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Original Research Article

QUALITY ASSESSMENT OF DICLOFENAC TABLETS MARKETING IN SAGAMU COMMUNITY, OGUN STATE, NIGERIA

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ABSTRACT

Substandard and fake drugs pose significant health risk globally. As the number of diclofenac brands increases worldwide, a continuous quality control testing is necessary to maintain the consistency of the products, their effectiveness and safety of patients. This study evaluated the in vitro chemical equivalence and in vivo analgesic efficacy of five brands of diclofenac potassium. Quality control tests including weight variation, friability, hardness, disintegration, dissolution, and content purity analysis were conducted as per the British Pharmacopoeia standards. Moreover, the in vivo analgesic effect was compared via the hot-plate method. The five brands (A, B, C, D, and E) had a 100% pass rate in weight variation, friability, hardness, and disintegration tests. Brands A, C, D and E failed the dissolution test with drug release percentages of 51.2%, 52.21%, 30.53% and 46.17% at 45 minutes respectively. Brand B, on the other hand, met the official standard with a drug release of 70.44%. The content purity analysis showed that Brands A, B, C, and E met the standards of the pharmacopoeia with purities of 97%, 95.5%, 100%, and 98.5%, respectively, and Brand D failed with a purity of 75%. Despite these discrepancies, all brands demonstrated significant in vivo analgesic activity. The findings from this study highlight the significance of continuous post-market surveillance to ensure safety, efficacy and strict adherence to quality standards.

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INTRODUCTION

Diclofenac is a non-steroidal anti-inflammatory drug (NSAID) belonging to the phenylacetic acid family. It is available in two forms namely, diclofenac sodium and diclofenac potassium [1]. In Japan, diclofenac sodium was launched in 1974 as a slow-release tablet to treat chronic pain by ensuring sustained drug release over an extended period [2].

Conversely, diclofenac potassium was designed to have a quick absorption and is effective for conditions requiring swift pain relief [1]. In addition to its analgesic effect, diclofenac has pronounced anti-inflammatory and antipyretic properties [1]. Diclofenac exerts its pharmacological effects by inhibiting cyclooxygenase-1 (COX-1) and cyclooxygenase-2 (COX-2), which play a major role in the production of prostaglandin E₂ (PGE₂), prostacyclins and thromboxanes. These are

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important in inflammatory and nociceptive mechanisms [3,4]. Moreover, diclofenac has anti-inflammatory effects, which are indirectly mediated by the lipoxygenase pathway [3]. Diclofenac is the most prescribed NSAID and is widely marketed as an over-the-counter drug [5]. It controls the biggest market share in comparison to other NSAIDs [5]. In Nigeria, diclofenac is commonly prescribed in hospital settings. In a retrospective study at Lagos University Teaching Hospital (LUTH), diclofenac potassium was found to be the second most prescribed NSAID in the outpatient clinics, after aspirin [6]. Likewise, in geriatric outpatient clinic of the University College Hospital (UCH), Ibadan, diclofenac was second to paracetamol in terms of prescription frequency [7]. Moreover, a study comparing the use of potentially inappropriate medications (PIMs) in older patients at UCH found that diclofenac was the most common PIM, accounting for 51.3% of all the reported PIMs [8]. In Nigeria, diclofenac tablets available in the market are either manufactured domestically or imported. Nevertheless, the high rate of counterfeit and substandard drugs highlights the need to have stringent quality control of such products. Research surveys on the quality of diclofenac tablet have shown alarming results. Indicatively, Ayorinde et al. [9] discovered that 60% percent of the tested drugs of diclofenac sodium did not pass the dissolution test, which is an activity of the drug release and bioavailability [9]. Similarly, Adeyemi et al. [10] discovered that only 13.3% of sampled diclofenac brands passed the chemical equivalence test, which was analysed using high-performance liquid chromatography (HPLC) to identify chemical purity [10].

In another study, the percentage of samples of diclofenac that were tested did not meet the British Pharmacopoeia requirements in terms of the percentage composition of diclofenac [11]. This finding is in line with those of Abdullahi and colleagues who indicated that there were substandard diclofenac tablets in samples that were analysed [12]. Their results indicate the existence of low-quality diclofenac tablet preparations and the importance of strict quality control audits. These measures play a crucial role in consumer safety, prescriber confidence, and the integrity of regulatory bodies charged with ensuring pharmaceutical standards. This study, therefore, focused on the quality assessment of five brands of diclofenac potassium tablets marketed in Sagamu, Ogun State, Nigeria.

MATERIALS AND METHODS

Chemical reagents/Instruments

Diclofenac Potassium (Sigma-Aldrich, U.S.A), High Performance Liquid Chromatography (HPLC Waters, U.S.A.), friability tester (DBK, India), hardness tester, dissolution test apparatus (Copley scientific, U.K.), disintegration tester (Copley scientific, U.K.) UV-Vis Spectrophotometer (Thermo Fisher Scientific, U.S.A.). All other reagents used for the study were of analytical and HPLC grade.

Collection of samples

Five (5) brands of diclofenac potassium (50 mg) uncoated tablets were purchased from different pharmacy outlets in Sagamu, Ogun state, Nigeria. Information regarding the manufacturing date, expiry date, batch number, country of manufacture, and the National Agency for Food and Drug Administration and Control (NAFDAC) registration number were documented. The samples were assigned codes A – E.

Uniformity of weight test

Twenty (20) tablets of each brand of diclofenac potassium were weighed individually using a digital weighing balance (Mettler Toledo, Switzerland). The average weight and the percentage weight variation for each brand was calculated using the formula below [13]

$$\text{Percentage weight variation} = \frac{\text{Individual tablet weight} - \text{Average weight}}{\text{Average weight}} \times 100$$

Friability test

A total of ten (10) tablets were randomly selected from each brand and weighed to determine their initial weight. The tablets were then subjected to abrasion and shock in a friabilator (DBK, India) at 25 revolutions per minute (rpm) for 4 minutes. During each revolution, the tablets were dropped from a height of six inches. After the procedure, the tablets were removed from the friabilator, de-dusted, and reweighed to determine their post-friabilation weight [13]. Tablet friability was determined by calculating percentage weight loss using the formula below:

$$\text{Percentage weight loss} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

Hardness test

The hardness of ten tablets from each brand of diclofenac potassium (50 mg) was evaluated using a tablet hardness tester. Each tablet was placed between the two jaws of the tester, and a force was

applied until the tablet fractured. The hardness of each tablet was measured as the amount of force required to crush the tablet and was recorded in newton [13].

Disintegration test

Six tablets from each brand of diclofenac potassium (50mg) were subjected to a disintegration test using the disintegration test apparatus. The apparatus has a transparent polyvinyl basket and contains six tubes of uniform diameter. Each tube had a stainless-steel wire mesh with a uniform mesh size, onto which the tablets were placed for testing. The tablets were completely immersed in the fluid medium (distilled water) maintained at 37 °C and rotated at 32 rpm. The disintegration time for each tablet was defined as the point at which the tablet completely disintegrated, leaving no residue in the basket [14].

Dissolution test

The United States Pharmacopoeia (USP) Dissolution Apparatus was used to perform dissolution tests on different brands of diclofenac potassium tablets (50 mg). The tablets were placed in a rotary basket and immersed in the dissolution medium (pH 6.8) at 37 °C, with rotation at 50 rpm. At intervals, 5 mL of the dissolution medium was withdrawn and filtered to remove particulate matter. Diclofenac potassium concentration in the withdrawn samples was determined using UV-Vis spectrophotometer at 276 nm. The volume of the vessels was kept constant by the addition of 5 mL of fresh phosphate buffer (pH 6.8) following each sampling. A standard diclofenac potassium calibration curve was plotted, and the concentration of diclofenac potassium dissolved at intervals of 5, 10, 20, 30, 45 and 60 minutes was calculated.

Quantitative analysis of selected diclofenac potassium brands using HPLC

HPLC analysis was performed according to standard procedures [13]. The stationary phase was a Waters 265 HPLC system with a 4.6 x 150 mm, 5 µM C18 column. The mobile phase was made up of acetonitrile and water in a 20:80 ratio and pumped at 1 mL/min by a quaternary pump. It was run at ambient temperature, and UV detection was done at 280 nm with an injection volume of 20 µL. The chromatographic conditions were equilibrated to obtain a steady baseline prior to analysis. A mixed standard solution of pure diclofenac potassium was made in the mobile phase filtered and injected with a manual injector. The chromatograms of the standard solutions of

diclofenac potassium at 10, 40, 80, 120, 160, 200, 240, 280 and 300 µg/mL were recorded.

For the analysis, twenty tablets from each brand were weighed and finely powdered. About 20 mg of the powdered sample was transferred to a 100 mL volumetric flask. Approximately 60 mL of distilled water was added, and the mixture was sonicated for 45 minutes. After cooling to room temperature, the solution was diluted to 100 mL. The solution was then filtered through a 0.45 µm syringe filter and transferred to HPLC vials. A 20 µL aliquot of the final solution, corresponding to a concentration of 0.2 mg/mL, was injected into the HPLC system for analysis.

Analgesic activity of different brands of diclofenac potassium (50 mg) on experimental rats

Thirty-five male albino rats (weight between 118–123g) were obtained from the Central Animal House, Faculty of Pharmacy, Olabisi Onabanjo University, Sagamu, Ogun State, Nigeria, where the experiment was also conducted. The animals were housed in clean, well-ventilated cages under standard environmental conditions and were acclimatized for two weeks prior to the commencement of the study. During this period, they were fed pelletized feed (Vital Feeds Ltd.) and provided with unrestricted access to water *ad libitum*.

The analgesic activity of various brands of diclofenac potassium was evaluated using the hot-plate method. The animals were randomly divided into seven groups. Experimental Groups I to V received 1 mg/mL intraperitoneal injections of the respective diclofenac brands. Group VI, serving as the negative control, received an equivalent volume of distilled water, while Group VII, designated as the positive control, was treated with the standard formulation of diclofenac potassium.

Each rat was placed on a hot plate maintained at 55°C within a restrainer. The reaction time or latency period defined as the time taken for the rats to respond to the thermal stimulus by licking their paws or jumping was recorded before (0 min) and at 15, 30, 45, and 60 minutes after the administration of the diclofenac treatments. To ensure the safety of the animals, the maximum reaction time was capped at 45 seconds to prevent tissue injury [15].

The experimental protocol for the use of animal in this study was reviewed and approved by the Research Ethics Committee of Olabisi Onabanjo

University Teaching Hospital, Sagamu, Nigeria (Approval No.: OOUTH/EC/25/0019).

Statistical Analysis

All data analyses were performed using GraphPad Prism software (version 8.0.1). An unpaired t-test was employed to compare the treatment groups with the control groups, with statistical significance set at a threshold of $*p < 0.05$.

RESULTS

Table 1: Details of selected diclofenac potassium (50 mg) tablets purchased from pharmacy outlets in Sagamu.

Brand code	Batch number	NAFDAC registration number	Manufacture date	Expiry date	Place of manufacture
A	0623NE03	A11-1234	06/2023	05/2026	Nigeria
B	211235	B4-0042	12/2021	12/2024	China
C	A043021	A4-8867	04/2023	03/2026	India
D	GG23004	B4-2667P	03/2023	02/2026	India
E	VP16211	A4-6297	04/2022	03/2025	India

Weight variation test

The average weights of selected diclofenac potassium brands ranged from 267.4 mg to 953.3 mg, with Brand A exhibiting the highest percentage

weight deviation, ranging from -3.85% to $+4.02\%$ (Table 2). All the tested samples passed the weight variation test and had their percentage weight variation within acceptable limits.

Table 2: Weight variation of selected brands of diclofenac potassium tablets (50 mg)

Brand code	Mean Weight (mg)	Range of percentage weight variation (%)	Number of tablets outside $\pm 5\%$ of the mean weight
A	597.0 ± 0.015	-3.85 - 4.02	0
D	267.4 ± 0.002	-1.27 - 0.97	0
C	886.4 ± 0.015	-2.97 - 1.64	0
D	942.0 ± 0.002	-1.16 - 1.06	0
E	953.3 ± 0.014	-2.54 - 2.17	0

Friability test

The friability test is used to assess the ability of tablets to maintain their inter-particulate bonding under mechanical stress. The friability test conducted on the selected brands of diclofenac

potassium tablets demonstrated that all brands were sufficiently durable to retain their structural integrity. The percentage friability ranged from 0.0213% to 0.8198% (Table 3).

Table 3: Friability test for selected brands of diclofenac potassium tablets (50 mg)

Brand code	Weight of ten tablets before friabilation (g)	Weight of ten tablets after friabilation (g)	%friability
A	5.974	5.927	0.7867
D	2.696	2.694	0.0742
C	8.417	8.378	0.4633
D	9.393	9.316	0.8198
E	9.388	9.386	0.0213

Hardness test

The hardness test carried out on each diclofenac potassium brand is presented in Table 4. The mean crushing strengths for Brands A–E were 97.61

N, 103.50 N, 116.25 N, 109.87 N, and 103.01 N, respectively. The crushing strength for all tested brands was within acceptable limits.

Table 4: Hardness test for selected brands of diclofenac potassium tablets (50 mg)

Crushing strength (N)											
Brand code	I	II	III	IV	V	VI	VII	VIII	IX	X	Mean $\pm$ S.D.
A	122.60	112.82	127.53	93.20	88.29	78.48	78.48	93.20	93.20	88.29	97.61 $\pm$ 17.37
B	107.91	88.29	127.53	98.10	98.10	103.01	98.10	98.10	88.29	127.53	103.50 $\pm$ 13.96
C	88.29	103.01	117.72	107.91	103.01	137.34	127.53	127.53	127.53	122.63	116.25 $\pm$ 15.17
D	132.44	98.10	127.53	107.91	98.10	98.10	112.82	103.01	93.20	127.53	109.87 $\pm$ 14.48
E	103.01	98.10	103.01	117.72	98.10	117.72	88.29	98.10	98.10	107.91	103.01 $\pm$ 92.49

Data representing hardness test of ten tablets from each brand of diclofenac potassium (50 mg).

Disintegration test

The disintegration profile of tested diclofenac potassium brands is presented in Table 5. All tested

samples disintegrated within the first six minutes of the test, achieving a 100% pass rate.

Table 5: Disintegration test for selected brands of diclofenac potassium tablets (50 mg)

Brand code	Mean disintegration time (minutes)	% Coefficient of variation
A	3.13 $\pm$ 0.72	23.00
B	4.42 $\pm$ 1.07	24.21
C	5.50 $\pm$ 1.20	21.82
D	0.40 $\pm$ 0.01	2.50
E	0.85 $\pm$ 0.50	58.82

Dissolution test

The dissolution test for diclofenac samples was calculated from the calibration curve of standard diclofenac potassium (Figure 1) which demonstrated a linear relationship between known concentrations and absorbance. The dissolution of each sample was represented as percentage drug

release from each diclofenac tablet and presented in Figure 2. At 45 minutes, Sample B achieved the highest drug release with 70.44%. In contrast, Brands A, C, D, and E failed to meet specified limits, achieving only 51.2%, 52.21%, 30.53%, and 46.17% drug release, respectively (Figure 2).

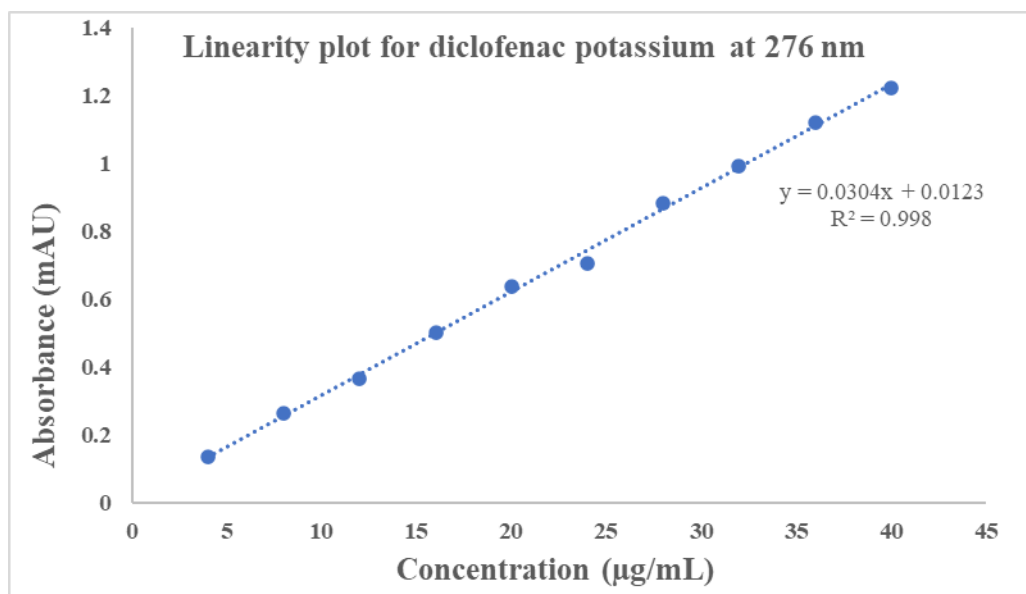


Figure 1: Calibration curve for standard diclofenac potassium at 276 nm showing a linear relationship between known concentrations of diclofenac potassium and absorbance using UV-Visible spectrophotometer

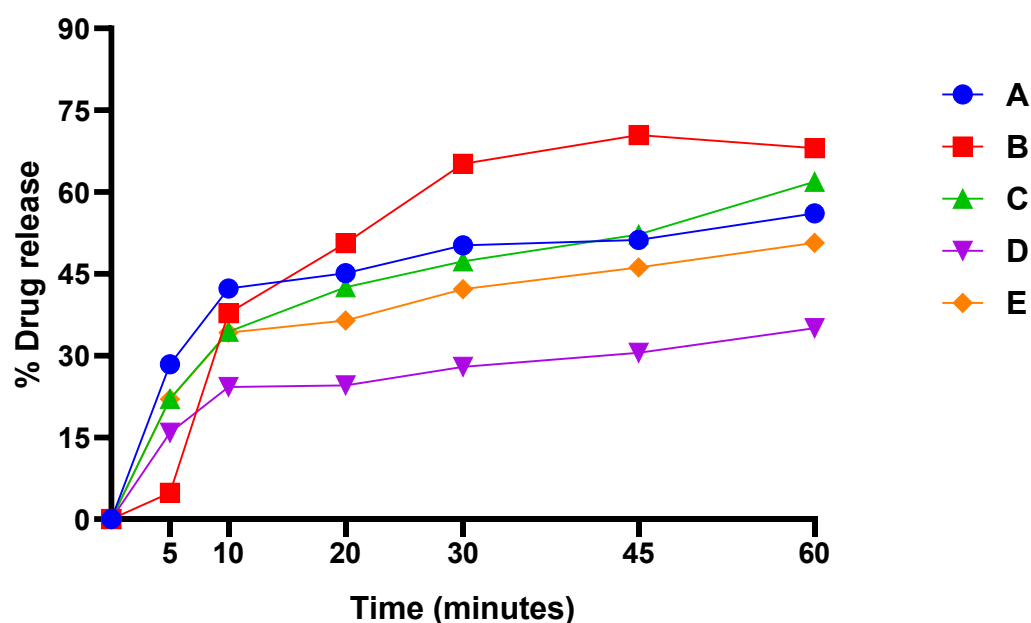


Figure 2: Graph of dissolution profile for diclofenac potassium (50 mg) brands

Quantitative analysis of diclofenac potassium (50 mg) tablets using HPLC

The quantification of diclofenac content for each brand was based on the calibration curve of reference standard of diclofenac potassium shown in Figure 3. The curve demonstrated a strong linear relationship between concentration and peak area,

with a $R^2=0.9995$. Samples A, B, C, and E successfully met the percentage purity requirements with values of 97%, 95.5%, 100%, and 98.5%, respectively (Table 6). In contrast, sample D failed the purity test with a percentage content of 75%.

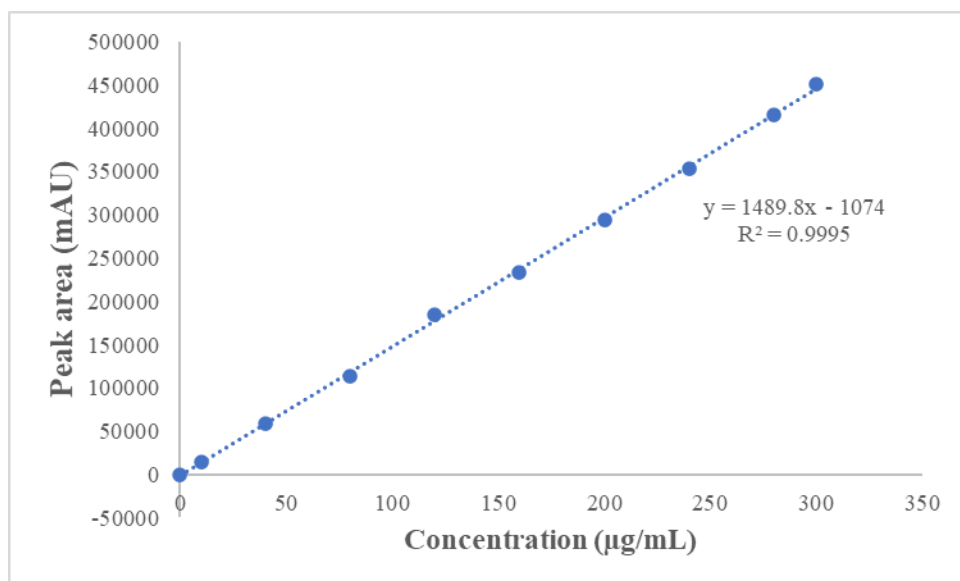


Figure 3: Linearity plot for standard diclofenac potassium, showing the relationship between peak areas and known concentrations for content purity analysis using HPLC.

Table 6: Content purity analysis of diclofenac potassium tablets (50 mg) using HPLC

Brand Code	Theoretical amount mg/ml	Experiment amount mg/ml	Label claim	Conc. (mg)	Percent content (%)	Status B.P specification 95 % - 105%
A	0.2	0.194	50mg	48.5	97	Pass
B	0.2	0.191	50mg	47.5	95.5	Pass
C	0.2	0.2	50mg	50	100	Pass
D	0.2	0.150	50mg	37.5	75	Fail
E	0.2	0.197	50mg	49.25	98.5	Pass

Analgesic activity of selected brands of diclofenac potassium tablets (50 mg) on experimental rats

The analgesic effect of selected diclofenac potassium brands was tested on experimental rats to examine their biological equivalence. At 15 minutes post-treatment, animals treated with all brands, except Brand A, exhibited a statistically significant reduction in pain compared to the

negative control group (Table 7). However, no significant difference in analgesic efficacy was observed in animals treated with the tested brands and the positive control at this time point. By 60 minutes post-treatment, all brands demonstrated a significant reduction in pain relative to the negative control group. When compared with the positive control, Brand E demonstrated comparable analgesic activity.

Table 7: In vivo analgesic activity of selected brands of diclofenac potassium tablets (50 mg) on experimental rats

		Duration of Treatment				
		0 min	15 min	30 min	45 min	60 min
Group	Brand code	Reaction time in seconds (Mean $\pm$ S.D.)				
I	A	12.6 $\pm$ 1.36	12.3 $\pm$ 1.17	12.7 $\pm$ 0.47 ^b	13.4 $\pm$ 1.02 ^b	15.5 $\pm$ 0.80 ^{a b}
II	B	12.06 $\pm$ 0.91	13.2 $\pm$ 0.75 ^a	14.0 $\pm$ 0.63 ^b	15.3 $\pm$ 0.76 ^{a b}	16.8 $\pm$ 0.53 ^{a b}
III	C	12.02 $\pm$ 0.45	13.0 $\pm$ 0.63 ^a	13.5 $\pm$ 0.5 ^b	14.7 $\pm$ 0.50 ^{a b}	16.0 $\pm$ 0.63 ^{a b}
IV	D	12.03 $\pm$ 0.03	14.5 $\pm$ 0.50 ^a	14.9 $\pm$ 0.41 ^a	16.3 $\pm$ 0.50 ^a	17.5 $\pm$ 0.50 ^{a b}
V	E	11.93 $\pm$ 0.04	13.1 $\pm$ 0.31 ^a	15.2 $\pm$ 0.35 ^a	16.9 $\pm$ 1.06 ^a	19.2 $\pm$ 0.75 ^a
VI	Negative control	12.03 $\pm$ 0.06	11.64 $\pm$ 0.49	12.86 $\pm$ 0.75	11.9 $\pm$ 0.41	13.3 $\pm$ 0.50
VII	Positive control	11.34 $\pm$ 0.03	13.5 $\pm$ 0.50	15.7 $\pm$ 0.49	17.0 $\pm$ 0.63	19.7 $\pm$ 0.76

Data presented as mean $\pm$ standard deviation (S.D.). Statistical significance at * $p < 0.05$, $n=5$. ^aStatistically significant when compared to negative control and ^bStatistically significant when compared to positive control.

DISCUSSION

Continuous post-marketing surveillance is necessary to guarantee the safety, quality, and therapeutic efficacy of pharmaceutical products during their shelf life. In this research, various brands of diclofenac potassium tablets were purchased from selected pharmacy stores in Sagamu, Ogun State, Nigeria. Analysis of their country of origin showed that 60% of the products were manufactured in India, 20% were produced in China and the remaining 20% was produced locally in Nigeria. This distribution reflects the country's reliance on imported pharmaceutical products to meet local demand. These findings are in line with earlier reports, which suggests a substantial influx of imported medicines into the Nigerian healthcare system [12, 16].

Quality control tests were performed on the various diclofenac brands to assess their compliance with standards. The weight variation test evaluates whether the weight of tablets falls within acceptable limits and indicates uniformity in production [13]. According to the British Pharmacopoeia (BP), the permissible weight variation range for tablets exceeding 250 mg is typically $\pm 5\%$ of the average weight [13,17]. The tested brands were all within the required BP limits since none of the brands had

a weight difference exceeding $\pm 5\%$. Furthermore, all tested samples also passed the friability test with percentage friability between 0.02 – 0.82%, achieving a 100% compliance. Official standards consider a friability test to be acceptable when the cumulative weight loss after testing is not more than 1% [17]. Pharmaceutical tablets should be strong enough to withstand mechanical forces, abrasion, chipping, and fracture during manufacturing, processing, and transportation [18].

Although pharmaceutical tablets should be hard enough to maintain inter-particulate bonding and resist mechanical forces, they must not be excessively hard or overly soft. A minimum crushing strength of 40 N is usually acceptable [14]. The outcome of the hardness test indicated that all the tested tablets needed crushing strength of more than 97% that exceeds the stated threshold. Although there is no universally applied strict maximum value, tablets with excessively high crushing strengths may become too hard. The hardness of tablets is affected by the pressure used during compression, which also affects friability, disintegration, dissolution and finally the absorption of the drug in the body [17]. Thus, the hardness of tablets is an important factor to be controlled to achieve maximum drug performance.

Interestingly, all the uncoated tablet brands tested in this study met the hardness and friability

requirements. In contrast, a study conducted earlier indicated that some uncoated diclofenac potassium tablets did not pass these tests as compared to coated ones [12]. This difference can be explained by the fact that the manufacturing processes are different. It is therefore essential to attain the right hardness to ensure that the mechanical strength and desirable drug release properties are maintained.

The measure of disintegration is another important element of the quality control testing of tablets. The disintegration test evaluates the breakdown of tablets into smaller particles or their constituent elements within the prescribed time when placed in a liquid medium under specified experimental conditions [13]. According to standards, uncoated tablets should disintegrate within 15 minutes [13]. In the case of the screened diclofenac brands, the disintegration time was between 0.40 and 5.50 minutes, which is within acceptable limits. In particular, the longest disintegration time was 5.50 minutes in Sample C, and the shortest disintegration time was 0.40 minutes in Sample E. Disintegration rates can be affected by several factors such as the types of binders, disintegrants and lubricants employed during formulation [14]. It is important to have tablets disintegrate within the required time to achieve the required drug absorption and therapeutic effect. Delayed disintegration can lead to therapeutic failure [14].

Furthermore, the dissolution pattern of each brand was observed over 60 minutes. Among the tested brands, Sample B achieved the highest drug release at 45 minutes, with 70.44% released. However, Brands A, C, D, and E failed to meet the standard, releasing only 51.2%, 52.21%, 30.53%, and 46.17%, respectively. Although these brands might release their drug content at later times, delayed drug release can negatively affect the onset of therapeutic action. According to recommended standards, not less than 70% of the labelled amount of diclofenac potassium should be released within 45 minutes [9,13]. Dissolution rate directly impacts the absorption and bioavailability of drugs and is essential for predicting drug's therapeutic performance.

The presence of multiple brands in the market can create confusion among healthcare professionals and patients regarding the choice of brand and the interchangeability of products [18]. Despite all the brands having the same labelled claim, they are not bioequivalent as they do not have equal drug release profile. Only Brand B met the recommended dissolution standard, while Brands A, C, D, and E failed the test.

To evaluate the content uniformity of the selected diclofenac brands, HPLC assay was employed [19]. Samples A, B, C, and E successfully met the percentage purity requirements with values greater than 95%. This aligns with the BP stipulated range of 95.0% – 105.5% [20]. However, Sample D failed the test with a percentage content of 75%. It is important to make sure that pharmaceutical products have the right proportion of active pharmaceutical ingredients (APIs). Underdosing may result in therapeutic failure and overdosing may increase the risk of adverse effects [18]. Non-compliance with established quality standards may result in substandard drugs, compromise patient safety and treatment [18]. The pharmaceutical companies must adhere strictly to good manufacturing practices (GMP) and have strict in-process controls to ensure product quality.

The in vivo evaluation of the analgesic activity of diclofenac potassium brands was done using the hot-plate method. The findings revealed notable variations in the onset of analgesic effects among treated animals. The rapid onset of analgesic effect is essential for patient relief, and this may depend on the disintegration and dissolution profile of the tablet, or physiological differences between the response of the animals to the drug [21]. All brands significantly reduced pain in treated animals at 60 minutes post treatment as compared to the negative control.

Overall, these results demonstrate the significance of constant quality control testing of pharmaceutical products. Manufacturers must adhere to good manufacturing practices, while regulatory bodies continue to ensure compliance with established specifications. This is important for guaranteeing that only safe and effective products are made available to the market.

CONCLUSION

In conclusion, all selected brands passed the uniformity of weight, friability, hardness, and disintegration tests. However, Samples A, C, D, and E did not satisfy the official requirement for their drug release profile. Moreover, content purity test of all the screened diclofenac potassium brands was within recommended limit except Brand D. Despite these variations, all the tested brands demonstrated significant analgesic activity in vivo. The findings from this study emphasize the need for continuous quality control and adherence to established standards to ensure both safety and effectiveness of pharmaceutical products.

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AUTHORS' CONTRIBUTION

LSK conceptualised and designed the study. TOP conducted the experimental work under the supervision of LSK and SIJ. MVB and TAB drafted the original manuscript. JD, KO, and LO proofread and edited the manuscript. All authors read and approved the final version of the manuscript.

CONFLICT OF INTEREST

The authors declare that they have no competing financial or personal relationships that could have influenced the work reported in this paper.

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