# Comparative Study of Different Marketed Preparation

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***Abstract-*** *For the treatment of acid reflux disease (GERD), functional dyspepsia, and acid reflux disorders, doctors frequently prescribe the fixed-dose combination (FDC) of omeprazole, a proton pump inhibitor (PPI), and dopamine D2 receptor antagonist, domperidone, which has prokinetic and antiemetic effects. By enhancing stomach motility and decreasing gastric acid secretion at the same time, this combination has a synergistic therapeutic effect. However, due to differences in formulation design, enteric coating technologies, and manufacturing standards, different marketed formulations of this FDC may have different pharmaceutical quality and therapeutic consistency. These variations may have a major effect on the release of the drug, its bioavailability, and eventually its clinical effectiveness.*

***Objective****:The objective of this research is to perform a thorough comparison of various commercially available formulations of Omeprazole and Domperidone combination capsules in terms of their physicochemical characteristics, in vitro drug release behaviour, and pharmaceutical quality. Assessing the degree of uniformity among marketed brands and determining their possible interchangeability based on dissolving performance and pharmacopeial standard compliance are the objectives.*

## I. INTRODUCTION

The illness known as gastro-oesophageal reflux disease (GERD) arises when the reflux of stomach contents results in uncomfortable symptoms and/or consequences like acid reflux or heartburn. Less than 5% of people in Asia have it, but 10% to 20% of people in Europe and the US do. It significantly affects the quality of life of the patient. Due to the severity of the condition and the vast range of symptoms, a more customised therapeutic strategy is now required. GERD is difficult to diagnose; the most common method is endoscopy, which involves invasive testing and symptom evaluation. According to the American College of Gastroenterology Guidelines, 20135, and the World Gastroenterology Organisation Global Guidelines, proton pump inhibitors (PPIs) are the cornerstone of GERD treatment when compared to antacids, prokinetics, and H2 receptor blockers.

According to earlier research, patients receiving PPI alone did not experience any meaningful symptom relief. Because of their late start of effect and inability to affect the nonacid component, which also contributes to reflux, proton pump inhibitors, an on-demand medication, may be appropriate for the long-term treatment of patients with GERDS. H+/K+-adenosine triphosphatase in the proton pump of the stomach parietal cells is inhibited by omeprazole, a very potent inhibitor of gastric acid secretion. Prokinetics like dopamine suppress the effects of endogenous dopamine in the gut, causing prolactin to be released and gastrointestinal peristalsis to speed up. When omeprazole and domperidone were administered together, no pharmacokinetic interactions that were clinically significant were observed. PPI and prokinetic drug combination therapy is a logical, appealing, and successful treatment option for GERD patients. It has a history of widespread use and has been shown to provide additional therapeutic benefits for GERD patients. Prior clinical studies have indicated that combination treatment is more effective than PPI alone in terms of endoscopic and symptomatic responses.Additionally, it might raise the patient's standard of living. Comparing the safety and effectiveness of omeprazole monotherapy versus omeprazole-domperidone combination for GERD was the goal of this study.

**Methods:**

Different marketed brands of Omeprazole 20 mg and Domperidone 10 mg capsule formulations were selected randomly from different retail sources. Each product underwent a series of standard quality control tests, including physical inspection, capsule weight variation, drug content uniformity, disintegration testing, and in vitro dissolution studies. Given the different solubility and release profiles of the two active ingredients, drug release was studied separately for Domperidone (immediate release) and Omeprazole (delayed-release enteric-coated pellets) using USP Apparatus II (paddle method). Dissolution media included 0.1 N HCl for Domperidone and phosphate buffer (pH 6.8) following an acidic phase for Omeprazole. UV-Visible spectrophotometry was used for drug quantification at appropriate wavelengths. Comparative dissolution profiles were statistically evaluated using similarity (f2) and difference (f1) factors.

**Determination of weight variation**

- To ensure that each capsule contains a uniform quantity of the formulation.
- Weigh 20 intact capsules individually and record their weights.

Determine the deviation of each capsule from the average weight.

Percentage Deviation=Individual Weight−Average Weight×100
Average Weight
Average Weight: 518.75 mg

| Capsule No. | Individual Weight (mg) | Deviation from Average (%) |
|---|---|---|
| 1 | 520 | 0.24% |
| 2 | 515 | -0.72% |
| 3 | 522 | 0.63% |
| 4 | 518 | -0.14% |
| 5 | 519 | 0.05% |
| 6 | 521 | 0.43% |
| 7 | 516 | -0.53% |
| 8 | 517 | -0.34% |
| 9 | 514 | -0.92% |
| 10 | 523 | 0.82% |
| 11 | 518 | -0.14% |
| 12 | 520 | 0.24% |
| 13 | 519 | 0.05% |
| 14 | 521 | 0.43% |
| 15 | 522 | 0.63% |
| 16 | 517 | -0.34% |
| 17 | 516 | -0.53% |
| 18 | 518 | -0.14% |
| 19 | 519 | 0.05% |
| 20 | 520 | 0.24% |

Stability testing of capsule

The purpose of capsule stability testing is to ascertain the physicochemical stability of the drug substance in the final drug product under the recommended storage conditions and the specified package, as well as the intrinsic stability of the active drug molecule and the impact of environmental factors (such as light, humidity, and temperature) on formulation components, the container, and the closure system. The battery of long-term stability, accelerated stability, and stress-testing test expected shelf life of the product.

Disintegration test


Test of Disintegration Six three-inch-long glass tubes that are open at the top and supported by a 10-mesh screen at the basket rack assembly's bottom make up the USP disintegration equipment. In order to measure the disintegration time, one capsule is put in each tube, and the basket rack is set up in a particular medium at 37±2ºC so that the capsule stays 2.5 cm below the liquid's surface as it rises and descends no closer than 2.5 cm from the beaker's bottom. The basket assembly holding the capsules is moved up and down at a frequency of 28 to 32 cycles per minute using a typical motor-driven device over a distance of 5 to 6 cm.The exam may also make use of perforated plastic discs. When placed on top of capsules, these give the capsules an abrasive effect. The discs are helpful for floating capsules, but they could not have any significance or increase test sensitivity. Run the machine for the allotted amount of time. In the event that the capsule passes the test,dissolve, and within the allotted time, every particle passes through the 10-mesh screen. There must be a mushy mass with no discernible firm centre if there is any residue left.

**Results**

Regulations governing pharmaceutical firms are constantly evolving in order to guarantee the quality of drugs. In the pharmaceutical sector, tests conducted both during and after manufacturing of pharmaceuticals in accordance with the standards of the various pharmacopoeias and the regulatory requirements of the unique nations determine the highest quality of pharmaceuticals. Although different pharmacopoeias recommend different kinds of IPQC and FPQC tests for pharmaceutical capsules with varying specifications and standards, the primary purpose of all pharmacopoeias is to ensure the highest quality of

pharmaceuticals for human health, as the current study makes evident.

Table 1. Percentage weight variation for Brand A and Brand B.

| Brand A % Wt. variation | Brand B % Wt. variation |
|---|---|
| 2.79 | 2.05 |

Table 2. Disintegration of Brand and Brand B.
Buffer Disintegration (pH 6.8):

| Capsule Unit | Disintegration Time (min) |
|---|---|
| 1 | 24 |
| 2 | 26 |
| 3 | 22 |
| 4 | 23 |
| 5 | 25 |
| 6 | 24 |

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