ORIGINAL PAPER

Quality Assessment of Metformin Hydrochloride Tablets Retailed in Lagos, Nigeria

A. A. ADEPOJU-BELLO[CAEF], B. O. OYAWALUJA*[BCDEF], K. B. ANALIKWU[BCD]

Department of Pharmaceutical Chemistry, Faculty of Pharmacy, University of Lagos, Lagos, Nigeria

A – research concept and design; B – collection and/or assembly of data; C – data analysis and interpretation; D – writing the article; E – critical revision of the article; F – final approval of article.

Abstract

Background: Metformin is a biguanide antihyperglycemic drug used with diet and exercise for glycemic control in type 2 diabetes mellitus.

Objectives: This research aims to compare and analyze different metformin products to ascertain their critical quality parameters. The goal is to ensure that prescribed medicine effectively treats patients and protects the public.

Materials and Methods: We evaluated the quality of ten metformin tablet brands in Lagos (Mushin and Surulere area) using official methods to assess weight, hardness, friability, disintegration time, and dissolution. Active ingredient content was also measured.

Results: Out of all the tablets tested, only 10 % had weights outside of the official British Pharmacopoeia 2002 limits (not more than two tablets should deviate from ±5% and none of the tablets should deviate by ± I0). The hardness test was passed by all the tablets (A minimum hardness of 4 kgF is a pass), while 80 % passed the friability test (weight loss of ≤ 1 %w/w is a pass). Additionally, all film-coated tablets disintegrated within 30 minutes according to United States Pharmacopoeia/National Formulary 2003 (film-coated tablets disintegrate within 30 minutes). Ninety percent of the tablets passed the dissolution test (drug release within 60 minutes should be between 93 and 103 %) and 90 % of all brands examined passed the assay test for the active ingredient contents. The British Pharmacopoeia 2019 standard was used for the dissolution test.

Conclusion: Routine pharmaceutical analysis is essential for the quality of pharmaceutical products and the safety of consumers.

Keywords: Metformin tablets, Pharmaceuticals, Quality assessment, Diabetes mellitus, oral hypoglycaemics.

INTRODUCTION

The quality assessment of drugs and their pharmaceutical formulations is very important and essential during the product development stage in the pharmaceutical industry. Analytical assessment is the critical approach to quality control of pharmaceutical products (Suryawanshi & Palled, 2022).

With the growth in pharmaceutical industries, the number of pharmaceutical products (branded as well as generic) is increasing in the market so maintaining its quality is the primary concern for manufacturers (Kalo *et. al*., 2015). The same generic drug can be manufactured by different pharmaceutical companies, which may look like or be different than the original and sold under different brand names and different costs (Chaudhary *et. al*., 2018).

Generally, generic as well as branded products contain the same type and quantity of active ingredients. So, a generic drug should be identical or bioequivalent to a brand drug concerning dosage form, safety, strength, route of administration, quality, performance

characteristics, and intended use (Mehnaz *et. al.*, 2018). But substandard drugs are also finding their place in the market due to ignorance, negligence, and personal profit of pharmaceutical companies and these differ from the original product in many aspects viz. concentration, quality, etc. So, to ensure the safety and reliability of any pharmaceutical dosage form in terms of quality, pharmaceutical companies should maintain the pharmacopoeial standards as prescribed by pharmaceutical regulatory authorities during the manufacturing of the drugs (Patel & Chota, 2011; Caudron *et. al.*, 2008; Jain *et. al.*, 2019). Therefore, quality control tests as per the standard official books like IP, USP, BP, etc. during manufacturing and also on the final product should be performed (Thakuri *et. al.*, 2016; Jannath et. al., 2018).

The pharmaceutical industry is one of the most regulated industries worldwide because the drugs produced must be safe and effective. The Food and Drug Administration requires testing of raw materials before manufacturing pharmaceutical products to establish their identity, purity, and quality (Jatto and Okhamafe, 2002). This analysis is an essential step in the production of pharmaceuticals and ensures that the product is suitable for its intended use. It includes testing of raw materials, Active Pharmaceutical Ingredients (APIs), excipients, and various additive-based finished products (Ahmed et. al., 2020). Quality is not an accident; it is the result of conscious efforts. Metformin (molecular formula $C_4H_{11}N_5$, molecular weight, 129.167 gm/mol) is the most widely prescribed anti-diabetic used for the treatment of type II (non-insulin-dependent diabetes mellitus) which acts by decreasing hepatic glucose production, intestinal glucose absorption, and improving insulin sensitivity by increasing peripheral glucose uptake and utilization (Kirpichnikov *et. al.*, 2002; Elango *et. al.*, 2014; Sachan *et. al.*, 2016; Daharwal *et. a*l., 2015). Various brands of metformin are available in the market so the quality of the various brands commercially available should be ensured to assess their quality control which helps in the selection of brand of the drug.

Using substandard drugs can have serious consequences, including adverse reactions, treatment failure, and even death. It is important to ensure that any medication purchased, including metformin hydrochloride tablets, is safe for consumption. There are recommendations for improving the quality of pharmaceutical products in Nigeria, including strengthening regulatory bodies, improving manufacturing standards, and increasing public awareness of the risks of using substandard drugs

METHODOLOGY

Materials and Methods

Materials

UV/Vis-Spectrophotometer, Analytical weighing balance, Ultrasonic bath, Dissolution tester, Disintegration tester, Erweka Friabilator, Monsanto Hardness tester, Filter paper (Whatman), Glasswares, Micropipette, Spatula, Porcelain pestle and mortar, Distilled water and Ten (10) brands of metformin tablets (film-coated, 500 mg).

Sample collection

Ten (10) brands of metformin tablets were randomly purchased from different registered pharmacies, coded, and subjected to analysis before their expiration dates. The physical requirements for packaging and labeling of drug samples which include the presence of the National Agency for Food Drug Administration and Control (NAFDAC) registration number, Batch number, manufacturing, and expiration dates were checked. The samples were coded as A to I and the official guidelines were employed for the tests.

Weight variation (uniformity of weight) test
Twenty (20) tablets from one brand of metformin labeled 500 mg unwrapped from its pack were selected at random. Then a zeroed electric weighing balance and foil paper were placed on the balance. The tablets were then weighed singly and the weights were recorded. The same procedure was repeated for all the remaining brands of metformin. The average weights were then determined. Tablets were weighed individually and the percentage of deviation of their weight from the average weight was determined for each tablet (Chang *et. al.*, 2000).

Hardness test

The tablet to be tested was unwrapped from its sachet and then placed on the holding edges of the anvil of the Monsanto hardness tester. Then the pointer was adjusted to the position on the scale by rotating the screw in the forward direction. The screw was then rotated until cracks or breaks in the tablet were observed. The amount of force (in KgF) it takes to break the tablet shows how hard the tablet is, and this value is shown on the scale. The procedure was repeated for the remaining tablets. All observations were noted down.

Friability test

Ten (10) tablets are weighed together before the test this is recorded as the initial weight (W1). The ten (10) tablets are then put into the Friabilator device. The Friabilator is then set to rotate the drum at 100 rpm for 4 mins. After 4 minutes, the tablets were removed from the drum and weighed again to get the final weight (W2) of the tablet brand. The percentage (%) friability was then ascertained. % Friability can be calculated by following the formula

$$\text{Friability (\%)} = \frac{(W1 - W2)}{W1} \times 100$$

Where;

W1 = weight of tablets before testing

W2 = weight of tablets after testing

The test is then repeated for the remaining brands of metformin.

Disintegration test

The apparatus was turned on and made to heat the water in the compartment. The basket-rack assembly was lifted from the empty beaker and cleansed before use. The apparatus was set to 37 °C. The apparatus was then assembled by filling the beaker with 500 ml distilled water. The distilled water in the beaker was then left to heat to 37 °C. Then, at random, six (6) tablets of a brand of metformin were unwrapped and placed on each of the tubes of the basket-rack assembly. The plunger switch was turned on setting the machine in motion while simultaneously starting the timer. The tablet basket-rack assembly was plunged in and out of the distilled water. The time it took each tablet to disintegrate and all particles passing through the mesh screen was noted down. After this batch, the basket-rack assembly was removed from the beaker and gently rinsed with water. The beaker was washed and rinsed. New distilled water was used for the next set of tablets. This was done for all the remaining brands of metformin and the individual tablet disintegration time was noted. (Odeniran et. al., 2021)

Dissolution test

The sample, collecting bottles, syringes, and syringe filters were all labeled accordingly. After ensuring that the water in the water bath is at the mark. 900 ml of distilled water was poured into the vessel of the apparatus. The apparatus was then set to 37 °C and warmed to that point. The device was set to 50 rpm. Aliquots of 5mL were withdrawn at intervals of 5, 10, 20, 30, 45, and 60 minutes and filtered using syringe filters. The equivalent volume of the medium was replaced to maintain sink conditions. Dilutions of 1:50 were made to the samples obtained from the dissolution medium. The absorbance of the withdrawn samples was determined at 233 nm using the UV-visible spectrophotometer. Metformin content was calculated taking 806 as the value of A (1%, 1 cm) at lambda maximum of 233 nm. The process was repeated with two other tablets from each batch to make triplicate determinations. (Odeniran et. al., 2021: BP 2019)

Assay: Twenty (20) tablets of each brand were weighed using an electric weighing balance and their average weight was calculated. The tablets were then finely powdered using a mortar and pestle. An equivalent weight of 100 mg of metformin hydrochloride was weighed and transferred into a 100 mL volumetric flask. Then 70 mL of distilled water was added and mixed well enough, and it was made to volume with distilled water and then filtered. The first 20 mL of the filtrate in the volumetric flask was discarded. 10 mL of the filtrate was taken with the aid of a syringe and diluted with distilled water to 100 mL. Again, 10 mL of the resulting solution was further diluted with distilled water to 100 mL to give a nominal concentration of 10 µg/mL. The samples were analyzed using a UV-Vis Spectrophotometer at a maximum wavelength of 232 nm in triplicates for all the samples. Distilled water was used as blank. The percentage content of the samples was calculated using the specific absorbance of 798 according to the monograph as A (1%) (Odeniran et. al., 2021: British Pharmacopoeia 2016).

RESULTS AND DISCUSSION

All the brands were within their shelf life at the time of the study. Ten (10) different brands of metformin obtained from different retail shops within the Lagos metropolis were subjected to several tests to assess their physical and chemical equivalence. However quantitative and qualitative tests were carried out including uniformity of weight test (weight variation), hardness test, friability test, disintegration test, and dissolution test. The quantitative test carried out is an Assay using UV Spectrophotometry.

Table 1: Samples and packaging information

Brand code	Batch number	NAFDAC number	Manuf. date	Expiry date	Tablet description
BRAND A	2025	A4-6597	28/20	09/25	Film-coated, white, round, embossed 'M 500' (one side) and 'SKG' (another side). 1 × 10 (Blister).
BRAND B	VFDIA36-0	04-0810	08/20	07/23	Film-coated, white, round, embossed 'HD'. 1 × 10 (Blister).
BRAND C	21003	B4-0076	03/21	02/24	Film-coated white, round, bisect, embossed 'DB 500'. 1 × 14 (Blister).
BRAND D	VTG 210005	A4-2278	1/21	12/23	Film-coated, white, capsule, embossed 'M 500' (one side) and 'FBT' (another side). 1 × 10 (Blister).
BRAND E	E207078	04-6233	03/21	02/26	Film-coated, round, embossed 'GL 500'. 1 × 21 (Blister).
BRAND F	FBL080	04-6426	11/21	21/24	Film-coated, white, round, embossed 'M 500' (one side) and 'NGC' (another side). 1 × 10 (Blister).
BRAND G	MP21607	A4-3332	06/21	05/24	Film-coated, white, round, embossed 'GM 500'. 1 × 14 (Blister).
BRAND H	MP22357	B4-8613	8/22	7/25	Film-coated, white, oval, embossed 'M 500'. 1 × 14 (Blister).
BRAND I	KX9321	B4-2914	09/20	08/23	Film-coated, white, round, embossed 'M 500'. 1 × 10 (Blister).
BRAND J	GT21452	B4-0684	07/21	06/25	Film-coated, white, round. 1 × 14 (Blister).

Table 2: Physical and mechanical parameters of brands of metformin tablets

Brand code	Uniformity of weight (g)	Hardness (kgF)	Friability (%)	Disintegration time (min)
Brand A	0.5635±0.014	7.25	0.002%	6:03
Brand B	0.5612±0.006	7.98	0.068%	5:46
Brand C	0.5487±0.012	9.08	0.049%	23:24
Brand D	0.6674±0.009	6.76	0.008%	7:01
Brand E	0.5348±0.006	6.93	0.004%	7:01
Brand F	0.5563±0.014	12.87	0.245%	11:17
Brand G	0.5662±0.006	7.42	0.05%	18:38
Brand H	0.6134±0.015	6.45	2.624%	0:33
Brand I	0.5227±0.005	9.98	2.097%	9:23
Brand J	0.5366±0.009	6.77	0.032%	7:37

Table 3: Percentage content of metformin in different brands of metformin tablets.

Brand code	Amount of drug claimed (mg)	Average amount determined (mg)	Percentage content (%)	Remark
Brand A	500mg	516	103.3	Passed
Brand B	500mg	459	91.8	Failed
Brand C	500mg	526	105.2	Passed
Brand D	500mg	481	96.2	Passed
Brand E	500mg	498	99.7	Passed
Brand F	500mg	480	96.0	Passed
Brand G	500mg	513	102.6	Passed
Brand H	500mg	495	99.0	Passed
Brand I	500mg	487	97.5	Passed
Brand J	500mg	508	101.7	Passed
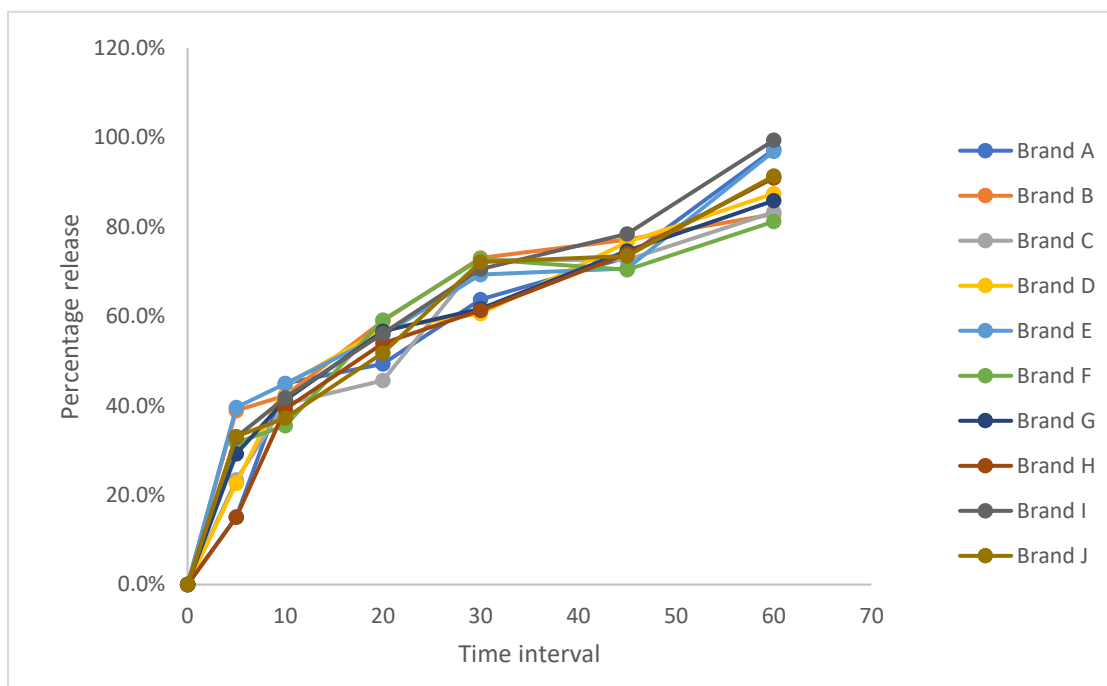
Figure 1: Drug release profile of brands of metformin tablets

important, and it can only be assured by a free granule flow, selecting the appropriate lubricant and punches with tight working length tolerances. According to British Pharmacopoeia, the weight uniformity for 20 uncoated or film-coated tablets states not more than two tablets should deviate from ± 5% and none of the tablets should deviate by ± I0. From the results obtained in the table above, all the brands had tablets that fell within the specification of less than ± 10%, and no two tablets deviated by ± 5%. The exception is Brand H metformin which had two tablets deviating by ± 5%. Factors causing weight variation might include the presence of tablet fragments or dust on the tablets when weighed. It can also be a systematic error caused by the inaccuracy of the weighing balance. Environmental factors such as the vibration of the table or wind from the air-conditioning may also cause fluctuation in the value presented by the weighing balance. However, the variation in the weight of the tablets may be explained by the following factors such as the flowing properties of the powder, the speed of the tableting machine, the pressure used in compression, and the type of machines used in tableting (Peeters et. al., 2015: Imayoshi et. al., 2023; Spaniol et. al., 2009). However, the two most common causes of weight variation are the differences in the bulk densities and particle size distribution during compression.

Tablets require a certain amount of strength or hardness to withstand the mechanical shocks of handling and transportation yet soft enough to be able to disintegrate properly after swallowing (Mansour and Isbera 2016). Since there is also a relationship between the hardness and dissolution rate of the tablets, the hardness of the tablets must be within the acceptable range. Hardness is one of the parameters used to characterize the mechanical strength of a tablet; it portrays the ability of the tablet to withstand the processes involved during manufacturing, transportation, storage, and use (Odeniyi et. al., 2003). A tablet is expected to be strong enough to withstand these conditions while it is also expected to break up to release its active medicament within a specified time (Odeniran et. al., 2021). A minimum hardness of 4 kgF is recommended for immediate conventional tablets and this may vary depending on the type of excipients incorporated into the formulation. Factors like the types of binders used, the nature of the active ingredient(s), and the composition of the ingredient(s) in the tablet will affect the hardness of the tablet; the tablet press speed, granulation flow, and air in the powder can also potentially affect tablet hardness (Ogah and Kadejo, 2013).

The results show that tablet hardness was between 6.1 and 15.1 kgF (Table 2). Brands A, H, and J have the lowest values in the measure of hardness (6.1, 6.1, and 6.4 kgF respectively) while brands F and I had the highest values (15.1 and 10.5 kgF respectively). The results show a slight difference in hardness values between the brands. The slight

difference could be attributed to different excipients incorporated into the tablet formulation and the manufacturing processes employed for the production of these tablets (Muaz et al., 2009).

In theory, tablet hardness is invariably related to tablet disintegration and dissolution, meaning very hard tablets may not disintegrate to release the active medicament within the stipulated time leading to therapeutic failure (Junior et. al., 2020; Odeniran et. al., 2021). In contrast, very soft tablets, on the other hand, may not have the ability to withstand handling, transportation, and storage. This did not apply in this case as the tablet's disintegration and dissolution did not correlate to the tablet's hardness. Neither did the tablet hardness correlate with tablet weight.

Friability is a measure of tablet strength assessed via resistance to fracture and abrasion and a percentage weight loss of ≤ 1 %w/w is considered an acceptable limit for tablet friability (Adetunji et. al., 2006: Odeniran et. al., 2021). Table 2 shows that the friability of the assessed tablets was between 0.00 and 2.62 %. Brand H Metformin with 2.624 % friability and brand I with 2.097 % friability were seen to be the most friable, meaning the tablet's structure has low stability and can break easily from irritation during transport or handling. Although Brand F had a very high hardness value (12.87 kgF) it was observed to be friable and could be attributed to the use of very high compression force which could cause internal stress in the tablet leading to very friable tablets. Thus, Brand H and Brand I failed the friability test, but all other brands passed because they had values within the specified limit. A weak tablet could be due to several factors, including poor tablet design, low moisture content, insufficient binder, and over-lubrication. Also, causes of the High friability of tablets include inadequate binder, drying of granules, and use of some excipients that give low friability at lower compression pressures (such as microcrystalline cellulose, silicified microcrystalline cellulose, magnesium silicate, polysorbate, sodium stearyl fumarate), too much or too little compression pressure, over-lubrication, improper tablet design (British Pharmacopoeia 2021).

The disintegration time of all the brands was between 0:22 min and 31:23 min (Table 2), it was observed that Brand H metformin proved to be the least hard and most friable, it was found to disintegrate fastest, showing a direct correlation between hardness and disintegration time. The remaining brands disintegrated between 4.01 and 8.37 min. All the

The production of uniform-weight tablets is extremely tablets assessed passed the disintegration time test by disintegrating within 30 min specified for film-coated tablets. However, a relationship is thought to exist between tablet mechanical strength and disintegration time in that; weak tablets that are prone to fracture are termed to be liable to break up when in a fluid thus shortening disintegration time. This correlation was observed with brand H in this assessment. This could be attributable to the different processes employed in the manufacture of these tablets. Binders, lubricants, and hardness were found to differ in their effects on disintegration, and these factors are discussed. One two-factor interaction was found and shown to be due to a more significant effect of hardness on tablets made with gelatin binder (Kwan et. al., 1957).

The dissolution test gives insight into the rate at which a drug dissolves and is made available in the biological system for optimum therapeutic response. Figure 1 shows that all the brands assessed released between 38.6 and 100% of metformin after 60 min with Brand G having the least amount of drug release (38.6%) which is outside the lower limit of the official specification (95.0 to 105.0%) as stated by the British Pharmacopeia. This shows that all but one of the brands assessed passed the in vitro dissolution test. Factors affecting tablet dissolution include drug solubility, salt formation, particle size, solid state characteristics, co-precipitation, the shape of the tablet, diluents, disintegrants, temperature, dissolution medium, etc. (Epshtein 2021).

Table 3 gives the result of the metformin assay showing the percentage content of the tablets. The BP limit for the labeled amount of metformin hydrochloride is required to be between 95.0 to 105.0%. Nine (9) of the brands had contents within the official specification but Brand B had 91.77% which is outside the lower limit specified. Four (4) brands had values between 96.03% and 98% (D, E, F, H & I) and the remaining five (5) had percentage contents greater than 100% (A, C, G & J) (Table 3). However, none of the brands had a percent content significantly greater than the official upper limit as specified in BP (105.0%). Thus, only 90% of all brands examined passed the contents of the active ingredient while 10% failed. This implies that the nine (9) brands that were within the monograph specification may be substituted or used as alternatives for each other because they are pharmaceutically interchangeable.

The presence of higher or lower content of metformin hydrochloride outside the monograph specification has severe consequences on the health status of the patient. Lower amounts of metformin hydrochloride below the accepted specification result in glucose buildup in the body which may eventually lead to treatment failure, resistance, and occurrence of complications which may eventually deteriorate the health of the patient(s) while, high amounts of metformin hydrochloride above the specification results in adverse effects like hypoglycemia, organ failure and possibly hypoglycemic related complications like coma or death. This study strongly suggests the need for random sampling and routine testing of marketed pharmaceutical products within the country to ensure that their quality follows the standard operating procedures of Good Manufacturing Practice (GMP) and International Best Practices.

CONCLUSION

The brands of metformin tablets circulating in Lagos varied considerably in their pharmaceutical quality. Thus, this assessment highlights the importance of routine quality assessment of pharmaceutical products circulating in the market to ascertain their quality to safeguard the health of the nation. It can be suggested from the results obtained from the study that frequent analysis of various brands of drugs is carried out using less expensive means to monitor the production consistency of batch-to-batch product release of each brand of metformin.

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*Address for correspondence**: Oyawaluja Bamisaye**

Department of Pharmaceutical Chemistry,
Faculty of Pharmacy,
University of Lagos,
Lagos, Nigeria .
Telephone: +2348023534167
E-mails: boyawaluja@unilag.edu.ng