Content available at: https://www.ipinnovative.com/open-access-journals

Current Trends in Pharmacy and Pharmaceutical Chemistry

Journal homepage: https://www.ctppc.org/

Original Research Article

Comparative in-Vitro dissolution study of some sitagliptin generic tablets under biowaiver conditions by UV-Spectroscopy

Vaibhav S. Adhao[1]*, Jaya P. Ambhore[1], Anant D. Bhuskat[1], Dishali V. Talokar[1]

[1]*Dept. of Quality Assurance, Dr. Rajendra Gode College of Pharmacy, Malkapur, Maharashtra, India*

ARTICLE INFO

Article history:
Received 18-05-2024
Accepted 28-06-2024
Available online 07-09-2024

Keywords:
Sitagliptin
Dissolution study
Biowaiver
Antidiabetic
Bioequivalence
UV spectroscopy

ABSTRACT

Purpose: The objective of this study is to evaluate the bioequivalence of generic sitagliptin tablets from different manufacturers using in-vitro dissolution study under biowaiver conditions through UV Spectroscopy, and compare them with the innovator brand.
Materials and Methods: The dissolution media consisted of three different buffers with varying pH levels, including HCl Buffer pH 2.0, Phosphate Buffer pH 4.0, and Phosphate Buffer pH 7.2. The dissolution process was conducted using a USP type-2 dissolution apparatus with a 900 ml basket. The rotational speed of the paddle was set at 50 RPM, while maintaining a temperature of 37.5°C +/- 2°C. Samples were collected at four different intervals as recommended by the USFDA, which were 15, 30, 45, and 60 minutes.
Results: Validation parameters such as Accuracy, Precision, Linearity, LOD, and LOQ were assessed. The dissolution profiles exhibited no significant variability between different brands and within the same brand. Furthermore, the dissolution results of all tablet formulations, including the innovator brand, were analysed using the difference factor (f1) and similarity factor (f2).
Conclusion: The findings from this study indicate that both generic brands of sitagliptin tablets meet the USFDA dissolution specifications and can be considered interchangeable.

1. Introduction

Approximately 500 million individuals globally suffer with diabetes and diabetes-related deaths account for almost 1.5 million deaths annually. In 2019 there were 1.5 million deaths directly associated with diabetes, with 48% of these deaths happening before the age of 70.[1] The rate of increase in prevalence has been higher in middle-income and low-income countries compared to high-income nations. Diabetes or diabetes mellitus (DM) develops when the pancreas fails to secrete enough insulin or the body is unable to utilize the insulin that is produced to regulate glucose level in body. Apart from alterations in lifestyle, there exist multiple categories of pharmaceutical drugs that decrease blood glucose levels through diverse modes of action. Some of these include insulin, sulfonylureas, thiazolidinediones, biguanides like metformin, meglitinides, insulin agonists like pramlintide, and analogues of glucagon-like peptide-1 (GLP-1) eg, exenatide. The first medication in a novel class that

blocks dipeptidyl peptidase-4's (DPP-4) proteolytic action is sitagliptin. sitagliptin makes strides glycaemic control by hindering DPP-4 inactivation of the incretin hormones glucagon like peptide-1 (GLP-1) and glucose–dependent affront tropic polypeptide (GIP). This represses glucagon discharge from alpha cells and moderates the assimilation of supplements into the blood stream and encourage causes an increment within the sum of affront discharge from beta cells.[2] It was approved by the US FDA for the treatment of type 2 diabetes mellitus in

* *Corresponding author*.
E-mail address: adhao.vaibhav@gmail.com (V. S. Adhao).

https://doi.org/10.18231/j.ctppc.2024.025

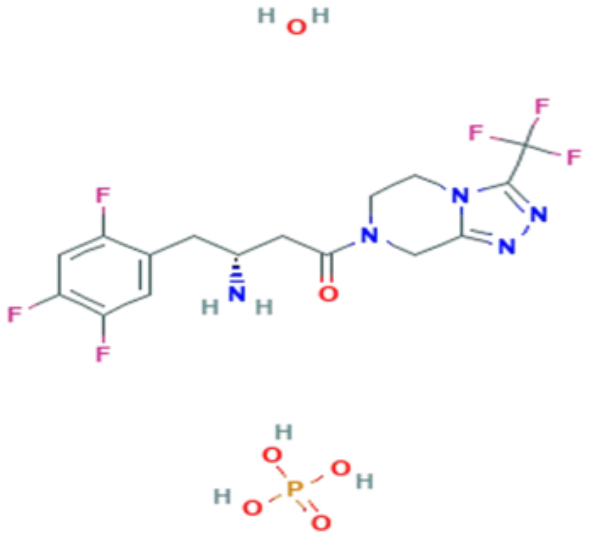

Figure 1: Chemical structure of sitagliptin

October 2006.

Sitagliptin phosphate monohydrate is chemically (3R)-3-amino-1-[3-(trifluoromethyl)-6,8-dihydro-5H-[1,2,4]triazolo[4,3-a]pyrazin-7-yl]-4-(2,4,5-trifluorophenyl)-butan-1-one-phosphoric acid; hydrate having molecular formula $C_{16}H_{20}F_6N_5O_6P$. Because hydrates are often more prevalent than water vapor, the formation of hydrates is very important in the pharmaceutical industry.[3] In individuals with type 2 diabetes, sitagliptin lower glucagon levels and boost insulin secretion, which lowers fasting glucose concentrations. Table 1 discusses a few chemical parameters.

The dynamic process of dissolution involves the migration of the dissolving solid's constituent molecules through a diffusion layer from the surface to the bulk solution. The dissolution test of drugs has been employed as an excellent tool to detect formulation problems that could change drug release in the body. Numerous factors, such as the drug's physicochemical characteristics, dosage form formulation, and manufacturing process, affect how well a drug dissolves from its dosage.[4] The ability of oral solid dosage forms to continuously and effectively release the active ingredients in aqueous medium, allowing the active compounds to be absorbed through the gastrointestinal tract. Two important factors for absorption are a drug's permeability and solubility. The potential for in vitro–in vivo correlation is evaluated by using the BCS classification. Thus the purpose of this study is to determine drug release patterns of marketed tablets of different brands by using UV analysis.

Prior to commencing the practical study, we conducted a brief survey on the available literature. It is worth noting that there has been limited research conducted on sitagliptin.[7] This monograph examines the use of the BCS to evaluate

Table 1: Physiochemical properties of sitagliptin.[5,6]

Sr. No.	Parameters	Description
1.	Molecular formula	$C_{16}H_{20}F_6N_5O_6P$
2.	Molecular weight	523.32 g/mol
3.	Chemical Abstracts Service (CAS)	654671-77-9
4.	Appearance	White to off-white, crystalline, non-hygroscopic powder
5.	Solubility	0.034 mg/mL
6.	Melting point	206.37°C
7.	pka	8.78
8.	λmax	230 nm

the bioequivalence of solid immediate-release oral dosage forms containing sitagliptin phosphate monohydrate. The study reviews solubility, permeability, dissolution, therapeutic index, applications, pharmacokinetics, pharmacodynamics, and interactions between the drug and excipients. The results suggest that the BCS-based biowaiver can be implemented for solid IR oral drug products containing sitagliptin phosphate monohydrate, provided the test product is formulated with approved excipients, and the test and comparator meet in vitro dissolution specifications. The researchers aim to design and evaluate a 50 mg tablet of Sitagliptin Phosphate using Response Surface Methodology.[8] Minitab 16 was used for RSM computations, resulting in 13 formulations. The study used Sodium Starch Glycollate and Croscarmellose Sodium as independent variables and the percent drug release at 15 minutes as dependent variables. Analytical technology was used to evaluate the formulations. The optimized tablet disintegrated in 14 seconds and showed an initial release of 99.072% within 15 minutes. Another researcher developed and validated a dissolution test for STG, and quantified by quantified by HPLC.[9] So focusing on in vivo-in vitro correlation the method was developed for dissolution study of sitagliptin. The method was tested for specificity, linearity, precision, and accuracy, and the stability of the sample in phosphate buffer pH 6.8 solutions for 24 hours. The method was linear, precise, and accurate, with a mean recovery of 98.51%. The developed method provides a good IVIVC for pH 6.8 phosphate buffer medium, useful for quality control of sitagliptin coated tablets.

2. Experimental

2.1. Instrumentation

The dissolution test was conducted using the ELECTROLAB Dissolution tester USP type-2 having 6 stations, specifically the TDL 08L model. The dissolution study sample was then analysed using the UV double beam spectrophotometer (SHIMADZU Model No. UV - 1800)

equipped with quartz cells. The sample was weighed using the WENSOR analytical balance Model no. MAB210.

3. Materials and Methods

The pure reference drug was gifted by Impulse Pharma Pvt. Ltd. which was further used as standard for the study. The marketed tablets of Sitagliptin phosphate monohydrate were purchased from local pharmacy store of different brands.

The necessary buffer solutions with different pH values were prepared by employing chemicals such as Di-Sodium hydrogen orthophosphate anhydrous of analytical reagent (AR) grade, potassium dihydrogen orthophosphate anhydrous, Hydrochloric Acid, Citric Acid, Glacial Acetic Acid and potassium chloride etc.

3.1. Methods

3.2. Preparation of HCl buffer pH 2.0

Making HCL pH 2.0 followed USP guidelines.[10] First, make the KCl solution by dissolving 0.745 grams of mixed KCl in 100 ml of water. In a 200 ml volumetric flask, add 50 ml of potassium chloride solution, 13 ml of 0.2 M HCl, and water upto 1liter.

3.3. Preparation of phosphate buffer pH 4.0

Phosphate Buffer pH 4.0 was made in accordance with IP. Using glacial acetic acid, first dissolve 5.04 g of disodium hydrogen phosphate and 3.01 g of potassium dihydrogen phosphate in enough water to make 1000 millilitres. Then, adjust the pH to 4.0. using glacial acetic acid.

3.4. Preparation of phosphate buffer pH 7.2

In accordance with USP[10], Phosphate Buffer pH 7.2 was prepared. Place 50 mL of the monobasic potassium phosphate solution in a 200-mL volumetric flask, add the 34.7ml volume of the 0.2M NaOH solution then add distilled water to make volume 1 Liter.

4. Preparation of Standard Stock Solution

Three distinct standard solutions were prepared using three distinct buffers. A 10 ml buffer solution was used to dissolve the medication equivalent to 10 mg. One logarithmic dilution of 1ml of this solution was used once more and at last, 3 ml were pipette out and diluted to make 10 ml, or 30 μg/ml of standard solution, which was then scanned at 267 nm.

4.1. Method validation

The reliability and accuracy of the developed method for sitagliptin analysis were meticulously assessed through a systematic method validation process as per the ICH Q2 (R1) guidelines. This essential step ensures that the analytical procedure is suitable for its intended purpose and complies with regulatory requirements. The method validation was performed for the linearity, accuracy, precision, and sensitivity (limit of detection (LOD) and limit of quantification (LOQ).[11–20]

4.2. Accuracy

The formulation solution of a constant concentration was spiked with pure drug solution (50%, 100%, and 150%) using the standard addition procedure in order to study accuracy. Percentage recovery and They computed the relative standard deviation.

4.3. Precision

The study of precision involved determining the mean, standard deviation, and relative absorbance of six solutions with identical concentrations (n = 6).

4.4. Linearity study

Initially, a sitagliptin stock solution was prepared for calibration sitagliptin phosphate monohydrate. A precise weight of 10 mg of pure sitagliptin was added to a volumetric flask, which was then filled to 100 ml with distilled water. A series of 10 ml volumetric flasks were filled with various aliquots of Sitagliptin at varying concentrations, such as 1, 2, 3, 4, 5, and 10 ml. The volume was then increased to the appropriate level using distilled water to obtain concentrations of 10, 20, 30, 40, 50, and 100 μg/ml, respectively. A spectrophotometer was used to scan the solutions in the 200–400 nm UV range. Using the spectrophotometer's UV-probe software, the spectrum was derivatized into first order, and the trough's amplitude was measured at 267 nm. The calibration plot was constructed as concentration vs. absorbance.

4.5. LOD and LOQ

In UV method development LOD & LOQ was determined by utilizing the following equation

LOD = 3.3 X SD/S

LOQ = 10 X SD/S

Where, S= Slope,

SD= Standard deviation of Y-intercepts.

4.6. Dissolution study

Three distinct sitagliptin tablets—Innovator, Generic 1 and Generic 2 were subjected to a comparative dissolution study in three different buffer media with varying pH levels. HCl Buffer pH 2.0, Phosphate Buffer pH 4.0, And Phosphate Buffer pH 7.2 were the three distinct media. Dissolution was carried out using a USP type-2 dissolution apparatus with a 900 ml basket. The paddle's rotational speed was

adjusted to 50 RPM. A temperature of 37.5°C +/- 2°C was maintained. The samples were collected at the four different intervals—15, 30, 45, and 60 minutes—that the USFDA recommended. 5 ml of an aliquot was taken out of the three-tablet basket, and each basket's sink condition was maintained by adding the same amount of buffer. The sample was dilute up to 10 ml in a volumetric flask, and its absorbance was measured at 267 nm wavelength using a UV spectrophotometer. Ultimately, the following formula was used by the X method to calculate the percent drug release.

5. Result

In accordance with ICH Q2B guidelines, the method was validated in order to ascertain the analyte's linearity, sensitivity, precision, and accuracy [11–21]. The drug solutions were made in accordance with the previously used protocol that was specified in the experiment.

5.1. Accuracy

The responses were reanalysed using the suggested method, and the accuracy results are shown in Table 2.

5.2. Precision

The degree of scatter (or closeness of agreement) between a set of measurements made by repeatedly sampling the same homogeneous sample under specified conditions is expressed as the precision of an analytical method. Reliability, intra- and inter-day precisions, and precision were used to evaluate the method's precision.

The precision of the developed approach was expressed as a percentage RSD. These results show how repeatable the assay is % RSD values less than 2 indicate that the procedure for calculating sitagliptin is accurate. The precision results are described in Tables 3 and 4.

5.3. Linearity

Over the concentration range of 10-100 μg/ml for Sitagliptin, an acceptable linear relationship was demonstrated by the linear regression results for the calibration curves. The linear regression equation y = 0.004x + 0.0027 was discovered and R^2 = 0.9995, the coefficient of determination. The graph of calibration curve was represented in Figure 2 with values in Table 5.

5.4. LOD and LOQ

Limit of detection (LOD) is refers as the lowest concentration of analyte that can be can be detected. Limit of quantification (LOQ) is refers as the lowest concentrate of analyte that can be quantified with suitable precision and linearity by using given formula. The LOD and LOQ for sitagliptin in distilled water were found to be 1.885 μg/ml and 5.712 μg/ml respectively.

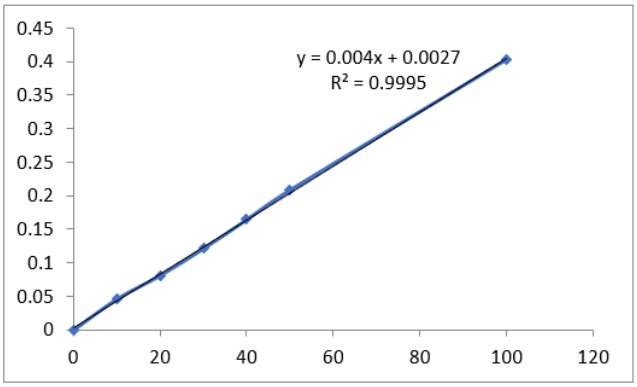

Figure 2: Calibration curve of sitagliptin

5.5. Dissolution study

The dissolution profile analysis is a crucial tool for assessing the development of the formulation as well as the final product. It also helps with batch-by-batch quality control and determines how closely a generic formulation resembles its innovator product. In all dissolution media, the drug release from the innovator brand and the generic brand was found to be somewhat similar. The innovator brand reached the maximum medication release in a pH 4.0 phosphate buffer. Within 15 minutes, all of the brands released roughly more than 80% of the medication in all dissolution media. The Q=80% in 30 minute dissolution criterion applies to immediate release solid oral medication formulations that have a high solubility drug ingredient. A greater quantity of drug was discharged from both generic brands in HCl buffer medium pH 2.0. The graphical representation of drug release profile of all tablets in different media is discussed in Figures 3, 4 and 5 and in Tables 6, 7 and 8 the actual percent drug release was shared.

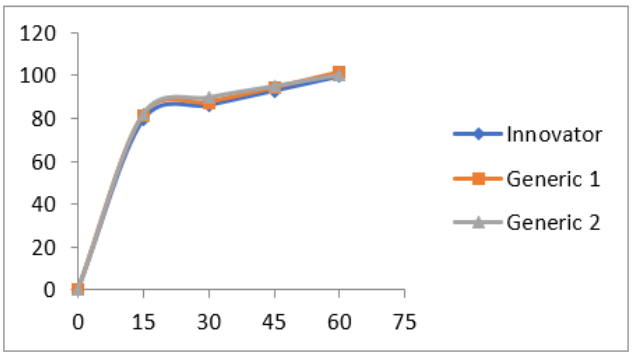

Figure 3: Dissolution profiles of sitagliptin tablets in 0.1N HCl Buffer pH 2.0

Table 2: Results of accuracy for sitagliptin

Tablet sample	Level of % recovery	Amount taken (μg/mL)	Amount of standard added (μg/ml)	Total amount recovered (μg/mL)	% Recovery	Average	Std. Dev	% RSD
	80	30	24	53.87	99.76			
	80	30	24	53.91	99.83	99.840	0.0835	0.0836
	80	30	24	53.96	99.93			
	100	30	30	59.64	99.40			
Sitagliptin	100	30	30	60.16	100.27	99.806	0.4360	0.4368
	100	30	30	59.85	99.75			
	120	30	36	66.11	100.17			
	120	30	36	65.95	99.92	99.823	0.4035	0.4042
	120	30	36	65.59	99.38			

Table 3: Interday precision data

Interday Precision	
Standard conc. Replicates	**30 μg/mL Absorbance**
1	0.123
2	0.121
3	0.119
4	0.120
5	0.123
6	0.122
Mean	0.1213
± SD	0.00
%RSD	1.346

Table 4: Intraday precision data

Intraday Precision	
Standard conc. Replicates	**30 μg/mL Absorbance**
1	0.121
2	0.124
3	0.118
4	0.119
5	0.120
6	0.119
Mean	0.1202
± SD	0.00
%RSD	1.778

Table 5: Absorbance of sitagliptin in water

Conc.	**Abs.**
10	0.046
20	0.081
30	0.121
40	0.164
50	0.208
100	0.402

Table 6: % drug release in 0.1N HCL pH 2.0

HCl 0.1N			
Time Point	**Innovator**	**Generic 1**	**Generic 2**
0	0	0	0
15	79.20	81.60	82.08
30	85.92	87.36	89.76
45	92.64	94.08	95.04
60	99.36	101.28	100.32

Table 7: % drug release in phosphate buffer pH 4.0

Phosphate Buffer pH 4.0			
Time Point	**Innovator**	**Generic 1**	**Generic 2**
0	0	0	0
15	81.32	83.22	84.49
30	87.04	90.21	90.85
45	97.84	95.93	97.20
60	101.01	99.74	99.11

Table 8: % Drug release in phosphate buffer pH 7.2

Phosphate Buffer pH 7.2			
Time Point	**Innovator**	**Generic 1**	**Generic 2**
0	0	0	0
15	88.74	84.56	86.23
30	91.26	92.93	93.77
45	96.28	94.60	97.95
60	99.63	100.47	98.79

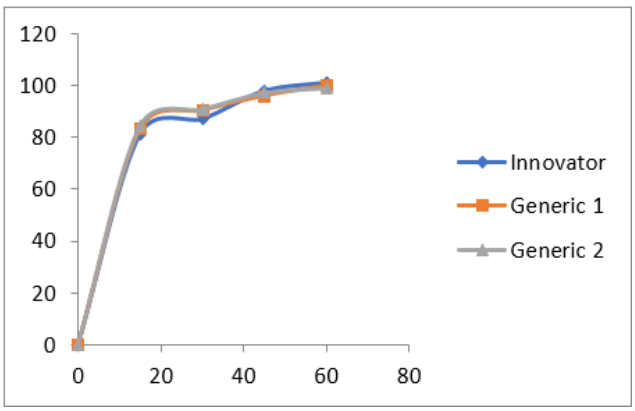

Figure 4: Dissolution profiles of sitagliptin tablets in phosphate buffer pH 4.0

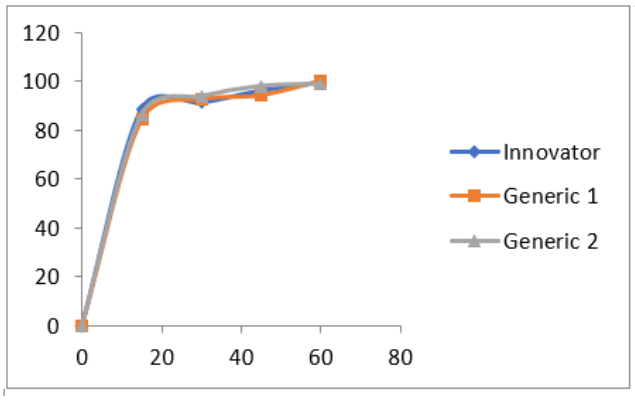

Figure 5: Dissolution profiles of sitagliptin tablets in phosphate Buffer pH 7.2

6. Disscussion

The dissolution process is impacted by multiple factors. When it comes to tablet formulation, the nature of excipients utilized and the rate at which the tablet disintegrates are extremely important. In the intestinal absorption of a drug substance from a solid oral dosage form, there are typically four main factors at play. These factors include the transit through the intestines, the permeability of the intestinal membrane, the surface area available for absorption, and the concentration profile of the drug in the intestinal lumen. By conducting a dissolution test in a specific medium, it is possible to predict the solubility characteristics of a drug.[22]

In order to compare the dissolution profiles of the brands, a model-independent approach was utilized, employing the difference factor F1 and similarity factor F2. Utilizing these techniques to compare dissolution profiles can offer more accurate insights into the dissolution characteristics of products being evaluated, aiding in the enhancement or creation of new formulations.[23] The difference factor f1

represents the percentage difference between two curves at each point, serving as a measure of the relative error between the two curves. On the other hand, the similarity factor f2 is obtained through a logarithmic reciprocal square root transformation of the sum of squared error, providing a measurement of the similarity in percent (%) dissolution between the two curves. The calculation of the difference factor f1 and similarity factor f2 involves the utilization of the following formulas.

$$F1 = \left\{ \frac{\sum_{t=1}^{n} (R_t - T_t|}{\sum_{t=1}^{n} R_t} \right\} \times 100$$

$$F2 = 50 log \left\{ \left(1 + \frac{1}{n} \sum_{i=1}^{n} (R_t - T_t)^2 \right)^{-0.5} \times 100 \right\}$$

Where, n = number of time point

R_t = Dissolution value of product at time t

T_t = Dissolution value for the test product at time t

In order to compare the similarity of two or more dissolving profiles, the Committee for Proprietary Medicinal Products (CPMP) and the USFDA have adopted the similarity factor f2 as a criterion. This agency is the European Agency for the Evaluation of Medicinal Products (EMEA). In its guidelines, the Canter for Drug Evaluation and Research (CDER) includes the similarity factor Figure 2. Examples of these guidelines are FDA (1997), which deals with immediate release solid oral dosage forms' dissolution testing, and FDA (2000, 15–16) which waives in-vivo bioavailability and bioequivalence studies for these forms based on a biopharmaceutics classification system.[24] For two dissolving profiles to be deemed comparable and bioequivalent, f1 and f2 should fall between 0 and 15 and 50 and 100.[25]

The f1, f2 values of various brands with regard to the selected innovator brand are displayed in Table 9. In f2 calculation only one measurement is generally considered after the comparator product has reached 85 % dissolution. However both the innovator and as well generic brand in measurement is typically taken into account in the f2 calculation in HCl Buffer pH 2.0, Phosphate Buffer pH 4.0, and Phosphate Buffer pH 7.2. Dissolution data are used to compute the F1 and F2 values. Every value for f2 is above 50, while every value for f1 is less than 15. Thus, from the calculation of f2 & f1 both the generic brands are interchangeable with the innovator band.

Table 9: Calculated difference factor (f1) and similarity factor (f2) of both generic sitagliptin tablet

Brand	0.1N HCl pH 2.0		Phosphate pH 4.0		Phosphate pH 7.2	
	F2	F1	F2	F1	F2	F1
Generic 1	83.92	3.81	83.92	3.81	83.92	3.81
Generic 2	76.85	8.32	76.85	8.32	76.85	8.32

7. Conclusion

Dissolution testing is a crucial in vitro assessment for evaluating drug products. Due to the lack of a specific dissolution method for sitagliptin in major pharmacopoeias, a comparative in vitro dissolution study of some sitagliptin generic tablets under biowaiver conditions by UV spectroscopy method was conducted using 3 buffer media: HCl Buffer pH 2.0, Phosphate Buffer pH 4.0, and Phosphate Buffer pH 7.2. The study was carried out at 37 ± 2 °C, with a paddle speed of 50 ± 5 rpm for a basket volume of 900ml for film-coated formulations, and 60 minute test duration.

The results obtained from this study suggest that both generic brands of sitagliptin tablets met the USFDA dissolution specifications and can be considered equivalent to the reference product. It is possible that these tablet formulations have similar dissolution profiles and can be used interchangeably. However, further in vivo studies are necessary to confirm this assumption.

8. Source of Funding

None.

9. Conflict of Interest

None.

The authors reached a consensus on the article prior to submission and declared no conflicts of interest.

Acknowledgments

The current research was conducted at Dr. Rajendra Gode College of Pharmacy, Malkapur. The authors thankful to the Principal of the institution for giving the chance to make a scientific contribution.

References

1. Diabetes. Available from: https://www.who.int/news-room/fact-sheets/detail/diabetes.
2. Reichal CR, Rao MG. Development and validation of spectrophotometric method for simultaneous estimation of gliclazide and sitagliptin phosphate monohydrate in bulk and pharmaceutical dosage form. *Int J Pharm Pharm Sci*. 2015;7(6):372–8.
3. Tieger E, Kiss V, Pokol G, Finta Z. Crystallisation of a salt hydrate with a complex solid form landscape. *Cryst Eng Comm*. 2017;19(14):1912–37.
4. Augsburgerx LL, Shangraw RF, Giannini RP, Shah VP, Prasad VK, Brown D, et al. Thiazides VIII: Dissolution Survey of marketed hydrochlorothiazide tablets. *J Pharma Sci*. 1983;72(8):876–81.
5. PubChem Compound Summary for CID 11591741, Sitagliptin phosphate monohydrate; 2004. Available from: https://pubchem.ncbi.nlm.nih.gov/compound/Sitagliptin-phosphate-monohydrate.
6. Stofella NC, Veiga A, Oliveira LJ, Montin EF, Andreazza IF, Filho MC, et al. Solid-state characterization of different crystalline forms of sitagliptin. *Materials*. 2019;12(15):2351.
7. Charoo NA, Abdallah DB, Bakheit AA, Haque KU, Hassan HA, Abrahamsson B, et al. Biowaiver monograph for immediate-release solid oral dosage forms: sitagliptin phosphate monohydrate. *J Pharma Sci*. 2022;111(1):2–13.

8. Shakya S. Formulation and optimization of immediate release tablet of sitagliptin phosphate using response surface methodology. *Int J Pharm Biol Med Sci*. 2015;4:7–12.
9. Lange AD, Batistel AP, Sfair LL, Carlosso J, Volpato NM, Schapoval EE, et al. Sitagliptin phosphate: development of a dissolution method for coated tablets based on in vivo data for improving medium sensitivity. . *Dis Tehncol*. 2014;21(2):17–22.
10. Convention TUSP. The United States Pharmacopeia and National Formulary USP 36-NF 31; ; 2013. Available from: https://search.worldcat.org/title/USP-36-NF-31-United-States-Pharmacopeia-:-National-Formulary/oclc/840900688.
11. Adhao VS, Chaudhari SR, Ambhore JP. Reverse phase-liquid chromatography assisted protocol for simultaneous determination of lamivudine and tenofovir disoproxil fumarate in combined medication used to control HIV infection: an investigative approach. *Futur J Pharm Sci*. 2021;7:1–11.
12. Adhao VS, Thenge RR, Sharma J, Thakare M. Development and validation of stability indicating RP-HPLC method for determination of safinamide mesylate. *Jordan J Pharm Sci*. 2020;1(1):49–59.
13. Adhao VS, Sharma J, Thakre M. Development and validation of stability indicating RP-HPLC method for determination of ceritinib. *Indones J Pharm*. 2018;28(9):241.
14. Adhao VS. RP-HPLC Method development and validation for the simultaneous estimation of Aceclofenac and Rabeprazole Sodium in the bulk and marketed formulation. *Indian J Pharm Pharmacol*. 2016;3(3):146–51.
15. Adhao VS, Thenge RR. Development and validation of stability indicating high performance liquid chromatography method for determination of baclofen. *Am J Pharmtech Res*. 2017;7(5):44–56.
16. Adhao VS, Ambhore JP, Thenge RR. Development and Validation of Stability Indicating High Performance Liquid Chromatography Method for Determination of Leflunomide. *Asian J Pharm Anal*. 2023;13(2):93–101.
17. Adhao VS, Ambhore JP. Reverse Phase-Liquid Chromatography Assisted Protocol for Determination of Molnupiravir Medication Used to SARS-CoV-2 Infection: An Investigative Approach. *Int J Pharm Sci Rev Res*. 2024;84(3):204–10.
18. Adhao VS, Ambhore JCS. Advancements and Insights in Forced Degradation Studies of Pharmaceuticals: A Comprehensive Review. *World J Pharm Pharm Sci*. 2024;3:1084–91.
19. Ambhore JP, Adhao VS, Cheke RS, Popat RR, Gandhi SJ. Futuristic review on progress in force degradation studies and stability indicating assay method for some antiviral drugs. *GSC Biol Pharm Sci*. 2021;16(1):133–82.
20. Adhao VS, Chaudhari SP, Ambhore JP. Stability Indicating RP-HPLC Method Development and Validation for Imeglimin HCL in Pharmaceutical Dosage form. *Chem Sci Int J*. 2024;33(4):1–10.
21. Guideline, I. H. T. Validation of analytical procedures: text and methodology. Q2 (R1)., 2055, 1(20), 5.
22. Rashed SS, Tushar RR, Ahmed F, Vabna NJ, Jahan L, Billah MM, et al. Comparative in vitro Dissolution Study of Clonazepam Tablets of Bangladesh by UV-Visible Spectrophotometry. *ACTA Pharm Sci*. 2021;59(4):1–4.
23. Serra CH, Storpirtis S. Comparação de perfis de dissolução da cefalexina através de estudos de cinética e eficiência de dissolução (ED%). . *Revista Brasileira de Ciências Farmacêuticas*. 2007;43(1):79–88.
24. Guidance for industry- Waiver of in vivo bioavailability and bioequivalence studies for immediate release solid oral dosage forms based on a biopharmaceutical classification system; 2000. Available from: https://www.gmp-compliance.org/guidelines/gmp-guideline/fda-guidance-for-industry-waiver-of-in-vivo-bioavailability-and-bioequivalence-studies-for-immediate-release-soloral-dosage-form.
25. Guidance for Industry: Dissolution Testing of Immediate Release Solid Oral Dosage Forms, FDA; 2018. Available from: https://www.fda.gov/media/70936/download.

Author biography

Vaibhav S. Adhao, Professor https://orcid.org/0000-0001-7664-4038

Jaya P. Ambhore, Associate Professor https://orcid.org/0000-0003-0846-8284

Anant D. Bhuskat, Student

Dishali V. Talokar, Student

Cite this article: Adhao VS, Ambhore JP, Bhuskat AD, Talokar DV. Comparative in-Vitro dissolution study of some sitagliptin generic tablets under biowaiver conditions by UV-Spectroscopy. *Curr Trends Pharm Pharm Chem* 2024;6(3):114-121.