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Research Article

In vitro Quality Evaluation of Six Brands of Metformin Hydrochloride Tablets Locally Manufactured in Ghana

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Abstract

Aim: To carry out an in vitro quality evaluation of six brands of Metformin Hydrochloride tablets locally manufactured in Ghana.
Place and Duration of Study: Department of Quality Assurance and Quality Control, Tradewinds Chemist Limited, Ghana from June 2024 to September 2024.

Methodology: Six brands of metformin hydrochloride tablets purchased from retail pharmacies were analyzed. Pharmacopoeia tests such as uniformity of weight, friability, disintegration and assay were carried out to assess the physicochemical properties of the six brands of metformin hydrochloride tablets. In vitro dissolution was also conducted to determine the percentage release of metformin hydrochloride (the active pharmaceutical ingredient) within a time-frame of 45 minutes.

Results: Test results of uniformity of weight indicated that all brands met the compendia specifications. All brands of uncoated metformin hydrochloride tablets passed the friability test with a value ranging from 0.47% w/w to 0.75% w/w. All tablets (both film coated and uncoated) passed the disintegration test according to British Pharmacopoeia specifications. Results obtained from the analysis using UV-Vis Spectrophotometer indicated that all brands of Metformin Hydrochloride Tablets passed the assay test in exception of MET A and MET D. All brands passed the dissolution test, with values ranging from 87.64±2.96% to 105.07±3.13%.

Conclusion: This study showed that the six brands of Metformin Hydrochloride tablets assessed in this study differ in pharmaceutical quality. All brands passed all pharmacopeia tests, in exception of MET A and MET D which failed the percentage content (assay) test.

Keywords: Diabetes Mellitus; Metformin hydrochloride; Quality evaluation

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Introduction

Diabetes continues to be a leading non-communicable disease globally [1]. About 537 million people within the ages of 20 and 79 years are battling with diabetes globally, with over 75% of such individuals living in low and middle-income countries. It is predicted that the burden of diabetes will continue to increase exponentially in Sub-Saharan Africa, with a projected increase of 134% by the year 2045 [2]. In Ghana, there are approximately 2.4 million people living with diabetes and about 7.5% of these people are adults [3]. Diabetes mellitus is characterized by chronic hyperglycaemia and defect in protein, fat and carbohydrate metabolism caused by deficiency in either insulin secretion or production, or both [4]. Type 2 diabetes mellitus remains the most common type of diabetes, accounting for about 90% of all cases of diabetes [5].

Management of diabetes is by synthetic oral hypoglycaemic drugs [6]. Metformin hydrochloride remains the most common management strategy for type 2 diabetes. Metformin hydrochloride is an oral antidiabetic drug, which belongs to the class biguanide [2]. Apart from its main use in managing type 2 diabetes, it also serves as prescription for people with polycystic ovarian disease, impaired glucose tolerance and prediabetes [7]. Although, the mode of actions of this drug is yet to be fully understood, some of its proposed mechanisms of action include; lowering the level of glucose production in the liver, upregulating the action of insulin resulting in an increase in glycogen production, enhancement of skeletal muscle sensitivity [8,9].

Due to the high cost and less availability of innovator drugs in low and middle-income countries, people from these countries heavily rely on generic drugs for the management of diseases, including type 2 diabetes mellitus. According to [10], about 34% of medicines in Sub-Saharan Africa are of poor quality. The marketing of substandard drugs has become a critical issue of public concern. Substandard

drugs can be classified as high or low concentration of active ingredients, contaminated drug, inactive ingredients, etc. [11]. The intake of substandard drugs is associated with many health risks, which include treatment failure and prolonged hospital stays. These further pose high economic burden on patients. The intake of substandard drugs could also lead to loss of lives [12]. Therefore, assessing the pharmaceutical quality of drugs is very critical.

Although there have been some studies on the assessment of the quality of Metformin Hydrochloride tablets in the Ghanaian market, these studies did not focus solely on brands of metformin hydrochloride tablets locally manufactured in Ghana. Therefore, this study aims at evaluating the pharmaceutical quality of six brands of metformin hydrochloride tablets solely manufactured in Ghana.

Materials and Methods

Study Area and Period

The study was conducted at the Quality Control Laboratory of Trade winds Chemist Limited, Ghana, from June 2024 to September 2024.

Study Design

The study was conducted using in-vitro quality control parameters to evaluate six brands of Metformin Hydrochloride Tablets locally manufactured in Ghana. The study employed various test procedures associated with pharmaceutical quality including uniformity of weight, friability, disintegration time, percentage content (assay) of Metformin Hydrochloride and dissolution.

Instruments

UV-spectrophotometer (Shimadzu UV-1700 Pharma Spec, India), analytical balance (ML304T/A00; China), tablet hardness tester (HT-01-10/0712, Veego), friability tester (Model: C-FY-20), disintegration test apparatus (T-TD-2, India), dissolution test apparatus (RC-6, India), pH meter (VSI-01ATC, VSI Electronics PVT. Ltd), mortar and pestle.

Reagents/Chemicals Used

Potassium dihydrogen orthophosphate, Sodium Hydroxide, Phosphate Buffer and distilled water.

Sampling Techniques and Sample Collection

Guidelines for Field Surveys of the Quality of Medicines was employed as the sampling technique for this study [13]. Six variably locally manufactured Metformin HCL brands with a label claim of 500 mg were randomly sampled from government health centers and private pharmacies in Kumasi, Ghana. All the six different brands were sampled by mystery shopper approach. The objective of the study was not declared to the shoppers and were instructed to procure 7 blisters (Blister = 10 tablets) of each brand of Metformin HCL. The blisters were bought in their original packaging as provided by the manufacturers. About 70 Metformin HCL were collected for each brand for the analysis. The product information such as drug substance name, expiration date, batch/lot numbers were coded by alphabets for each brand (Table 1). After purchase, all collected samples were transported to the Tradewinds Chemist Limited Quality Control Laboratory and stored according to the specified storage conditions stated on the product labels until analysis.

Code	Batch Number	Expiry Date
A	3010Z	10/27
B	T0136033	06/25
C	B.N 03	06/25
D	N.N004	11/27
E	A24014	12/26
F	08	10/25

Table 1: Profile of sampled Metformin Hydrochloride Tablets manufactured in Ghana.

Sample Analyses

Uniformity of Weight: Twenty (20) tablets were randomly selected from each brand and individually weighed using an analytical balance (Model: ML304T/A00). The mean and standard deviation were calculated for each brand, then the percentage of weight deviation was calculated by using ± 5 % deviation limit of the cut weight of each of the brands as stated in British Pharmacopoeia 2020 (Ph. Eur. method 2.9.5).

Friability Test: Ten tablets were selected for each of the brands and was carefully weighed before testing. The tablets were then placed in the drum of friability tester (Model: C-FY-20) and rotated at the speed of 25 rpm for 4 minutes. After 100 revolutions and de-dusting, tablets were re-weighed and the friability percentage was calculated by the following equation [14].

$$\%\ Friability = \frac{Initial\ weight - Final\ weight}{Initial\ weight} \times 100$$

Hardness Test: Ten tablets were randomly selected from each brand and the hardness of the tablets was determined using a hardness tester machine (HT-01-10/0712 Veego, India). The tablets were placed between two anvils and forces were applied to the anvils, measuring the crushing strength that caused a tablet to break. The average hardness of each brand was calculated and the standard deviation determined.

Disintegration Test: Disintegration of the tablets were determined for all brands at a temperature of 37±0.5°C using tablet disintegration test apparatus. 1 L beaker was filled by 900 mL of distilled water (disintegration medium) and placed in the disintegration test apparatus. Then six tablets were randomly selected from each brand and placed in the basket rack assembly which consist of six cylindrical tubes and then placed on the rotor of the disintegration test apparatus. The time taken for the tablets to disintegrate and pass through the mesh was recorded and the mean time taken was calculated [14].

Assay of Metformin Hydrochloride Tablets: Twenty (20) tablets of metformin hydrochloride were weighed and powdered using a mortar and pestle. Then 0.1 g of the powered metformin hydrochloride was shaken with 70 mL of distilled water for 15 minutes and topped up to a total volume of 100 mL with distilled water and then filtered. After discarding the first 20 mL, 10 mL of the filtrate was diluted to 100 mL with distilled water then 10 mL of the resulting solution was further diluted to 100 mL with distilled water. The absorbance of the resultant solution was determined at a wavelength of 232 nm and the concentration of metformin hydrochloride was calculated using 798 as the value of A (1%, 1 cm), and this was used to calculate the drug content. Distilled water was used as a blank.

Dissolution Test: The dissolution test was conducted according to the British Pharmacopoeia (BP). A buffer was prepared from potassium dihydrogen orthophosphate and adjusted to pH 6.8 by the addition of 1M sodium hydroxide. The basket was rotated at a fixed speed of 100 rpm, and the temperature was maintained at 37± 0.5°C. Three tablets were randomly selected for each brand and then subjected to the test. 10 mL of samples were taken from each dissolution test vessel at a sampling time of 45 minutes. The sample was filtered then 10 mL of the filtrate was diluted to 100 mL with distilled water. 10 mL of the resulting solution was further diluted to 100ml with distilled water and assayed for drug content by measuring the absorbance at 233 nm using a UV-Vis spectrophotometer. Phosphate buffer was used as a blank. This was followed by the calculation of the total content of metformin hydrochloride in the medium taking 806 as the value of A (1%, 1 cm).

Results

Profile of Selected Brands of Metformin Hydrochloride Tablets locally manufactured in Ghana (Table 2).

BRAND	Description	Mean Diameter (mm) ±SD	Mean Thickness (mm)±SD	Mean Weight (g) ± SD
MET A	White round film coated tablet	12.304±0.04	5.005±0.05	0.636±0.02
MET B	White round film coated tablet	12.197±0.04	4.784±0.23	0.596±0.01
MET C	White round film coated tablet	12.273±0.03	5.043±0.04	0.612±0.01
MET D	White round uncoated tablet	12.306±0.03	4.984±0.04	0.598±0.00
MET E	White round uncoated tablet	12.271±0.03	5.045±0.04	0.617±0.01
MET F	White round uncoated tablet	12.304±0.04	5.286±0.05	0.534±0.002

Table 2: The table above shows the description, mean diameter, mean thickness and mean weight of the selected brands of Metformin Hydrochloride Tablets locally manufactured in Ghana.

Uniformity of Weight of Metformin Hydrochloride Tablets

Test results of uniformity of weight in this study indicated that all brands met the compendia specifications. Based on BP 2020 guidelines, uniformity of weight test is considered passed if not more than two individual tablets weight deviate from the average weight by ± 5% for coated and uncoated tablets with average weight of 250 mg or more (Table 3).

BRAND	Lower Limit (g)	Upper Limit (g)	Number of Tablets That Deviated By ±5%
MET A	0.604	0.668	None
MET B	0.566	0.626	None
MET C	0.581	0.643	2
MET D	0.568	0.628	None
MET E	0.586	0.648	None
MET F	0.507	0.561	None

Table 3: The table above describes the uniformity of weight of six brands of Metformin Hydrochloride Tablets Locally Manufactured in Ghana.

Friability Test of Metformin Hydrochloride Tablets

In this study, all brands of uncoated Metformin Hydrochloride tablets passed the friability test with a value ranging from 0.47% w/w (MET F) to 0.61% w/w (MET D) as shown in table 4. Based on BP guidelines, uncoated tablets with a maximum weight loss of 1.0% are accepted to have passed the friability test (Table 4).

BRAND	Initial Weight	Final Weight	Weight Loss	% Weight Loss
MET A	-	-	-	-
MET B	-	-	-	-
MET C	-	-	-	-
MET D	6.52	6.48	0.04	0.61
MET E	6.70	6.65	0.05	0.75
MET F	6.41	6.38	0.03	0.47

Table 4: This table shows the friability of six brands of Metformin Hydrochloride Tablets Locally manufactured in Ghana.

Hardness of Metformin Hydrochloride Tablets

According to non-official USP specifications, oral tablets normally exhibit a minimum hardness of 4 $Kgcm^{-3}$. The results of the hardness test in this study as shown in table 5 below indicated that only MET F met the non-official USP specification for Hardness of oral tablets (Table 5).

BRAND	Mean Hardness (Kgcm-3) ± SD
MET A	3.173+0.25
MET B	2.530±0.39
MET C	3.395±0.96
MET D	2.674±0.25
MET E	3.390±0.96
MET F	4.132±0.54

Table 5: Hardness of different brands of Metformin Hydrochloride Tablets Locally Manufactured in Ghana.

The Disintegration of Metformin Hydrochloride Tablets

All tablets (both film coated and uncoated) passed the disintegration test according to BP with specifications of NMT 15 minutes and NMT 30 minutes for uncoated and coated tablets respectively as shown in table 6.

BRAND	Disintegration Time/Min
MET A	14
MET B	10
MET C	23
MET D	2
MET E	10
MET F	8

Table 6: The table above shows the disintegration time of six brands of Metformin Hydrochloride Tablets Locally Manufactured in Ghana.

Assay of Selected Brands of Metformin Hydrochloride Tablets

The results obtained from the analysis using UV-Vis Spectrophotometers indicated that all brands of Metformin Hydrochloride

Tablets in exception of Brands A and D met BP specifications of (95-105) % of percentage content as shown in table 7.

BRAND	Mean Absorbance	Assay (%)
MET A	0.855±0.01	106.37
MET B	0.791±0.02	98.68
MET C	0.797±0.01	99.99
MET D	0.757±0.03	94.43
MET E	0.784±0.01	98.82
MET F	0.783±0.02	98.10

Table 7: The table above shows the assay of selected brands of Metformin Hydrochloride Tablets Locally Manufactured in Ghana.

Dissolution of selected brands of Metformin Hydrochloride Tablets Manufactured in Ghana

Based on BP 2020 specifications, the minimum percentage release (dissolution) of Metformin Hydrochloride (the active ingredient) should be 70% within a period of 45 minutes. All brands passed the dissolution test, with values ranging from 87.64±2.96% (MET D) to 105.07±3.13% (MET F) as shown in table 8.

BRAND	Mean Drug Release (%) within 45 minutes±SD
MET A	103.383±1.60
MET B	101.02±2.67
MET C	101.52±1.67
MET D	87.64±2.96
MET E	88.88±1.51
MET F	105.07±3.13

Table 8: The table above shows the Percentage Release (Dissolution) of selected brands of Metformin Hydrochloride Tablets manufactured in Ghana.

Discussion

Previous reports have indicated that the quality of pharmaceutical drugs in Sub-Saharan Africa continue to be compromised [10], signifying that the assessment of the quality of pharmaceutical drugs is crucial. In this study, six different brands of metformin hydrochloride tablets locally manufactured in Ghana were thoroughly assessed through various Pharmacopoeia tests such as uniformity of weight, friability, disintegration and assay, as well as in-vitro dissolution test. The profile of the various brands of metformin hydrochloride tablets were also assessed as indicated in table 1. The average weight of the various brands of metformin hydrochloride tablets range from (0.534± 0.02) g to (0.636±0.02) g. These recorded average weights are similar to those of a study carried out by [15] who recorded weights of metformin hydrochloride tablets ranging from 0.5162±0.00 g to 0.6999±0.00 g.

Assessing the uniformity of weight of tablets is very essential, as this ensures that ingredients are equally distributed in each tablet. This even distribution ensures that there is consistency in the bioavailability of the Active Pharmaceutical Ingredient (API). In other words, this prevents incidence of overdosing or under-dosing. From table 3, Test results of uniformity of weight in this study showed that all brands of metformin hydrochloride tablets considered in this study met the compendia specifications, which indicates that the active pharmaceutical ingredient, metformin hydrochloride is evenly distributed in all tablets, implying that there may be no cases of under-dosing or overdosing.

Friability takes into account the strength of tablets. In other words, it is the ability of a tablet to resist mechanical stress during manufacturing and transportation processes [16]. This is measured as percentage weight loss. A friability less than 1% is considered suitable while friability more than 1% is unacceptable [17]. Table 4 indicates that all brands of uncoated metformin hydrochloride tablets passed the friability test with a value ranging from 0.47% w/w to 0.75% w/w.

Disintegration time is a very important quality test parameter. It measures the time taken for a tablet to break apart into small granules when in contact with a volume of fluid. It is associated with the time taken to breakdown inter-particulate bonds holding a tablet together, leading to the release of the active pharmaceutical ingredient [18]. According to [17], the disintegration time of an uncoated tablet should not be more than 15 minutes while that of a film-coated tablet should not be more than 30 minutes. From the results obtained (Table 6), all tablets (both film coated and uncoated) passed the disintegration test. The disintegration time for coated tablets corresponds with their hardness, where MET B with a hardness of (2.530±0.39) $Kgcm^{-3}$ had the lowest disintegration time of 10 minutes while MET C with a hardness of (3.395±0.96) $Kgcm^{-3}$ had the highest disintegration time of 23 minutes.

Table 7 shows the percentage content (assay) of the various brands of metformin hydrochloride tablets assessed in this study. According to [17], the ideal percentage content of metformin hydrochloride should range from 95.0% to 105.0%. In this study, all brands of metformin hydrochloride tablets in exception of MET A (106.37%) and MET D (94.43% met this specification. This higher percentage content recorded in MET A could be due to the addition of higher amount of the active pharmaceutical ingredient during the granulation process while a lower percentage content recorded in MET D could be due to insufficient amount of metformin hydrochloride added during the granulation process [19]. A percentage content of metformin hydrochloride outside the British Pharmacopeia specifications could result in adverse health effects [20]. While a lower percentage content of metformin hydrochloride (out of limit) could lead to the build-up of glucose, resulting in treatment failure, a higher amount (out of limit) could result in adverse health effects such as hypoglycemia, organ failure and hypoglycemic associated health consequences including coma and death [20].

Dissolution measures the extent and rate of formation of solution from dosage forms including tablets. This test parameter is important as it takes into account the bioavailability and therapeutic effectiveness of drugs. According to [17], the minimum percentage release of metformin hydrochloride tablets should be 70% within a timeframe of 45 minutes. As indicated in Table 8, all brands passed the dissolution test, with values ranging from (87.64±2.96) % to (105.07±3.13) %. This is an indication that the Active Pharmaceutical Ingredient (API) is readily available in solution leading to absorption and subsequent therapeutic effectiveness.

Conclusion

This study showed that the six brands of Metformin Hydrochloride tablets assessed in this study differ in pharmaceutical quality. All brands passed pharmacopeia tests such as uniformity of weight,

disintegration test and dissolution test. All uncoated brands passed the Friability test. However, in terms of percentage content, all brands of Metformin Hydrochloride met the required specifications, in exception of MET A and MET D. MET A recorded a higher percentage content beyond the British Pharmacopeia standard while MET D recorded a lower percentage content below the British Pharmacopeia standard. It is therefore recommended that regulatory bodies carry out routine assessment and surveillance on Metformin Hydrochloride Tablets and other essential medicine to ensure these drugs meet the required pharmaceutical qualities.

Disclaimer (ARTIFICIAL INTELLIGENCE)

Author (s) hereby declare that NO generative AI technologies such as Large Language Models (ChatGPT, COPILOT, etc.) and text- to image generators have been used during writing or editing of this manuscript.

Consent and Ethical Approval

It is not applicable.

Competing Interests

Authors have declared that no competing interests exist.

Author's Contribution

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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