

Comparative Evaluation of the Physicomechanical Quality of Commercially Available Paracetamol Tablets Marketed in Gombe Metropolis, Nigeria

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Abstract

Paracetamol (also known as acetaminophen, or under brand names like Tylenol® or Panadol®) is a widely used, over-the-counter (OTC) analgesic and antipyretic medication designed to relieve mild to moderate pain and reduce fever. This study is aimed to assess the quality of paracetamol tablets 500 mg manufactured by indigenous companies in Nigeria by evaluating their physical properties, assay results, and dissolution profiles. The compliance of these tablets with the acceptable official criteria in the BP and USP were evaluated. A comparative dissolution test was carried out to ascertain the dissolution behavior for the innovator product (Panadol®) and the locally manufactured ones in circulation in Gombe metropolis. Five different brands (A-E), randomly purchased from various pharmaceutical premises across Gombe metropolis, with 98 tablets from each brand, were compared with the innovator brand (Panadol®) with particular interest in their weight variation, hardness, friability, assay, and dissolution test based on the BP and USP specifications. All samples A-E in this study met the acceptable criteria set by the BP and USP. The mean tablet hardness ranged from 9.42 to 19.57 Kgf, indicating adequate mechanical strength across all brands A-E. Friability values ranged from 0.40% to 1.25%, with one brand exceeding the pharmacopeial limit of 1%. Disintegration times (ranged from 1.53 to 5.00 minutes), all brands complied with the pharmacopeial requirement of within 15 minutes. Weight uniformity results showed percentage deviations between 0.81% and 4.53 %; all brands met acceptable pharmacopeial criteria. Similarly, the assay procedure, which evaluates the safety, efficacy and consistency of the various samples were in consonance with the USP criteria of 90.0% to 110.0. The dissolution test, which assesses the percentage release of the API within a specified time, demonstrated that at 15 min, samples A and B shifted profoundly from Panadol®. The findings indicate that most evaluated brands complied with established BP and USP requirements.

Keywords: Paracetamol tablets, organoleptic, physicochemical properties, Gombe.

INTRODUCTION

Paracetamol is typically used to manage the following conditions without a doctor's prescription [1] pain relief, fever reduction, cold/Flu symptoms and period pains. Paracetamol is among the most widely used over the counter (OTC) analgesic/antipyretic drugs globally, commonly available for managing mild to moderate pain, fever, and headaches [2]. In developing countries like Nigeria, paracetamol plays a central role in primary care due to its accessibility, affordability, and perceived safety [3]. Local community studies also show a high reliance on self-medication with paracetamol, underlining the importance of ensuring that the tablets available on the market meet quality standards [2].

Ensuring the quality of pharmaceutical products is critical for therapeutic efficacy, patient safety, and public confidence in healthcare systems. For tablet formulations, assessing mechanical strength

properties such as hardness, friability, and disintegration is essential. Hardness reflects a tablet's ability to withstand mechanical stress during packaging and distribution, friability measures resistance to chipping or breaking under abrasion, and disintegration assesses how readily the tablet dissolves in body fluids, which is vital for drug absorption and therapeutic action [3]. Failures in these parameters may indicate poor quality and can compromise drug effectiveness, potentially leading to treatment failure or safety issues [3].

International pharmacopeias (USP and BP) provide detailed guidelines and limits for these quality tests to guide manufacturers and regulators in ensuring acceptable product performance. Despite these standards, quality discrepancies persist in many markets, particularly in low and middle-income regions where regulatory surveillance may be limited.

In Nigeria, several studies have highlighted variability in the quality of locally marketed paracetamol brands. For example, research in Katsina Metropolis found that some paracetamol brands failed to meet certain pharmacopeial quality tests, suggesting inconsistencies in product quality [4]. Additionally, studies conducted in the Federal Capital Territory (Abuja) reported variations in physicochemical quality parameters among different brands of paracetamol tablets, despite most conforming to some standards [5]. These findings demonstrate the need for continual monitoring of pharmaceutical products to protect public wellbeing.

The National Agency for Food and Drug Administration and Control (NAFDAC) is the federal authority mandated to ensure the safety and efficacy of drugs and food products distributed, sold, or used in Nigeria [6]. According to its official mandate, NAFDAC oversees the local manufacture of pharmaceutical products, ensuring compliance with approved specifications and standards [7]. The agency's regulatory framework includes: product registration; ensuring Good Manufacturing Practice (GMP); regular inspection of locally manufactured products; unscheduled visits to site laboratories; market surveillance; and enforcement actions against substandard products [6-10]. These functions are essential for maintaining pharmaceutical quality and safeguarding public health.

Despite the regulatory structures in place, there remains a lack of localized investigation into the quality and mechanical properties of paracetamol tablets locally marketed. Gombe Metropolis, located in the North East region of Nigeria, shares similar pharmaceutical market challenges, yet there is no published research on the usage of paracetamol tablets marketed in this region. The region experiences high temperatures and humidity that may affect tablet stability. Additionally, the coexistence of formal pharmacies and informal drug outlets can contribute to inconsistent product quality and handling practices. Given the high usage of paracetamol for self-medication and primary healthcare, it is essential to evaluate whether the products available to consumers meet accepted standards of quality and performance; by conducting diligent laboratory evaluation of mechanical and physicochemical properties on some of the samples in circulation. Findings are expected to have implications for regulatory control, manufacturing quality assurance, and consumer safety, ultimately supporting efforts to ensure that medicines consumed in Gombe Metropolis are safe, effective, and of acceptable pharmaceutical quality.

MATERIALS AND METHOD

MATERIALS

The materials used in this research work are: Digital vernier caliper, Monsanto hardness tester, electronic balance, friabilator, disintegration tester, melting point machine. Panadol brand of paracetamol tablets (GSK) was taken as the standard. Drug Samples: Six (6) different varieties of paracetamol tablets, 500mg were bought at random from different registered pharmaceutical premises within Gombe Metropolis, North East Nigeria.

The brands were labeled with codes A-F.

METHODS

Weight Uniformity Test

Weight uniformity ascertains the percentage content of Active Pharmaceutical Ingredient (API) in the tablet. To carry out this evaluation twenty (20) tablets of paracetamol 500 mg were weighed using an electronic balance (Siemens Munich, Germany). The average was calculated as well as the standard deviation using equation 1.

$$CV = \frac{\text{Standard Deviation}}{\text{Mean Weight}} \times 100 \quad [1]$$

Where CV = coefficient of variation

As stated by the USP, tablet weighing greater than 325 mg, there should not be more than two tablets deviating from the average by more than 5%. This procedure was repeated in a triplicate.

Tablet Crushing Strength

The crushing strength of the tablets was assessed at ambient conditions using a Monsanto tablet hardness tester (Monestry Machine Ltd, Speke, Liverpool, England, UK) which performs diametrical compression. Each tablet was placed in between the tester's platen and an adjustable knob was gradually tightened until it touched the tablet. Sufficient pressure was applied to break the tablet. Only results from tablets that cleanly broke into two halves without any signs of lamination were considered. The final result was obtained by averaging the values from three such measurements.

Five tablets, 500 mg of each sample were tested using the hardness tester, and the crushing strength of the tablet was measured. The average hardness of the tablets was calculated, and the standard deviation was determined. The test was carried out in triplicate.

Thickness and Diameter Test

Measurement of tablet thickness and diameter ensures consistency in physical dimensions, which aids in identification, packaging compatibility, and patient acceptability. These measurements are typically taken with a vernier caliper or micrometer screw gauge on a sample of tablets (often 20 units). The mean and standard deviation are then calculated to describe the variation.

Friability Test

To evaluate the degree of friability of the tablets from each batch, ten tablets were randomly selected, dusted and weighed. The tablets were placed in a Roche friabilator (Erweka GmbH, Germany) and subjected to its tumbling actions at 25 revolutions per minute for four minutes. Afterwards, the tablets were once again dusted and reweighed to determine the percentage loss of weight.

Disintegration Time Test

As per the BP [13-14], six tablets from each batch were utilized for disintegration studies in distilled water at 37°C using an Educational Sciences Disintegration Apparatus (ES Eagle Scientific Limited, Nottingham, United Kingdom).

The disintegration time was taken to be time no granules of any tablet was left on the mesh of the apparatus.

Dissolution Test

In dissolution test, the release rate of paracetamol from tablets was determined using the rotating basket (USP Apparatus 1) method. Each tablet was placed in a cylindrical basket of stainless wire mesh attached to a variable speed drive mechanism and suspended in a glass vessel containing 900 mL of distilled water kept at 37°C ± 0.5°C. The apparatus was set to rotate at 100 rpm and was started simultaneously with a stop clock. A 5 mL sample of the dissolution medium were removed at designated time intervals and replaced with an equal volume of fresh sample of dissolution medium. The absorbance of the removed samples was measured using a UV spectrophotometer (Unicam, England), from which the concentration of drug dissolved was calculated.

Assay of Paracetamol Tablets

The standard assay for paracetamol tablets follows the USP or BP method [13-14]. A 100 mg of paracetamol standard was weighed, dissolved in 0.1M NaOH and diluted to 100 mL with the same solvent to form standard solution (1 mg/mL). ten (10) mL of the stock of 100 mL was diluted with 0.1M NaOH to form the working standard (100 µg/mL). Twenty (20) tablets were weighed and powdered, from which 100mg paracetamol was weighed and dissolved in 0.1M NaOH, diluted to 100 mL and filtered. Ten (10 mL) of the filtrate was diluted to 100 mL and filtered. Ten (10 mL) of the filtrate was further diluted to 100 mL with NaOH, giving rise to sample solution (100µg/mL). Absorbance was measured for both standard and sample solutions at 243 nm against 0.1M NaOH as blank. The measurements were repeated to get average absorbance.

$$\% \text{ Assay} = \frac{A_{\text{sample}} \times C_{\text{standard}}}{A_{\text{standard}} \times C_{\text{sample}}}$$

A_{sample} = Absorbance of sample solution
 A_{standard} = Absorbance of standard solution
 C_{standard} = Concentration of standard solution (mg/mL)
 C_{sample} = Concentration of sample solution (mg/mL)

Visual Examination

Twenty paracetamol tablets (500 mg) were samples from each brand and physically inspected for their color, shape, texture, and size [17-18].

RESULTS

The organoleptic and physicochemical evaluation of five brands of 500mg paracetamol tablets was conducted to assess their compliance with established pharmacopeial quality standards with respect to the innovator product. The results obtained from the various tests are presented in the tables below:

Table 1 presents the label information and organoleptic properties of the six brands of paracetamol tablets selected for the study. The information includes the manufacturing date, expiry date, batch number, country of origin, and the address of the manufacturing company which is essential for regulatory compliance and product traceability. The organoleptic evaluation assessed tablet colour, shape, coating, and surface texture as a preliminary quality control measure to identify visible defects and evaluate general manufacturing quality and consumer acceptability.

Table 2 presents the physicochemical properties of the six brands of paracetamol tablets evaluated in the study. The parameters assessed include crushing strength, friability, disintegration time, weight uniformity, melting point, and dimensional characteristics (diameter and thickness). These tests were carried out to determine the mechanical strength, handling stability, compliance with pharmacopeial specifications, identity and purity of the active ingredient, and uniformity in tablet size. These parameters serve as important indicators of manufacturing quality, product integrity, and expected therapeutic performance.

Table 1: Label Information and organoleptic properties of Selected Brands of Paracetamol Tablets

Brand	DOM	E.D	Batch No.	C/O	Colour	Shape	Coating	Texture
A	12/2024	12/2027	GT0124071	Nigeria	White	Oval/Caplet	Uncoated	Smooth and glossy
B	07/2025	07/2030	2428E	Nigeria	White	Round	Uncoated	Slightly rough, chalky surface
C	09/2025	08/2028	P3130	Nigeria	White	Round	Uncoated	Moderately smooth, minimally chalky
D	07/2023	07/2026	23187	Nigeria	White	Round	Uncoated	Slightly rough, chalky surface
E	08/2025	07/2029	PLD25262	Nigeria	White	Round	Uncoated	Moderately smooth surface
F	08/2025	07/2028	PT1089	Nigeria	White	Round	Uncoated	Slightly rough to moderately smooth

Key: DOM - Date of Manufacture, E.D - Expiry Date, C/O - Country of Origin

Table 2: Physicomechanical Properties Results of Samples A-E and Panadol® Tablets

Acceptance Criteria		A	B	C	D	E	PANADOL®	Remarks
White color	Physical observation	White color	White color	White color	White color	White color	White color	Normal
Less than 5%	Weight variation	0.557±0.005	0.616±0.013	0.562±0.011	0.541±0.010	0.568±0.021	0.669±0.012	Pass
4 - 8 Kgf	Crushing strength	0.81	2.18	1.94	1.81	4.53	1.77	Normal
>5.1 Kgf	Hardness	9.42	12.52	14.36	12.79	10.50	19.57	Normal
Less than 1%	Friability result	0.40	0.91	1.25	0.82	0.86	0.38	Normal
Less than 15 min	Disintegration	3.00	1.53	3.57	1.59	2.23	5.00	Pass
	Diameter	12.585	13.083	12.507	12.507	12.647	7.858	Consistent
	Thickness	4.069	4.267	3.923	3.923	4.049	5.847	Consistent
169-170°C	Melting Point	180	167	170	170	170	185	No much deviation

DISCUSSION

The quality evaluation of six brands of 500 mg paracetamol tablets marketed in Gombe Metropolis was carried out to determine their compliance with pharmacopeial standards. Parameters assessed included visual examination, weight uniformity, crushing strength, friability, disintegration time, tablet dimensions, and melting point. The findings were compared with the standards of the British Pharmacopoeia (BP) [12-15] and United States Pharmacopoeia (USP) [21-22], and their implications for drug quality, patient safety, and regulatory control are discussed below.

Organoleptic Properties

The organoleptic properties of paracetamol tablets, including visual examination and labeling, were assessed to ensure they meet the necessary standards. In the study, all six brands of paracetamol tablets met the essential labeling requirements, including manufacturing and expiry dates, as well as NAFDAC registration numbers [6-8]. These labeling elements are critical for ensuring product traceability and safety, preventing the circulation of counterfeit medicines, as emphasized by NAFDAC (2020) [8-11]. As for the physical appearance, all tablets were white in color. The reference brand was an uncoated oval (caplet-shaped) tablet, while Brands A to E were round and uncoated. Variations in coating and shape are common in tablet manufacturing and may affect handling, consumer acceptability, and appearance. Film coating typically improves the tablet's appearance, reduces dusting, and enhances surface smoothness. On the other hand, uncoated tablets might appear chalky, depending on the formulation and compression process. Importantly, no visible defects, such as cracking or discoloration, were noted, suggesting good physical integrity and acceptable manufacturing quality across all brands.

Weight Uniformity

Weight uniformity is an essential factor for ensuring consistent dosing of the active pharmaceutical ingredient (API), especially for commonly used drugs like paracetamol. In this study, the mean tablet weights of all six brands were within acceptable limits for 500 mg tablets, indicating that adequate control was exercised during the tablet compression process. Most of the brands met the BP requirement that states tablet with an average weight greater than 250 mg should not have more than two tablets deviating from the mean by more than $\pm 5\%$, and no tablets should deviate by more than $\pm 10\%$.

The percentage coefficient of variation (%CV) further confirmed this, with reference brand and brands A to C showing relatively low %CV values (0.81–2.18%), indicating good uniformity and efficient manufacturing. However, Brand D showed a higher %CV (4.53%), suggesting potential variability in granule flow, particle size distribution, or compression conditions. While this remains within acceptable limits, it may point to the need for further optimization in the manufacturing process to ensure batch-to-batch consistency.

Hardness and Friability

Hardness is a key parameter for assessing a tablet's ability to withstand mechanical stresses during handling, packaging, and transport. The reference product had the highest hardness value (19.57 kgf), followed by Brands C (14.36 kgf) and D (12.79 kgf). Brand A, however, recorded the lowest hardness value (9.42 kgf), suggesting it may be more susceptible to mechanical damage. While sufficient hardness is essential to prevent breakage, excessively hard tablets may cause delayed disintegration and slow drug release.

Friability, which measures the resistance of a tablet to abrasion, was also assessed. All brands, except Brand D, complied with the BP specification of a friability value of less than 1%. Brand D showed a friability of 1.25%, indicating increased fragility. High friability values suggest poor tablet cohesion, which can lead to chipping or breakage during handling, potentially compromising the accuracy of doses and patient compliance. This highlights a potential issue in the formulation or manufacturing process of Brand D that requires attention.

Disintegration Time

Disintegration time is a critical parameter for ensuring the active ingredient is released promptly after administration. According to the BP [13-14; 21-22], paracetamol tablets should disintegrate within 15 minutes. All six brands met this requirement, demonstrating acceptable tablet breakup and drug release. Brand B had the fastest disintegration time (1 minute 53 seconds), while the reference brand had a longer disintegration time (5 minutes). The slightly longer disintegration time of the reference brand can be attributed to its higher hardness and uncoated surface, but it still met pharmacopeial standards. This indicates an appropriate balance between mechanical strength and tablet performance, as faster disintegration does not always correlate with better performance, depending on the tablet's physical properties.

Diameter and Thickness

Tablet dimensions, including diameter and thickness, influence packaging efficiency, handling, and consumer acceptability. In this study, there was minimal variation in tablet dimensions across the brands. Brands A to E showed consistent diameter and thickness, while the reference brand had slightly larger dimensions due to its uncoated form. Such differences are common and do not negatively affect disintegration time or overall tablet performance. Consistent dimensions help ensure effective packaging, ease of identification, and batch consistency, all of which are essential for maintaining the quality of the product during storage and distribution.

Melting Point

The melting point of the active ingredient is an important indicator of purity and chemical stability [23]. Paracetamol has a known melting point range of 169–170°C. In this study, all six brands showed melting point values within this established range.

This suggests that the paracetamol in all brands was chemically stable and not degraded due to poor manufacturing or improper storage conditions. Uniform melting point values across all brands indicate the use of high-quality raw materials and adherence to good manufacturing practices [23]. No significant deviations from this range were observed, which would otherwise indicate potential contamination or degradation.

Assay Test

Assay tests ensure a drug product is safe, effective, and consistent from batch to batch [13-14]. It is one of the core quality control tests in pharmaceuticals, and it achieves four main things: it confirms potency and dosage accuracy; ensure product consistency; monitor stability over time; and meet regulatory compliance. Agencies such as FDA, EMA, NAFDAC and USP require assay results for drug approval and ongoing quality. Without a passing assay, a product can't be legally marketed. The acceptable criteria by the USP and BP is 90% to 110%. The results in this research have shown that all the samples tested from the locally manufactured products complied with the acceptable criteria of the USP and BP [6-8, 13, 21], (Table 3).

Table 3: Assay Results of Samples A-E and Panadol®.

	Samples					Panadol®
	A	B	C	D	E	
Assay (90%–110%)	93.6	92.4	91.5	96.6	91.9	93.4
Remarks	Pass	Pass	Pass	Pass	Pass	Pass

However, statistical analysis, shows significant difference between sample D and Panadol® ($p = 0.02$) (Table 4).

Table 4: Statistical Analysis of Results

Description	Mean	Standard deviation	p value
Panadol®	93.4	1.12	Ref
A	93.6	1.13	0.84
B	92.4	1.14	0.33
C	91.5	1.15	0.11
D	96.6	1.12	0.02
E	91.9	1.14	0.18

Dissolution Test

Results of dissolution test showed that at times 15 and 30 min., samples A and B shifted remarkably from Panadol®. However, from 45-120 min., all the tested samples showed results in compliance with Panadol® (Table 6). As observed in table 7, sample E displayed a pronounced difference from Panadol® ($P = 0.03$).

Table 6: Amount of paracetamol (API) released in the dissolution medium

	Time (min)	Samples					
		A	B	C	D	E	Panadol®
Dissolution (BP >80%)	15	67.40	61.40	95.0	94.90	94.90	97.50
	30	97.80	96.70	97.90	98.00	98.60	99.40
	45	98.40	97.80	99.80	98.70	98.70	99.90
	60	99.60	98.50	100	99.90	100	100
	75	100	99.50	100	100	100	100
	90	100	100	100	100	100	100
	120	100	100	100	100	100	100

Table 7: Statistical Analysis for Dissolution Results.

Description	Dissolution (30 min)	SD	p value
Panadol®	99.90	1.26	
A	97.8	1.22	0.11
B	96.7	1.19	0.03
C	97.9	1.23	0.12
D	98.00	1.24	0.13
E	98.60	1.25	0.27

Conclusion

The evaluation of the organoleptic properties revealed that all five brands met the essential labeling requirements, including manufacturing and expiry dates, and NAFDAC registration numbers. This is crucial for drug traceability and patient safety, as it helps prevent the circulation of counterfeit medicines. The evaluation of physicochemical properties showed that most brands complied with the acceptable criteria of BP and USP. However, variations in weight uniformity, friability, and hardness were observed in some brands. Despite these variations, all brands met the pharmacopeial disintegration time. All the tested samples complied with the acceptable criteria required for assay and dissolution. BP specifications on physical parameters, assay, and dissolution. However, two samples (A and B) fell below the criteria.

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