A Reaserch Article on Concept of Comparative Study of Different Marketed Preparation

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Abstract- *This study's goal is to perform in-vitro quality control testing on diclofenac sodium tablets using the disintegration and dissolving test, drug assay, weight variation test, and friability test. In the trial, two brands of diclofenac sodium tablets—Brand A and Brand B—were used. According to the findings of quality control (QC) tests, both Brand A and Brand B of diclofenac sodium tablets meet USP requirements. Regarding weight variation, Brands A and B have variances of 2.79% and 2.05% above the mean weight limit, respectively. Within the 10% USP standard limits, the lower mean weight limit variances are 1.21% and 1.27%, respectively.According to friability testing, Brands A and B had average friability of 0.062% and 0.01% mass loss, respectively, falling within the USP's 1% mass loss restrictions. Regarding medication assay, Brands A and B both fall within the 85%–115% USP range, respectively. According to the disintegration test, Brands A and B fall inside a 15-minute time interval segment; their respective disintegration times are 6.69 and 7.02 minutes. Within a 45-minute test period, the medication dissolution percentage for Brand B of Diclofenac Sodium was 90.7%.*

The pharmacopoeia limits established by the USP standards are met by brands A and B. According to the friability test, both Brands A and B's mass loss fell within the acceptable range of 1%. Comparably, both brands fall within the typical range of 10% above or below the mean weight in terms of weight variation. The medication availability for both brands fell within the designated 85%–115% standard range, according to the drug assay. They completed the dissolution and disintegration tests in less than 45 and 15 minutes, respectively.

I. INTRODUCTION

One of the most widely used non-steroidal anti-inflammatory medications (NSAIDs) is diclofenac sodium. Diclofenac sodium is widely known for its analgesic, antipyretic, and anti-inflammatory properties. Gout, spondylitis, orthoarthritis, and rheumatoid arthritis have all been successfully treated with diclofenac sodium. Patients who have had surgery have also utilized diclofenac sodium. Prostaglandin synthetize is the enzyme that diclofenac sodium inhibits. Among the primary side effects of diclofenac sodium include nausea, vomiting, dizziness, and gastrointestinal disruption or pain. Diclofenac sodium's oral bioavailability and excretion half-life are around 60% and 1.1-1.8 hours, respectively. Diclofenac sodium's pKa value is 4.0, and it dissolves more readily in intestinal fluid than in the stomach's acidic fluid.

Due to their exceptional patient compliance, tablets are the most often utilized dose type. Wet granulation and direct compression are two of the three primary tablet manufacturing techniques that are most frequently employed in the pharmaceutical sector. A suitable tablet production method has been chosen based on the kind of API and the nature of the excipient. Wet granulation plays a significant role in tablet manufacture due to its many benefits, which include better granule cohesiveness and compressibility, consistent medication and color distribution, and enhanced flow properties.

Quality Control Test

1. Weight Variation Test – Ensures uniformity in tablet Weight.
2. Hardness Test – Measures tablet strength (kg/cm²).
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 diclofenac sodium 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
1o	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= $\frac{\text{Average Weight – Individual Weight}}{\text{Average Weight}}$ ×100

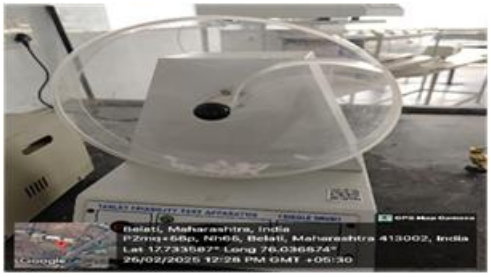
Hardness Test

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/cm²) [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:

%Friability= $\frac{\text{W1 - W2}}{\text{W1}}$ ×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^2) [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. Friabilityand disintegration time of both brands.

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

II. CONCLUSION

The diclofenac sodium 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 diclofenac sodium 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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