

# A Research Article on Concept of Comparative Study of Different Marketed Preparation

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## ABSTRACT:

The purpose of this study is to use the drug assay, weight variation test, friability test, and disintegration and dissolving test to conduct in-vitro quality control testing on Paracetamol tablets. Two brands of Paracetamol pills, Brand A and Brand B, were utilized in the experiment. Both Brand A and Brand B of Paracetamol tablets satisfy USP criteria, per the results of quality control (QC) tests. In terms of weight variation, Brands A and B deviate from the mean weight restriction by 2.79% and 2.05%, respectively. The lower mean weight limit variations are 1.21% and 1.27%, respectively, within the 10% USP standard limits. Friability tests revealed that Brands A and B were within the USP's 1% mass loss limits, with average friability of 0.062% and 0.01% mass loss, respectively. Both Brands A and B are within the 85%–115% USP range in terms of drug assay. Based on the disintegration test, Brands A and B had disintegration times of 6.69 and 7.02 minutes, respectively, and fall within a 15-minute time interval segment. The medicine dissolution percentage for Brand B of Paracetamol was 90.7% throughout the course of a 45-minute test.

Brands A and B meet the pharmacopoeia limits set by the USP standards. Both Brands A and B's mass loss, as determined by the friability test, was within the permissible limit of 1%. In comparison, the weight variance of both brands is within the usual range of 10% above or below the mean weight. The drug assay indicated that both brands' medicine availability was within the specified 85%–115% standard range. In less than forty-five and fifteen minutes, respectively, they finished the dissolution and disintegration tests.

## INTRODUCTION:

is one of the most often used non-steroidal anti-inflammatory drugs (NSAIDs). Paracetamol analgesic, antipyretic, and anti-inflammatory qualities are well established. has been effectively used to treat rheumatoid arthritis, gout, spondylitis, and ortho arthritis. Paracetamol has also been used by surgical patients. Paracetamol inhibits an enzyme called prostaglandin synthetize. Paracetamol main adverse effects include nausea, vomiting, light headedness, and pain or disturbance in the gastrointestinal tract. The oral bioavailability and excretion half-life of Paracetamol are around 60% and 1.1-1.8 hours, respectively. With a pKa of 4.0, Paracetamol dissolves more easily in intestinal fluid than in the acidic fluid of the stomach.

Tablets are the most commonly used dose type because of their outstanding patient compliance. Two of the three main tablet manufacturing processes that are most commonly used in the pharmaceutical industry are wet granulation and direct compression. Based on the type of API and the excipient's characteristics, an appropriate tablet production technique has been selected. Because of its various advantages, including as improved granule cohesiveness and compressibility, uniform drug and color distribution, and improved flow characteristics, wet granulation is used extensively in tablet manufacturing.

- **Quality Control Test**

1. Weight Variation Test – Ensures uniformity in tablet Weight.
2. Hardness Test – Measures tablet strength (kg/cm<sup>2</sup>).
3. Friability Test – Checks resistance to breaking/crumbling.

4. Disintegration Test – Determines the time required for Tablet breakdown.
5. Dissolution Test – Assesses drug release rate in a given Medium.
6. Assay (Potency Test) – Measures the active Pharmaceutical ingredient (API) content.
7. Uniformity of Content – Ensures each tablet contains the Correct drug amount.

• **Weight Variation Test**

The weight of ten different brands of Paracetamol tablets was determined with the help of an electronic balance and the observed results have been included in the table below (Mean values ± SD, n=3)

Table No.	Brand A	Brand B
1	-1.01	-1.27
2	-0.16	0.55
3	1.13	2.05
4	0.85	2.01
5	-0.1	-0.86
6	-0.24	-1.24
7	-0.06	-0.45
8	0.91	0.88
9	2.79	-0.63
10	0.85	-1.8
11	0.09	-0.78
12	-0.25	0.72
13	-0.26	-0.14
14	-1.1	0.41
15	-0.61	0.15
16	0.12	0.5
17	-1.21	0.6
18	-0.62	0.63
19	0.05	0.23
20	0.52	-0.93

- Weigh 20 tablets individually and calculate the average weight.
- Compare individual tablet weights to the average.

**Formula:**

$$\%Deviation = \frac{\text{Average Weight} - \text{Individual Weight}}{\text{Average Weight}} \times 100$$

• **Hardness Test**

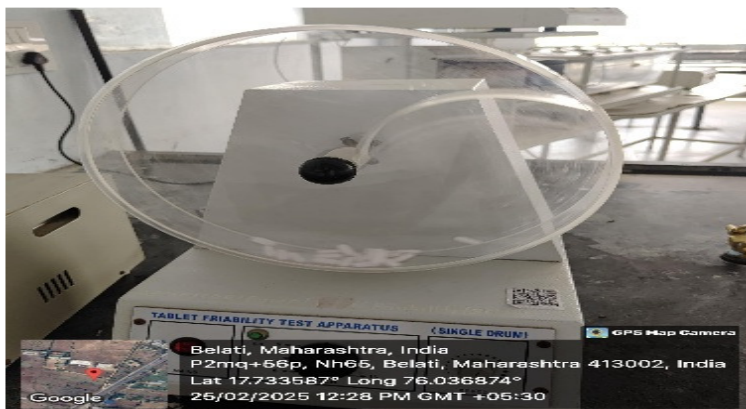
Ten tablets of each brand were chosen at random for the hardness test, and the tablets’ crushing strength was assessed. The standard deviation was calculated together with the tablet’s average hardness.



Brands	Hardness Values (kg/cm <sup>2</sup> ) [Sample]
Brand A	5.2, 5.5, 5.4, 5.3, 5.6, 5.5...
Brand B	6.1, 6.3, 6.2, 6.0, 6.4, 6.2...

Measure the force required to break a tablet using a Monsanto or Pfizer hardness tester.

• **Friability Test**



- Weigh 10 tablets (W1) and place them in a friabilator (100) revolutions at 25 rpm for 4 min).
- Remove dust and weigh again (W2).

**Formula:**

$$\% \text{ Friability} = \frac{W1 - W2}{W1} \times 100$$

• **Disintegration Test**

- From each brand, six tablets were chosen at random and put in the disintegration device, which is filled with 900 millilitre (disintegration medium) of distilled water (disintegration medium) kept at 37±1°C. The average amount of time required to break down the tablet and get through the mesh was determined by timing how long it took.



- Place 6 tablets in disintegration apparatus with water at 37 ± 2°C.
- Observe the time taken for complete disintegration.

- **Expected Outcomes**
- **Quality Assessment:** Identify which marketed tablet formulation meets pharmacopeial standards.
- **Efficacy Comparison:** Evaluate drug release and potency among different brands.
- **Uniformity & Consistency:** Determine variations in weight, hardness, friability, and content uniformity.
- **Regulatory Compliance:** Ensure all tested formulations meet IP/USP/BP specifications.
- **Best Formulation Selection:** Recommend the most suitable brand based on QC test performance.
- **Patient Safety & Effectiveness:** Confirm that the selected formulation provides consistent therapeutic benefits.
- **Results**

Table 1. Percentage weight variation for Brand A and Brand B.

Tablet No	Brand A % Wt. variation	Brand B % Wt. variation
Highest	2.79	2.05
Lowest	1.21	1.27

Table 2. Mean of Hardness test for Brand A and Brand B.

Brand	Hardness Values (kg/cm <sup>2</sup> ) [Sample]	Mean ± SD
Brand A	5.2, 5.5, 5.4, 5.3, 5.6, 5.5...	5.4 ± 0.2
Brand B	6.1, 6.3, 6.2, 6.0, 6.4, 6.2...	6.2 ± 0.2

Table 3. Friability and disintegration time of both brands.

Brand Tablet	% Friability	Disintegration Time (Min)
A	0.06	6.69
B	0.01	7.02

## CONCLUSION:

The Paracetamol tablet brands A and B are both found to be within the pharmacopoeia limit. Friability, weight fluctuation, dissolve rate, disintegration time, and drug assay were the tests conducted on the two brands. According to the findings of QC testing on Paracetamol tablets, these tests are required to ascertain a dosage form's safety, effectiveness, and bioavailability. In order to verify medications in accordance with pharmacopoeia standards and preserve drug safety and efficacy for the human body, a thorough variety of analyses aids in both qualitative and quantitative drug evaluation. These tests must be conducted periodically.

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