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Comparative *In-vitro* Quality Evaluation of Six Commercially Available Brands of Metformin Tablets Marketed in Dhaka, Bangladesh

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ABSTRACT

Background: Metformin hydrochloride, categorized as a biguanide, serves as the preferred first line pharmacological option for managing diabetes mellitus (type II). Numerous branded tablets of metformin HCl are currently marketed but it is challenging to choose the appropriate brand which is effective and affordable.

Methods: In this work, the criteria for quality control such as weight variation, assay, friability, dissolution analysis and hardness testing are developed to analyze and differentiate the six commercially available brands of metformin (500 mg) tablets in Dhaka, Bangladesh.

Results: The six brands of metformin tablets exhibited visual inspections, hardness range of 4–9 kg/cm², and high physical integrity, with maximum friability of 0.167%. The percentage of drug content and weight variation for all samples was within the USP specification of 100±5%. All samples also met the USP dissolution specification of at least 80% dissolution in 30 minutes. Specifically, the dissolution rate at 30 minutes ranged from 72.5% to 82.4% across the six brands. All brands, except brand D (with an f_2 value of 40.6), were considered bio-equivalent to the innovator brand (Brand A) based on the f1 (≤15) and f2 (≥50) fit factors. Overall, the findings indicated that each of the six brands met the USP requirements.

Conclusion: All six brands met USP quality requirements, indicating potential interchangeability among them. Patients may therefore use any of the six brands as an alternative without considering the price difference.

Keywords: Assay; Diabetes; Dissolution; Friability; Hardness; Interchangeable Drug; Metformin; Quality Control; Visual Inspection.

1. Introduction

Metformin is an oral anti-hyperglycemic drug which dissolves readily in water [1]. However, only half of the orally ingested dosage is absorbed through the gut. Hence, metformin is designated under class III medication in the BCS system due to its poor permeability and site specific absorption because of the effects of excipients [2].

In this contemporary epoch, metformin hydrochloride is the mostly prescribed worldwide drug from biguanide class for the management of polycystic ovarian syndrome (PCOS) and diabetes type II. It is regarded as a safer alternative to sulphonylureas because it does not induce weight gain and has a low risk of hypoglycemia [3,4]. Furthermore, due to the cardio-protective effect, it is considered superior to the thiazolidinediones [5,6].

In many developing countries, patients are more worried about the high cost of some branded medications rather than the diseases they are suffering from [7,8]. Hence, patients may choose drugs that are comparatively lower cost with same generic substitution [9,10]. Thus, the study intends to mollify the unwavering belief of patients that the generic drugs also have bioequivalence and therapeutic equivalence to brand drugs if every quality assessment parameter is being followed properly according to the guidelines of pharmacopeia [11,12]. Hence, evaluation and comparative study of various commercially available brands of metformin should be checked for ensuring better quality of medicines by performing weight variation, drug content assay, hardness levels, dissolution rate and friability [13].

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1.1. Study Objectives

1) To check the color, shape, texture, manufacturing date and expiration date of the tablets by visual inspection.
2) To determine the uniformity of tablet weight.
3) To check the amount of drug present in the tablets by assay method.
4) To measure the strength of the tablets by hardness test.
5) To evaluate the friability test for the physical integrity and resistance of tablets during handling.
6) To estimate the rate and extent of drug release profile of the tablets.
7) To compare the results and ensure overall quality and reliability of marketed metformin tablets.

2. Materials and Methods

2.1. Materials and Equipments

Six distinct 500 mg tablets of metformin hydrochloride were procured from a registered pharmacy in Dhaka, Bangladesh. Apart from this, pure metformin hydrochloride, reference standard, was obtained from Bangladesh University, Dhaka. Every evaluation was carried out before the tablets' expiration date. The entire experiment was conducted using analytical quality NaOH pellets, potassium dihydrogen phosphate along with distilled water throughout. All sample brands were coded as shown in table 1. A UV-1800 model Shimadzu spectrophotometer (double-beam, Japan), an electronic analytical balance (AS 220.R2 PLUS), Dissolution apparatus, Monsanto hardness tester, Friability tester were used to complete the work. Furthermore, Microsoft excel was used for statistical data analysis.

Table 1. Brand selected for analysis

Brand code	Label claim	Price (tk)
A	500 mg	4.02
B	500 mg	4.00
C	500 mg	3.00
D	500 mg	4.00
E	500 mg	4.00
F	500 mg	4.00

2.2. Methods

2.2.1. Visual inspection: The color, shape, texture, manufacturing date and expiration date of the chosen metformin tablet brands were assessed separately through visual inspection, which is presented in table 2 [12].

Table 2. Visual parameters

Brand code	Color	Shape	Texture	Mfg. date	Exp. date
A	White	Rounded	Smooth	01/2022	12/2024
B	White	Cylindrical	Smooth	11/2021	10/2024
C	Yellow	Rounded	Smooth	10/2022	09/2025
D	White	Cylindrical	Smooth	09/2021	08/2024
E	White	Cylindrical	Smooth	11/2021	10/2024
F	White	Rounded	Smooth	12/2022	11/2025

2.2.2. Weight variation analysis: The weight of every brand's tablets was quantified utilizing a digital balance and their mean weight was computed. The percentage deviation of each tablet from the mean weight was calculated [14].

2.2.3. Friability test: Friability test is typically carried out to examine the potential loss of tablet weight during handling and transportation. According to the USP Pharmacopoeia, friability should be not more than 1%. The weight of twenty tablets of each brands were recorded and calculated percentage of friability using the ratio of loss weight and initial weight multiply by 100 [14].

2.2.4. Hardness test: A Monsanto hardness tester helped evaluate the tablets' crushing strength. Hence, twenty tablets of each brand were subjected to machine and recorded the tablet crushing strength. If the crushing strength lies within are 4 kg/cm^2 – 10 kg/cm^2, then tablet passes the hardness test [15].

2.2.5. Content assay: An assay is carried out to confirm the actual quantity of API present in the tablet that they claimed in the label. 10 mg pure standard metformin hydrochloride was dissolved within a volumetric flask measuring 100 mL and Adjusted to the final volume with 0.1 N solution of hydrochloric acid. After filtration, A 10 mL filtrate aliquot was delivered within a laboratory volumetric flask of 100 mL and followed by dilution with water till the mark to create a standardized test solution at a10 µg/mL strength. Again, 20 tablets from all brands were weighed utilizing digital balance and mean weight was taken with the help of mortar and pestle, tablets were powdered finely and equivalent quantity of metformin HCl tablet 100 mg was dispensed within a volumetric flask measuring 100 mL. Following this, sample was integrated with 50 mL distilled water aliquot and shaken with a mechanical shaker for fifteen minutes and further added water to the calibration mark. After filtration, 10 mL filtrate aliquot was poured within a laboratory volumetric flask measuring 100 mL and completed to volume. Afterwards, 10 mL was shifted to a second volumetric container (100 mL) and filled with distilled water to reach 100 mL for preparing the sample solution. The absorbance of samples and standard solution was determined at λmax 232 nm utilizing a spectroscopy device (UV-Visible) with water as the blank for reference [16]. The tablet's assay (mg) was computed using the equation: 10 c (Au/As). Where, c served as the quantity (µg/mL) of metformin HCl and Au and As are the absorbance of sample and reference respectively.

2.2.6. Dissolution test: For constructing the standard curve, an aliquot of purified metformin HCl weighing 10 mg was added to phosphate buffer and the final volume was fixed at 100 mL within a laboratory volumetric flask. After filtration, 10 mL filtrate aliquot was placed within a laboratory volumetric container (100 mL) and then diluted to get the standard solution of 10 µg /mL concentration. The solutions at varying concentrations (2–10 µg/mL) were prepared through proper dilution and the absorbance was observed at max 232 nm using UV-visible spectrophotometer. The absorbance was positioned against their corresponding concentration to generate the calibration curve (Figure 1). The graph was used to derive the linearity equation for subsequent calculations.

The dissolution testing was conducted using USP equipment 2 (paddle method) with six replicates at 37±0.5°C in 900 mL of buffer medium (phosphate), adjusting pH 6.8 using 1 M sodium hydroxide. The paddle was set to rotate at 100 rpm. During all experiments, four 10 mL samples were collected at 15-minute intervals up to 60 minutes

with micropipettes, and the medium was replaced to ensure sink condition was maintained. Withdrawn samples underwent Whatman filtration and were diluted subsequently. Absorbance of each sample was quantified through spectrophotometry with an UV-visible wavelength at 232 nm.

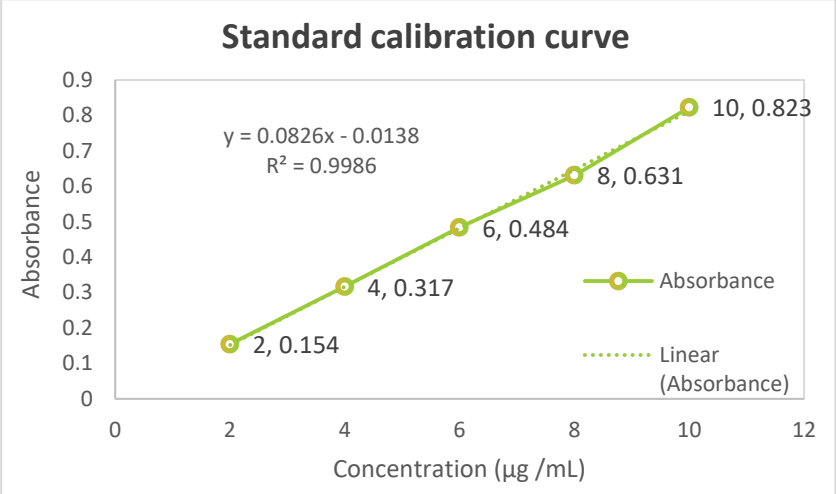

Figure 1. Standard calibration curve for metformin HCl with equation, $y = 0.0826x - 0.0138$ and $R^2 = 0.9986$

Using mean values, the release percentages were computed for all tablet brands in Microsoft excel. A model-independent method was applied using fit factors f_1 and f_2, defined as difference and similarity factors, which were computed comparing the test brand and reference brand given in equation (1) and (2). In assessing the equivalence of two dissolution trends, the range of f_1 was 0–15, whereas f_2 lay within 50–100. The f_1 and f_2 defined as:

$$f1=\left\{\frac{\sum |Rt-Tt|}{\sum Rt}\right\}\times 100 \qquad \ldots(1)$$

$$f2=50\log\{1\div\sqrt{[1+\frac{1}{n}\sum (Rt-Tt)(Rt-Tt)]}\times 100\} \qquad \ldots(2)$$

here n denotes the count of sampling times during dissolution, while Rt value and Tt value represent the percent dissolution of the reference and test formulations [17,18].

3. Results and Discussion

To assess the equivalence of the pharmaceutical products, six distinct commercially available branded tablets of metformin HCl, which are coded in table 1 alongside the price and dose, from Dhaka, Bangladesh, underwent quality control testing. Apart from that, visual inspections, which are inscribed in table 2, are carried out to check the color, shape, texture, manufacturing date and expiration date for six branded tablets. All selected brands complied with the USP quality specifications including the evaluation of tablet weight variation, tablet hardness, friability, extent of dissolution and drug content profiles with fit factors.

The uniformity of each brand of tablets was checked and compared with each other brand tablets. According to the USP guidelines, ±5% weight deviation is allowed for 500 mg tablet. The study revealed that the weight variation

test for the six distinct brands' tablets of metformin HCl (500 mg) complied with the USP specification and presented in table 4.

Appraisal of tablet rigidity revealed hardness values between 4–9 kg/cm² range, but A, B and F brands' tablets did not pass in this non- official assessment as per the USP parameter (4-6 kg/cm^2) where the crushing values for A, B and F brands tablets were 8.7, 8.3 and 9kg/cm^2 respectively. Brand B and F showed the minimum and maximum hardness accordingly, with more than two time difference between them. The dissolution profile appeared independent of tablet hardness, possibly due to the presence of a film coating that modulates drug release [15]. Another reason for the hardness deviation may be explained by the different excipients used in the formulation (Table 4).

The friability test results for all brands were highly satisfactory with maximum withstand strength of 0.167% (Table 4). As the USP specification, the friability test for metformin hydrochloride (500 mg) is less than 1%. Hence, all of our test samples were passed in friability test.

Furthermore, the assay technique was employed for six brands of metformin hydrochloride to show that the percentage of drug content is how much close to the value of Label claims (500 mg). In this study, all samples showed values within the USP specifications (100 ± 5%) of active component (Table 3).

Table 3. Comparative evaluation for tablet weight variation, drug content assay, hardness levels and friability of six branded metformin tablets

Brand code	Weight variation (mg)		Hardness (kg/cm^2)	% Friability	% Drug content
	Mean ± SD	Deviation allowed (±5%)			
A	548 ± 4.9	520.6-575.4	8.7	0.073	101.8
B	553 ± 3.1	525.4-580.7	8.3	0.073	102.6
C	688 ± 10.1	653.6-722.4	4.2	0.005	100.5
D	616 ± 7.9	585.2-646.8	4	0.163	103.8
E	604 ± 4.3	573.8-634.2	5.8	0.167	102.5
F	552 ± 4.9	524.4-579.6	9	0.072	102.2

Dissolution was another widely method for oral dosage forms to check the bioavailability and absorption rate of drug. The present study demonstrated that all samples met the USP specification of at least 80% dissolution in 30 minutes. To calculate the drug release profile, a standard calibration curve is constructed, which is shown in Fig. 1 and the findings are demonstrated in Table 4. The dissolution pattern of sample C and D were comparatively better than the other four brands of metformin tablets, although the dissolution data were satisfactory for all six branded of metformin tablets (Figure 2).

Table 4. Comparative data for dissolution studies of six branded metformin tablets

Time (min)	A	B	C	D	E	F
15	30.1	32.8	40.1	43.2	35.5	25.7
30	78	79	80.3	82.4	78.9	72.5
45	81.5	82	87.8	90.2	83.8	81.9
60	89.5	89.7	90.9	94.1	90.1	89.1

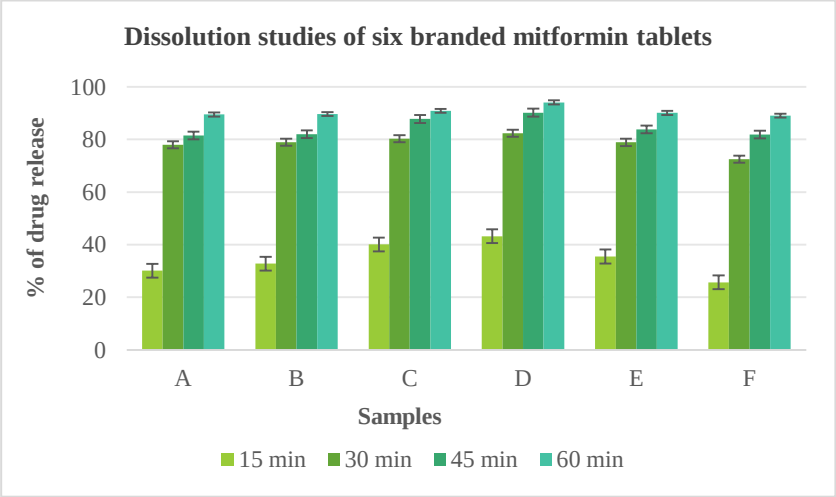

Figure 2. Statistical comparison for dissolution studies of six branded metformin tablets

However, all chosen metformin hydrochloride brands exhibited the release profile more than 80% within 45 minutes. In the calculations of fit factors, brand A was considered as the innovator brand. The values of f_1 and f_2 factors were computed using equations 1 and 2 respectively and the obtained data were satisfactory as bioequivalent with the innovator brand except the f_2 value of brand D (Table 5).

Table 5. Fit factors for the six metformin hydrochloride tablet brands derived from the mean value of six tablets

	Fit factor	
Brand	**f_1**	**f_2**
A/B	1.6	80.8
A/C	7	50.5
A/D	11	40.6
A/E	3.3	66.4
A/F	3.8	63.2

4. Conclusion

The findings affirmed that the metformin hydrochloride oral tablets from six distinct manufacturers can be utilized interchangeable as the comparative evaluation of different brands assures their efficacy and potency within the USP Specifications. So, patients can use any of six brands tablets freely as an alternative tablet for a specific brand without considering the price of the tablets. To provide a more comprehensive assessment of product quality of metformin tablets across the market of Bangladesh, the following future studies should be investigated:

1) Expand the study to include more than six commercially available brands.
2) Include different formulation types of tablets (immediate release and extended release).
3) Assessment of storage conditions like temperature, humidity.
4) Perform dissolution studies using different pH media.
5) Extend the study to evaluate in-vivo studies.

Declarations

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Competing Interests Statement

The authors declare that they have no competing interests related to this work.

Consent for publication

The authors declare that they consented to the publication of this study.

Authors' contributions

All the authors took part in literature review, analysis, and manuscript writing equally.

Availability of data and materials

Supplementary information is available from the authors upon reasonable request.

Institutional Review Board Statement

Not applicable for this study.

Informed Consent

Not applicable for this study.

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