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Comparative quality evaluation of different brands of paracetamol tablets marketed in juba using TLC, disintegration, and spectroscopic methods

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Abstract

Paracetamol is one of the most used analgesic and antipyretic drugs worldwide and an essential medicine in the management of pain and fever. However, variations in the quality of marketed paracetamol brands may affect their therapeutic efficacy and patient safety. This study aimed to conduct a comparative quality evaluation of different brands of paracetamol tablets marketed in Juba, South Sudan, using Thin Layer Chromatography (TLC), disintegration testing, and spectroscopic methods in accordance with British Pharmacopoeia (BP), United States Pharmacopeia (USP), and World Health Organization (WHO) standards. Five paracetamol tablet brands were randomly collected from community pharmacies and analyzed. TLC confirmed the presence of paracetamol as the active ingredient in all brands, with Rf values (0.72-0.76) matching that of the reference standard (0.74). Disintegration times ranged from 4.2 to 12.8 minutes, all within the BP limit of 15 minutes. Spectroscopic analysis showed that assay values ranged from 96.8% to 103.6%, complying with USP requirements (95-105%). Overall, all brands met pharmacopeial standards for identification, disintegration, and assay, though minor variations were observed among brands. These differences may be attributed to formulation and manufacturing practices. The findings suggest that the paracetamol brands available in Juba are of acceptable quality and safe for therapeutic use. Nevertheless, continuous post-market surveillance and regulatory monitoring are recommended to ensure sustained medicine quality, strengthen local quality control systems, and protect public health in South Sudan.

Keywords: *Paracetamol, Quality evaluation, TLC, Disintegration, Spectroscopy, Juba, Pharmacopeial standards*

1. Introduction

Paracetamol (acetaminophen) is one of the most widely used over-the-counter analgesic and antipyretic drugs

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globally, valued for its effectiveness in relieving pain and reducing fever with minimal gastrointestinal side effects compared to Nonsteroidal Anti-Inflammatory Drugs (NSAIDs). It is commonly prescribed for the management of mild to moderate pain conditions such as headaches, muscle aches, and fever associated with infections. Due to its affordability, availability, and inclusion in the World Health Organization (WHO) Model List of Essential Medicines, paracetamol remains an essential component of primary healthcare systems, particularly in low- and middle-income countries.

However, the increasing availability of multiple brands of paracetamol in local markets raises concerns regarding their quality, safety, and therapeutic efficacy. Poor-quality medicines, including substandard and counterfeit products, can lead to therapeutic failure, drug resistance, and adverse health outcomes. Previous studies in various regions, including parts of Africa, have revealed variations in the quality of paracetamol tablets with respect to active ingredient content, disintegration time, and dissolution profiles. In South Sudan and neighboring countries, limited research has been conducted to evaluate the quality consistency of paracetamol brands available in the market, despite widespread use and public health significance.

Therefore, this study was designed to conduct a comparative quality evaluation of different brands of paracetamol tablets marketed in Juba using Thin Layer Chromatography (TLC), disintegration tests, and spectroscopic methods. The main objectives were to assess the physicochemical quality attributes of selected brands, verify their compliance with pharmacopeial standards, and provide scientific evidence to support regulatory authorities in ensuring the quality and safety of paracetamol products distributed in the region.

2. Materials and methods

2.1. Sample collection

Different brands of paracetamol tablets marketed in Juba, South Sudan, were randomly purchased from community pharmacies and drug outlets. Each brand was labeled and coded to conceal its identity during analysis. All samples were within their shelf-life period and stored under recommended conditions until testing. The reference standard paracetamol powder was obtained from a certified supplier and used for comparison.

2.2. Thin Layer Chromatography (TLC) analysis

TLC was performed to confirm the presence and identity of paracetamol in each brand. Silica gel GF254 plates were used as the stationary phase, and a suitable solvent system consisting of ethyl acetate: methanol: ammonia (8:1:1 v/v) served as the mobile phase. Standard and sample solutions were prepared by dissolving an accurately weighed amount of paracetamol in methanol. Spots were applied using a capillary tube and developed up to 8 cm. After drying, the plates were visualized under ultraviolet (UV) light at 254 nm, and the retention factor (Rf) values of the sample spots were compared with that of the reference standard according to British Pharmacopoeia (BP, 2020) guidelines.

2.3. Disintegration test

The disintegration time of each paracetamol tablet brand was determined using a standard disintegration apparatus as described in the British Pharmacopoeia (BP, 2020). Six tablets from each brand were tested in distilled water maintained at 37 ± 0.5 °C. The time taken for complete disintegration of each tablet, leaving no palpable residue, was recorded. Tablets were considered to comply if they disintegrated within 15 minutes, as per pharmacopeial specifications.

2.4. Spectroscopic analysis

Ultraviolet-visible (UV-Vis) spectrophotometry was employed for quantitative determination of paracetamol content. A known weight of powdered tablets equivalent to 100 mg of paracetamol was accurately measured, dissolved in 0.1 M NaOH, and diluted with distilled water to obtain a final concentration within the linear range. The absorbance was measured at a wavelength of 257 nm using a UV-Vis spectrophotometer, and the concentration of paracetamol was calculated by comparison with a standard calibration curve. The assay results were evaluated according to United States Pharmacopeia (USP, 2020) specifications, which require the drug content to be within 95-105% of the labeled amount.

All analyses were performed in triplicate to ensure reproducibility, and results were interpreted in line with pharmacopeial standards (BP, USP, and WHO guidelines) for quality assessment of pharmaceutical products.

3. Results

3.1. Thin layer Chromatography (TLC) analysis

All tested brands produced distinct spots corresponding to that of the paracetamol reference standard when visualized under UV light at 254 nm. The Rf values of the sample spots ranged between 0.72 and 0.76, which closely matched the reference standard (Rf = 0.74). This confirmed the presence of paracetamol as the active ingredient in all brands tested. Minor variations in spot intensity were observed, suggesting slight differences in formulation or excipient content (Table 1 and Figure 1).

Table 1: TLC results for different paracetamol brands

Brand code	Rf value (sample)	Rf value (standard)	Identification result
A	0.73	0.74	Complies
B	0.75	0.74	Complies
C	0.72	0.74	Complies
D	0.76	0.74	Complies
E	0.74	0.74	Complies

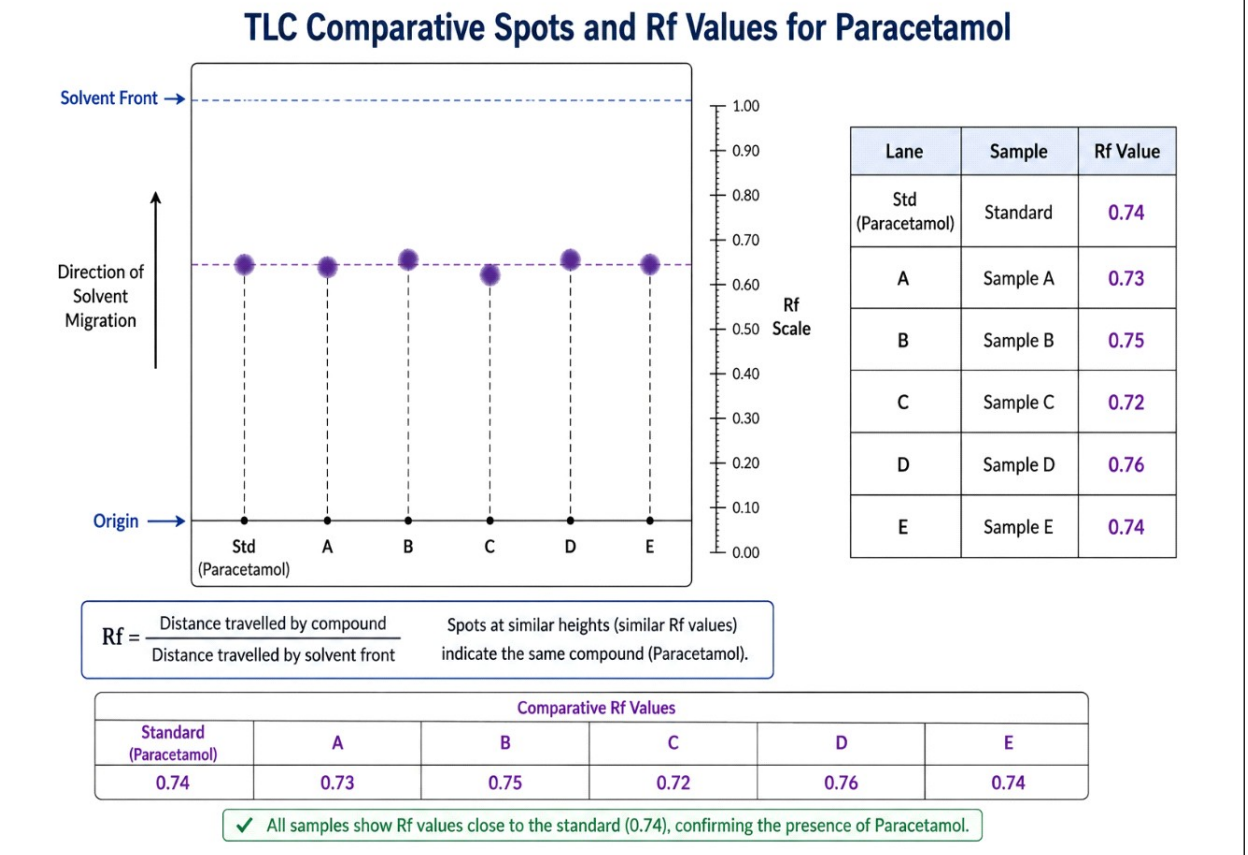

Figure 1: TLC plate showing paracetamol spots under UV light (254 nm)

Note: Illustration: Bands corresponding to sample and standard paracetamol spots with similar Rf values.

3.2. Disintegration test

The disintegration times of all brands ranged between 4.2 and 12.8 minutes, meeting the BP (2020) requirement that uncoated tablets should disintegrate within 15 minutes. However, Brand D showed the longest disintegration time (12.8 min), approaching the upper pharmacopeial limit, while Brand A disintegrated the fastest (4.2 min), indicating good tablet formulation and excipient performance (Table 2 and Figure 2).

Table 2: Disintegration time of paracetamol tablet brands

Brand code	Mean disintegration time (min) ± SD	BP limit (≤15 min)	Compliance
A	4.2 ± 0.3	≤15	Pass
B	6.8 ± 0.4	≤15	Pass
C	8.5 ± 0.6	≤15	Pass
D	12.8 ± 0.5	≤15	Pass
E	5.6 ± 0.2	≤15	Pass

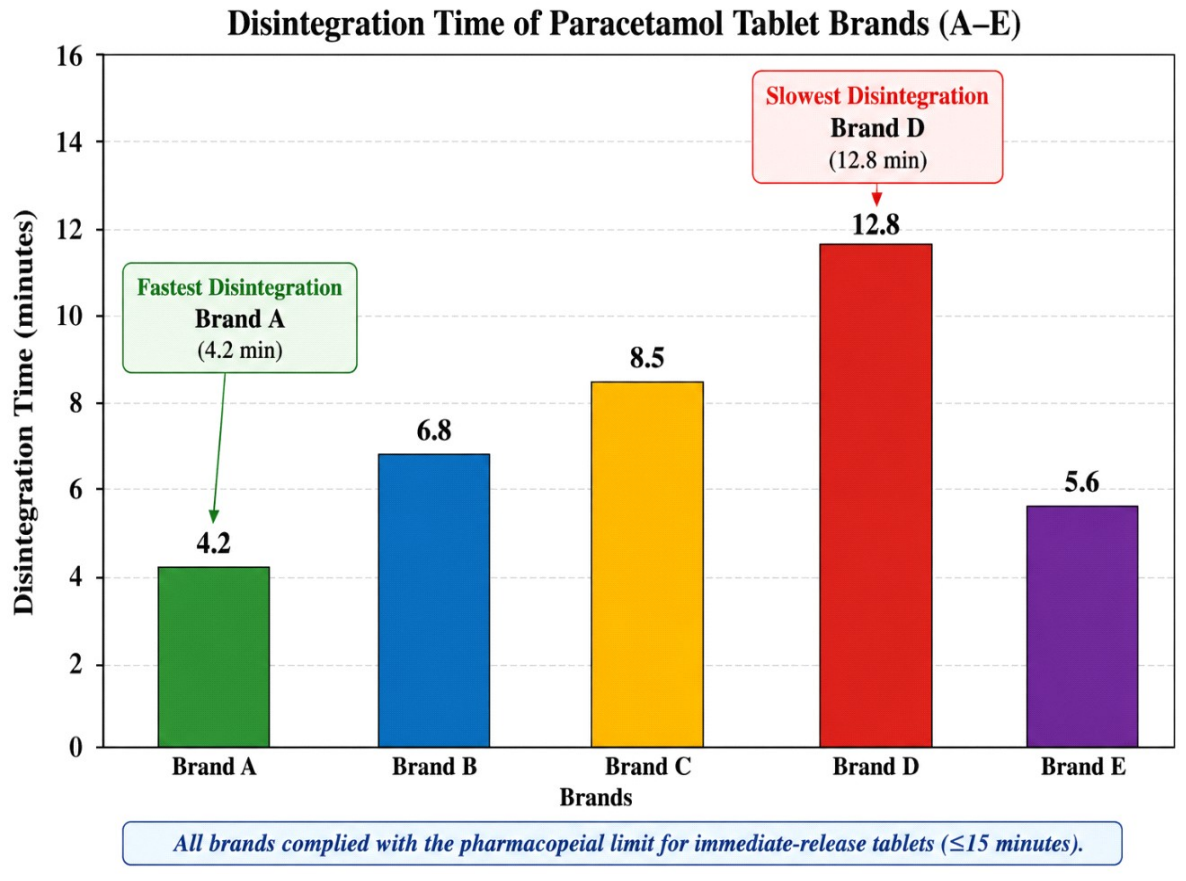

Figure 2: Disintegration time comparison among brands

Note: Bar graph showing variation in disintegration times of brands A–E, with Brand A being fastest and Brand D slowest.

3.3. Spectroscopic (UV-vis) analysis

The UV spectrophotometric assay showed that all brands contained paracetamol within the acceptable range of 95-105% of the labeled claim. The absorbance was measured at 257 nm, and results indicated minor differences in drug content among brands. Brand B exhibited the highest drug content (103.6%), while Brand D showed the lowest (96.8%) (Table 3) and percentage assay (Figure 3).

Table 3: Spectrophotometric assay results of paracetamol brands

Brand code	Mean absorbance (257 nm)	% Assay (label claim)	USP acceptance range (95-105%)	Compliance
A	0.655	100.2	95-105	Pass
B	0.677	103.6	95-105	Pass
C	0.662	101.3	95-105	Pass
D	0.634	96.8	95-105	Pass
E	0.668	102.5	95-105	Pass

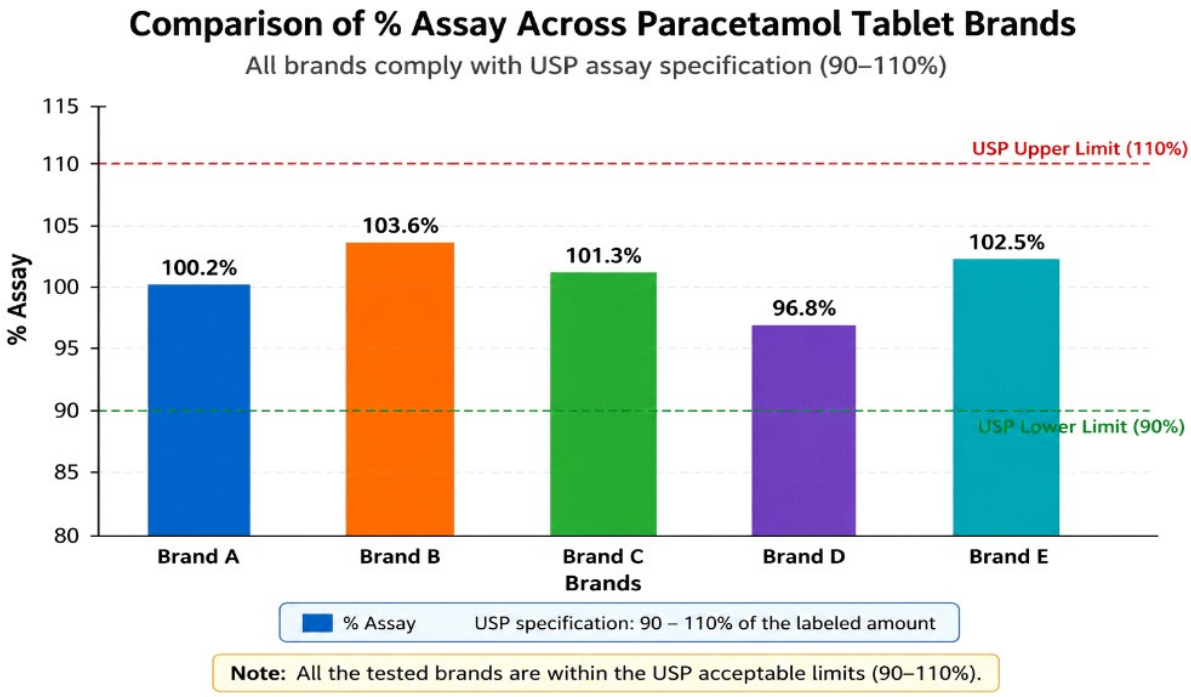

Figure 3: Percentage assay of paracetamol tablet brands

Note: Bar chart comparing % assay across brands; all within USP limits.

3.4. Comparative summary

Overall, all tested brands complied with BP/USP/WHO standards for identification, disintegration, and

Table 4: Summary of quality evaluation parameters

Brand	TLC (Rf match)	Disintegration (min)	% Assay	Overall compliance
A	0.73 (match)	4.2	100.2	Pass
B	0.75 (match)	6.8	103.6	Pass
C	0.72 (match)	8.5	101.3	Pass
D	0.76 (match)	12.8	96.8	Pass
E	0.74 (match)	5.6	102.5	Pass

assay. Nevertheless, minor variations in disintegration time and drug content were observed among brands, possibly reflecting differences in formulation or manufacturing quality control.

3.5. Summary of findings

- All brands contained genuine paracetamol as confirmed by TLC.
- All disintegration times met BP standards (≤15 min).
- All assay values were within the USP acceptance range (95-105%).
- Minor formulation differences were noted, but overall product quality was acceptable for all brands marketed in Juba.

4. Discussion

The present study evaluated the quality of different brands of paracetamol tablets marketed in Juba using Thin Layer Chromatography (TLC), disintegration testing, and UV-Visible spectrophotometric assay in accordance with BP/USP/WHO standards. The findings demonstrated that all tested brands contained paracetamol as the active ingredient, disintegrated within the pharmacopeial limits, and had assay values within the acceptable range of 95-105% of the labeled claim. These results indicate that the sampled products generally meet quality requirements for safety and efficacy.

The TLC analysis confirmed the presence of paracetamol in all brands, as evidenced by Rf values that closely matched the reference standard. Similar results were reported by Olaniyi *et al.* (2019) in Nigeria and by Mugoyela and Mwambete (2010) in Tanzania, where paracetamol tablets from various manufacturers exhibited comparable Rf values and confirmed identity with reference standards. The consistency in Rf values among brands suggests that counterfeit or adulterated samples were not detected in the study area.

The disintegration test showed variation among brands, ranging from 4.2 to 12.8 minutes, though all remained within the BP (2020) acceptable limit of 15 minutes for uncoated tablets. Differences in disintegration time may be attributed to variations in formulation factors such as the type and concentration of disintegrants, binders, and lubricants used by different manufacturers. Similar variations were reported in studies from Ethiopia and Uganda, where disintegration times varied significantly between local and imported brands, yet most met pharmacopeial standards (Gashaw *et al.*, 2018; Njoroge *et al.*, 2021). Rapidly disintegrating tablets, such as Brand A in this study, may ensure faster onset of therapeutic action, whereas longer disintegration times, as observed in Brand D, could delay drug release but still remain acceptable.

The spectroscopic assay revealed that the percentage of paracetamol content ranged from 96.8% to 103.6%, all within the USP (2020) acceptance range. These results are consistent with earlier studies conducted in Kenya, Sudan, and Nigeria, which found that most paracetamol brands complied with pharmacopeial limits, though occasional substandard products were identified (Adegbolagun *et al.*, 2007; Elkhier and Hamad, 2017). The minor differences in assay results may reflect variations in raw material purity, manufacturing practices, or storage conditions.

From a public health perspective, the findings are reassuring, as all brands tested met essential quality parameters. This implies that consumers in Juba are likely receiving paracetamol tablets with consistent therapeutic potency. However, the observed variability in disintegration and assay results underscores the importance of continuous post-market surveillance and quality monitoring by the South Sudan National Medicines and Food Control Authority (2024). Weak regulatory oversight in resource-limited settings can allow substandard or poorly manufactured products to circulate, posing risks such as treatment failure, toxicity, or reduced public trust in healthcare systems.

In conclusion, the study confirms that the paracetamol brands available in Juba generally conform to international quality standards. Nonetheless, the slight variations detected among brands highlight the need for strengthened pharmaceutical quality control, periodic regulatory inspections, and capacity building in local analytical testing. Sustained quality assurance efforts will help safeguard public health and ensure that essential medicines like paracetamol remain safe, effective, and reliable for the population.

5. Conclusion

This study assessed the quality of different brands of paracetamol tablets marketed in Juba using Thin Layer Chromatography (TLC), disintegration, and spectroscopic methods in accordance with BP, USP, and WHO standards. The findings revealed that all tested brands contained genuine paracetamol as the active ingredient, disintegrated within the acceptable pharmacopeial limit of 15 minutes, and had drug content within the USP range of 95-105% of the labeled claim. These results indicate that the sampled paracetamol tablets are of satisfactory quality and suitable for therapeutic use.

However, minor variations in disintegration time and assay values among brands suggest differences in manufacturing quality, formulation composition, or storage conditions. Such variations, though within limits, highlight the need for consistent post-market quality monitoring to maintain consumer confidence and ensure therapeutic effectiveness.

6. Recommendations

6.1. Regulatory authorities

- The South Sudan National Medicines and Food Control Authority should strengthen pharmaceutical quality surveillance programs, including random sampling and testing of commonly used medicines such as paracetamol.
- Implement stricter Good Manufacturing Practice (GMP) compliance inspections and enforce regulatory actions against substandard or noncompliant manufacturers.
- Establish or support national quality control laboratories equipped for routine testing following WHO guidelines.

6.2. Pharmacies and distributors

- Ensure procurement of medicines only from licensed and reputable suppliers.
- Maintain proper storage conditions to prevent degradation of active ingredients, particularly in hot and humid environments.
- Participate in pharmacovigilance programs by reporting any suspected quality-related issues or therapeutic failures.

In summary, while the paracetamol brands analyzed in this study generally meet international quality standards, continuous quality assessment, regulatory vigilance, and good pharmaceutical practices are vital to safeguard public health and ensure that safe and effective medicines are consistently available in South Sudan.

Author contributions

Jacob Thon Bior designed, conducted, and wrote the manuscript. All authors reviewed and approved the final version.

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