

Original Article

Comparative Evaluation of Marketed Paracetamol Tablet Brands

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ABSTRACT

Background: The therapeutic reliability of immediate-release solid dosage forms is critically dependent on both their physicochemical quality attributes and the kinetics of in-vitro drug release under physiologically relevant conditions. Paracetamol (acetaminophen) remains among the most widely dispensed analgesics and antipyretics globally, yet inter-brand variability in formulation composition and manufacturing processes may influence dissolution behaviour and, consequently, clinical performance. **Objective:** This study aimed to conduct a systematic comparative evaluation of three commercially available Paracetamol 500 mg immediate-release tablet brands (Brand A, B, and C) procured from the Indian pharmaceutical market, assessing both compendial quality parameters and multimedia in-vitro dissolution profiles across multiple simulated gastrointestinal pH environments. **Methods:** Physical quality evaluation encompassed weight variation, tablet thickness, hardness, friability, and disintegration time, conducted in accordance with Indian Pharmacopoeia (IP) guidelines. Dissolution testing was performed using IP Apparatus II (Paddle) at $37 \pm 0.5^\circ\text{C}$ and 50 rpm in four dissolution media, Purified Water, 0.1N HCl, pH 4.5 Acetate Buffer, and pH 5.8 Phosphate Buffer with spectrophotometric quantification at 247 nm. **Results:** All three brands complied with IP weight variation limits ($\pm 5\%$). Inter-brand differences were observed in hardness (7.20–11.40 kg/cm²), friability (0.13–0.85%), and disintegration time (40 seconds to 3 minutes 06 seconds). In all four-dissolution media, all brands released $\geq 80\%$ of the labelled drug content within 30 minutes, fulfilling the IP dissolution criterion. Brand C, characterized by the highest friability and shortest disintegration time, consistently exhibited the most rapid dissolution profile. Brand B demonstrated the most uniform release pattern, while Brand A achieved robust complete dissolution with the highest structural integrity. **Conclusion:** The study establishes a demonstrable correlation between physical formulation parameters, particularly friability and disintegration behaviour and in-vitro dissolution kinetics. Multimedia testing confirmed that the dissolution profiles of all three brands are largely pH-independent, attributable to paracetamol's inherently high aqueous solubility. All evaluated brands satisfy IP compendial standards and may be considered pharmaceutically equivalent and therapeutically interchangeable.

Key words: Paracetamol, immediate-release tablets, in-vitro dissolution, pharmaceutical equivalence, pH-independent dissolution.

Oral solid dosage forms remain the most widely used pharmaceutical preparations owing to their convenience, stability, cost-effectiveness, and patient compliance [1]. Among these, immediate-release (IR) tablets are specifically formulated to disintegrate and release the active pharmaceutical ingredient rapidly after oral administration, thereby ensuring prompt therapeutic action [2,3]. The quality and performance of IR tablets are greatly influenced by formulation variables such as excipient composition, manufacturing process, compression force, hardness, friability, and disintegration characteristics [4]. These parameters collectively affect the dissolution behaviour of the dosage form,

which in turn plays a critical role in determining drug bioavailability and therapeutic efficacy [4]. Paracetamol (acetaminophen; 4'-hydroxyacetanilide) is one of the most extensively used over-the-counter analgesic and antipyretic drugs worldwide [5]. It is commonly prescribed for the management of mild to moderate pain and fever and is considered a first-line therapeutic agent due to its favourable safety profile when administered at recommended doses [6]. Because of its widespread clinical use across paediatric, adult, and geriatric populations, maintaining consistent quality and performance among marketed paracetamol tablet formulations is of significant pharmaceutical and public health importance [7,8].

Access this article online

Received – 12th May 2026

Initial Review - 4th July 2026

Accepted – 9th July 2026

Quick Response Code

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According to the Biopharmaceutics Classification System (BCS), paracetamol is categorised as a Class I drug, possessing high solubility and high permeability [9]. For BCS Class I drugs, dissolution is generally rapid and is not considered the rate-limiting step for absorption under normal physiological conditions [10]. Nevertheless, variations in formulation and manufacturing practices among different commercial brands may alter important physical characteristics of tablets, thereby influencing drug release kinetics and dissolution profiles [11]. Such inter-brand variability may ultimately affect the onset of therapeutic action and overall product performance.

Dissolution testing is regarded as one of the most important in-vitro quality control tests for oral solid dosage forms [12]. It provides valuable information regarding the rate and extent of drug release from the formulation, serving as a surrogate indicator of in vivo drug absorption and bioavailability. Pharmacopoeial standards, including those specified by the Indian Pharmacopoeia (IP), establish dissolution requirements to ensure batch-to-batch consistency and product quality [13]. In addition to pharmacopoeial evaluation, the assessment of non-pharmacopoeial parameters such as tablet hardness, friability, weight variation, and disintegration time offers further insight into formulation integrity and manufacturing quality [14]. The gastrointestinal tract exhibits a dynamic pH environment, ranging from highly acidic conditions in the stomach to near-neutral and slightly alkaline conditions in the intestine [15]. Since dissolution behaviour may vary with changes in pH, evaluating formulations in multiple dissolution media provides a more comprehensive understanding of drug release characteristics under simulated physiological conditions [16]. Media such as purified water, 0.1 N hydrochloric acid, pH 4.5 acetate buffer, and pH 5.8 phosphate buffer are commonly employed to assess pH-dependent dissolution behaviour and formulation robustness [17]. Although several studies have investigated the quality characteristics of marketed paracetamol tablets, many reports have focused on limited physicochemical parameters or a single dissolution medium [18,19]. Comprehensive studies correlating physical tablet properties with dissolution kinetics across multiple physiological pH conditions remain limited, particularly for formulations available in the Indian pharmaceutical market [20,21].

Therefore, the present study evaluated the pharmaceutical quality and dissolution behaviour of three commercially available brands of Paracetamol 500 mg immediate-release tablets marketed in India. The study aimed to assess both pharmacopoeial and non-pharmacopoeial quality parameters and to investigate the dissolution profiles of the selected brands in different dissolution media representing physiological pH conditions. Furthermore, the study aimed to investigate whether variations in physical tablet characteristics affect

dissolution kinetics and whether the tested brands meet the Indian Pharmacopoeia dissolution specifications.

2. MATERIALS AND METHODS

2.1 Procurement of Tablet Samples

Three commercially available brands of Paracetamol 500 mg immediate-release tablets (designated as Brand A, Brand B, and Brand C) were procured from licensed retail pharmacies in India. All brands were within their stated shelf-life at the time of testing.

2.2 Physical Quality Evaluation

Physical quality evaluation was performed in accordance with Indian Pharmacopoeia (IP 2022) specifications using the following tests:

- **Uniformity of Weight:** Twenty tablets from each brand were individually weighed using a calibrated Shimadzu analytical balance. The mean weight and percentage deviation from the mean were calculated. The IP limit for tablets weighing ≥ 250 mg permits a maximum deviation of $\pm 5\%$ for individual tablets.
- **Thickness:** The thickness of five randomly selected tablets per brand was measured using a calibrated digital Vernier calliper. Mean thickness and percentage relative standard deviation (%RSD) were calculated to assess manufacturing consistency.
- **Hardness:** The mechanical crushing strength of five tablets per brand was determined using a Monsanto hardness tester and recorded in kg/cm^2 . Mean hardness and %RSD were calculated.
- **Friability:** Friability was evaluated using a Roche Friabilator (Electrolab). Ten tablets from each brand were weighed (initial weight W_1), subjected to 100 revolutions at 25 rpm, dedusted, and reweighed (final weight W_2). Percentage friability was calculated as: $\% \text{ Friability} = [(W_1 - W_2) / W_1] \times 100$. The IP limit is $< 1.0\%$ w/w.
- **Disintegration Time:** The disintegration test was performed using an Electrolab disintegration tester with six tablets per brand in 900 mL of Purified Water at $37 \pm 2^\circ\text{C}$. The time for complete disintegration of all tablets (no residue remaining on the screen) was recorded. The IP limit for uncoated immediate-release tablets is not more than (NMT) 15 minutes.

2.3 In-Vitro Multimedia Dissolution Testing

Dissolution testing was conducted using Apparatus II (Paddle type, Electrolab dissolution tester) in compliance with IP 2022 General Chapter Specifications. The paddle rotation speed was maintained at 50 rpm and the dissolution medium temperature was controlled at $37 \pm 0.5^\circ\text{C}$ throughout. Six tablets from each

brand were tested per dissolution medium. Dissolution Media: Four dissolution media were employed to simulate the varying pH environments of the gastrointestinal tract: (i) Purified Water (pH ~6.0–6.5); (ii) 0.1N Hydrochloric Acid (simulated gastric fluid, pH 1.2); (iii) pH 4.5 Acetate Buffer; and (iv) pH 5.8 Phosphate Buffer. Sampling and Analysis: Aliquots of 10 mL were withdrawn at predetermined time intervals of 10, 20, 30, 45, and 60 minutes, with immediate replacement of an equal volume of fresh dissolution medium to maintain sink conditions. Withdrawn samples were filtered through 0.45 µm membrane filters and appropriately diluted with the respective dissolution medium. Absorbance was measured at λ_{max} 247 nm using a UV-Vis spectrophotometer, and the percentage of drug dissolved at each time point was calculated. The IP criterion for paracetamol IR tablets specifies that not less than 80% (Q) of the labelled amount should dissolve within 30 minutes.

3. RESULTS

3.1 Uniformity of Weight

Weight variation was assessed for 20 tablets from each brand. Brand A had a mean weight of 664.95 mg with percentage deviations ranging from -1.80% to +3.90%. Brand B yielded a mean weight of 620.65 mg (range: -1.44% to +1.44%), while Brand C had a mean weight of 593.75 mg (range: -1.85% to +2.35%). All three brands complied with the IP limit of $\pm 5\%$ for tablets weighing ≥ 250 mg. The narrow deviation ranges, particularly for Brand B, indicate a high degree of manufacturing precision and batch-to-batch consistency.

3.2 Thickness

Mean tablet thickness for Brand A, B, and C was 4.23 mm, 4.19 mm, and 4.20 mm, respectively. The %RSD values were 0.396%, 0.495%, and 0.568%, respectively (Table 1). Brand A demonstrated the highest dimensional uniformity (%RSD 0.396%), reflecting superior die-fill consistency during compression. The inter-brand thickness differences were minimal, indicating comparable tablet dimensions across all three formulations.

3.3 Hardness

Mean hardness values were 11.40 ± 0.548 kg/cm² (Brand A), 7.20 ± 1.304 kg/cm² (Brand B), and 9.40 ± 1.342 kg/cm² (Brand C). Brand A exhibited the highest crushing strength and the best intra-brand uniformity (%RSD 4.805%). Brand B demonstrated the lowest compaction force, with the highest %RSD (18.109%), suggesting greater inter-tablet variability in compression.

3.4 Friability

Percentage friability values were 0.39% (Brand A), 0.13% (Brand B), and 0.85% (Brand C). All three brands complied with the IP/USP friability limit of $<1.0\%$ w/w. Brand C

Table 1. Thickness (mm), Hardness (kg/cm²), and Friability (%) of Paracetamol Tablet Brands

Parameter	Brand A	Brand B	Brand C
Mean Thickness (mm)	4.23 $\pm$ 0.017	4.19 $\pm$ 0.021	4.20 $\pm$ 0.024
%RSD (Thickness)	0.396	0.495	0.568
Mean Hardness (kg/cm ²)	11.40 $\pm$ 0.548	7.20 $\pm$ 1.304	9.40 $\pm$ 1.342
%RSD (Hardness)	4.805	18.109	14.273
Friability (%)	0.39	0.13	0.85
Compliance	Pass	Pass	Pass

exhibited the highest surface fragility, while Brand B, despite its lower hardness, demonstrated the greatest surface cohesion and the lowest propensity for abrasion-mediated mass loss - a finding with direct implications for its dissolution behaviour.

3.5 Disintegration Time

Disintegration times were 1 min 26 sec (Brand A), 3 min 06 sec (Brand B), and 40 sec (Brand C). All brands satisfied the IP limit of NMT 15 minutes. Brand C achieved the most rapid disintegration, consistent with its highest friability. Conversely, Brand B, despite possessing the lowest hardness exhibited the slowest disintegration, attributable to its highly cohesive surface structure and the lowest friability (0.13%). This paradoxical relationship between hardness and disintegration time in Brand B highlights the critical role of surface cohesion and binder characteristics over compaction force in governing tablet breakdown (Table 2).

Table 2. Disintegration Times of Marketed Paracetamol Brands

Brand	Disintegration Time	IP Limit	Result
Brand A	1 min 26 sec	NMT 15 min	Pass
Brand B	3 min 06 sec	NMT 15 min	Pass
Brand C	40 sec	NMT 15 min	Pass

3.6 In-Vitro Multimedia Dissolution Studies

Average percentage drug release data for all three brands across the four-dissolution media are summarised in Table 3.

Table 3. Average Percentage Drug Release (%) of Paracetamol Brands A, B, and C across Four Dissolution Media.

Time	Purified Water			0.1N HCl			4.5 Acetate Buffer		
	A	B	C	A	B	C	A	B	C
10 min	66	66	77	67	65	80	64	63	78
20 min	87	85	100	87	86	103	85	84	100
30 min*	101	100	101	101	100	104	100	99	102
45 min	103	101	102	102	101	105	102	100	103
60 min	105	104	103	104	103	105	103	102	104
Average	92.4	91.2	96.6	92.2	91.0	99.4	90.8	89.6	97.4

* Denotes the IP-critical 30-minute time point.

Across all four dissolution media, all three brands achieved $\geq 80\%$ drug release within 30 minutes, fulfilling the IP dissolution specification. In Purified Water and 0.1N HCl, Brands A and B each released approximately 87% and 85–86% of the drug by 20 minutes, respectively, reaching complete dissolution ($\geq 99\%$) by 30 minutes. Brand C demonstrated markedly accelerated dissolution in all three of these media, achieving near-complete release (77–80%) even at the 10-minute time point and reaching a stable dissolution plateau (100–104%) by 20 minutes. In pH 5.8 Phosphate Buffer, all three brands exhibited a slightly more gradual initial release profile, with all converging to $\geq 98\%$ drug release by the 30-minute mark (Table 4)

Table 4. Average Percentage Drug Release (%) in pH 5.8 Phosphate Buffer

Time Point	Brand A (%DR)	Brand B (%DR)	Brand C (%DR)
10 min	64	63	75
20 min	83	83	97
30 min*	98	98	98
45 min	100	99	99
60 min	100	100	103
Average	89.0	88.6	94.4

* Denotes the IP-critical 30-minute time point. All values represent mean of six units.

DISCUSSION

The present study demonstrated that all three commercially available Paracetamol 500 mg immediate-release tablet brands complied with Indian Pharmacopoeial specifications for weight variation, hardness, friability, disintegration, and dissolution, confirming their pharmaceutical equivalence and acceptable formulation quality. Despite overall compliance, distinct differences in physicomachanical characteristics significantly influenced early-phase dissolution behaviour across the tested formulations. Brand C, which exhibited the highest friability (0.85%) and shortest disintegration time (40 seconds), consistently showed the fastest dissolution profile in all media, likely due to rapid penetration of dissolution medium, accelerated matrix erosion, and increased effective surface area for drug release. This finding is consistent with the established relationship between increased porosity, reduced structural cohesion, and enhanced dissolution kinetics. In contrast, Brand B demonstrated the lowest crushing strength (7.20 kg/cm²), lowest friability (0.13%), and longest disintegration time (3 minutes 06 seconds), suggesting the presence of a cohesive binder matrix or hydrophobic excipient system capable of retarding aqueous penetration and matrix disruption. Similar behaviour has been reported in formulations containing polymeric binders such as hydroxypropyl methylcellulose (HPMC) or hydrophobic lubricants. Nevertheless, Brand B released $\geq 99\%$ drug content within 30 minutes in all media and exhibited the most uniform dissolution pattern, indicating superior formulation consistency. Brand A, characterised by the highest hardness (11.40 kg/cm²), moderate friability (0.39%), and intermediate disintegration time (1 minute 26 seconds), demonstrated robust structural integrity and

reproducible dissolution kinetics with minimal inter-unit variability. Collectively, these findings confirm that excipient composition, and compression characteristics can significantly influence dissolution kinetics even in highly soluble immediate-release formulations.

A clinically important observation of the present investigation was the largely pH-independent dissolution behaviour of all evaluated formulations. Dissolution profiles generated in Purified Water, simulated gastric fluid (0.1 N HCl), acetate buffer (pH 4.5), and phosphate buffer (pH 5.8) showed highly comparable release patterns, with only a slight transient lag in pH 5.8 buffer during the initial phase that resolved completely by 30 minutes. This behaviour is consistent with the Biopharmaceutics Classification System (BCS) Class I properties of paracetamol, which possesses high aqueous solubility and high intestinal permeability. Due to its relatively high pKa (~9.5), paracetamol remains predominantly unionised across the physiological gastrointestinal pH range, thereby facilitating rapid dissolution independent of medium pH. The findings therefore support the regulatory rationale for BCS-based biowaiver consideration for immediate-release paracetamol formulations.

The present results are in strong agreement with previous international studies evaluating marketed paracetamol formulations. Thakuri *et al.* (2016) reported that Nepalese market brands achieved $\geq 80\%$ drug release within 45 minutes according to British Pharmacopoeial specifications and $\geq 85\%$ within 30 minutes according to Indian Pharmacopoeial criteria, with acceptable content uniformity [22]. Similarly, Kar *et al.* (2015) observed dissolution values ranging from 79.82% to 103.53% within 45 minutes among Bangladeshi brands [23]. Teklu *et al.* (2014) demonstrated that paracetamol tablets marketed in Ethiopia released 97.6–109% drug content within 30 minutes, closely corresponding to the dissolution plateau values observed in the present study (approximately 97–106%) [24]. Likewise, Alwadi *et al.* (2022) reported consistent and predominantly diffusion-controlled dissolution behaviour among acetaminophen brands marketed in Saudi Arabia [25]. Compared with these investigations, the formulations evaluated in the current study demonstrated comparable or superior dissolution performance, achieving near-complete drug release within 30 minutes across all physiologically relevant dissolution media. From both regulatory and therapeutic perspectives, the most significant outcome of the study is the confirmation of pharmaceutical equivalence and potential therapeutic interchangeability among the evaluated brands. All formulations achieved the pharmacopoeial requirement of releasing not less than 80% drug content within 30 minutes in all dissolution media, supporting their compliance with BCS-based biowaiver principles. However, the marked inter-brand variability in friability and disintegration behaviour indicates

meaningful formulation and manufacturing differences that may assume greater relevance under altered physiological conditions such as hypochlorhydria, delayed gastric emptying, post-bariatric surgical states, or food–drug interactions. Certain limitations should also be acknowledged. Statistical comparative analyses, including ANOVA and model-independent dissolution comparison using f_1/f_2 similarity factors, were not performed. In addition, drug content assay was not included in the evaluation protocol, and only three brands were investigated, limiting broader extrapolation of the findings to the wider Indian pharmaceutical market. Finally, although calibration and linearity data were employed for dissolution quantification, these analytical validation parameters were not included in the present manuscript and should be incorporated in future studies to ensure complete methodological transparency.

CONCLUSION

This study demonstrated that three commercially available brands of Paracetamol 500 mg immediate-release tablets marketed in India complied with all Indian Pharmacopoeial quality specifications for both physicochemical evaluation and multimedia in-vitro dissolution performance. Dissolution kinetics across purified water, simulated gastric fluid (0.1 N HCl), acetate buffer (pH 4.5), and phosphate buffer (pH 5.8) were largely pH-independent, consistent with the Biopharmaceutics Classification System (BCS) Class I characteristics of paracetamol, with all formulations achieving the pharmacopoeial criterion of $\geq 80\%$ drug release within 30 minutes. The study further established a mechanistically relevant correlation between physical formulation attributes and dissolution behaviour, wherein Brand C exhibited accelerated dissolution attributable to increased friability and rapid disintegration, Brand B demonstrated comparatively slower disintegration yet highly uniform release kinetics due to its cohesive surface matrix despite lower hardness, and Brand A showed robust and reproducible dissolution behaviour associated with superior structural integrity. Collectively, these findings confirm the pharmaceutical equivalence and potential therapeutic interchangeability of the evaluated formulations while highlighting the significance of multimedia dissolution profiling as a more discriminative and physiologically relevant quality assessment approach than single-medium testing, particularly in the context of regulatory evaluation and biowaiver considerations. Future studies should incorporate formal statistical comparison of dissolution profiles using model-independent similarity factors (f_1/f_2), quantitative drug content assay, and broader post-marketing surveillance involving a larger range of commercially available formulations to enable more comprehensive characterisation of paracetamol tablet quality within the Indian pharmaceutical market.

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How to cite this article : Subramaniyan G , Kumar S.M, Rextan R.M, Dhivagar S, Karpagavalli P, et. al. Comparative Evaluation of Marketed Paracetamol Tablet Brands. *Indian J Pharm Drug Studies*. 2026; Online First.

Funding: None

Conflicts of Interest: None Stated