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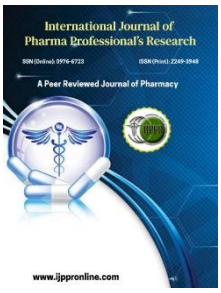

Market Comparative Study of Paracetamol (PCM) & Diclofenac

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Keywords:
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ABSTRACT:

Now a day in the market 2 types of dosage forms is available in the market one Generic dosage form and other branded dosages which there is there is a difference in the price of the tables or dosages as well as the quality of the product. The quality of the product is verified from the standards present in the IP (Indian Pharmacopeia). In the test of the 2 products are taken both branded and Generic Paracetamol drugs & Diclofenac Drug. The validation process which has been performed in the process is weight variation, size, hardness, friability, and disintegration time. The results of the tests conducted on both generic and branded forms of Paracetamol and Diclofenac can be observed that there are some differences in terms of weight variation, size, hardness, friability, and disintegration time. As the branded formulation is following maximum validation but the generic dosage form follows the minimum parameter.

Introduction:

As the treatment of the desises human being the depends on the medication. Now days in the market there are 2 type of the dosages forms are available for the treatment which are generic and braded dosage form. As it follows

Generic Drug- Instead of the innovator drug, which has a brand name under which the chemical composition of the drug is sold, generic drugs refer to the chemical composition of a drug. In terms of dose, potency, administration method, quality, and mechanism of action, it is typically identical to a patented medicine and performs the same task for which it was designed. When referring to household goods, the term "generic" denotes that the item is less expensive, may be less effective, and a knockoff of a name-brand product

Branded Drug- It is a unique product that a pharmaceutical business has created. For a while, it had exclusive manufacturing and distribution rights (patent). A brand-name medication is a tiny dose that a pharmaceutical company develops, produces, and markets. When a novel drug is discovered, the firm applies for a patent to prevent others from producing and selling copies of the

drug. To make the medicine stand out in the market, it currently has two names: a generic nameand a brand name.

Similarity between generic and branded drug [1-3]

- Need to have the same active components.
- Their performance and qualityare comparable.
- It must be administered in the same route each time.
- Generic medications are just as secure as name branded drugs.
- The bioavailability is the same.

Difference between generic and branded medicine [4]

- It must have several inactive components.
- Cheaper than branded medications are generic versions.
- Because generic and branded medications differ in shape, size, colour, and branding, they seem differently.
- While generic drugs lack a patent on their manufacturing and distribution, branded drugs have exclusive rights (patents) to both for a set length of time.

Thinking of people about generic drug [5]

- If it's secure or not.
- Why generic medications are more affordable low generic prices could indicate lowerthan-expected quality?
- Why do they appear different?
- Do generic drugs work as well as branded ones?

Paracetamol Drug the OTC analgesic drug paracetamol is frequently used to treat the symptoms of mild to moderate pain. Additionally, it has good antipyretic qualities and is used to lower body temperature in feverish individuals. There are both name-brand and generic paracetamol (500 mg) tablets available.[6-7]

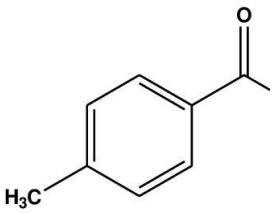

Fig 1 Structure of PCM

Diclofenac Drug

Diclofenac sodium was developed with the intention of producing a nonsteroidal anti-inflammatory drug with exceptional tolerability and high activity. Drug transport through biologic membranes, the atomic and spatial structure of the molecule, and the electronic structure were all taken into consideration.

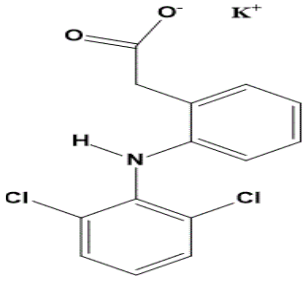

Figure 2 Structure of Diclofenac

Material & Methodology

Material

Study Area and period

The study was carried out from November to January 2023 at the Bareilly International University's BIU College of Pharmacy, which is located north of the Indian city of Bareilly.

Study Design

The in-vitro quality control parameter of the commercially available paracetamol and diclofenac tablet, both branded and generic, which are available in Bareilly city, was evaluated using the experimental in-vitro study design. In order to conduct the study, a number of quality-related test techniques, including weight variations, hardness and disintegration time, friability, dissolving profile, were used.

Instruments

Instruments used were: Analytical balance (model: ALE-223 Bioway medical lab equipment co., Ltd, China), tablet hardness tester (VMT;

Item code 180513784 Blow N Glow Scientific is manufacturing of laboratory equipment Pune, Maharasthra INDIA), Disintegration tester (Model B.J-3, Shangai famo Machinery manufacture),dissolution test apparatus (RC-6, India) Friabilitytest apparatus (model KI-92-01 Kumar sale corporation Mumbai INDIA).

Sample collection

Two widely used paracetamol and diclofenac, both branded and generic, were gathered from independent pharmacies in Bareilly, India. Each dose of paracetamol was 500 mg and diclofenac were 50mg tablets for the analysis, about 10 paracetamol and diclofenac tablets from each brand and generic were gathered. Information on each branded and generic product, including the name of the producer, the date the product was manufactured, and its expiration date.

Table 1: Generic tablets used in the study

Sr. No	Generic Name	Batch No.	Mfg Date	Expiry Date	Labelled Strength	Manufacturer
1.	Paracetamol	SPT-00073	09/2021	08/2023	500mg	Savya Pharmaceuticals
2.	Diclofenac	PNPB-110	07/2022	06/2024	50mg	Pfinext Life Science

Table 2: Branded tablets used in the study

Sr. No	Brand Name	Batch No.	Mfg Date	Expiry Date	Labelled Strength	Manufacturer
1.	Paracetamol	DOASO251	07/2022	06/2026	500mg	Micro Labs Ltd.
2.	Diclofenac	PC0132	03/2022	02/2025	50mg	Win Medicare Pvt

Methods

According to the Indian Pharmacopoeia, all evaluation tests were completed.

Physical Examination of Paracetamol

Five tablets were taken off the sheet and closely inspected with the naked eye to determine their physical characteristics (appearance, colour, break line, any cracked edges, or any deformations) for every kind of paracetamol, the procedure was repeated.[8-11]

Physical Examination of Diclofenac

Five tablets were taken off the sheet and closely inspected with the naked eye to determine their physical characteristics (appearance, colour, break line, any cracked edges, or any deformations) for every kind of diclofenac, the procedure was repeated.[12]

Weight Variation Test

Each tablet from each brand was independently weighed with a digital analytical balance. Use 5 tablets to calculate the average weight. Calculate the individual tablet's percentage departure from the mean weight. The calculation of deviations followed IP norms.[13-15]

Thickness and Diameter

Variations in tablet thickness and diameter may cause problems with counting and packaging, in addition to weight fluctuation that exceeds permitted limits. Tablet thickness and diameter should be kept to 5% of a specified value. The diameter and thickness of the tablet were determined using Vernier callipers.[16-18]

Hardness Test

The ability of the tablet to endure applied pressure is referred to as hardness. The Monsanto Hardness Tester's fixed and moving jaws were used to hold the test tablet. By sliding the screw knob forward, the force being exerted to the tablet's edge was gradually increased until the tablet broke. The scale's readout, which shows the amount of force needed to break the tablet, was taken down. The weight of the material used, the

distance between the upper and lower punches at the time of compression, and the pressure utilised during compression all affect how hard a tablet is. The type and quantity of materials employed during formulation also affect the hardness. If the final tablet is too hard, it might not break down in the necessary amount of time, and if it's too soft, it might not hold up to handling during packing and transportation. [19-20]

Friability Test

The ability of the tablets to survive abrasion during packing, handling, and transportation can be assessed using a friability test. The friabilator has a plastic chamber that rotates at a speed of 25 rpm. Weighted tablets are added to the tumbling chamber, where they are rotated for four minutes at a speed of 100 revolutions. The tablets experience shock when they drop from a distance of six inches throughout each revolution. The pills are once again weighed after 100 spins. The weight decrease reveals the friability. Maximum weight loss of 0.8% t should be considered appropriate.[21-22]

Disintegration Test

The disintegration apparatus, which is filled with 900 mL of distilled water (the disintegration medium) and kept at 37°C, was loaded with six tablets at random from each brand and placed inside. The time it took for the tablet to break up and go through the mesh was timed, and the average time was computed.[23]

Dissolution Test

A solid solute enters a solution through a process known as dissolution. Pharmaceutically speaking, dissolution is the rate at which a drug ingredient transfers mass into the dissolution medium or solvent under controlled conditions involving the liquid/solid interface, temperature, and solvent composition. It is a changing dynamic property that describes how a homogeneous mixture of a solid or liquid can be created in a solvent. The crystal's breakdown into individual ions, atoms, or molecules and their transit into the solvent causes it to happen chemically. Dissolution is increasingly evolving into a technique for predicting bioavailability and, in some cases, replacing clinical investigations to determine bioequivalence. It is one of the most significant quality control tests done on pharmaceutical dosage forms.[24]

Market Cost Evaluation

In terms of cost, generic tablets are typically less expensive than branded tablets. This is because the manufacturers of generic drugs do not have the same development and marketing costs as the manufacturers of brand-name drugs. In terms of efficacy and safety, generic and branded tablets are considered to be equivalent. Both are required to meet the same standards for quality, purity, and potencyset byregulatory agencies such as the FDA.

A generic tablet is a medication that is equivalent to a brand-name product in dose, strength, route of administration, quality, and intended use, but does not carry the brand name. A branded tablet is a medication that is marketed under a specific brand name by a pharmaceutical company.

Table 3 Market Cost Evaluation

Sr no.	Generic Product	Price /tab (MRP)	Branded Product	Price/tab (MRP)
1	Tablet Biofla m-500mg (Paracet amol 500 mg 1 strip)	10.00	Tablet Dolo-500mg (Paracetamol 500mg 1 strip)	16.96
2	Tablet DICLOJIN PLUS (Diclofenac sodium 50mg 1 strip)	28.20	Tablet Diclomol (Diclofenac sodium 50mg1 strip)	85.00

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RESULT AND DISCUSSION

Weight variation test

- Collective weight calculates average weight per tablet.
- As weight of individual tablet is more than 250 mg so consider 5% variation.
- Calculate 5% variation from average value.

Table 4: weight variation for paracetamol tablet (Generic)

Sr no.	Individual weight (gm)	Mean weight (gm)	Weight variation in (%)
1	0.62	0.64	3.125
2	0.65	0.64	1.53
3	0.63	0.64	1.56
4	0.64	0.64	0
5	0.65	0.64	-1.53

Mean % Weight Variation: 0.325%

Table 5: weight variation for paracetamol tablet (Branded)

Sr no.	Individual weight (gm.)	Mean weight (gm.)	Weight variation in (%)
1	0.59	0.59	0
2	0.61	0.59	3.38
3	0.60	0.59	0.004
4	0.58	0.59	1.69
5	0.59	0.59	0

Mean % Weight Variation: 0.343%

Table 6: Weight variation for diclofenac tablet (Generic)

Sr no.	Individual weight (gm)	Mean weight (gm)	Weight variation in (%)
1	0.69	0.7	1.42
2	0.71	0.7	1.4
3	0.68	0.7	2.85
4	0.71	0.7	-1.4
5	0.71	0.7	-1.4

Mean % Weight Variation: 0.014%

Table 7: weight variation for diclofenac tablet (Branded)

Sr no.	Individual weight (gm)	Mean weight (gm)	Weight variation in (%)
1	0.59	0.6	1.67
2	0.61	0.6	1.67
3	0.60	0.6	0
4	0.59	0.6	1.67
5	0.59	0.6	1.67

Mean % Weight Variation: 0.668%

Friability test

- Operate the friabilator for 100 revolutions.
- Once again remove drum and dedust tablets.
- Check tablets for capping, lamination and chipping.

Sr. no.	Drug Type	Weight of measured tablet before friability	Weight of measured tablets after friability	% Friability
1	Paracetamol (generic)	3.21	3.16	1.557
2	Paracetamol (branded)	2.96	2.94	0.67
3	Diclofenac (generic)	3.48	3.45	0.86
4	Diclofenac (branded)	2.39	2.37	0.836

Table 7: Friability for all tablets

Observation Table

Table 8: Observation Table

Sr.no	Test name	Paracetamol		Diclofenac	
		Generic	Branded	Generic	Branded
1	Weight variation (%)	0.325%	-0.343%	0.014%	0.668%
2	Thickness (mm)	3.95	4.0	3.82	3.90
3	Diameter (mm)	15.04	15.6	12.85	12.90
4	Hardness (kg/cm^2)	4.5kg	9kg	6.4 kg	8.9kg
5	Friability (%)	1.557	0.67	0.86	0.836
6	tion time(min)	3.30 (sec)	4.30(sec)	2.34(sec)	4.24 (sec)

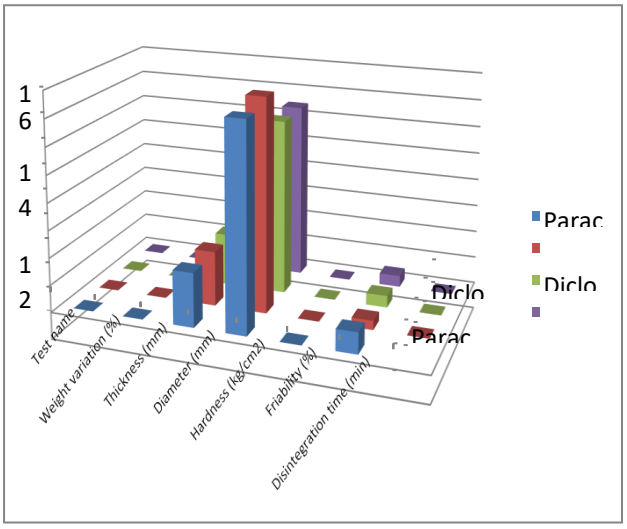

Fig 3: Observation value through graphically

DISCUSSION

Paracetamol and Diclofenac, in both their generic and branded forms. The tests conducted are weight variation, thickness, diameter, hardness, friability, and disintegration time.

Weight variation (%) is a test that determines whether the weight of the tablet is consistent with the amount of active ingredient it contains. The results show that the generic Paracetamol has a weight variation of 0.325%, while the branded version has a weight variation of 0.343%, meaning it has slightly less weight than it should. Similarly, the generic Diclofenac has a weight variation of 0.014%, while the branded version has a weight variation of 0.668%, indicating that it has more weight than it should.

Thickness (mm) and Diameter (mm) are tests that determine the size of the tablets. The results show that the branded version of Paracetamol is slightly larger in diameter (15.6 mm) than its generic version (15.04 mm). The

thickness of the two versions is almost the same, with the branded version being slightly thicker. On the other hand, the branded Diclofenac tablet is thinner (3.82 mm) and smaller in diameter (12.90 mm) than its generic counterpart.

Hardness (kg/cm2) is a test that measures the tablet's ability to withstand pressure without breaking or crumbling. The results indicate that the branded version of both medications is harder than the generic version.

Friability (%) is a test that determines the ability of the tablet to withstand mechanical shock during transportation and handling. The results show that both generic and branded versions of Diclofenac have lower friability than Paracetamol. Disintegration time (min) is a test that determines how longit takes for the tablet to break down into smaller particles in the stomach. The results show that the generic version of Diclofenac has a faster disintegration time (2.34 seconds) than its branded counterpart (4.24 seconds). On the other hand, the branded version of Paracetamol has a faster disintegration time (4.30 seconds) than the generic version (3.30)

CONCLUSION

Based on the results of the tests conducted on both generic and branded forms of Paracetamol and Diclofenac, it can be observed that there are some differences in terms of weight variation, size, hardness, friability, and disintegration time. The weight variation test showed that the branded Paracetamol has slightly less weight than it should, while the branded Diclofenac has more weight than it should. The branded version of both medications is harder than the generic version. In terms of size, the branded Paracetamol is slightly larger in diameter than its generic version, while the branded Diclofenac is thinner and smaller in diameter than its generic counterpart. Both generic and branded versions of Diclofenac have lower friability than Paracetamol. The disintegration time test showed that the generic version of Diclofenac has a faster disintegration time than its branded counterpart, while the branded version of Paracetamol has a faster disintegration time than the generic version. Overall, these test results provide valuable information to consumers and healthcare professionals when making decisions about which form of medication to use.

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