Research Article

Comparative Quality Control Evaluation of Generic and Branded Paracetamol Tablets

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Received: 08-05-2026; **Revised:** 23-07-2026; **Accepted:** 29-07-2026; **Published online:** 20-08-2026.

ABSTRACT

Paracetamol (acetaminophen) has been one of the most commonly used analgesic and antipyretic drugs and is available as both a branded and generic product. The present study was designed to evaluate the comparative quality control of branded and marketed generic paracetamol tablets in terms of their compliance with pharmacopoeia standards and to ensure their therapeutic equivalence. The quality control criteria, such as weight fluctuation, hardness, friability, disintegration time, dissolution profile and assay of active pharmaceutical ingredients (API), were examined. Different marketed brands and generic samples were procured and analysed as per Indian Pharmacopoeia (IP) guidelines. Most of the formulations tested were within the official specifications. However, there were some small differences between the brands and generic products in characteristics such as rate of dissolution and hardness. The drug content and release profiles, although in different formulations, were all acceptable, indicating similar efficacy. Researchers found that generic paracetamol tablets are therapeutically equivalent to the branded ones and are a cheaper alternative without compromising on quality. It has to be quality consistent, and patients have to be safe, which means constant monitoring and rigorous quality control evaluation.

Keywords: Therapeutic equivalence, Tablet evaluation parameters, Pharmacopoeia standards, Dissolution test, Branded drugs, Generic drugs.

INTRODUCTION

Paracetamol (acetaminophen) is one of the most widely used over-the-counter drugs worldwide for pain and fever relief. It is often made into tablets and sold under brand names and also as a generic drug because it works, is safe and is inexpensive. Generic medicines are frequently regarded as interchangeable with branded products in clinical practice, despite the fact that concerns about their quality, consistency and therapeutic equivalence remain.[1]

The quality of tablet formulations is essentially influenced by different physicochemical criteria such as weight variation, hardness, friability, disintegration time, dissolving profile, and assay of the active pharmaceutical ingredient (API). These parameters are significant as they influence the drug release, bioavailability and ultimately therapeutic efficacy.[2] The Indian Pharmacopoeia, United States Pharmacopoeia, and World Health Organization have created severe rules for pharmaceutical items to satisfy quality requirements. Although regulations are in place, differences in formulation techniques, excipient composition, and manufacturing processes may result in differences in the quality attributes of generic and branded paracetamol tablets. Such variations have been shown in several studies to significantly influence the mechanical strength and dissolution characteristics of tablets, which may influence drug absorption and clinical performance.[3] Hence, systematic quality control tests of the marketed products should be performed to verify their conformity to the standards prescribed in the pharmacopoeia.

The objective of the present study was to comparatively assess the quality control of marketed generic and branded paracetamol tablets to assess their compliance with official standards and to establish their therapeutic equivalence. This will ensure efficacy, safety, and patient confidence in generic medicines.

MATERIALS AND METHODS

Two varieties of generic and branded paracetamol tablets with a label claim of 500 mg were obtained from local medical stores in the city. Finally, two different tablets were used for evaluation.

Chemicals

Potassium dihydrogen phosphate, sodium hydroxide, and distilled water. All compounds utilised were of analytical grade.

Equipment's

Analytical balance, Monsanto hardness tester, Friabilator, Disintegration test apparatus,

Dissolution apparatus (USP Type II), UV-Visible spectrophotometer

Methods

The study used the Indian Pharmacopoeia 2026 to check the in vitro quality of paracetamol tablets using different analytical techniques and procedures described in the pharmacopoeia.

PROCEDURE OF EVALUATION

Various analytical methods and tests are required to develop and manufacture pharmaceutical formulations. For evaluation, the following quality control tests were performed for both tablets in the study.

1. Hardness Test[4]

A tablet hardness tester is used to measure the hardness of tablets for this test. The Monsanto, Pfizer and Schleuniger hardness testers are popular. Two plungers are placed in the barrel of the Monsanto hardness tester, with a spring in between. At first, the reading is set to zero, and the plunger on the bottom is pushed against the tablet. Then, a threaded bolt is turned to tighten the top plunger and make the tablet break. A pointer moves along the scale to show the amount of force applied when the spring is being pushed together. Kilograms are used to measure the breaking force. In this test, ten pills are tested for hardness. The allowable range of hardness is normally 4–6 kg (40–60 N).

2. Friability test[5]

An Electrolab EF-2 Friabilator (USP) was used in this investigation to assess the tablets' friability, and the results were reported as a percentage (%). Each formulation's ten pills were weighed separately before being put in the friabilator. The machine was operated for 4 minutes at a speed of 25 rotations per minute (25 rpm), which is equivalent to 100 revolutions.

The tablets were weighed once again following the test.

The percentage friability was then calculated using the following formula:

$$\text{Friability (\%)} = [(IW - FW) / IW] \times 100$$

Where: Iw = Total initial weight of tablets

Fw = Total final weight of tablets after the test

3. Weight variation test[6,7]

Tablets, which are on average 80 mg or less, should not vary from tablet to tablet by more than 10%. This test is conducted to ensure that tablets contain the correct dosage of medicine and to see if there is a difference in weight between the tablets. The die diameter and the tablet machine's weight adjustment cam were used to modify the tablets' weight during production. An analytical balance was used to weigh each of the twenty tablets for the test. The weight of each tablet was then compared to the average weight of the tablets. The % weight variation was computed as the difference between the individual weight and the

weight. The following formula was used: Weight Variation (%) = (IW − AW)/AW × 100

Where: IW = Individual weight of tablet

AW = Average weight of tablets

Table 1: Limits for weight variation test as per IP, BP, USP[8]

Average mass (mg)		Percent Deviation (%)
IP/BP	**USP**	
80 mg or less	130mg or less	±10 %
More than 80mg or less than 250mg	130mg to 324 mg	±7.5%
250 mg or More	More than 324 mg or More	± 5%

4. Disintegration Test:[8]

The USP disintegration equipment is made up of six glass tubes about 3 inches long and open at the top. Each tube is connected to a basket rack assembly and has a bottom over which a 10-mesh screen is positioned. For the disintegration test, each tube was filled with one tablet. The basket rack was then immersed in a suitable medium maintained at 37 ± 2 °C. In the test, the tablets were moving in the liquid. During the upward movement, the tablets remained about 2.5 cm below the surface of the liquid, and during the downward movement, they did not approach closer than 2.5 cm to the bottom of the beaker.

The basket assembly was moved up and down (28-32 cycles/min) by a motor-driven device through a distance of 5-6 cm. Abrasive action was produced by placing perforated plastic disks over the tablets to keep floating tablets from coming to the surface. The test was normally run for 15 minutes on uncoated tablets unless otherwise stated.

The test is passed if a tablet disintegrates completely and all of the particles pass through the 10-mesh screen within the specified time. If any residue remains, it should be a mushy mass with no hard core. The USP says all six tablets must dissolve completely. If one or two of the tablets fail, the test is repeated with 12 more tablets. If at least sixteen of the eighteen tablets dissolve completely, the tablets pass the test.

5. Dissolution test[9,10]

Dissolution testing was performed using the U.S.P. Type II (paddle) dissolving equipment. The dissolution medium was phosphate buffer pH 5.8. 900 mL of the buffer was maintained at 37 ± 0.2 °C. The paddle was rotated at 50 rpm and the tablet was placed at the bottom of the dissolution tank. Samples were taken in 1 mL using pipette at a fixed interval of 5, 10, 20, 30, 45 and 60 minutes. The same volume of fresh phosphate buffer (pH 5.8) was added after each withdrawal at the same temperature to maintain sink conditions.

The obtained samples were diluted to 10 mL with fresh dissolution media and filtered to remove any undissolved particles. The absorbance of the filtered samples was measured on a UV-Visible spectrophotometer at a wavelength (λ max) of 243 nm. From this the proportion of medication release was calculated. The process was continued for another one hour to study the dissolving profile of the paracetamol tablets.

6. Assay of Paracetamol Tablets [11,12,13]

A) Preparation of 0.1 N Sodium Hydroxide Solution

Weigh out 0.4 g of sodium hydroxide (NaOH) precisely, then dissolve it in distilled water. To create a 0.1 N NaOH solution, the volume was increased to 100 mL.

B) Preparation of Standard Solution

Ten milligrams of properly weighed pure paracetamol were added to a 100-millilitre volumetric flask. Dissolve the drug

in 0.1 N NaOH and add 100 mL to make the stock solution. To prepare a series of standard solutions, transfer 1, 2, 3, 4, and 5 mL of this stock into separate 10 mL volumetric flasks and dilute with 0.1 N NaOH to the appropriate level. This led to concentrations of 10, 20, 30, 40, and 50 µg/mL. Each solution's absorbance was measured at 257 nm using 0.1 N NaOH as a blank. The regression equation (Y = mx + c) was discovered after a calibration curve of absorbance vs. concentration was plotted.

C) Preparation of Sample Solution

Ten tablets were ground into a fine powder. A weighted quantity of powder equivalent to 10 mg of paracetamol was added to a 100 mL volumetric flask. Once dissolved in 0.1 N NaOH, dilute to the proper amount. After pipetting out 2 mL of this solution, dilute it to 10 mL with 0.1 N NaOH. The absorbance was measured at 257 nm. The concentration of the sample was determined using the calibration curve or regression equation (Y = mx + c).

RESULT AND DISCUSSIONS

1. Weight variation test

The weight of both the branded and the generic tablets was much the same (Table 1). It stayed within the Indian Pharmacopoeia's allowed range of plus or minus five per cent for tablets that're larger than 250 milligrams. The weight of the tablets was the same across all the samples. The branded tablets had a little variation in weight. This means the company that made the branded tablets did a better job of making sure the tablets were all the same. The generic and branded tablets were very similar in consistency. The difference between the two was very small. Both the branded and generic tablets are of high quality, and people can depend on them.

2. Hardness Test

The branded and generic tablets are strong enough and their hardness is just right it is between 4-8 kg/cm^2. (Table 2) The branded tablets are a little harder than the tablets, which means they can handle stress a little better. Both the branded and generic tablets are quality and do not break easily but the difference, between them is not really important.

3. Friability Test

Both the branded and generic brands had friability scores below 1 percent (Table 3). This shows they are strong and do not wear out easily. The branded version was a bit better, than the one. It had a smaller weight loss, which means it is more durable. However, both versions were stable and of quality. They also met the standards.

4. Disintegration Test

The Indian Pharmacopoeia says that tablets should break down in fifteen minutes or less (Table 5). Both the branded tablets and the generic tablets break down a lot faster than that. The branded tablets break down a bit faster, than the tablets. This means that the branded tablets fall apart quickly in the liquid they are put in. Both the branded tablets and the generic tablets work just as well and are good quality. They meet all the requirements.

Table 2: Comparative Evaluation of Weight Variation of Generic & Branded Tablet

Sample	Avg Weight (mg)	Max Deviation (%)	IP Limit	Result
S1 – Generic	633 mg	1.50%	±5%	Pass
S2 – Branded	642 mg	1.09%	±5%	Pass
S3 – Generic	633 mg	0.95%	±5%	Pass
S4 – Branded	642 mg	0.93%	±5%	Pass

Table 3: Comparative Evaluation of Hardness Study of Generic & Branded Tablet

Sample	Trial 1 (kg/cm²)	Trial 2	Trial 3	Avg Hardness (kg/cm²)	Result
S1 – Generic	5.8	6.0	5.9	5.9	Pass
S2 –Branded	6.2	6.4	6.3	6.3	Pass
S3 – Generic	5.7	5.9	5.8	5.8	Pass
S4 –Branded	6.1	6.3	6.2	6.2	Pass

Table 4: Comparative Evaluation of Friability Analysis of Generic & Branded Tablet

Sample	Initial Weight (g)	Final Weight (g)	% Loss	Limit (<1%)	Result
S1 – Generic	6.500	6.460	0.62%	<1%	Pass
S2 –Branded	6.520	6.490	0.46%	<1%	Pass
S3 – Generic	6.480	6.440	0.62%	<1%	Pass
S4 –Branded	6.510	6.480	0.46%	<1%	Pass

Table 5: Comparative Evaluation of Disintegration Time of Generic & Branded Tablet

Sample	Trial 1	Trial 2	Trial 3	Avg Time	IP Limit	Result
S1-Generic	6.5 mins	6.8 mins	6.6 mins	6.63 mins	≤15 min	Pass
S2-Branded	5.2 mins	5.5 mins	5.3 mins	5.33 mins	≤15 min	Pass
S3-Generic	6.4 mins	6.7 mins	6.5 mins	6.53 mins	≤15 min	Pass
S4-Branded	5.1 mins	5.4 mins	5.2 mins	5.23 mins	≤15 min	Pass

5. Dissolution Test

The test results for both branded drugs showed that over 80 per cent of the drug was released in thirty minutes.

Table 6: Comparative Evaluation of Dissolution Profile of Generic & Branded Tablet

Time (min)	% Drug Release			
	S1	**S2**	**S3**	**S4**
5	28%	35%	30%	36%
10	48%	55%	50%	56%
15	65%	72%	67%	73%
30	85%	92%	87%	93%
45	93%	98%	94%	97%

This met the standards set by the Indian Pharmacopoeia. The branded drug released a bit more of the drug at the start. The generic drug released it at a similar rate overall. Both drugs had release patterns and good quality. This means they should work as well as each other. Both generic and branded drugs showed dissolution behaviour. They both had quality.

6. Assay (% Purity)

The test results for both the generic and the branded medicines are within the allowed limits of 95 to 105 per cent as specified by the Indian Pharmacopoeia. The branded medicine had a higher purity percentage compared to the generic medicine, which means it had a slightly better accuracy in terms of content. The generic medicine and the branded medicine both met the standards set by the pharmacopoeia. Had similar drug content and quality. The Indian Pharmacopoeia sets these standards for the medicine and the branded medicine to follow.

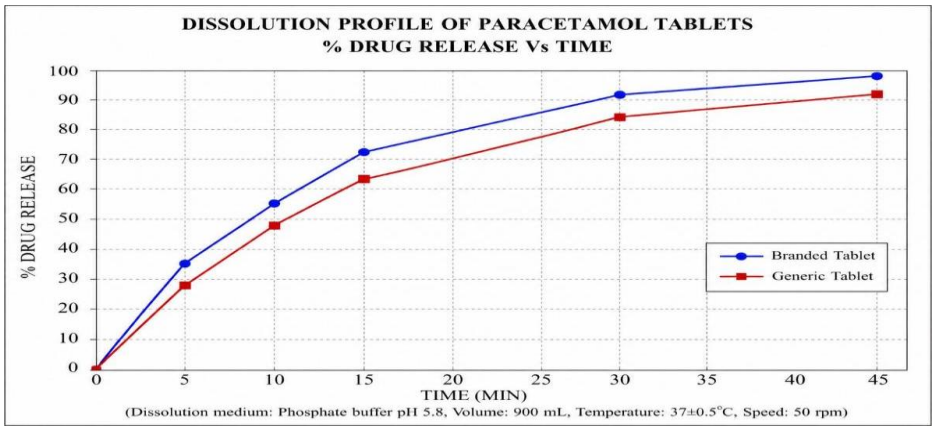

Figure 1: Comparative Dissolution Profile of Generic & Branded Tablet

Table 7: Comparative Assay Analysis of Generic & Branded Tablet

Sample	Absorbance	Calculated % Purity	IP Limit (95–105%)	Result
S1 – Generic	0.485	97.0%	95–105%	Pass
S2 – Branded	0.495	99.0%	95–105%	Pass
S3 – Generic	0.490	98.0%	95–105%	Pass
S4 – Branded	0.500	100.0%	95–105%	Pass

CONCLUSION

The comparative quality control evaluation of Paracip-500 mg (generic) and Crocin Advance 500 mg (branded) tablets demonstrated that both formulations comply with the official standards of the Indian Pharmacopoeia. All tested parameters including weight variation, hardness, friability, disintegration, dissolution and assay were found within acceptable limits. Although the branded formulation showed slightly better performance in terms of hardness, friability, disintegration time, dissolution rate and assay values, the differences were minimal and not significant. The generic formulation exhibited comparable quality, uniformity and drug release characteristics. Overall, the study confirms that both generic and branded paracetamol

tablets are pharmaceutically equivalent, safe, effective and meet required quality standards, supporting the use of generic products as cost-effective alternatives to branded medicines.

Source of Support: The author(s) received no financial support for the research, authorship, and/or publication of this article.

Conflict of Interest: The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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