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# Comparative Quality Assessment Studies of Marketed and Generic Ciprofloxacin Tablets

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**ABSTRACT:**
Objective: A wide range of bacterial infections can be treated with the broad-spectrum antibiotic ciprofloxacin. A fluroquinolone antibiotic of the second generation that treats a variety of bacterial infections is ciprofloxacin. The purpose of the study was to compare the formulation of 500 mg ciprofloxacin tablets between branded and generic brands. The current study set out to assess the quality control of tablets containing both branded and generic ciprofloxacin. There will be an interpretation and discussion of the study's findings and outcomes. Methods: 500 mg pills of both brand and generic Ciprofloxacin from retail pharmacies, and as advised by the manufacturers, were used unofficial criteria and in-vitro testing to evaluate the pharmaceutical quality of the tablets. A UV spectrophotometric method was used to evaluate the assay content, dissolution test, friability test, hardening test, disintegration time and uniformity of weight while evaluating the tablets. Result: Both official and informal quality control tests recommended for Ciprofloxacin pills were satisfactory, and both branded and generic tablets met IP guidelines. Conclusion: Based on their compliance with both official and unofficial quality control tests, the results showed that the overall quality of all tested ciprofloxacin tablets—both commercial and generic was satisfactory.

**KEYWORDS:** Ciprofloxacin, Branded drug, Generic drug, Fluoroquinolone antibiotics, quality assessment

## I. INTRODUCTION:

In the current day, antibiotics are the most widely used drugs and are used to treat microbial illnesses[3]. Ciprofloxacin is an antibiotic that belongs to the fluoroquinolone medication class. Since the late 1980s and early 1990s, ciprofloxacin has been the second-generation quinolone antibiotic with the broadest use[1,14]. Germany's Bayer made the discovery back in 1981. This medication was the first oral broad-spectrum antibiotic to be authorized by the Food and Drug Administration (FDA) for use in the United States in 1987. The World Health Organization (WHO) has included it on its list of essential medicines since it is one of the most crucial drugs required in the foundation of healthcare[2,8]. The most effective fluoroquinolone derivative, ciprofloxacin, has a wider spectrum of antibacterial action against both Gram-negative and Gram-positive aerobic and anaerobic pathogens. The cell wall of the bacterium has been blocked [1,3].

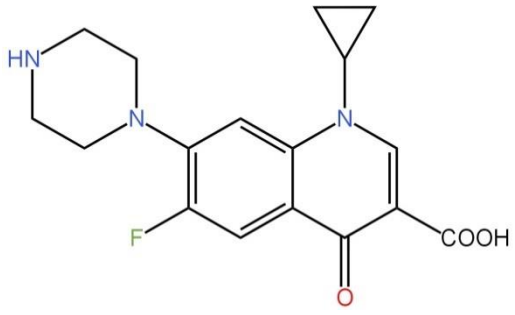


**FIGURE 1: CIPROFLOXACIN**

It is frequently used for the prevention of surgery as well as the treatment of gonorrhoea, skin and soft tissue infections, bone and joint infections

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lower respiratory tract infections, bacterial diarrhoea, and urinary tract infections. It would seem that ciprofloxacin is the medicine of choice that doctors most frequently recommend for the treatment of the aforementioned illnesses. It works primarily by preventing the bacterial cells' DNA-gyrase and topoisomerase IV from functioning, both of which are necessary for bacterial DNA replication. Pseudomonas aeruginosa is one of the bacteria that it works best against. The lung function of those who have cystic fibrosis and bronchiectasis significantly deteriorates because to P. aeruginosa. Its parenteral and oral dose versions are intended to treat respiratory tract infection flare-ups. Ciprofloxacin is used to treat a wide range of clinical conditions, including inflammatory bowel disease and infectious enteritis. It also induces nitric oxide production and suppresses the production of pro-inflammatory cytokines. Additionally, it has the ability to cause apoptosis in a number of human cancer cell lines, including colon cancer cells. Around healthy pH levels of 7.4, the zwitterions form of ciprofloxacin predominates, with a shift toward the cationic form around pH 6.5. The organic anion and organic cation transporters in the renal tubular cells are likely to interact with zwitterion. Ciprofloxacin dosages ranging from 200 mg (twice daily) to 400 mg (three times daily) have been utilized in critically sick patients without renal impairment, but a dosage modification is indicated in patients with substantially impaired renal function, i.e. a 50% dosage decrease has been proposed. Foods containing Ca2+ and Al3 (divalent and trivalent cations) as well as milk should not be administered at the same time as ciprofloxacin oral dosage. Food interactions with ciprofloxacin can impact how quickly and how much of it is absorbed, which primarily results in low therapeutic concentrations of the drug and ultimately therapeutic failure[4,13]. As a generic drug, it is affordable and readily available. Generic ciprofloxacin products are in greater demand and need of supply expansion for usage by those in developing nations which fall below the poverty line. Comparing generic medications to the innovator drug requires that they be chemically and bio pharmaceutically identical [5,8]. Since generic producers do not incur the expenditures associated with the creation of a new medicine, their goods are often far less expensive than their branded counterparts. Bioequivalence studies become crucial in order to help to attain therapeutic efficacy while also assisting in the substitution of branded with generic medications for affordability. When two drug products are given at the same molar dose under similar circumstances in an appropriately designed study, bioequivalence has been defined as the absence of a significant difference in the rate and extent to which the active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action (i.e., a significant difference in the bioavailability of two drug products) [6,7].

## II. MATERIAL AND METHODS:

### Materials

Analytical balance, volumetric flasks, spatula, pipettes, funnel, 1 cm quartz cells, mortar and pestle, beakers, vernier calliper, Monsanto Hardness Tester, Tablet disintegration test apparatus IP, Friability test apparatus, UV Spectrophotometer (PG instrument).

Branded ciprofloxacin tablets Ciprodac 500 were manufactured by Cadila Pharmaceuticals Limited and the generic ciprofloxacin tablets were manufactured by Goa Antibiotics and Pharmaceuticals Limited.

### Methods

### Weight Variation

In order to perform the weight variation test, 20 tablets are individually weighed, their average weight is determined, and then the weights of each tablet were compared to the average. If the acceptance value of the first 10 dose units is less than or equal to 15%, the dosage uniformity standards are satisfied. The subsequent 20 units and the acceptance value if it is higher than 15%. If none of the individual contents of any dosage unit is less than 15% or greater than 25%, and the final acceptance value of all 30 dosage units is less than or equal to 15%, the standards have been met.

If the tablets contain 25 mg or more of drug substance and that makes up 25% or more (by weight) of one tablet, the weight variation test would be a reliable means of assessing the uniformity of drug content in the tablets. if the weight of a tablet is roughly equivalent to the theoretical weight. Given that excipients account for the majority of the weight of tablets containing moderate or low dose medications, the weight variation test is obviously insufficient to ensure uniform potency[ 9,16,11].

### Hardness Test

For tablets to withstand the mechanical shocks of handling during production, packaging, and shipping, they need to have a specific amount

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of strength, or hardness, and resistance to friability. Oral tablets range in hardness from 4-10kg.

The Monsanto hardness tester, a reading of zero is obtained by bringing the bottom plunger into direct contact with the tablet. The tablet eventually breaks when a threaded bolt is turned, forcing the upper plunger up against a spring. A pointer moves along a gauge in the barrel as the spring is compressed to show the force. The zero force reading is subtracted from the force of fracture after it has been measured [10,16].

**Thickness and diameter**

A micrometer can be used to measure the crown thickness of certain tablets, allowing for precise measurements and providing details on how differently each tablet varies from the next. Other production control methods include stacking 5 or 10 tablets in a holding tray so that their total crown thickness may be assessed using a sliding calliper scale. However, if the punch and die tooling has been satisfactorily standardized and the tablet machine is operating properly, this method is adequate for production work [16,13].

**Friability Test**

The friability test is official in USP but not in BP and IP. The laboratory friability tester is known as the Roche friabilator. This device, subjects a number of tablets to the combined effects of abrasion and shock by utilizing a transparent synthetic polymer chamber with an internal diameter between 283 and 291 mm and a depth between 36 and 40 mm that revolves at 25 ±1 rpm. The tablets were tumbled from a distance of six inches at each turn of the drum by a curved projection. Normally, a pre-weighed tablet sample is placed in the friabilator (initial weight as w1), which is then operated for 100 revolutions. After testing, the tablets are dusted and reweighed (final weight as w2) [12,16].

The friability, f, is given by:

$$\text{Friability (\%)} = \frac{\text{initial weight (W1)} - \text{final weight (W2)}}{\text{initial weight (W1)}} \times 100$$

For the majority of tablets, a weight loss of not more than 1% is deemed acceptable.

**Disintegration Test**

Disintegration also known as breaking down the tablet into tiny pieces or granules is the first crucial step toward solution. A device that is specified in the USP/NF is used to gauge how long tablets take to break down. Film-coated tablets break down in half an hour.

For the disintegration test in water, 6 glass tubes that are 3 inches long, open at the top, and pressed up against a 10-mesh screen at the bottom end of the basket rack assembly make up the USP device used to test disintegration. One tablet is placed in each tube and the basket rack is placed in a 1L beaker of water, simulated gastric fluid. Six tablets from each generic and brand product were used at 37 ± 0.5 °C with a disintegration device. The duration of disintegration took to be the moment that no particle was left on the container [14,16].

**Dissolution**

The initial justification for utilizing tablet disintegration tests was that, when a tablet breaks down into smaller pieces, it provides a higher surface area to the dissolving media and must thus be connected to the drug's availability to the body. The test tolerance is given as a percentage of the medication dissolved within the allotted time as indicated on the label [15,16].

A dissolution apparatus IP/USP/BP was used for the dissolution investigations. The 900 ml of 0.1 N HCl, pH 1.2, was kept at 37 ± 0.5 °C served as the dissolving medium. Five millilitres of the dissolution samples were taken out of each dissolution experiment and replaced on a regular basis with an equal volume of new dissolution medium. A UV-VIS spectrophotometer was used to measure the amounts of released ciprofloxacin in collected dissolution samples relative to a blank. The highest wavelength measured was 325 nm [6,13].

**Content Uniformity (Assay)**

A content uniformity test was used to ensure uniform potency for tablets containing the sample in this test, and at least 10 of them are individually tested. Not less than 85% nor more than 115% of the medication content specified on the label must be present in nine of the ten pills. The tenth tablet's content cannot be less than 75% or greater than 125% of what is shown on the label [12,16].

Twenty tablets of each generic and branded medicines were weighed and crushed. A 100 ml volumetric flask was filled with the powder that is equal to 100 mg of ciprofloxacin. Next, 0.1 N HCl was added to get the volume up to 100 ml. The powdered substance was dissolved by vigorous shaking. Using a UV-VIS spectrophotometer against a blank, absorbance values were determined

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at the maximum wavelength (λ max) of these concentrations following appropriate dilution. The maximum wavelength (λ max) of 325 nm was found by scanning all samples between 200 and 400 nm [6].

Ciprofloxacin, C17H18FN3O3, is present in tablets in amounts that are neither less than 90% not more than 110% of the specified amount [18].

## III. RESULTS AND DISCUSSION:

| | WEIGHT VARIATION | HARDNESS | THICKNESS | DIAMETER | FRIABILITY (%) | DISINTEGRATION | CONTENT UNIFORMITY |
|---|---|---|---|---|---|---|---|
| **BRANDED TABLET** | 0.668±0.45g | 4.5Kg/cm$^2$ | 0.5 cm | 0.8 cm | 0.014±0.001 | 15 min 30sec | 99.33±0.25 % |
| **GENERIC TABLET** | 0.645±0.35g | 4.2Kg/cm$^2$ | 0.4 cm | 0.9 cm | 0.28±0.003 | 12 min 55 sec | 97.33±0.46 % |

**TABLE 1: COMPARISON OF PARAMETERS OF BRANDED AND GENERIC CIPROFLOXACIN TABLETS**

| SAMPLING TIME(MIN) | % DRUG RELEASE FROM BRANDED CIPRODAC 500 TABLETS | % DRUG RELEASE FROM GENERIC CIPROFLOXACIN TABLETS |
|---|---|---|
| 10 MIN | 48.2 ± 0.913 | 42.68 ± 1.324 |
| 20 MIN | 52.9 ± 0.924 | 48.33 ± 0.935 |
| 30 MIN | 61.71 ± 1.256 | 59.21 ± 0.897 |
| 40 MIN | 75.85 ± 0.854 | 74.48 ± 0.973 |
| 50 MIN | 89.32 ± 1.058 | 86.54 ± 1.563 |
| 60 MIN | 97.12 ± 0.908 | 96.01 ± 0.926 |

**TABLE 2: DISSOLUTION TEST RESULTS**

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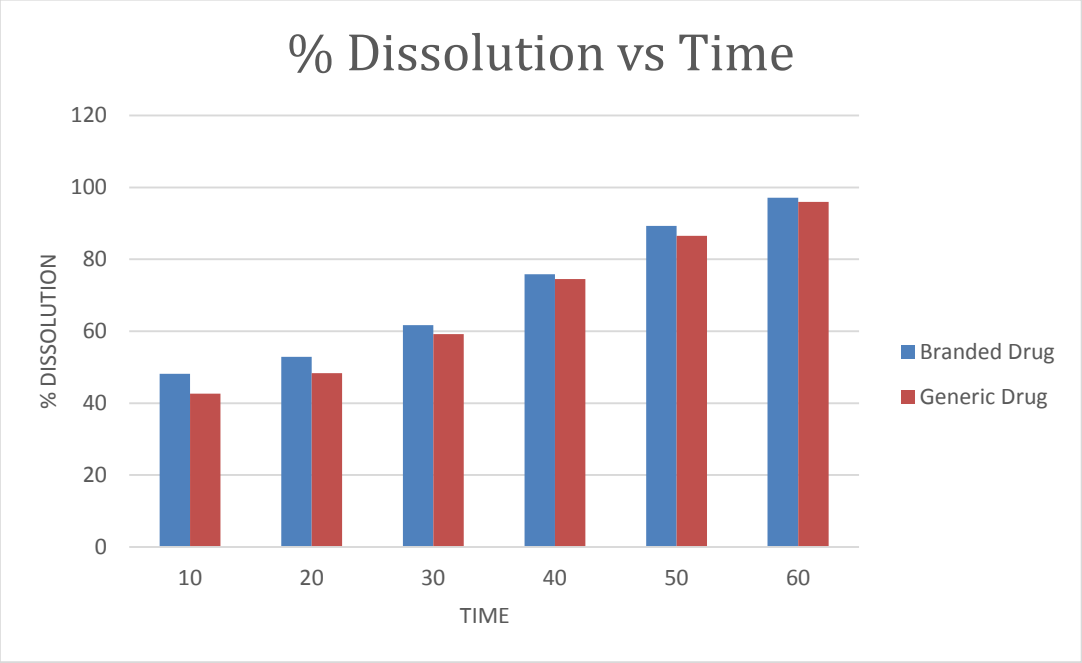


**FIGURE 2: % DISSOLUTION VS TIME**

Among these, the most common causes of poor quality are inadequate facilities and the use of inferior raw materials. As a result, it is essential to examine the quality. Pharmacopeial testing verifies these characteristics in accordance with predetermined criteria. Both the branded and generic of ciprofloxacin tablets was acquired from various retail pharmacy locations in Hyderabad, and it underwent tests for assay: branded(99.33±0.25%) > generic(97.33±0.46%), thickness: branded(0.5cm) > generic(0.4cm), Diameter: branded(0.8cm) < generic(0.9cm), weight variation: branded(0.668±0.45g) > generic(0.645±0.35g), friability: branded(0.014±0.001%) < generic(0.28±0.003%), hardness: branded(4.5kg/cm$^2$) > generic(4.2kg/cm$^2$), disintegration: branded(15 min 30sec) > generic(12 min 55 sec) and dissolution: branded > and generic as shown in figure 2.

## IV. CONCLUSION:

Examining the local supply of ciprofloxacin tablets both branded and generic, was the goal of the current study. This investigation showed that all ciprofloxacin tablets, whether they were branded or generic, satisfied the requirements of the Indian Pharmacopoeia's quality control measures. In order to satisfy the quality criteria for therapeutic efficacy, both generic and branded ciprofloxacin tablets are available on the market.

The goal of the study was to assess the market's available brand name and generic ciprofloxacin tablets for quality. According to the physicochemical analysis, every single ciprofloxacin tablet, both brand-name and generic, has undergone testing for uniformity of weight, thickness, and diameter, friability, hardness, disintegration, and Content Uniformity (assay). Tablet diameter, friability, hardness, disintegration time and dissolution did not directly correlate with each other or with tablet thickness. There was slightly difference observed between branded and generic ciprofloxacin tablets. The findings of this present study indicated slightest variations between branded and generic drugs with respect to in vitro drug release, which in turn may also bring impact to the in-vivo bioavailability parameters of the drug.

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