J. Bangladesh Acad. Sci. 50(1); 99-106: March 2026 DOI:https://doi.org/10.3329/jbas.v50i1.83761

Journal of Bangladesh Academy of Sciences

Journal homepage: http://www.bas.org.bd/publications/jbas.html

Research Article

Quality evaluation of near-expiry locally manufactured paracetamol tablets from rural health centers in Punjab, Pakistan

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ARTICLE INFO

Article History

Received: 16 August 2025
Revised: 15 February 2026
Accepted: 18 February 2026

Keywords: Paracetamol, Near-expiry drugs, Quality control parameters, Pharmacopeial compliance.

ABSTRACT

This study evaluated the pharmaceutical quality of near-expiry locally manufactured paracetamol 500 mg tablets collected from rural health centers in Punjab, Pakistan. Five commercial brands were assessed for key quality parameters, including physical characteristics, mechanical strength, disintegration, dissolution, and active pharmaceutical ingredient (API) content, in accordance with United States Pharmacopeia (USP) and British Pharmacopoeia (BP) standards. Weight variation, hardness, friability, disintegration, dissolution, and assay tests were performed using standard pharmacopeial methods. All brands complied with pharmacopeial limits for weight variation (616.0±38.2 mg), hardness (5.04±0.89 kg/cm²) and disintegration time (185-876 s). Friability remained within acceptable limits (< 1.0 %) for all brands except brand D (1.141±0.05%), which exceeded the specified limit. Dissolution testing showed that 4 brands released more than 80 % of the drug within 30 mins, whereas Brand D exhibited slightly lower drug release (79.38±1.12%). API assay results (95.90-99.89%) confirmed acceptable chemical stability across all formulations. Overall, the majority of near-expiry paracetamol tablets retained acceptable physicochemical quality, with only minor deviations observed in one brand, supporting their potential use in emergency and resource-limited settings.

Introduction

Paracetamol (acetaminophen) is one of the most widely used analgesics and antipyretics globally and is listed by the World Health Organization (WHO) as an essential medicine due to its safety, affordability and effectiveness (Babu et al., 2023; WHO, 2025). In low and middle-income countries (LMICs) such as Pakistan, paracetamol forms a core component of primary and emergency healthcare, particularly in rural areas where treatment options are limited and reliance on low-cost generic medicines is high.

Rural health facilities in Pakistan, including basic health units (BHUs) and dispensaries, often depend on locally manufactured generic medicines to meet patient demand. However, these facilities frequently face challenges related to inadequate storage conditions, limited climate control, weak inventory management and insufficient post-market surveillance. Such factors can adversely affect the physical integrity, dissolution behaviour, and chemical stability of pharmaceutical products as they approach their expiry date (Newton et al., 2010; Caudron et al., 2008).

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Several studies conducted in South Asia and other LMICs have demonstrated that the quality of essential medicines, including analgesics, may vary depending on storage conditions, manufacturing practices, and regulatory oversight. Although some drug products may retain acceptable potency beyond their labeled expiry date, others may fail pharmacopeial requirements, potentially compromising therapeutic effectiveness and patient safety (Lyon et al., 2006; Kushwaha et al., 2025; Marisa et al., 2024).

Most published studies evaluating the quality of paracetamol tablets in Pakistan have focused on samples obtained from urban pharmacies or controlled laboratory environments. These studies generally report satisfactory compliance with pharmacopeial standards but do not reflect real-world storage and distribution in rural healthcare settings (Alsaifi and Alyahawi, 2018; Almuzaini et al., 2013; Nayyar et al., 2012; Uddin et al., 2020). Importantly, data on near-expiry medicines, particularly those supplied to rural health centers, remain extremely limited (Aslam et al., 2010).

There is a lack of peer-reviewed evidence assessing the pharmaceutical quality of locally manufactured, near-expiry paracetamol tablets at the point of use in rural Pakistan. This gap is critical; as such medicines are often used during shortages, emergencies, or public health crises, where decisions regarding continued use, redistribution, or disposal must be informed by scientific evidence rather than assumption.

This study intends to evaluate the pharmaceutical quality and stability of near-expiry locally manufactured paracetamol 500 mg tablets collected from rural health centers in Punjab, Pakistan. Standard quality control tests, including weight variation, hardness, friability, disintegration, dissolution, and active pharmaceutical ingredient (API) assay, were performed in accordance with BP and USP guidelines. The findings were intended to determine whether these tablets retain acceptable quality and may be suitable for use in emergency and resource-limited rural healthcare settings.

Materials and Methods

Reagents and materials included distilled water, 0.1 N HCl, 0.1 M NaOH, 250 mL volumetric flasks, and droppers. Pharmaceutical quality assessment of the collected samples was conducted using standard laboratory instruments: an analytical balance (Mettler Toledo), for weight variation, a tablet hardness tester (Erweka TBH 100), a friabilator, a disintegration apparatus (ZT 320), and USP Type I (basket) and Type II (paddle)dissolution apparatus. A UV/Vis spectrophotometer (Shimadzu UV- 1800) was used for the quantitative determination of paracetamol content in dissolution media. All quantitative measurements were performed according to USP/BP guidelines and results are reported as mean ± SD.

Sample collection and sampling strategy

Five samples of locally manufactured paracetamol tablets (500 mg) nearing expiry dates were collected in September 2023 from healthcare facilities located in Punjab, Pakistan. Sampling sites included the Rural Health Centre Shahdara (Lahore), Polio Center Narowal, Green Pharmacy Narowal, and two rural locations in the Gujranwala district. A combined purposive stratified random sampling approach was adopted. Purposive sampling was used to specifically target near-expiry paracetamol tablets, as these products are more likely to be encountered in rural healthcare settings with slower stock turnover. Stratification was based on geographical location and manufacturer, ensuring representation of multiple locally operating pharmaceutical companies. Within each site, tablet strips were randomly selected from available stock to minimize selection bias. The collected tablets were coded as brands A-E (Table 1) to blind manufacturer identity during laboratory analysis.

Weight variation

Weight variation testing was conducted in accordance with pharmacopeial procedures (Akhtar et al., 2022). For each brand, tablets (n=20) were

Table 1. Parameters of locally packaged paracetamol tablets.

Code	Manufacturing company	Date of sample collection	Manufacturing date	Expiry date	Mode of packaging
A	Aneeb Pharmaceuticals, 24-Km Bedian Road Lahore, Pakistan	09-2023	04-2019	04-2024	Blister
B	Stanley Pharmaceuticals, 84- B Industrial Estate, Hayatabad Peshawar, Pakistan	09-2023	05-2020	05-2024	Blister
C	Evolution Pharmaceuticals, Industrial Estate Rawal Islamabad, Pakistan	09-2023	05-2020	05-2024	Blister
D	Legacy Pharmaceuticals, Industrial Estate, Hayatabad Peshawar, Pakistan	09-2023	04-2019	04-2024	Blister
E	Citi Pharma, 3 Km, Head Balloki Road, Phool Nagar Kasur, Pakistan	09-2023	04-2020	04-2024	Blister

selected and individually weighed using an analytical balance. The average tablet weight and percentage deviation for each tablet were calculated. Results were expressed as mean±SD (n=20), and compliance with pharmacopeial limits was assessed.

Hardness test

Tablet hardness was determined using a Monsanto hardness tester(Santosh et al., 2015). For each brand, 10 tablets (n=10) were randomly selected and tested individually by applying force (kg/cm²) until fracture occurred. The hardness values were recorded and reported as mean±SD (n=10).

Friability test

Friability was evaluated using a Eureka friabilator to assess the mechanical resistance of tablets during handling (Kusuma et al., 2015). A pre-weighed sample of tablets (6.5 g approx.) from each brand was subjected to 25 rpm for 4 min. After dedusting, tablets were reweighed, and the percentage friability was calculated using equation (1). Each test was performed once per brand as per pharmacopeial recommendation, and results were reported as percentage weight loss (n = 1).

$$\text{Friability (\%)} = \frac{Wi - Wf}{Wi} \times 100 \quad (1)$$

Where W_i = Weight before test, W_f = Weight after test.

Disintegration test

Disintegration testing was carried out using six tablets per brand (n=6**)** in accordance with pharmacopeial guidelines (Marisa et al., 2024). Each tablet was individually placed in the tube of the disintegration tester basket rack assembly, with a disk placed over each tablet to prevent floating. The basket assembly was immersed in a 1 L beaker containing 0.1 N HCl at 37 ± 0.5 °C and operated at 30 rpm. The time taken for complete disintegration of each tablet into particles small enough to pass through the mesh screen (typically 2 mm) without visible residue was recorded. Results were expressed as mean disintegration time±SD (n=6)**.**

Dissolution test

Dissolution studies were performed using a USP Type I (basket) apparatus. Six tablets per brand (n =

6) were individually tested in 900 mL of 0.1 N HCl (simulated gastric fluid), maintained at 37 ± 0.5 °C, with the basket rotating at 150 rpm. Aliquots (2 mL) were withdrawn at 10 min intervals up to 30 min and replaced with an equal volume of fresh pre-warmed medium to maintain sink conditions. Each collected sample was diluted to 10 mL, filtered, and the filtrate absorbance was measured at 222 nm using a UV/Visible spectrophotometer. Drug release was calculated using a previously constructed calibration curve. Dissolution results were reported as mean percentage drug release ± SD (n=6)**.** All brands met the USP requirement of at least 80% drug release within 30 min (Akhtar et al., 2022).

Assay analysis

Assay testing was conducted to quantify the active pharmaceutical ingredient (API) content of paracetamol tablets in accordance with established pharmacopeial procedures (Marisa et al., 2024). For each brand, twenty tablets (n=20) were accurately weighed, finely powdered, and a sample equivalent to 0.15 g of paracetamol was taken for analysis. The sample was transferred to a volumetric flask containing 50 mL of 0.1 M NaOH, then diluted to 100 mL with distilled water. The mixture was shaken for 15 min to ensure complete extraction of the API and then diluted to a final volume of 200 mL with distilled water. After filtration, a 10 mL aliquot of the clear filtrate was transferred to a second volumetric flask, mixed with 10 mL of 0.1 M NaOH, and diluted to 100 mL with distilled water. The absorbance of the resulting solution was measured at 257 nm using a UV/Visible spectrophotometer. Assay results were expressed as mean±SD (n=20)**,** providing an assessment of content uniformity and analytical precision (Table 2).

Results and Discussion

All tablet samples exhibited acceptable visual characteristics, including uniform color, smooth surfaces, and absence of visible defects such as cracks. Minor variations in scoring and imprint clarity were observed, which may influence identification but are likely to affect pharmaceutical performance. All tablets were white, odorless, and crystalline, consistent with standard paracetamol tablet formulations.

Weight variation

Weight variation is a critical quality indicator of dose uniformity in uncoated tablets, reflecting consistency in granulation and die filling during manufacturing.

According to USP specifications, tablets weighing more than 250 mg must not deviate by more than ±5 % from the mean weight. All tested brands (A-E) complied with this requirement, with mean tablet weights ranging from 568.1±3.9 mg (brand C) to 673.5±4.2 mg (brand A) (Table 2). Compliance with pharmacopeial limits indicates adequate control of the manufacturing process and uniform distribution of API. Similar findings have been reported for locally manufactured paracetamol tablets in Pakistan, India, and Bangladesh, where acceptable weight variation was observed even in near-expiry products (Luhar et al.,2023; Mj et al., 2023; Salisu et al., 2017; Kar and Kar, 2020).

Hardness test

Tablet hardness reflects mechanical strength and resistance to breakage during handling, transportation, and storage (Alderborn, 2002). In this study, hardness values ranged from 4.02 to 6.07 kg/cm², within the USP recommended range (4-10 kg/cm²) for uncoated tablets. Brand D exhibited the highest hardness (6.07±0.40 kg/cm²), suggesting a higher compression force or increased binder concentration during manufacturing (Table 2). While adequate hardness is necessary for physical stability, excessive hardness is known to adversely affect tablet disintegration and dissolution by reducing porosity and liquid penetration (Desai et al., 2014). This is consistent with brand D's slower disintegration and lower dissolution compared with other brands.

Friability

Friability testing evaluates a tablet's ability to withstand mechanical stress during handling and

distribution (Alderborn, 2002). The BP and USP specify that the acceptable friability limit is not more than 1% for uncoated tablets. Brands A, B, C, and E demonstrated friability values within acceptable limits, 0.375%, 0.237%, 0.937% and 0.135%, respectively, indicating satisfactory mechanical integrity (Table 2). In contrast, brand D exhibited a friability of 1.141%, exceeding the pharmacopeial threshold, consistent with poor resistance to mechanical stress (Patere et al., 2015). Elevated friability in brand D, despite relatively high hardness, suggests structural brittleness rather than insufficient compression. This pattern may result from uneven binder distribution, excessive lubricant interfering with particle adhesion, poor granulation, and environmental stress during storage (Waterman and Adami, 2005). Similar patterns have been reported in Nigeria, Pakistan, and Bangladesh, where isolated brands failed friability testing due to formulation or storage deficiencies (Luhar et al.,2023; Mj et al., 2023; Salisu et al., 2017; Kar and Kar, 2020).

Table 2. Pharmaceutical evaluation of paracetamol tablets (Mean ± SD).

Sample code	Weight variation (mg)	Hardness (kg/cm^2)	Friability (%)	Disintegration time (s)	Assay/API (%)
A	673.5 ± 4.2	4.05 ± 0.30	0.375	185 ± 11	98.90 ± 0.74
B	601.5 ± 4.0	5.09 ± 0.33	0.237	363 ± 13	99.76 ± 0.72
C	568.1 ± 3.9	4.02 ± 0.31	0.937	315 ± 12	98.35 ± 0.75
D	596.7 ± 4.0	6.07 ± 0.40	1.141	876 ± 11	95.90 ± 0.71
E	641.0 ± 4.2	5.99 ± 0.32	0.135	225 ± 10	99.89 ± 0.74

USP Standards: Weight variation: ±5 %; Hardness: 4-10 kg/cm^2; Friability: < 1 %; Disintegration time: ≤ 900 s; API content: 95-105 %.

Disintegration test

Disintegration testing ensures that tablets break down into smaller particles under physiological conditions (Desai et al., 2014; Molavi et al., 2020), ensuring the availability of the active pharmaceutical ingredient (API) for absorption. According to BP and USP, uncoated tablets should disintegrate within 15 min in purified water or simulated gastric fluid. All brands complied with pharmacopeial limits, demonstrating complete disintegration within 900s (Table 2). Brand A exhibited the fastest disintegration time (185±11s), followed by brand E (225±10s), brand C (315±12s), and brand B (363±13s). Brand D, though within the acceptable limit, showed a significantly longer disintegration time (876±11s), indicating a slower disintegration rate, which may affect the onset of therapeutic action. Prolonged disintegration in brand D is likely due to high hardness, reduced porosity, or insufficient disintegration efficiency, which can also be exacerbated by moisture-induced binder hardening during storage (Waterman and Adami, 2005). This suggests the importance of regular quality monitoring in decentralized healthcare settings. These observations align with studies showing that extended disintegration times directly correlate with slower dissolution in immediate-release paracetamol tablets (Mj et al. 2023; Molavi et al., 2020).

Dissolution test

Dissolution testing evaluates the in-vitro release rate of the API under simulated gastrointestinal conditions (BPC, 2024). According to USP standards, a minimum of 80 % drug release within 30 min is required for immediate release of paracetamol tablets to be considered pharmaceutically acceptable. The dissolution profiles of all 5 brands' tablets were evaluated at 5,

10, 15, and 30 min intervals (Fig. 1). All brands demonstrated increasing drug release over time, consistent with expected dissolution kinetics. Brands A (85.78%), B (89.36%), C (91.89%), and E (90.77%) exceeded the USP requirement of ≥ 80 % drug release within 30 min, with brand C achieving the most rapid release. Brand D released only 79.38 %, slightly below the USP threshold, consistent with its high hardness, extended disintegration time, and elevated friability (Kar et al., 2015). Among all samples, brand C showed the most rapid release, with 35.75% at 5 min and over 91% by 30 min, indicating superior dissolution performance.

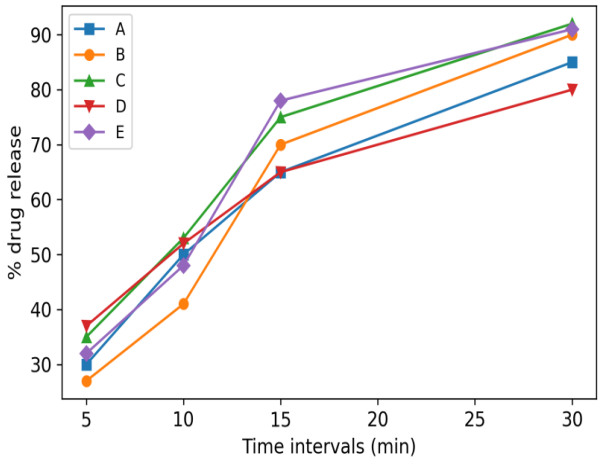

Fig.1. Dissolution profiles of local Paracetamol tablets.

In contrast, brand B exhibited a slower initial release (27.38% at 5 min), although it met the 30 min specification. These findings suggest that although most near-expiry paracetamol tablets retained acceptable dissolution characteristics, brand D's slight deviation may indicate compromised bioavailability, especially in time-critical therapeutic applications. This slight deviation may be due to improper granulation reducing surface area, uneven binder distribution, and moisture effects during prolonged storage near expiry (Patere et al., 2015; Waterman and Adami, 2005; Molavi et al., 2020). This underscores the need for rigorous post-distribution quality monitoring, particularly in rural settings where older stock may persist in circulation. Regional studies confirm similar trends: most brands in Bangladesh and Pakistan met dissolution criteria, but isolated brands occasionally failed due to formulation inconsistencies (Mj et al., 2023; Kar and Kar , 2020).

Assay/API analysis

Assay analysis was conducted to determine the percentage of active pharmaceutical ingredient (API) present in each tablet and to verify compliance with pharmacopeial standards. All brands, A (98.90±0.74%), B (99.76±0.72%), C (98.35±0.75%), D (95.90±0.71%), and E (99.89±0.74%), demonstrated API content within USP limits (95–105%) with brand D at the lower end (Table 2). This indicates that observed physical deficiencies (friability, disintegration, dissolution) are primarily due to formulation or mechanical factors rather than chemical degradation (Halbert, 2000). However, since the assay values remained compliant, the observed performance issues for brand D are more likely attributable to physical and mechanical instability rather than to a significant loss of API.

Brand D's combination of higher friability, extended disintegration, and lower dissolution reflects an imbalance between mechanical robustness and drug release requirements. The literature indicates that robust tablets must balance compression strength with porosity and disintegrant efficiency; failure to optimize this balance often results in compromised dissolution even when assay values remain within acceptable ranges (Lawal et al., 2015). Therefore, the observed deviations in Brand D likely stem from manufacturing variables (binder/disintegrant level, compression force, granulation quality) and possibly from storage conditions that alter tablet physical properties over time. This emphasizes the need for adherence to good manufacturing practices, routine post-distribution quality monitoring, and stronger supply chain storage conditions, particularly in resource-limited and rural healthcare settings where environmental control is less reliable.

Conclusion

This study evaluated the pharmaceutical quality of near-expiry, locally manufactured paracetamol

tablets collected from rural healthcare facilities across Punjab, Pakistan. All tested brands complied with pharmacopeial specifications for weight variation, hardness, disintegration time and active pharmaceutical ingredient content, demonstrating acceptable physicochemical stability and preservation of chemical potency close to expiry. However, one brand (D) exceeded the friability limit and showed marginally reduced dissolution, releasing 79.38 % of the drug content within 30 min, slightly below USP requirements. These deviations are likely attributable to formulation imbalance, suboptimal granulation or compression, and possible moisture-related effects during storage. Overall, the findings indicate that most near-expiry paracetamol tablets retain adequate mechanical integrity and in-vitro performance, supporting their potential use in emergency and resource-constrained settings. Nonetheless, stringent adherence to Good Manufacturing Practices, controlled storage conditions, and routine post-distribution quality monitoring remain essential to ensure consistent therapeutic efficacy throughout the product shelf life.

Funding source

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Acknowledgment

The authors sincerely acknowledge the University of Engineering and Technology Lahore for providing resources and colleagues for their valuable contributions and guidance.

Authors contribution

All authors contributed equally.

Conflict of interest

Authors declare no competing interests.

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