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COMPARATIVE STUDY OF SOME GENERIC AND BRANDED FORMULATION

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Abstract: Both Aceclofenac and Paracetamol are non-steroidal anti-inflammatory drugs. The primary goal is to evaluate four distinct brands of Aceclofenac and Paracetamol tablets that are sold in Indian public pharmacies. Although generic medications share the same active components, variations in formulation methods and excipients have been shown to affect their quality and effectiveness. According to research, cyclooxygenase (COX) is inhibited by Aceclofenac and Paracetamol, which results in a decrease in pain perception or the transmission of neuropathic pain. A few testing techniques (drug assay, disintegration, weight variation, and friability tests) are employed for quality control.

Index Terms **- Aceclofenac, Paracetamol, tablet, Dissolution, Disintegration, Branded, and Generic.**

I. INTRODUCTION

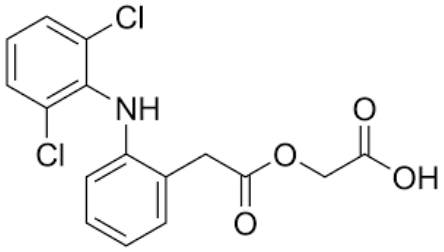
The most safest and convenient of drug delivery system is oral drug delivery system and it is also most preferred administration route. Therefore, it is essential to assess each drug's flawless quality maintenance for human health. Tablet is the most popular dossge form in comparison with the other dosage forms. The majority of medicine compounds may be prepared as tablets, and the technique of making them is fairly straightforward and adaptable [1]. The molecular weight of Aceclofenac is 354.99 and the molecular formula is C16H13Cl2NO4.2, 1, 2, 2- [2-[2-(2, 6 dichlorophenyl) amono phenyl) Oxyacetic acid] is a very potent anti-inflammatory medication. Aceclofenac functions by obstructing the body's production of cyclooxygenase. The synthesis of several chemicals in the body, including prostaglandins, is aided by cyclooxygenase [5]. Paracetamol (molecular weight: 151.16; formula: C8H9NO2) 1, 2, N (4- hydroxyl phenyl) acetamide is a popular analgesic medication that works wonders for treating fever and pain in both adults and children. Non-steroidal anti-inflammatory cytokine inhibitors, which are Aceclofenac and Paracetamol, are mostly used for treatment of various disease condition like inflammation and pain in the condition like rheumatoid arthritis also osteoarthritis. The medication acts by preventing the enzyme cyclooxygenase (COX) from producing prostaglandins (PG), which are responsible for fever, edema, and pain [21]. Based on permeability and solubility, drug substances are divided into four groups by the BCS (Biopharmaceutical Classification System) system. In BCS class III drug, such as paracetamol, which is high soluble and has low permeability, and BCS class II medications, such as aceclofenac, which is poor soluble and high permeable.

Generic drug/medicine -

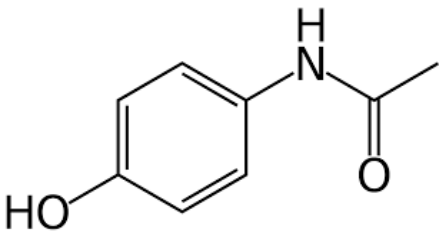
The FDA states that a drug product's strength of dosage form, route or site of administration, performance and quality and features are all comparable to those of a branded product. It is a copy of a branded medication whose exclusive right to manufacture and market medicine has expired due to a patent [4].

Branded drug -

The pharmaceutical company is the one who developed the original product. For a limited time, it has the exclusive right to manufacture and distribute also called patent. A branded drug is a tiny medication which a pharmaceutical company has discovered, developed, and is selling. When the new medication is discovered, that company will applies for the approving patent to prevent another businesses from duplicating and dispose of the medication. To differentiate itself in the market, the medication currently goes by two names: a brand name and a generic name. Pharmaceutical companies are the ones who initially discover and develop brand-name medications. The FDA approves brand-name medications through the submission of a New Drug Application that includes information about the chemistry of product, efficacy and safety of dosage form, manufacturing of drug, dosage form of drug, packaging and labelling of the product packaging characteristics that must be proven. Only with FDA approval can the creative company use this brand name for exclusive marketing medication during the 20-year or specified patent protection period. Brand-name medications are typically sold for a premium to offset the costs associated with drug development and research [4].



1. Aceclofenac



2. Paracetamol

1.1 Mechanism of Action –

Aceclofenac and Paracetamol work as analgesics by inhibiting COX-2, which lowers the number of inflammatory prostaglandins that are produced from arachidonic acid. The inhibition of cyclooxygenase (COX1 and COX2), and the synthesis of prostaglandin are the three mechanisms that underpin the mode of action. According to studies, cyclooxygenase (COX) is inhibited by Aceclofenac and Paracetamol. It may inhibits N-methyl-D-aspartate and substrate P receptor. It results in the transduction of neuropathic pain or diminished pain perception. Because Aceclofenac and Paracetamol inhibit the cyclooxygenase1, cyclooxygenase2 and prostaglandin, they are linked to anti-inflammatory and analgesic effects.

1.2 Quality Control Testing –

The process of ensuring whether or not a product or service meets the required level of quality is known as quality control. It may consist of tasks required for the monitoring and validation of specific attributes of a good or service. Quality in the context of pharmaceuticals refers to assessing and managing the level of excellence or grade of processes and products. The amount of medication in the formulation that is labeled and the body's ability to absorb it are two crucial elements that determine how effective a tablet formulation is. To ensure that the finished product is of the appropriate standard. Testing for quality control (QC) guarantees the efficacy, safety, and effectiveness of drugs. It uses specialized equipment to guarantee that drug tests are conducted by established standards. The quality control test like weight variation, friability test, diameter and thickness test, hardness, dissolution test, disintegration and potency of drug like assay.

1.3 Characteristics of Aceclofenac and Paracetamol -

1. Both drugs belong from NSAID class.
2. At the room temperature, both two drugs are solid in state.
3. It has the appearance like white crystals.
4. Both medication have been recommended to treat ocular inflammation, arthritis, inflammation of the cornea and discomfort.
5. The both drug have 1-2 hours of biological half – life.

1.4 Side Effects of Aceclofenac and Paracetamol -

1. Very rare anaemia
2. Rare hypersensitivity
3. Very rare insomnia
4. Common headache

5. Very rare visual disturbance
6. Nausea, vomiting, diarrhea, Rashes

1.5 Instruments and reagents to be used -

For performing the comparative study of some generic and branded formulation review it have used various instrument and reagents are used. In that Tablet Hardness tester, Electro lab, Friabilator , USP dissolution apparatus , USP disintegration apparatus, Digital PH meter, Whatman filter paper (10 mesh), UV-visible spectrophotometer, Analytical precision balance instruments are used and Aceclofenac, Paracetamol, Phosphate buffer and distilled water are used as a reagent.

II. LITERATURE REVIEW

The title of equivalent literature review for the study was given to be (i) Comparative in vitro dissolution study of Aceclofenac Marketed Tablets in Two Different Dissolution Media by Validated Analytical Method (ii) A comparative study on the dissolution profiles and Equivalent assessment of some the generics of Aceclofenac tablets available in Lagos Nigeria (iii) Comparative in vitro equivalence evaluation of some Aceclofenac generic tablets marketed in Bangladesh (iv) Comparative study on quality analysis on marketed diclofenac sodium tablets of different brands available in Bangladesh (v) A Comparative Evaluation of Cost and In-vitro Study between Branded and Generic Medicine (vi) Comparative Study of Generic and Branded Products (vii) Comparative in- vitro study of generic versus brand paracetamol products.

III. MATERIALS AND METHODS

3.1 Dosage Form/Sample Collection –

The dosage strength of Aceclofenac and Paracetamol contain 100 mg and 325 mg respectively was purchased in local pharmacy store.

The production license number, a batch number, production date or manufacturing date, and date of expiration of the sample was carefully examined. The branded drugs are Zerodol p is used as a standard or reference and the generic drugs used to study are Glenpar AC, Acnac p, and Fico p as a test. They was randomly assigned as A, B, C, and D as a code and it get stored properly [8].

Table 1 - The formulation used for this study

Code	Brand Name	Mfg. Date	Expiry Date	Batch No.	Labelled strength	Manufacture
A	Zerodol P	06/2023	05/2025	FRW153043AS	Aceclofenac (100 mg) with Paracetamol (325 mg)	Ipca laboratories
B	Glenpar AC	03/2023	02/2023	TGP230459	Aceclofenac (100 mg) with Paracetamol (325 mg)	Glenmark pharmaceutical
C	Acnac-p	12/2022	11/2024	WHT15721	Aceclofenac (100 mg) with Paracetamol (325 mg)	Noel pharma Pvt Ltd
D	Fico P	02/2023	01/2025	EMT2302022	Aceclofenac (100 mg) with Paracetamol (325 mg)	Emcure Pharmaceutical

3.2 Determination of diameter and thickness –

To find the average thickness and diameter, each of twenty tablet was used once at a time from four different brands, and determine their diameter and thickness by using the electronic digital caliper [8].

3.3 Weight variation test –

During the production of any product, a weight variation test was conducted to determine the effectiveness of the dosage unit. The product active component or ingredient was impacted by any fluctuation in weight. According to IP, a reduction of 10% was made for tablet containing 80 mg or less, 7.5% difference for tablet containing 80-250 mg and 5% difference for tablet more than 80-250 mg. The tablet was expected to pass the specification test, when not exceed two tablets out of 20 tablet was outside the percentage limit [16].

3.4 Friability test –

Among the 10 tablets was chose from each sample formulation, first it get weight and then it was placed in friability chamber for 25 rpm for 4 min. after the complete the time interval it get again weight and check the difference of weight. Then it percentage friability was calculated by using the difference of weight. Similarly done the same procedure for other four brands using in this study. The standard limit of the percentage friability is less than 1%, if it get less than 1% then it will pass the quality control test.

3.5 Hardness test –

An automated hardness of the tablet tester was used for determining the crushed force (Pfizer). The force or pressure applied to the surface of the tablet can be progressively raised until it breaks by turning the screw knob upward direction. From each brand, ten tablets are chosen at random, then the force during which each of them is crushed was recorded [16].

3.6 Disintegration test –

Disintegration means the liquid impact on internal bonds of tablet which result is the internal bonds are break. First of all the insert the 900 ml suitable solvent in basket like distilled water or phosphate buffer then the tablet is pour into the basket and run out the machine and record the time that the braking down the internal bond of tablet. There is no any exact correlation between the term disintegration and dissolution. It was expected that there is minimum the disintegration time then the maximum the dissolution time, or in opposite. The disintegration time denote to determine the bioavailability of dosage form. As per the IP the limit the time required for the uncoated tablet uncoated tablet is 15 minute while coated tablet was 30 minute [16].

3.7 Dissolution test –

The dissolution term means the solute of solid, liquid or gaseous phase soluble in suitable solvent. Phosphate buffer was used as a solvent which maintaining the Phis 6.8. For using the apparatus maintain the temperature at 37±0.5 °C and at 50 RPM. In the experiment at 10 minute interval time withdrawn 1ml sample and add equivalent solvent with it and this sample was dilute with its 10 ml phosphate buffer and then check its absorbance at 266.4 nm which is isobestic point of Aceclofenac and Paracetamol. The sample was withdrawn at time interval is 0, 10, 20, 30, 40, 50, and 60 minute. Then determine the concentration of sample further calculated [8].

3.8 Assay –

The term assay is used to determine the potency of drug. The assay was calculated by an isobestic point method. Take 10 tablet, weight and crushed with fine powder. Take powder to equivalent weight and it is dissolved in 100 ml methanol and it placed for sonication. Then it was filtered the solution and take few ml solvent and dilute the solvent and check the absorbance at the 266.4 nm (at isobestic point) by using spectroscopy. By using UV spectroscopy the absorbance value checked at the maximum wavelength (λmax). The visible sample scan at the 400 to 200 nm, the maximum wavelength was found to be 274.5 nm for Aceclofenac and 244 nm for Paracetamol [8].

IV. RESULT AND DISCUSSION

To provide the most efficient possible quality control, pharmaceutical dosage forms must be tested in vitro regularly. Four different Aceclofenac and Paracetamol formulation are successfully evaluated by weight variation test, hardness test, thickness test, friability test, disintegration test, dissolution test, and assay for tablet [16].

4.1 Weight variation -

Weight variation test is successfully carried out by electronic digital weighing balance. All the tablets are in given specific limit by USP. Get 20 tablets and weigh individual and getting the mean of that tablet [2].

Table 2 – Weight variation test observation

Tablet code	Average weight
A	0.548±0.11
B	0.701±0.04
C	0.678±0.02
D	0.623±0.01

(Values are expressed as mean ± standard deviation, n=20)

4.2 Diameter and Thickness test -

Potential issues with tablet weight as well as the content can be identified early on by routinely measuring the diameter of the tablets.

The data is mentioned in table no 3, the brand B show that highest diameter that is 17.5 mm, and the brand A show lowest diameter is 16 mm. And in case of thickness the all brand have same average thickness is 5 mm [8].

4.3 Hardness test -

Hardness affects how things break down. The soft tablets are more difficult to handle when the coating, and if it is hard, it cannot dissolve within the allotted time. Thus, sufficient resistance to powdering, friability, and tablet hardness are prerequisites for high-quality products. The typical hardness of oral tablets ranges from 2 to 10 kg. Table 3 shows that of the four brands, brand A had the lowest hardness (2.3 kgF) and brand C had the highest hardness (7.1 kgF) [8].

4.4 Friability test -

The tablets' good mechanical strength is revealed by the friability testing. The specification for friability is not more than 1%. As shown in Table no 3, all the four brand (A, B, C, and D) has friability percentage result is less than 1%. Out of four brands the brand A show maximum percentage friability that is 0.79% and the brand C show the minimum percentage friability that is 0.52% [8].

4.5 Disintegration test –

Disintegration test is very important for the tablet dissolution. It play important role in dissolution of tablet. For the carried out disintegration test we use calibrated disintegration apparatus. Uncoated tablets are supposed to dissolve in 15 minutes as per the USP. Table 3 shows the time required for the disintegration test. All the brands used in this study are in given specific limit as per the USP. There are time 7.41 minute taken by the brand A as a maximum time to disintegration of tablet while brand D tablet took 1.92 minute for disintegration as a minimum time [8].

Tablet 3 – A review of quality control test performed on several brand

Tablet code	Diameter (mm) (n=10)	Thickness (mm) (n=10)	Hardness (Kg) (n=10)	Friability (%) (n=10)	Disintegration time (min) (n=6)
A	16±0.48	5±0.25	2.3±0.45	0.79±0.02	7.41±0.34
B	17.5±0.52	5±0.25	4.8±61	0.56±0.04	2.01±0.36
C	17±0.51	5±0.25	7.1±0.83	0.52±0.06	2.63±0.31
D	17±0.51	5±0.25	6.7±0.78	0.64±0.05	1.92±0.34

(All the values are expressed as mean ± standard deviation)

4.6 Calibration curve –

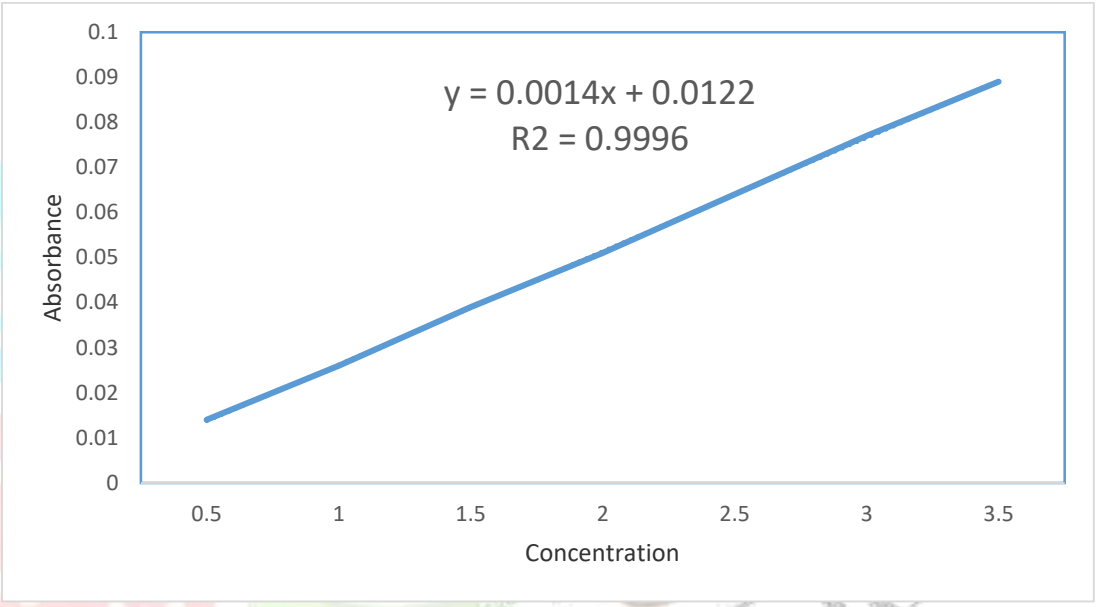


Fig 1 – Calibration curve for Aceclofenac drug

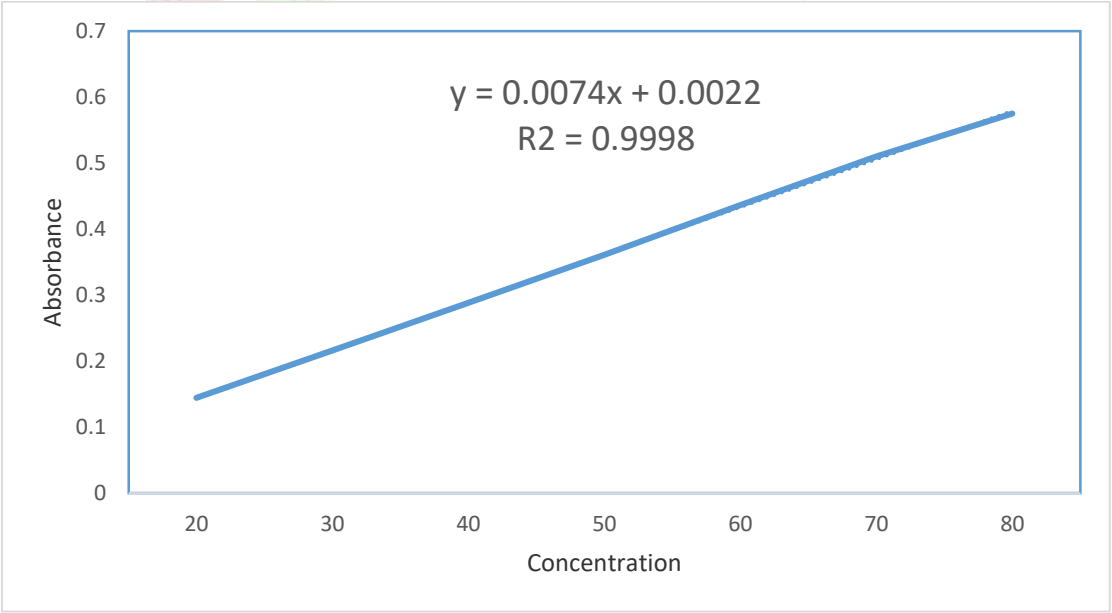


Fig 2 – Calibration Curve for Paracetamol drug

4.7 Dissolution test -

As an official test, Dissolution test is important test in the quality control. For dissolution test carried out the standard dissolution test apparatus is used. It is a process which the tablet particle is dissolved in the suitable solvent. The in vitro dissolution test is important for absorption in the GIT tract. From the data mentioned in table 4, it shows only branded drug is achieved above the 90% dissolution rate that is 92.68%. Brand A shows maximum dissolution rate as well as the brand B shows the minimum dissolution rate or drug release as a 77.58% in a 60 minute [8].

Table 4 – the percent drug release at time interval of 60 minute

Time interval in minutes	% release of Aceclofenac and Paracetamol tablet			
	A	B	C	D
0	0±0	0±0	0±0	0±0
10	31.78±0.24	27.60±0.36	30.63±1.05	28.66±0.59
20	43.55±1.04	40.70±1.56	40.50±0.28	36.45±2.64
30	54.43±1.16	52.39±1.42	49.58±1.38	49.44±1.23
40	67.41±2.44	59.44±2.48	63.43±1.68	57.50±1.13
50	79.44±2.48	68.60±2.98	78.36±2.08	69.66±2.62
60	92.68±3.24	77.58±1.83	85.58±2.66	79.39±.63

(All the values are expressed as mean ± standard deviation, n=6)

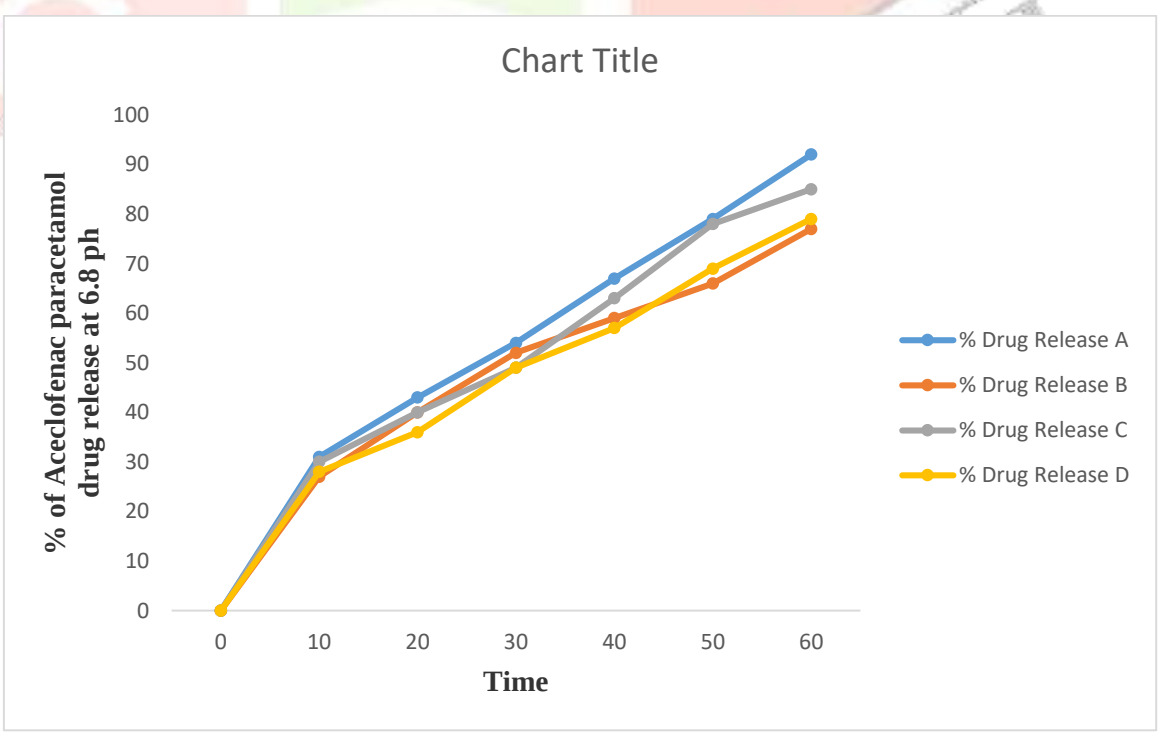


Fig 3 – Comparative study of dissolution of tablet

4.8 Assay -

The Assay determine the potency of drug that is how much drug concentration present in the tablet or formulation. The potency value was found to be between 90% - 110% which is within the USP limit. The data mentioned in table no 5, the concentration of all brand drug is obtained in given specific limit as per USP limit. The drug concentration was found to be in range of 100±10 %. Brand A shows the maximum drug concentration and brand B shows the minimum drug concentration.

Table 5 – The potency of drug release of Aceclofenac and Paracetamol

Tablet code	% of Aceclofenac & Paracetamol
A	99.23±1.50
B	91.68±4.99
C	95.42±4.30
D	94.69±5.88

(Values are expressed as mean ± standard deviation, n=10)

V. CONCLUSION

Pharmaceutical formulations. This study focuses on comparing the QC parameters of generic and branded formulations of aceclofenac and paracetamol combinations. QC tests typically include assessments of physical characteristics, chemical properties, and dissolution profiles. The comparative study of QC tests on generic and branded formulations of aceclofenac and paracetamol combinations revealed the following key points:

- Uniformity of Weight: Both types of formulations were within acceptable limits, with branded formulations showing slightly better consistency.
- Hardness and Friability: Branded formulations demonstrated marginally minimum hardness and lower friability, indicating better mechanical strength and handling properties.
- Disintegration: Both formulations disintegrated within acceptable time frames, ensuring appropriate bioavailability.
- Assay of Active Ingredients: Both formulations met the pharmacopeia standards for active ingredient content, ensuring potency and therapeutic efficacy. But branded formulation have higher potency by comparing with generic formulation.
- Dissolution Profiles: While branded formulations had slightly better dissolution profiles, generic formulations still met the required standards.

Overall, the study concludes that both generic and branded formulations of aceclofenac and paracetamol combinations are of acceptable quality, though branded formulations exhibit marginally better physical and dissolution characteristics.

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