



**INTERNATIONAL JOURNAL OF  
PHARMACEUTICAL SCIENCES**  
[ISSN: 0975-4725; CODEN(USA): IJPS00]  
Journal Homepage: <https://www.ijpsjournal.com>



## Research Article

# Simple UV-Spectrophotometric Assay and In-Vitro Bioequivalence Studies of Some Generic Metformin Hydrochloride Tablets Marketed in Bayelsa State

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## ARTICLE INFO

Published: 06 May 2026

### Keywords:

Metformin HCl,  
Bioequivalence, Biowavier,  
Half-life, difference factor,  
similarity factor,  
independent model,  
dependent model

### DOI:

10.5281/zenodo.20055836

## ABSTRACT

Metformin hydrochloride (MFH) is a biguanide derivative and antihyperglycemic agent. It is the first-line therapy for type-2 diabetes mellitus (T2DM). Presently, there is vast generic MFH brands in the local pharmaceutical market and, patients and physicians are faced with difficulty for the choice of brand with optimal efficacy that will elicit appropriate therapeutic action. A UV-Spectroscopic assay method for MFH at 240nm ( $\lambda_{max}$ ) in buffer solution was applied in an invitro drug release study, to evaluate the bioequivalence of five generic brands (B–F) and the innovator brand (A) under WHO biowaiver conditions – using the independent model (difference factor,  $f_1$  and similarity factor,  $f_2$ ) and dependent model (zero/first order kinetics). The hardness and friability ranged from 2.2–7.9 KgF and  $6.7 \pm 0.42$  to  $9.5 \pm 0.33\%$  respectively. The disintegration time ranged from 5.41–10.35minutes, while dissolution profile was  $\geq 85\%$  at  $t_{30}$ . Assuming first order kinetics, the invitro drug release constant  $k$ , ranged from  $(2.69–11.77) \times 10^{-2} \text{ min}^{-1}$ , half-life ( $t_{1/2}$ ) - from 5.87 – 10.82 minutes and the rate of release was 2.69 - 3.26 ( $\% \cdot \text{min}^{-1}$ ). Calculated  $f_1$  and  $f_2$  values ranged from 6–15 and 44–61 respectively. These values implies that generics (B–F) and innovator (A) were comparable. The content of all brands, ranged from  $96.32 \pm 1.15\%$  to  $104.26 \pm 1.49\%$  and met the stipulated BP (2022) and USP (2020) requirement. The conformity of all MFH brands to regulatory standards and the comparative in vitro studies has demonstrated that the generics are pharmaceutically equivalent and bioequivalent to the innovator brand, and hence supports their interchangeability.

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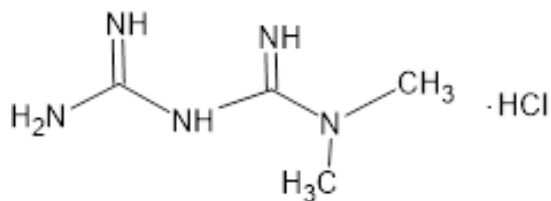
Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.



## INTRODUCTION

### Background on Metformin

Metformin hydrochloride (MFH), with IUPAC name - N, N-dimethyl imido dicarbonimidic diamide hydrochloride (Figure 1) is a biguanide derivative. It is an antihyperglycemic agent widely used in the management of type 2 diabetes mellitus (T2DM). Since its approval by the United States Food and Drug Administration (FDA) in 1994, metformin has remained the first-line pharmacological therapy for T2DM, particularly in overweight or obese patients with preserved renal function (Rena et al., 2017). It is available in both immediate-release (IR) and extended-release (XR) formulations and is also marketed in fixed-dose combinations with other antidiabetic agents. Metformin exerts its antihyperglycemic effects primarily by reducing hepatic gluconeogenesis, decreasing intestinal glucose absorption, and improving peripheral insulin sensitivity through enhanced glucose uptake and utilization in skeletal muscle. Unlike insulin secretagogues and certain other antidiabetic agents, metformin does not typically cause hypoglycemia or hyperinsulinemia. In addition to lowering fasting and postprandial plasma glucose levels, it has been associated with favorable effects on body weight and lipid metabolism (Mouasher et al., 2025)



**Figure 1: Chemical structure of Metformin Hydrochloride**

Bioequivalence refers to the absence of a significant difference in the rate and extent of absorption of the active ingredient from two pharmaceutical products when administered at the same molar dose under similar conditions.

Demonstration of bioequivalence ensures that a generic product performs in the same manner as the innovator (reference) product in terms of safety and efficacy (U.S. Food and Drug Administration [FDA], 2001). Regulatory agencies such as the FDA, NAFDAC, etc., require bioequivalence studies to establish therapeutic and chemical equivalence between a generic drug and its branded innovator counterpart (Nasir et al 2004). Usually, pharmacokinetic parameters – such as maximum concentration in plasma ( $C_{max}$ ), time to reach maximum concentration ( $T_{max}$ ), area under the plasma concentration–time curve (AUC), and in-vitro equivalence studies of drug release under biowaiver conditions are compared between the test (generic) and reference (innovator) formulations (Bunu *et al.*, 2023; Vaikosen *et al.*, 2024a; Vaikosen *et al.*, 2024b). For approval by Regulators, a generic product must demonstrate chemical and therapeutic equivalence (same active ingredient, dosage form, strength, and route of administration) and bioequivalence to the reference drug. Once bioequivalence is established, the generic product is considered therapeutically interchangeable with the innovator product (Bunu et al., 2023; Ebiere et al., 2023). Various analytical methods for the quantification of MFH in different dosage forms and invitro bioequivalence studies have been reported. Assay methods includes, non-aqueous potentiometric titrimetric method (British Pharmacopoeia [BP], 2009), spectrophotometric methods (Bhadru et al., 2024; Ahmed et al., 2020), conductimetric titration (Sarton et al., 2009), HPLC (Vasudevan et al., 2001, Arayne et al., 2008), flow-injection chemiluminescence (Al-Ghannam & Sheikha M. 2003; Khalili, Z & Shariati-Rad. 2018; Sun et al., 2006). Other assay methods are - ion-selective electrode (Hussein et al., 2022), capillary electrophoresis (Al-Thikrallah et al., 2023), and adsorptive catalytic square-wave voltammetry (El-Desoky et al., 2005). Presently, there is vast

generic brands of MFH in the local pharmaceutical markets and this makes the study imperative. In addition, end users and physicians are faced with increasing difficulty for the choice of optimal medication that will elicit appropriate therapeutic action (Jain et al., 2008). Hence, this study is aimed at assessing the quality of some MFH brands marketed in Bayelsa State and, applying UV-Spectroscopic method to examine the invitro bioequivalence of generic brands under biowaiver conditions.

## 2. MATERIALS AND METHODS

### 2.1 Materials

#### 2.1.1 Reagent and equipment

All the chemicals used were of analytical grade.

Six (6) different brands of metformin HCl (including the innovator brand) were purchased from retail pharmacies in Yenagoa, Bayelsa State. The reference product or innovator brand – was coded A, while the other brands were coded B, C, D, E and F. Disodium hydrogen orthophosphate (LobaChemie, India), potassium dihydrogen orthophosphate (JHD), distilled water. Analytical Weighing Balance (Ohaus, USA), Tablet Disintegration Apparatus (Perkins, USA), Roche Tablet Friabilator (Veego, India), Monsanto Tablet Hardness Tester, Tablet Dissolution Apparatus (Heusenstamm, Germany), UV-Visible spectrophotometer (Perkins, USA).

### 2.2 Methodology

#### 2.2.1 Uniformity of weight

Twenty (20) tablets were randomly selected from each brand and weighed individually on an analytical balance. Each weight was recorded. The twenty tablets were then collectively weighed to determine the total weight, from which the mean

weight of the tablets was calculated. The percentage deviation of each individual tablet from the mean weight was subsequently determined (BP, 2009).

#### 2.2.3 Friability Tests

Twenty (20) tablets from each brand were accurately weighed and subjected to abrasion using a Roche friabilator operated at 25 revolutions per minute (rpm). After completion of the test, the tablets were reweighed, and the percentage weight loss was calculated and recorded for each brand (United State Pharmacopoeia [USP], 2020).

#### 2.2.2 Hardness Test

The crushing strength of the tablets was determined using a Monsanto hardness tester. Five (5) tablets were randomly selected from each brand, and the force required to crush each tablet was recorded (BP, 2009).

#### 2.2.4 Disintegration test

Six (6) tablets from each brand were evaluated using a Veego disintegration apparatus in distilled water maintained at  $37 \pm 0.5^\circ\text{C}$ . The disintegration time was recorded as the time required for complete disintegration, defined as the point at which no tablet residue remained on the apparatus screen (U.S. Food and Drug Administration [FDA], 2008).

### Determination of maximum absorption wavelength and Calibration curve

The maximum wavelength and calibration curve in phosphate buffer for drug release were determined. To 100mg standard metformin HCl powder, in a 100 mL volumetric flask, 10 mL of phosphate buffer solution was added, mixed and made to mark. An aliquot of 0.4 mL of the solution



was transferred into a 25 mL<sup>-1</sup> volumetric flask and filled to the mark with the same buffer solution. The resultant solution was scanned in the UV range (200-380 nm) of a spectrophotometer to obtain the maximum absorption ( $\lambda_{\max}$ ).

The following concentrations - 2, 4, 6, 8, 16, 32 and 64  $\mu\text{g mL}^{-1}$  were prepared from the stock solution of 1000  $\mu\text{g mL}^{-1}$ . Their absorbance values were measured at the maximum wavelength for MFH in the spectrum above. A calibration curve was obtained by plotting absorbance values against concentrations

### 2.2.5 Dissolution test and drug release

The in vitro dissolution study was performed using a dissolution rate apparatus in phosphate buffer (pH 6.8). The buffer solution (900 mL) was introduced into each dissolution vessel, and one tablet was placed in each basket. The test was conducted at 100 rpm and maintained at  $37 \pm 0.5^\circ\text{C}$ . At predetermined time intervals (5, 10, 15, 30, 45, and 60 minutes), 5 mL aliquots were withdrawn from a point midway between the surface of the dissolution medium and the top of the basket. Each withdrawn volume was immediately replaced with an equal volume (5 mL) of fresh dissolution medium to maintain sink conditions. The samples were filtered using 0.45  $\mu\text{m}$  Millipore filter paper and analyzed using a UV-Visible spectrophotometer at the maximum wavelength for MFH in phosphate buffer solution (pH 6.8;  $\lambda_{240\text{ nm}}$ ). The amount of metformin HCl released was determined from a calibration curve (BP, 2009).

Formula for determination of percentage of release include;

Concentration of drug ( $\mu\text{g/ml}$ ) = (slope  $\times$  absorbance)  $\pm$  intercept

Amount of drug released(mg/ml) =

$$\frac{\text{Concentration} \times \text{Dissolution bath volume} \times \text{dilution factor}}{100}$$

percentage released (%) =

$$\frac{\text{amount of drug released} \times 100}{\text{Total drug strength}}$$

### Dissolution profile comparison and bioequivalence of generics to innovator brand

The US FDA performance validation test requirements were used to assess the dissolution profiles of innovator (A) and generic (B – F) brands (FDA, 2008); in addition, with the 80% minimum release within 30 minutes from the commencement of experiment as stipulated by the USP and BP (USP, 2020; BP, 2009). Furthermore, the independent model technique of difference factor ( $f_1$ ) and similarity factor ( $f_2$ ) (equations 1 and 2) were used to evaluate the dissolution profiles of the generics in comparison to the innovator brand using all-time amplitudes (FDA (2008), (Diaz et al., 2016). The use of the similarity factor  $f_2$  as a criterion for comparing the similarity of two or more dissolution profiles have been approved by the FDA and the European Agency for the Evaluation of Medicinal Products (EMA) (Diaz et al., 2016). The use of kinetics - a comparative-dependent model for bioequivalent studies was adopted - assuming a first-order for the release of actives (equation 3)

$$f_1 = \left\{ \sum_{t=1}^n |R_t - T_t| / \sum_{t=1}^n R_t \right\} \times 100$$

..... equation 1

$$f_2 = 50 \times \text{Log} \left\{ \left[ 1 + \frac{1}{n} \sum_{t=1}^n (R_t - T_t)^2 \right]^{-0.5} \times 100 \right\}$$

..... equation 2

**Where:**

n = Number of time points.

$R_t$  = Mean dissolution value of the reference product at time

$T_t$  = Mean dissolution value of the test product at time

$$[A]_{t=n} = [A]_{t=0} \exp(-kt) \quad \text{..... equation 3}$$

$[A]_{t=0}$  = Initial concentration (t = 0mins)

$[A]_{t=n}$  = Concentration (t = n mins)

### 2.2.6 Assay

Twenty (20) tablets from each brand were separately weighed, and the mean tablet weight was calculated. Each brand was finely powdered, and a quantity equivalent to 100 mg of metformin hydrochloride was accurately weighed and transferred into a 100 mL volumetric flask. Approximately 70 mL of distilled water was added, mixed thoroughly, and the volume was made up to 100 mL with distilled water. The solution was filtered, and the first 20 mL of the filtrate was discarded. One (1) mL of the filtrate was diluted to 100 mL with distilled water to obtain a final concentration of 10 µg/mL. The samples were analyzed in triplicate using a UV–Visible spectrophotometer at a maximum wavelength of 232 nm. Distilled water served as the blank. The percentage content of metformin HCl was calculated using a specific absorbance value of 798 (A, 1%, 1 cm) in accordance with British Pharmacopoeial monograph [BP, 2022].

### Data analysis

The uniformity of weight was analyzed using simple statistics, while dissolution profiles of the generics and innovator were done graphically and by calculation applying the independent and dependent models. The difference factor ( $f_1$ ), similarity factor ( $f_2$ ), and kinetic drug release variables – release rate constant k, half-life ( $t_{1/2}$ ), correlation coefficient ( $R^2$ ), etc., were determined using Microsoft Excel, 2016.

## 3. RESULT AND DISCUSSION

### 3.1 Uniformity of Weight

Table 2 shows the average tablet weights of the six brands of metformin HCl (500 mg), with average weight ranging from 531.4 mg to 620.4 mg. The percentage deviation ranged from 0.46 to 4.06. According to pharmacopoeial specifications, tablets weighing more than 250 mg are permitted a maximum deviation of  $\pm 5\%$  from the mean weight. All brands exhibited percentage deviation within the acceptable range (Abozaid et al., 2022). It is pertinent to mention, that weight uniformity is a critical quality control parameter, as it provides an indirect measure of dose uniformity and ensures consistent distribution of the active pharmaceutical ingredient (API) within individual dosage units. Significant deviations may predispose to variability in bioavailability and therapeutic response. Therefore, failure to comply with weight uniformity limits may compromise product reliability and clinical performance (Awofisayo et al., 2010).

**Table 1. Uniformity of Weight of Innovator and Generic Metformin Brands**

PARAMETER	SAMPLES					
	A	B	C	D	E	F
Mean Weight (mg)	533.30	620.40	565.35	569.95	539.30	531.40
Std. Deviation	3.86	9.54	7.02	14.00	21.77	21.67
% Deviation	0.73	1.54	1.24	2.47	4.06	4.03
Pharmacopoeial Limit (%)	5.00	5.00	5.00	5.00	5.00	5.00

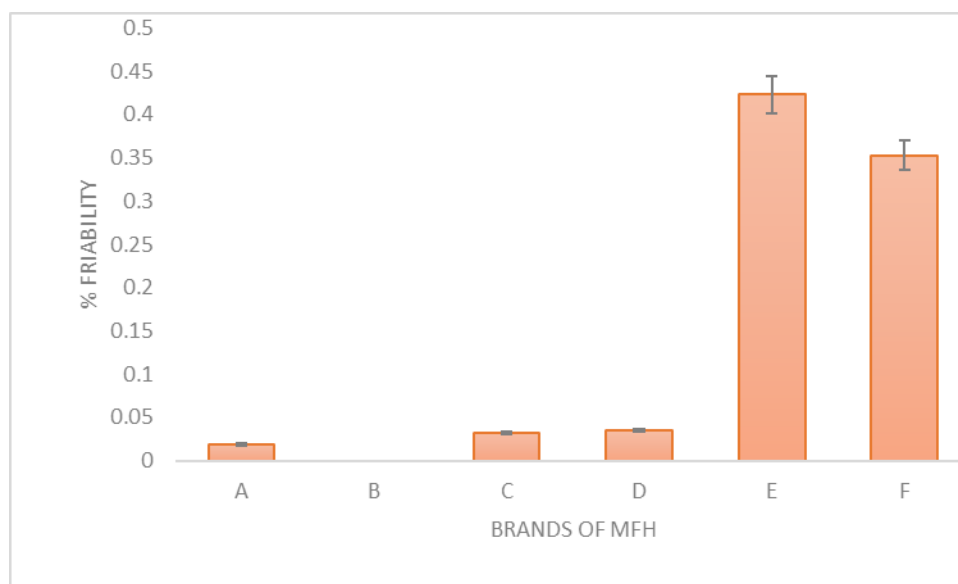


Compliance Status	Pass	Pass	Pass	Pass	Pass	pass
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## 4.2 Friability Test

Figure 3, shows the values obtained in friability test. The friability values of the assessed brands ranged from 0.00% to 0.423%, indicating that all products complied with pharmacopeial requirements. These findings suggest adequate mechanical integrity and resistance to fracture,

thereby ensuring the tablets can maintain physical stability throughout their shelf life (Abozaid et al., 2022). Friability assesses the mechanical strength of tablets and their ability to withstand abrasion and mechanical shock during handling, packaging, transportation, and storage. A percentage weight loss of  $\leq 1\%$  w/w is generally considered acceptable for conventional tablets (USP, 2022)

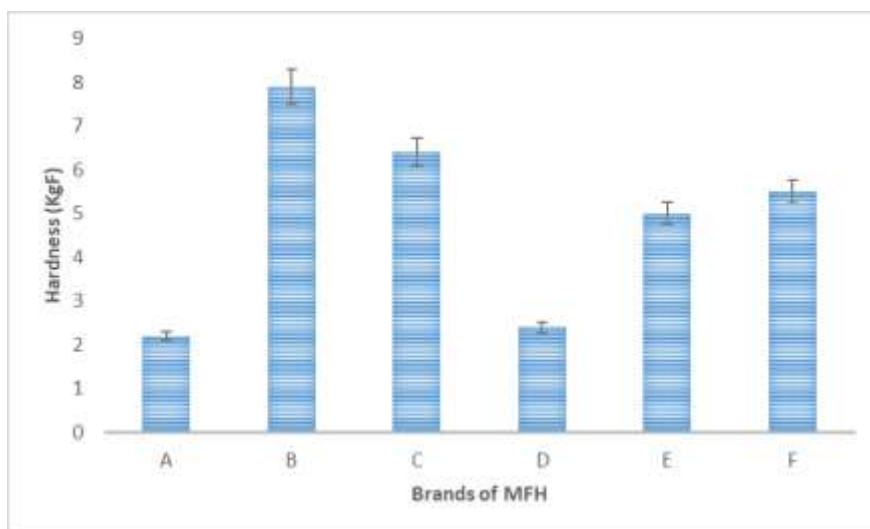


**Figure 2: Friability of innovator and generic metformin HCl brands.**

## 4.3 Hardness (Crushing Strength) Test

The hardness values ranged from 2.2 to 7.9 KgF (Table 3). Brands A and D exhibited the lowest crushing strengths (2.2 KgF and 2.4 KgF, respectively), while Brand B demonstrated the highest value (7.9 KgF). Brands C, E, and F showed intermediate values of 6.4 KgF, 5.0 KgF, and 5.5 KgF, respectively. Variations, in hardness among brands may be attributed to differences in formulation components (e.g., type and concentration of binders and excipients), compression force applied during manufacture, and coating characteristics (Oluwatoyin et al., 2021). Tablet hardness is closely associated with disintegration and dissolution behavior.

Excessively hard tablets may delay disintegration and drug release, potentially leading to suboptimal therapeutic outcomes. Conversely, tablets with insufficient hardness may lack adequate mechanical stability, increasing the risk of breakage during handling. Tablet hardness reflects the capacity of a tablet to resist mechanical stress during packaging, transportation, and storage, while still allowing appropriate disintegration and drug release after administration. For immediate-release conventional tablets, a crushing strength of 4 – 10 (KgF) is generally recommended, although this may vary depending on formulation characteristics and intended product performance (Abozaid et al., 2022).

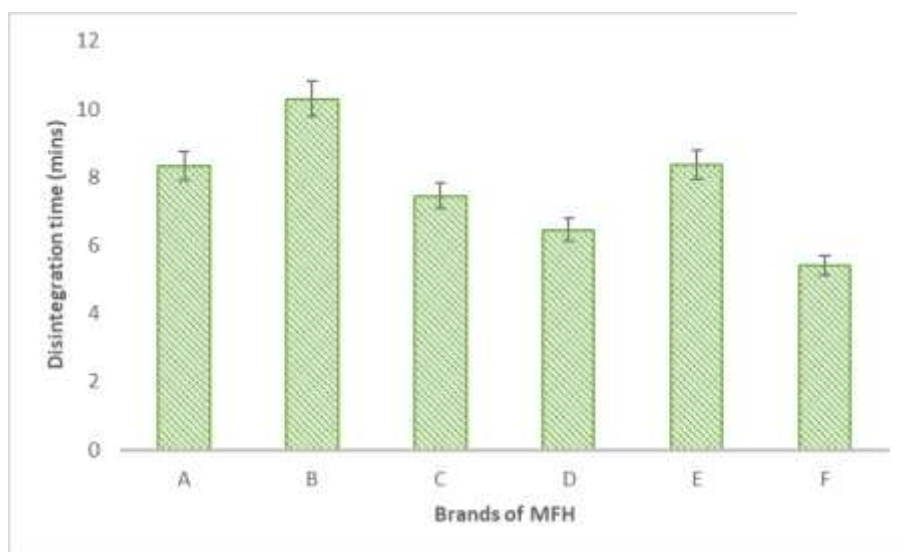


**Figure 3: Hardness of Innovator and Generic Metformin brands.**

#### 4.4 Disintegration Time

Figure 5, shows that the disintegration times for all brands ranged from 5.41 to 10.35mins, with innovator brand at 8.33 mins. Brand B, was found to have demonstrated the longest disintegration time. All evaluated brands complied with the pharmacopeial specification for film-coated tablets, which requires disintegration within 30 minutes. This indicates that the active pharmaceutical ingredient (API) is readily released from the binding matrix to elicit appropriately its therapeutic action (BP, 2009).

Disintegration refers to the breakdown of a tablet into smaller fragments upon contact with a liquid medium as a result of the disruption of inter-particulate bonds hereafter facilitating subsequent dissolution and absorption (Ghourichay et al., 2021). It is pertinent to mention that in addition to longest disintegration time showed by Brand B, it also exhibited the highest hardness and the least friability – this trend is suggestive of a direct relationship amongst these three parameters. It is expected that tablets with high hardness and low friability are likely to exhibit longer disintegration time,



**Fig 4: Disintegration time of innovator and generic metformin HCl brands**

### Determination of maximum absorption and calibration curve for dissolution profile

The UV absorption spectrum for MFH in phosphate buffer (pH 6.8) is presented in Figure 5, with maxima at 240 nm. Also, the calibration curve is a straight-line graph, while the equation

is;  $y=0.0048x + 0.0016$ , with the correlation coefficient ( $R^2$ ) being 0.9997. These  $R^2$  values depicted good linearity between absorbance and concentration of MFH, with Beer's Law obeyed in the concentration range of 2 – 64  $\mu\text{g mL}^{-1}$ . In addition, the slope and intercept were 0.0048 and 0.0016 respectively.

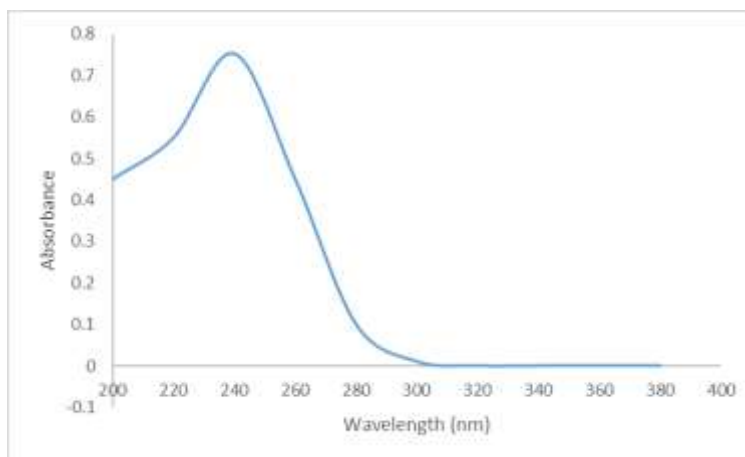


Figure 5: UV Spectrum of 16  $\mu\text{g/mL}$  MFH in phosphate buffer pH 6.8

### 4.5 Dissolution Test

Figure 6 shows the percentage drug release profile for the innovator and generic brands.

Over 85% of MFH was released within 30 minutes for the innovator and generic brands. This result complied with the pharmacopeial requirements (BPC, 2022; USP, 2020) for the dissolution rate with respect to the innovator and generic brands investigated - with the order of attainment being E

> D > F > A > C > B at  $t_{30}$ . Although, the innovator brand was fourth in the rating of the order of percentage released of metformin HCl at  $t_{60}$ , there was no remarkable variation, and all the generic brands were deemed comparable, hence, all brands (innovator and generic brands) were considered equivalent with respect to the invitro drug release profile using phosphate buffer (pH 6.8) (Awofisayo et al., 2010; BP, 2009; Vaikosen *et al.*, 2024b).

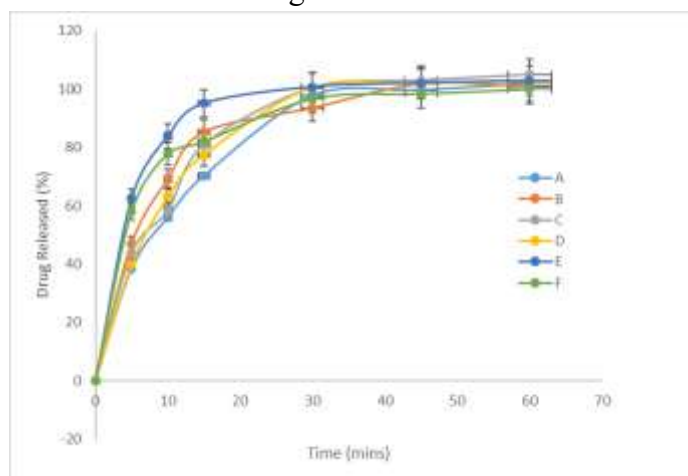


Figure 6: Dissolution profile of Innovator and Generic Metformin brands

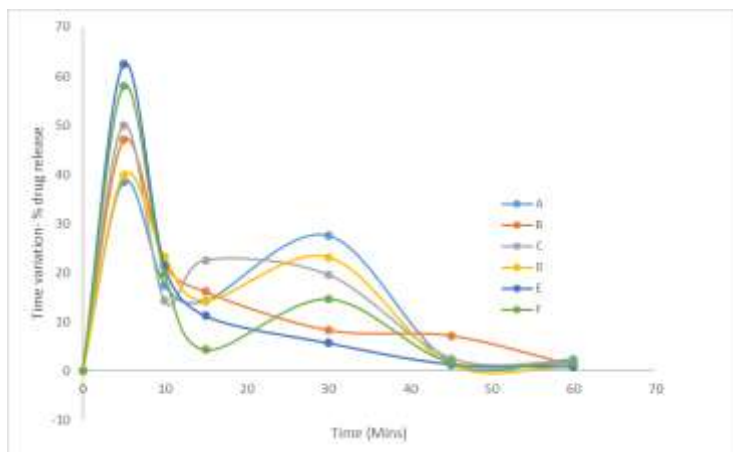
### Dissolution profile comparison and equivalence of generics to innovator brand

The independent model (difference factor,  $f_1$  and similarity factor,  $f_2$ ) and dependent model (zero and/or first order kinetics) are simple and viable comparison approach for the assessment of bioequivalent between two formulations. The comparative analysis conducted using the difference factor ( $f_1$ ) and similarity factor ( $f_2$ ) is presented in Table 3. Calculated  $f_1$  and  $f_2$  values for the in vitro dissolution profile ranged from 6 – 15 and 44 – 61 respectively. In applying the independent model, two dissolution profiles are considered similar and bioequivalent, only if the  $f_1$  value lies between 0 and 15, while  $f_2$  must be between 50 and 100 (FDA, 2008). This implies that all the brands (B – F) were comparable to the innovator brand, with respect to the difference factor  $f_1$  and the similarity factor  $f_2$ . Also, the comparative dependent model for bioequivalent

studies was applied by assuming first-order kinetics (Costa P et al., 2001), with the drug release rate constant ( $k$ ) calculated iteratively and the rate of drug release (%/min) (Table 2). The in vitro drug release constant  $k$  for metformin HCl over a six-time amplitude ( $t_5 - t_{60}$ ) ranges from  $(2.69 - 11.77) \times 10^{-2} \text{ min}^{-1}$ , while half-life ( $t_{1/2}$ ) – time taken for 50% of the drug's label claim to be released, was from 5.87 – 10.82 minutes and the rate of release ranges between 2.69 and 3.26 ( $\% \cdot \text{min}^{-1}$ ). The correlation coefficients  $R^2$  were  $\geq 0.5515$  except for brand E, that was 0.4824. For values  $\geq 0.5$  implies a positive and strong correlation between the amount of drug released and time. The definitive-time MFH release profile, shows a sharp peak of 38 – 62% release, within the first amplitude of 5 minutes for all brands (Figure 7). This portrays that all brands of MFH investigated were formulated as immediate or rapid release medication (Al-jazairi et al., 2008; Kassaye et al., 2013).

**Table 2: In vitro kinetic variables for innovator and generic brands**

Sample code	Dependent model				Independent model	
	Rate of drug release (%/min)	Rate constant ( $k$ ) ( $\text{min}^{-1}$ )	Half-life ( $t_{1/2}$ ) (min)	Correlation coefficient ( $R^2$ )	$f_1$	$f_2$
A	2.69	$6.40 \times 10^{-2}$	10.82	0.7481	-	-
B	3.03	$7.77 \times 10^{-2}$	8.92	0.6286	9	51
C	3.16	$6.46 \times 10^{-2}$	10.73	0.7070	11	44
D	2.86	$7.73 \times 10^{-2}$	8.97	0.6981	11	44
E	3.26	$10.38 \times 10^{-2}$	6.68	0.4824	15	39
F	2.94	$11.77 \times 10^{-2}$	5.87	0.5515	6	61



**Figure 7: Definitive-time percentage drug release of metformin HCl**

#### 4.6 Assay of Active Ingredient

The percentage content of all MFH brands ranged from  $96.32 \pm 1.15$  to  $104.26 \pm 1.49$  (Table 3). The innovator and generic brands were found satisfactory when compared to the stipulated BP (2022) and USP (2020) specifications (BP, 2009, USP, 2023). The student-t tests for accuracy and precision based on the label claim (500 mg/tablet) and quantities found in brands ranged from 1.33 to 2.43 (Table 3), while values between the innovator brand (A) and generics (B – F) were from 1.44 to 2.04 – all test values were  $< 3.18$  (tabulated) at

95% confidence level for 3 replicates. The aforementioned implies that there was no significant difference between label claims of all brands and the assay values obtained and between brand A (Innovator) and brand B - F (generics) (Vaikosen *et al.*, 2024). Furthermore, the relative standard deviation (%RSD,  $n = 3$ ) and standard error of the mean (SEM) ranged from 0.53 to 1.65 and 1.17 to 3.75 respectively, with the least values recorded by the innovator brand for both properties. These values suggest that there was high reproducibility and reliability, with satisfactory accuracy of method.

**Table 3: Assay of different brands of metformin HCl**

Sample ID (Brands)	Label claim (mg/capsule)	Amt found $\pm$ Sd (mg/capsule)	%RSD	SEM	Drug Content (%)	Student t-test for A
A	500	$491.21 \pm 2.61$	0.53	1.17	$98.24 \pm 0.52$ $t = 1.42$	-
B	500	$515.71 \pm 8.21$	1.59	3.67	$103.14 \pm 1.64$ $t = 1.57$	$t = 1.44$
C	500	$521.296 \pm 7.43$	1.43	3.32	$104.26 \pm 1.49$ $t = 1.75$	$t = 1.49$
D	500	$487.042 \pm 7.36$	1.51	3.29	$97.41 \pm 1.47$ $t = 1.33$	$t = 1.67$
E	500	$509.98 \pm 8.39$	1.65	3.75	$102.00 \pm 1.68$ $t = 2.08$	$t = 2.04$
F	500	$481.58 \pm 5.75$	1.19	2.57	$96.32 \pm 1.15$ $t = 2.43$	$t = 1.92$

\*Tabulated t-value 3.18 ( $n = 3$ )

#### 5. CONCLUSION

Compliance with assay requirements and weight uniformity indicates that drug products are of accurate and consistent formulation. The evaluation of six brands of 500 mg metformin hydrochloride tablets demonstrated that all products met stipulated pharmacopeial quality requirements. Uniformity of weight, friability, and hardness tests indicated acceptable mechanical strength and consistent dosage, while disintegration and dissolution profiles confirmed that the tablets are capable of releasing the active

ingredient appropriately under physiological conditions. Furthermore, assay results revealed that the metformin content in the all brands fell within the British Pharmacopoeia (BP, 2022) specified range of 95–105% of the labeled claim, reflecting satisfactory content uniformity and formulation accuracy. The conformity of all evaluated brands to official specifications suggests pharmaceutical equivalence and hence supports their potential interchangeability with the innovator product (Siraj *et al.*, 2025).

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**HOW TO CITE:** Adesegun J. Kashimawo, Evans K. Edoghotu, Chidiogo F. Umeanozie, Price P. K. Joffa, Edebi N. Vaikosen, Simple UV-Spectrophotometric Assay and In-Vitro Bioequivalence Studies of Some Generic Metformin Hydrochloride Tablets Marketed in Bayelsa State, *Int. J. of Pharm. Sci.*, 2026, Vol 4, Issue 5, 1252-1264. <https://doi.org/10.5281/zenodo.20055836>

