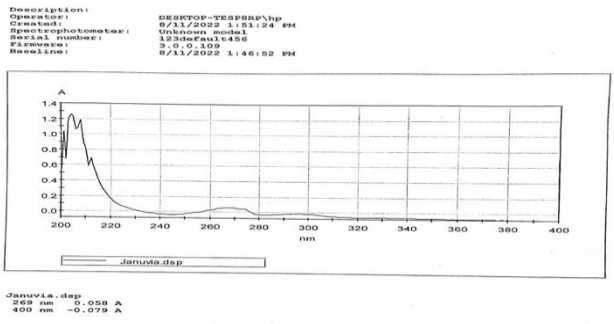
Additionally, it was shown that sitagliptin is a very efficient medicine in the control of diabetes mellitus type II, hence the quality equivalency shown in this study between generic and innovator brands conforms that local brands are expected to work as innovator brand(13).

WHO require drug products to contain 95-105 percent of the drug entity in the medication at the time of release of product from the manufacturers' site, and once it reaches commercial shelves should at least contain 90-110% of the active chemical entity, hence this study concluded with the results which were in consonance with the guidelines proposed by the WHO and the local and international brands were therapeutically comparable(14).

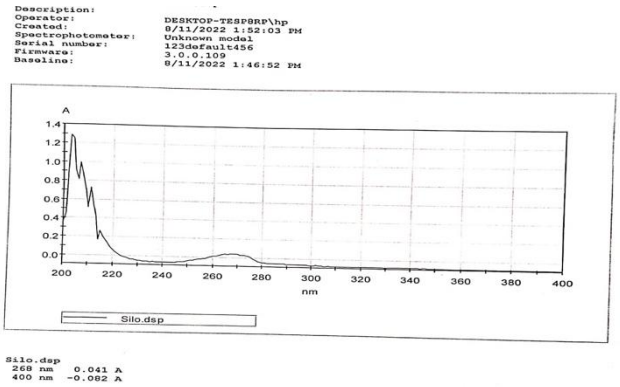
ASSAY SPECTRUMS



Standard



Sample 1



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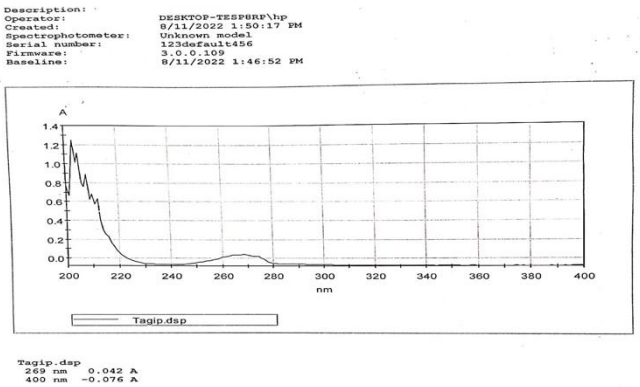

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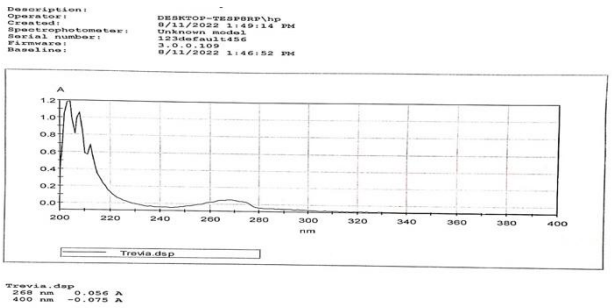
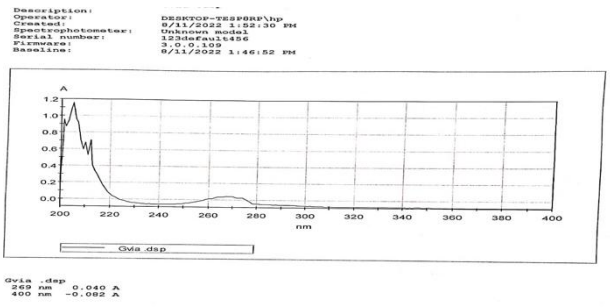


Sample 4



Sample 5

Figure 2: Spectrogram of Assay of 5 brands of Sitagliptin along with standard

CONCLUSION

All the sitagliptin samples collected from the local market were complying with the standards given in British pharmacopoeia and WHO at the very moment when selected for weight uniformity, thickness, diameter test, disintegration, dissolution and assay were conducted. In this study, no substandard or counterfeit brand emerged. The medicinal products from local and multinational brands may be regarded as pharmaceutical equivalents and can be prescribed as an alternate choice to each other.

Conflict of Interest

Authors declare no conflict of interest.

Ethical consideration

The study involved only laboratory testing of oral antidiabetics and did not required approval of research ethics committee as no animal/human subjects or their data was used.

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