Research Article

# *In vitro* Comparative Study of Branded and Generic Market Pantoprazole Sodium Tablets

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**ABSTRACT**

Various doses are available in the market, including generic and branded formulations, with costs varying based on type and product quality. Quality assessment follows Indian Pharmacopeia (IP) criteria. Both generic and branded pantoprazole variants undergo bioequivalence studies, involving tests for weight variation, size, hardness, and friability, disintegration, and dissolution parameters. The study revealed that the branded formulation adheres to rigorous validation standards, while the generic dosage conforms to minimum criteria. In 0.1N HCl, none of the products exhibited disintegration, cracks, or swelling after one hour. However, all products disintegrated in phosphate buffer as per IP specifications. Most medications achieved 85% solubility within 60 minutes, meeting pharmacopeial requirements. Nevertheless, the dissolution rates of certain generic medications varied significantly at 60 and 120 minutes. In conclusion, both branded and generic pantoprazole sodium tablets met the in vitro quality control testing requirements outlined in the official monograph.

**Keywords:** Pantoprazole sodium, tablets, comparative dissolution, quality control testing, *in vitro*.

## INTRODUCTION

India is renowned as the "pharmacy of the world," with a flourishing pharmaceutical sector known for its significant innovations in providing affordable, life-saving medications. The country has become a leading global supplier of generic drugs, representing a cost-effective alternative to brand-name counterparts. Despite this, approximately 4.5% of domestically distributed generic pharmaceuticals in 2018 were identified as unsatisfactory by the Central Drug Standard Control Organization (CDSCO). This issue is attributed to the lack of consistent testing facilities nationwide. India faces challenges unique to its context, such as corruption facilitating drug licenses through political or bureaucratic connections, in contrast to the stringent quality control measures and regular quality checks in the United States. Compounding the problem, India's drug control efforts are hindered by insufficient funding, resources, and workforce, exacerbating the quality control situation. The Indian generic drugs market, valued at USD 24.53 billion in 2022, is expected to grow at a Compound Annual Growth Rate (CAGR) of 6.97%, reaching USD 130 billion by 2030. Despite the challenges posed by the COVID-19 pandemic, the generic pharmaceutical sector has maintained growth momentum, with generics constituting 70-80% of the retail market. The growing aging population in India has fuelled demand for affordable and effective generic medicines, positioning them as a viable alternative to branded drugs, as indicated by the economic survey of 2022-23. The global market for generic pharmaceuticals is projected to expand from an estimated USD 390.57 billion in 2020 to approximately USD 574.63 billion by 2030, with a CAGR of 5.59% between 2021 and 2030. The focus of the study involves comparing the dissolving characteristics of solid dosage forms between innovator (reference products) and generic counterparts (tested products).[1]

### Branded vs generic medicines

A branded medicine represents a distinct pharmaceutical product developed by a specific pharmaceutical company, holding exclusive rights for its manufacturing and distribution. On the other hand, generic medicine is a replicated version of the original branded product, introduced to the market after the expiration of patent protection or exclusive rights. Both branded and generic medicines adhere to international manufacturing standards, and they may be marketed under different brand names, incorporating varying fillers, binders, and lubricants. These differences contribute to unique characteristics such as color, shape, taste, and odor. A generic drug is a prescription pharmaceutical designed to be chemically identical to an established brand-name drug concerning dose form, safety, potency, mode of administration, quality, and performance characteristics. In 2008, the Indian government initiated the "Jan Aushadhi" project through the department of pharmaceuticals, promoting the exclusive sale of generic versions of medications in Jan Aushadhi pharmacies, emphasizing accessibility and affordability. Despite substantial increases in the government's health budget over the past 25 years, India continues to grapple with escalating medical costs. Despite the significant growth of the pharmaceutical industry, healthcare professionals in India face persistent challenges related to the pricing and accessibility of crucial medications. Despite governmental initiatives, ongoing discussions persist regarding the efficacy of generic medications.[2]

**Myths about generic drug**

There are several false beliefs and misunderstandings about generic medications. It is critical to dispel these misconceptions to advance truthful knowledge and comprehension. The following are some widespread misconceptions regarding generic medications:

- **Brand-name medications are more effective than generic medications:** This is a widespread misperception. The active components, dose form, potency, and mode of administration of generic medications are identical to those of brand-name medications. To be approved by the FDA, generic medications must exhibit bio equivalency, or a comparable rate and degree of bloodstream absorption compared to name-brand medications.[3]
- **Generic medications are of a lower caliber:** The same high requirements for quality must be met by generic and name-brand medications. Both brand-name and generic medications are subject to FDA regulation to guarantee their high quality, safety, and efficacy. The extensive testing required by generic drug producers establishes the product's equivalentity to the name-brand medication.
- **Drugs that are generic take longer to act:** The mechanism and pace of action of generic medications are identical to those of their name-brand equivalents. A generic medication has the same therapeutic effect as a name-brand medication once it enters the bloodstream.
- **Brand-name and generic medications have varied appearances:** Although a generic drug's color, shape, or size may differ from that of a brand-name drug, these modifications have no bearing on the safety or effectiveness of the medication. The FDA makes sure that the active components in generic medications are the same as those in brand-name medications.
- **Brand-name medications are safer than generic medications:** Before pharmaceuticals are approved by regulatory bodies, both generic and name-brand medications are subjected to extensive safety testing. The safety profile of generic medications is identical to that of brand-name medications.
- **Drugs bearing a brand name are subject to less stringent regulations than generics:** Both brand-name and generic medications are subject to FDA regulation to guarantee that the same requirements for quality, safety, and efficacy are met. To be approved, generic medications must meet the same stringent requirements as name-brand medications.
- **Doctors do not trust generic medications or recommend them:** Many medical experts, including doctors, frequently recommend generic medications. They are aware of the bioequivalency requirements and regulatory standards that guarantee the efficacy and security of generic drugs.

It is imperative that patients and healthcare professionals are aware of the stringent regulatory procedures that generic drugs go through to debunk these misconceptions and encourage the use of secure and reasonably priced substitutes for name-brand treatments.[4]

**PANTOPRAZOLE**

Pantoprazole is categorized as a proton pump inhibitor, exerting its pharmacological effect by inhibiting stomach acid production. This intervention proves beneficial for individuals diagnosed with gastroesophageal reflux disease (GERD) or ulcers, as it alleviates symptoms and reduces the risk of esophageal or gastric damage. Pantoprazole is also indicated for conditions like Zollinger-Ellison syndrome, characterized by excessive stomach acid production. The available form of pantoprazole is in the shape of enteric-coated tablets. Its mechanism of action involves the irreversible binding to proton pumps, leading to a sustained inhibition of gastric acid output. The active component in pantoprazole delayed-release tablets is sodium 5-(difluoromethoxy)-2-[(3,4-dimethoxy-2-pyridinyl) methyl] sulfinyl, which is a substituted benzimidazole.

The substance responsible for inhibiting gastric acid secretion in pantoprazole is -1H-benzimidazole sesquihydrate, with a molecular weight of 432.4 and an empirical formula of C16H14F2N3NaO4S x 1.5 H2O. It demonstrates high solubility in water, limited solubility in phosphate buffer at pH 7.4, and near insolubility in n-hexane. Furthermore, the stability of the compound in aqueous solution is contingent upon the pH level.[5-10]

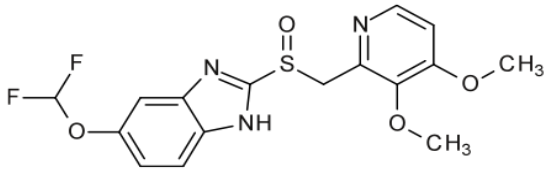


**Figure 1:** Structure of Pantoprazole

The present investigation compared the dissolving behavior of four tablets from different brands purchased from the national market under varied experimental settings. The formulations contain the same amount of active ingredient but differing excipients, such as diluents, disintegrants, lubricants, binders, and surfactants, in kind and/or quantity.

The release properties of the dosage forms may be affected by these formulation changes, which may have a significant impact on the drug's bioavailability and raise the issue of the products interchangeability.[11-13]

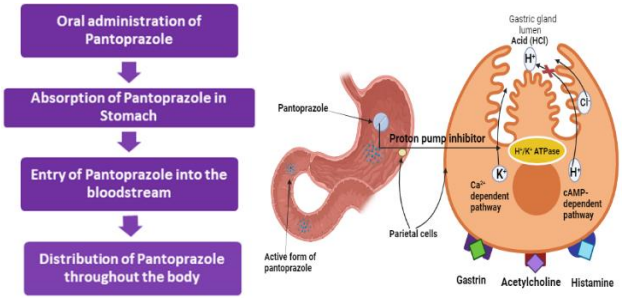


**Figure 2:** Mechanism of Action of Pantoprazole

## MATERIALS AND METHODS

### Product Procurement:

Four different samples of pantoprazole tablets were brought from local pharmacy and local health center.

**Table 1:** Different Samples of Pantoprazole Tablets

| Sample Code | Sample Name | Manufacturer Name and Address | Batch No. | Manufacturing Date | Expiry Date |
|---|---|---|---|---|---|
| **BRANDED DRUG** | | | | | |
| BD 1 | Pan 40 | Alkem Health Sciences, Mumbai. | 23441250 | 04/2023 | 09/2025 |
| BD 2 | Pantosec 40 | Cipla Ltd, Mumbai. | PNS230205 | 02/2023 | 01/2025 |
| **GENERIC DRUG** | | | | | |
| GD 1 | Pantoprazole 40 mg (Jan Aushadhi) | Pharmaceuticals & Medical Devices Bureau of India, Rajasthan. | TPB204 | 10/2022 | 09/2024 |
| GD 2 | Pantoprazole 40 mg (TamilNadu Govt. Supply) | Unicure India Ltd, Uttar Pradesh. | PPT1106Z | 06/2023 | 05/2025 |

## QUALITY CONTROL TESTS

### General Appearance

The tablets underwent a comprehensive evaluation of their overall appearance, wherein observations encompassed characteristics such as shape, color, diameter, thickness, and odor.[15, 16]

### Weight Variation Test

Each tablet from each brand was weighed separately with a digital analytical balance. Use 20 tablets to calculate the average weight. Calculate the individual tablet's percentage departure from the mean weight. The calculation of deviations should follow the IP norms.[17, 18]

**Table 2:** Percentage Deviation Allowed Under Weight Variation Test as per IP

| S. No. | Average Weight of Tablets | % Weight Variation Acceptable |
|---|---|---|
| **1** | Less than 85 mg | 10 |
| **2** | 85 to 250 mg | 7.5 |
| **3** | Greater than 250 mg | 5 |

### Tablet Thickness:

Tablet thickness is predominantly influenced by die filling and the physical properties of the material undergoing compression forces during tablet formation. Six tablets were utilized for thickness measurement using Digital Vernier Calipers. The desired thickness range was identified to be 2.0 - 4.0.[19]

### Hardness Test:

The tablet's resistance to applied pressure is defined as hardness. Six tablets were employed for the assessment. The Monsanto Hardness Tester, featuring fixed and moving jaws, secured the test tablet. Incremental force was applied to the tablet's edge by advancing the screw knob until fracture. The scale recorded the force required to break the tablet. Various factors such as material weight, distance between upper and lower punches during compression, and compression pressure contribute to tablet hardness. Formulation materials also impact hardness, and if the tablet is excessively hard, it may exhibit delayed disintegration or, if too soft, it may be susceptible to handling issues during packing and transportation.[20-22]

### Friability:

Friability is the percentage weight loss of a tablet within a container due to the removal of fine particles from its surface. Obtain a representative sample of 20 tablets, ensuring they are free from defects and damage. Weigh the tablets collectively and record the initial weight. Place the tablets into the friabilator drum, ensuring even distribution. Set the friabilator to the specified number of revolutions, commonly 100 or 200. Initiate the mechanical agitation, allowing the tablets to rotate within the drum. After completion of revolutions, carefully remove the tablets, gently de-dust, and clean to eliminate loose particles. Weigh the tablets again, recording the final weight. Calculate the percentage weight loss using the formula. Compare the obtained friability percentage with established acceptance criteria. Typically, a friability value of less than 1% is considered acceptable for most tablet. Record the results and ensure proper documentation of the friability.[23, 24]

% Friability = [(Initial weight – Final weight)/Initial weight] x 100

**Disintegration Test:**

Ensure the disintegration test apparatus is set up according to the relevant pharmacopeial standards (e.g., USP, IP). Place the disintegration test basket into the disintegration test apparatus. Prepare the appropriate disintegration test medium as per the specified conditions (e.g., 0.1N HCl, phosphate buffer pH-7.4). Maintain the test environment at the specified temperature (e.g., 37°C ± 2°C). Insert one tablet into each of the six tubes of the disintegration test basket. Place a disc on top of each tablet within the tubes. Immerse the basket in the dissolution medium, ensuring the tablets are fully immersed. Start the disintegration test apparatus, allowing it to run for the predetermined time. Visually observe each tube for disintegration, noting the time at which there is no palpable mass remaining. Record the disintegration time for each tablet in seconds or minutes. Conduct the test with additional tablets as needed. Analyze the disintegration results, comparing them against the specified pharmacopeial requirements or in-house standards. Document the test conditions, observations, and results, ensuring proper record-keeping for quality control purposes.[27]

**Drug Content:**

Triturate a known quantity of the pantoprazole tablet (generic or branded) in a mortar to obtain a fine powder. Transfer the powdered sample into a 100 ml volumetric flask. Add a small amount of 0.1N hydrochloric acid to aid in solubilization. Shake the flask well to ensure thorough mixing. Make up the volume to the 100 ml mark with 0.1N hydrochloric acid, ensuring complete dissolution of the drug. This solution represents the stock solution. Take 1 ml of the stock solution and dilute it to 100 ml with 0.1N hydrochloric acid in another volumetric flask. Measure the absorbance of the solutions at a specific wavelength, often around 234nm, using a UV-visible spectrophotometer. Use the obtained absorbance values to calculate the drug content using the Beer-Lambert law or a standard calibration curve. The drug content is expressed as a percentage of the labeled amount.[28]

**Dissolution Studies:**

The USP type 2 apparatus was utilized to evaluate the release rate of both branded and generic pills using the rotating basket method. Two hours were dedicated to the dissolution tests with the 900 cc of 0.1 N hydrochloric acid. Then, for the next two hours, 50 rpm and 37°C ± 0.5°C were used in conjunction with the 7.4 pH phosphate buffer. Forty milligrams of PMBI, government hospital tablets from Tamilnadu, and branded, commercially available generic tablets were all included in each basket. At prearranged intervals, samples (5 ml) were removed from the dissolution device and replaced with 5 ml of brand-new dissolution liquid. At 289 nm, the absorbance of these solutions was determined.[29]

## RESULTS AND DISCUSSION

**Physical Evaluation of Tablets**

**Table 3:** Physical Parameters of Pantoprazole Sodium Tablets

| S. No. | Physical Parameters | BD1 | GD1 | BD2 | GD2 |
|---|---|---|---|---|---|
| 1. | Weight Variation (%) *** | 0.72 ±3.20 | 2.50 ±0.92 | 1.45 ±1.59 | 1.75±1.32 |
| 2. | Thickness (mm) ** | 4.10±24.22 | 3.8 ±6.07 | 3.48 ±0.66 | 3.10 ±31.41 |
| 3. | Hardness (kg/cm$^2$) ** | 4.30 ±0.54 | 3.7 ±6.23 | 4.90 ±0.47 | 3.64 ±0.63 |
| 4. | Friability (%) *** | 0.38 ±6.07 | 0.41 ±5.62 | 0.30 ±7.69 | 0.48 ±4.80 |
| 5. | Drug Content (%) * | 101.23 ±0.02 | 95.21 ±0.02 | 92.5 ±0.25 | 98.36 ±0.02 |
| 6. | Disintegration Time in Gastric Fluid (0.1N HCL) * | No evidence for 1h | No evidence for 1h | No evidence for 1h | No evidence for 1h |
| 7. | Disintegration Time in Intestinal Fluid (pH 7.4 phosphate buffer) * | Completely disintegrate in 2 h | Completely disintegrate in 2 h | Completely disintegrate in 2 h | Completely disintegrate in 2 h |

*n=3; **n=6; ***n=20 whereas n represents number of tablets used for the test

**Dissolution profile of four branded tablets in Acid buffer (0.1 HCL)**

**Table 4:** Cumulative % Drug Release of Diclofenac Sodium in Acidic Buffer

| Time (mins) | BD1 | GD1 | BD2 | GD2 |
|---|---|---|---|---|
| **30** | 1.43% | 5.31% | 0.48% | 3.13% |
| **60** | 3.37% | 5.5% | 0.70% | 4.82% |
| **90** | 4.82% | 7.98% | 5.31% | 6.78% |
| **120** | 5.71% | 11.37% | 5.79% | 8.46% |

**Dissolution profile of four branded tablets in phosphate buffer (pH 7.4)**

**Table 5:** Cumulative % Drug Release of Diclofenac Sodium in Phosphate Buffer

| Time (mins) | BD1 | GD1 | BD2 | GD2 |
|---|---|---|---|---|
| 150 | 68.9% | 52.18% | 48.9% | 52.8% |
| 180 | 75.4% | 66.4% | 68.2% | 69.4% |
| 210 | 88.6% | 83.5% | 84.3% | 74.5% |
| 240 | 97.4% | 93.3% | 93.2% | 95.2% |

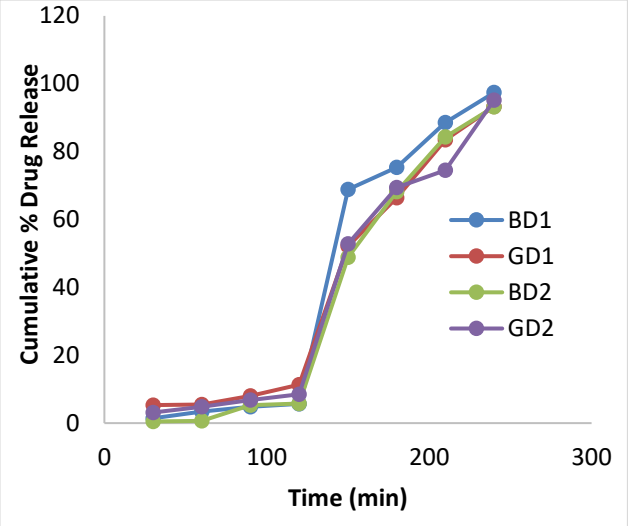


**Figure 3:** cumulative % drug release graph of pantoprazole sodium tablets

**Comparative Multi-point Dissolution Profile**

The comparative analysis of the area under the dissolution-time curves for three test samples and the innovator product was conducted through the application of similarity (f2) and difference (f1) factors. These factors are mathematically expressed as:

$$f_1 = \left\{\left[\sum_{t=1}^{n}|R_t - T_t|\right] \Big/ \left[\sum_{t=1}^{n} R_t\right]\right\} \times 100$$

$$f_2 = 50 \times log\left\{\left[1 + (1/n)\sum_{t=1}^{n}(R_t - T_t)^2\right]^{-0.5} \times 100\right\}$$

Where,

Rt - percentage drug dissolved at each time point for the innovator

Tt - percentage drug dissolved at each time point for the test products.

n - number of dissolution samples.

T - time events for collecting samples from dissolution medium.

f1 and f2 factors are calculated for 3 reference products sample GD1, BD2, GD2 against the innovator product sample BD1 by using the tech publish.com online software.

**Table 6:** Similarity and Difference Factor of Pantoprazole Sodium Tablets

| Formulation | Similarity Factor F2 | Difference Factor F1 |
|---|---|---|
| GD1 | 56 | 14 |
| BD2 | 55 | 12 |
| GD2 | 55 | 13 |

As per FDA specification the similarity factor F2 between the innovator product and reference product should be equal to or more than 50 and difference factor F1 should be equal to or less than 15.[30, 31]

## DISCUSSION

All the brands had a good strength, which is necessary for safe handling and shipment. BD1 had the highest hardness, whereas the other brands had equivalent hardness. The friability of all brands was less than 1%. Tablets that have restricted friability have less tendencies to form powder during handling and transportation. Pantoprazole levels in each tablet brand were within the IP 2022 guidelines. The weight variation test was passed by all tablet brands. According to I.P 2022, if the tablets are uniform in weight, they are likely to be uniform in drug content. As a result, IP 2022 only suggests a weight variation test on tablets when the drug forms more than half of the tablet. Because all the brands passed the weight variation test, it is assumed that all the tablets have the same medication content. All the tablet brands passed the IP disintegration test, suggesting that they will totally disintegrate in the intestine in 2 hours but not in the stomach. Pantoprazole tablets from all brands passed their disintegration test as recommended by IP 2022. Even though all brands passed the IP 2022, disintegrating test, there was difference in Pantoprazole dissolution rate from brand to brand. Sample 1 has high dissolution release percent of about 97.4%when compared to another samples. Despite the fact that the branded medication met all assessment criteria and exhibited the highest drug release, the other test samples demonstrated equivalence to the branded samples. All three test samples satisfied the Food and Drug Authority (FDA) specification for the f2 factor, which mandates a minimum of 50% for equivalence to the innovator sample. Additionally, concerning comparative in vivo multi-point dissolution, all test samples also fulfilled the criteria for the difference factor, F1, which should be less than 1 to establish equivalence to the reference products.

## CONCLUSION

All the brands have passed all the formal testing set by IP 2022. The formulation ingredients in the tablet, the physical form of the medicine employed in the tablet, and the manufacturing procedures differ from manufacturer to manufacturer, which is responsible for the observed disintegration profiles variation. Hence the similarity and difference factor of the test samples are under the limits of the of FDA guidelines. At the end of the conclusion, we can conclude that govt supply medicines and cost-efficient generic medicines is experimentally equivalent in terms of strength, purity, and other parameters in compared to high-cost branded medicines which is economically and pharmacologically effective.

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