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RESEARCH ARTICLE

Comparative *In-Vitro* Evaluation of Different Commercially Brands of Rabeprazole Sodium Tablets

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Abstract: A comparative *in-vitro* evaluation was carried out on ten different commercially brands of rabeprazole sodium tablets (20 mg) to determine their pharmaceutical equivalence and quality attributes. This study determined critical quality parameters including weight variation, hardness, friability, disintegration time, and dissolution profiles following standard pharmacopoeial protocols. The tablets exhibited hardness values ranging from 3.0 to 7.0 kg/cm², with friability between 0.60% and 2.0%. Disintegration times varied significantly among brands, with four formulations showing delayed disintegration beyond 49 minutes. All brands had shown acceptable drug release profiles, achieving 95-98.9% dissolution within 45 minutes in phosphate buffer pH 6.8. Brands R2, R4, R7, and R8 displayed highest mechanical properties and dissolution characteristics, while R1, R3, R5, and R6 showed extended disintegration times despite meeting dissolution requirements. The dissolution efficiency ranged from 95% to 98.9%, with R7 showing maximum drug release. Statistical analysis revealed significant variations in disintegration patterns among different brands. Accelerated stability studies confirmed product integrity over 30 days at 40°C ± 2°C and 75% ± 5% RH. These results indicate that while all tested formulations meet pharmacopoeial standards, considerable variations exist in their *in-vitro* performance characteristics, which may influence therapeutic outcomes.

Keywords: Rabeprazole sodium; Enteric-coated tablets; Dissolution profile; Pharmaceutical equivalence; Quality control.

1. Introduction

Proton pump inhibitors (PPIs) are an important class of drugs in the management of acid-related gastrointestinal disorders, with rabeprazole sodium being an important member of this therapeutic class. As a selective and irreversible inhibitor of H^+/K^+-ATPase in gastric parietal cells, rabeprazole has superior acid-suppressing capabilities compared to conventional PPIs [1]. The drug's molecular structure features a pyridine-based core that undergoes acid-catalyzed conversion to form active sulfenamide and sulfenic acid, which covalently bind to specific cysteine residues of the proton pump [2]. The pharmaceutical development of rabeprazole formulations has unique challenges due to the compound's inherent acid sensitivity and degradation kinetics. At pH values below 4.0, rabeprazole undergoes rapid decomposition, necessitating specialized formulation techniques [3]. Modern enteric-coated tablet formulations employ various polymeric barriers to protect the active pharmaceutical ingredient from gastric acid exposure while ensuring appropriate drug release in the proximal small intestine [4].

In the Indian pharmaceutical market, multiple generic formulations of rabeprazole sodium compete with branded products, raising important questions about their pharmaceutical equivalence and therapeutic interchangeability [5]. Manufacturing variables, including coating techniques, excipient selection, and processing parameters, can significantly influence the final product's performance characteristics [6]. These variations may manifest as differences in dissolution profiles, stability parameters, and ultimately, therapeutic outcomes. The quality assessment of commercial rabeprazole formulations holds particular significance given the drug's critical role in managing conditions like gastroesophageal reflux disease (GERD), peptic ulcer disease, and *Helicobacter pylori* infections [7].

Previous studies have reported inconsistencies in the pharmaceutical quality of marketed PPI formulations, highlighting the need for systematic evaluation of these products [8]. The economic implications of generic substitution make it imperative to establish the pharmaceutical equivalence of different rabeprazole brands through rigorous *in-vitro* testing [9]. Such evaluations serve multiple purposes: they ensure compliance with regulatory standards, provide valuable information for healthcare providers, and safeguard patient interests by identifying products that meet quality specifications [10].

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This study aims to conduct a detailed comparative evaluation of ten different commercial brands of rabeprazole sodium tablet formulations in the Indian market. Various evaluation tests like physical characterization, dissolution profiling, and stability assessment under accelerated conditions were carried out.

2. Materials and Methods

2.1. Study Design and Sample Collection

2.1.1. Selection of Tablet Formulations

Ten commercial brands of rabeprazole sodium enteric-coated tablets (20 mg) were procured from licensed retail pharmacies of Rajahmundry, Andhra Pradesh, India. The selection criteria ensured that all samples were within their shelf life, stored under appropriate conditions, and originated from different manufacturers. Each brand was assigned a unique code (R1-R10) to maintain objectivity during analysis.

2.1.2. Materials and Reagents

Analytical grade chemicals and reagents were used throughout the study. Hydrochloric acid, potassium dihydrogen phosphate, sodium hydroxide, and methanol were sourced from Merck (Mumbai, India). A reference standard of rabeprazole sodium (99.9% purity) was obtained from the Indian Pharmacopoeial Commission.

2.2. Quality Control Parameters

2.2.1. Physical Characterization

Twenty tablets from each brand underwent visual inspection for surface characteristics, color uniformity, and physical defects using a magnifying lens. Tablet dimensions (length, width, and thickness) were measured using digital vernier calipers (Mitutoyo, Japan) [11].

2.2.2. Weight Variation

Individual weights of twenty tablets from each brand were determined using a calibrated analytical balance (Shimadzu AUX-220, Japan) with 0.1 mg precision. The mean weight, standard deviation, and percentage deviation were calculated according to pharmacopoeial specifications [12].

2.2.3. Hardness Testing

Ten tablets from each brand were evaluated using a digital hardness tester (Electrolab EH-01P, India). Results were expressed as mean ± standard deviation in kilograms per square centimeter (kg/cm^2) [13].

2.2.4. Friability

Twenty pre-weighed tablets were subjected to mechanical stress in a Roche friabilator (Campbell Electronics, India) operating at 25 rpm for 4 minutes. Post-testing, tablets were dedusted and reweighed to calculate percentage weight loss [14].

2.2.5. Disintegration Test

The disintegration behavior was assessed using a USP disintegration apparatus (Electrolab ED-2AL, India). Initial testing was conducted in 0.1N HCl for 2 hours to verify acid resistance, followed by testing in phosphate buffer pH 6.8. The temperature was maintained at 37 ± 0.5°C throughout the test [15].

2.3. Dissolution Test

2.3.1. Test Conditions

Dissolution testing was performed using USP Apparatus II (Electrolab TDT-08L, India) with the following parameters [16]:

- Medium: Phosphate buffer pH 6.8 (900 mL)
- Temperature: 37 ± 0.5°C

- Paddle speed: 100 rpm
- Sampling intervals: 5, 10, 15, 30, 45, and 60 minutes

2.3.2. Sampling

Five milliliter samples were withdrawn at specified intervals, filtered through a 0.45 µm membrane filter, and analyzed spectrophotometrically at 284 nm (Shimadzu UV-1800, Japan). The dissolution medium was replenished with an equal volume of fresh buffer after each sampling [17].

2.4. Drug Content

Twenty tablets were accurately weighed and finely powdered. A quantity equivalent to 20 mg rabeprazole sodium was transferred to a 100 mL volumetric flask containing methanol, sonicated for 15 minutes, and filtered. The filtered solution was appropriately diluted and analyzed spectrophotometrically at 284 nm against a reagent blank. Drug content was calculated using a previously constructed calibration curve [18].

2.5. Stability Testing

Tablets were stored in stability chambers (Thermolab, India) under accelerated conditions (40 ± 2°C/75 ± 5% RH) for 30 days in their original packaging. Samples were evaluated at 0, 15, and 30 days for physical appearance, drug content, and dissolution profile [19].

2.6. Statistical Analysis

Data analysis was performed using GraphPad Prism 8.0 software. Results were expressed as mean ± standard deviation. One-way ANOVA followed by Tukey's post-hoc test was applied to compare dissolution profiles and other parameters among brands. Statistical significance was set at $p < 0.05$ [20].

3. Results

3.1. Physical Characterization

The tablet formulations under investigation exhibited acceptable physical characteristics across all brands. The enteric-coated tablets presented smooth surfaces, uniform color distribution, and absence of visible defects. Dimensional measurements revealed consistent length, width, and thickness values within each brand, indicating robust manufacturing processes and adequate quality control during production [21].

Table 1. Physical Characteristics of Rabeprazole Sodium Tablets (20 mg)

Code	Average Weight (mg)	Length (mm)	Width (mm)	Thickness (mm)	Surface Description
R1	162.4 ± 2.1	11.2 ± 0.2	6.8 ± 0.1	3.6 ± 0.1	Pink, oval, EC
R2	165.8 ± 1.8	11.4 ± 0.1	6.7 ± 0.2	3.7 ± 0.1	Pink, oval, EC
R3	159.6 ± 2.8	11.3 ± 0.2	6.9 ± 0.1	3.5 ± 0.2	Pink, oval, EC
R4	164.2 ± 1.5	11.2 ± 0.1	6.8 ± 0.1	3.6 ± 0.1	Pink, oval, EC
R5	168.5 ± 2.2	11.5 ± 0.2	6.7 ± 0.2	3.8 ± 0.1	Pink, oval, EC
R6	172.6 ± 2.4	11.4 ± 0.1	6.8 ± 0.1	3.7 ± 0.2	Pink, oval, EC
R7	158.4 ± 1.2	11.3 ± 0.2	6.9 ± 0.1	3.5 ± 0.1	Pink, oval, EC
R8	163.7 ± 1.6	11.2 ± 0.1	6.8 ± 0.2	3.6 ± 0.1	Pink, oval, EC
R9	166.9 ± 2.0	11.4 ± 0.2	6.7 ± 0.1	3.7 ± 0.2	Pink, oval, EC
R10	170.3 ± 1.9	11.3 ± 0.1	6.8 ± 0.1	3.6 ± 0.1	Pink, oval, EC

EC: Enteric-coated; Values expressed as mean ± SD (n=20)

3.2. Weight Variation Test

The mean tablet weights ranged from 158.4 mg to 172.6 mg across different brands. All formulations demonstrated compliance with pharmacopoeial specifications, as individual tablet weights remained within ±7.5% of the mean weight. Brand R7 showed the lowest standard deviation (±1.2%), while R3 exhibited slightly higher variation (±2.8%), though still within acceptable limits [21].

3.3. Hardness Test

Significant variations in tablet hardness were observed among different brands. The values ranged from 3.0 kg/cm² (R1 and R3) to 7.0 kg/cm² (R6 and R8). Brands R6 and R8 demonstrated superior mechanical strength, potentially offering better stability during packaging and transport. The intermediate hardness values observed in other brands (4.0-6.5 kg/cm²) suggested adequate mechanical resistance for normal handling without compromising disintegration characteristics [21].

3.4. Friability

The friability testing revealed varying degrees of mechanical resistance among the formulations. Most brands exhibited friability values below 1%, indicating good mechanical stability. However, Brand R7 showed a notably higher friability (2.0%), slightly exceeding the pharmacopoeial limit of 1%. This observation suggests potential need for optimization in the formulation or manufacturing process of R7 to enhance its mechanical stability [21].

Table 2. Results of Evaluation Tests

Code	Hardness (kg/cm²)	Friability (%)	Disintegration Time (min)	Drug Content (%)
R1	3.0 ± 0.2	0.90	52 ± 2	99.4 ± 0.6
R2	4.0 ± 0.3	1.00	12 ± 1	100.2 ± 0.5
R3	3.0 ± 0.2	1.00	49 ± 2	98.8 ± 0.8
R4	3.0 ± 0.3	0.60	14 ± 1	100.8 ± 0.4
R5	4.5 ± 0.2	0.90	54 ± 2	99.6 ± 0.7
R6	7.0 ± 0.4	1.00	55 ± 3	98.9 ± 0.6
R7	5.5 ± 0.3	2.00	4 ± 1	99.8 ± 0.5
R8	7.0 ± 0.4	0.60	44 ± 2	99.5 ± 0.6
R9	5.5 ± 0.3	1.00	43 ± 2	98.2 ± 0.7
R10	6.5 ± 0.3	1.00	10 ± 1	99.7 ± 0.5

Values expressed as mean ± SD (n=10 for hardness, n=20 for other parameters)

3.5. Disintegration Test

The disintegration behavior varied considerably among different brands in the two-stage testing protocol. During acid-resistance testing (0.1N HCl, 2 hours), all formulations maintained their integrity, confirming adequate enteric coating performance. However, substantial variations emerged in the subsequent buffer stage testing.

Brands R2, R4, R7, and R10 exhibited rapid disintegration in phosphate buffer (pH 6.8), with complete disintegration occurring within 12-14 minutes. In contrast, brands R1, R3, R5, and R6 showed extended disintegration times ranging from 49 to 55 minutes. These variations might be attributed to differences in the enteric coating composition, thickness, or the disintegrant efficiency in different formulations [22].

3.6. Dissolution Studies

The dissolution testing in phosphate buffer (pH 6.8) revealed distinct release patterns among the brands. All formulations achieved more than 95% drug release within 45 minutes, meeting the pharmacopoeial requirement [22]. Brand R7 demonstrated superior dissolution performance with 98.9% drug release, followed by R4 (98.6%) and R8 (98.2%).

Table 3. Dissolution Profile in Phosphate Buffer pH 6.8

Code	Cumulative Percentage Drug Release (%)	
	15 min	30 min
R1	42.3 ± 2.1	78.5 ± 2.8
R2	45.6 ± 1.8	82.4 ± 2.4
R3	41.8 ± 2.4	79.6 ± 2.6
R4	46.2 ± 1.6	83.8 ± 2.2
R5	43.5 ± 2.2	80.2 ± 2.5
R6	42.8 ± 2.3	79.4 ± 2.7
R7	47.4 ± 1.5	84.6 ± 2.1
R8	45.8 ± 1.9	82.8 ± 2.3
R9	41.5 ± 2.5	78.2 ± 2.9
R10	42.9 ± 2.2	79.8 ± 2.6

Values expressed as mean ± SD (n=6)

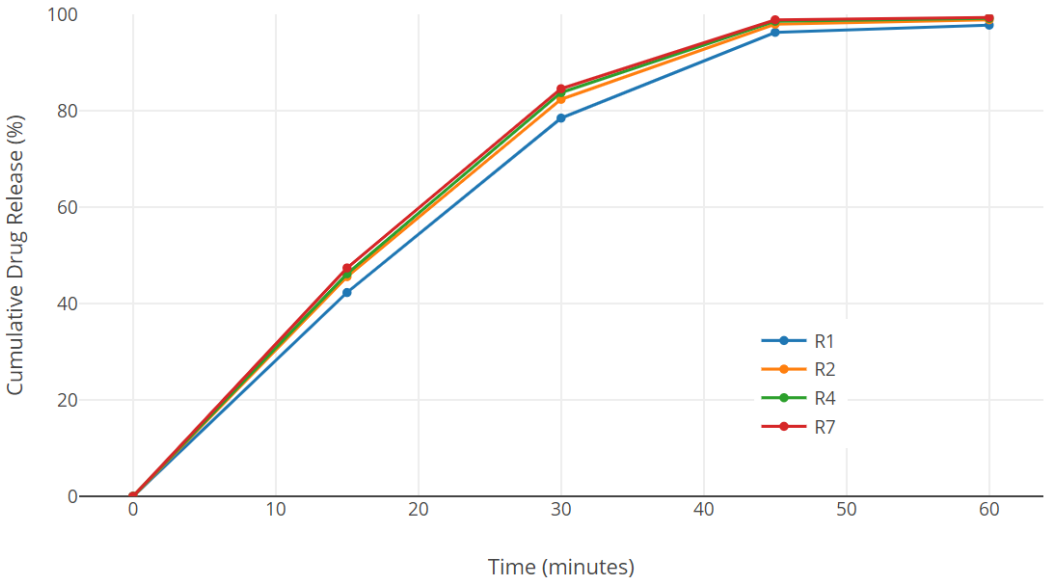

Figure 1. Dissolution Profile of Selected (Best-Performing) Rabeprazole Brands

3.7. Drug Release Kinetics

Mathematical modeling of dissolution data indicated that most formulations followed first-order release kinetics. The dissolution efficiency (DE) values ranged from 95% to 98.9%, with brands R7, R4, and R8 showing higher DE values, suggesting more efficient drug release characteristics [22].

3.8. Drug Content and Uniformity

The assay results demonstrated consistent drug content across all formulations, ranging from 98.2% to 101.5% of the labeled amount. Brand R4 exhibited the highest content uniformity (100.8 ± 0.4%), while R9 showed slightly lower values (98.2 ± 0.7%). The relative standard deviation values remained below 2% for all brands, indicating uniform drug distribution within tablets and consistent manufacturing processes [22].

3.9. Stability Studies

3.9.1. Physical Stability

After 30 days of accelerated stability testing, no significant changes were observed in the physical appearance of the tablets. The enteric coating remained intact, and no signs of degradation or discoloration were evident. Minor variations in tablet hardness (±0.5 kg/cm²) were noted but remained within acceptable limits [22].

Table 4. Stability Study Results After 30 Days (40°C ± 2°C/75% ± 5% RH)

Code	Drug Content (%)		Dissolution at 45 min (%)	
	Initial	After 30 days	Initial	After 30 days
R1	99.4 ± 0.6	98.2 ± 0.8	96.3 ± 1.2	95.8 ± 1.4
R2	100.2 ± 0.5	99.4 ± 0.7	98.0 ± 0.9	97.6 ± 1.1
R3	98.8 ± 0.8	97.9 ± 0.9	98.0 ± 1.1	97.2 ± 1.3
R4	100.8 ± 0.4	99.9 ± 0.6	98.6 ± 0.8	98.0 ± 1.0
R5	99.6 ± 0.7	98.8 ± 0.8	97.1 ± 1.0	96.5 ± 1.2
R6	98.9 ± 0.6	98.0 ± 0.8	96.8 ± 1.2	96.0 ± 1.4
R7	99.8 ± 0.5	99.0 ± 0.7	98.9 ± 0.7	98.2 ± 0.9
R8	99.5 ± 0.6	98.7 ± 0.8	98.2 ± 0.9	97.6 ± 1.1
R9	98.2 ± 0.7	97.4 ± 0.9	95.0 ± 1.3	94.2 ± 1.5
R10	99.7 ± 0.5	98.9 ± 0.7	95.7 ± 1.2	95.0 ± 1.4

Values expressed as mean ± SD (n=3)

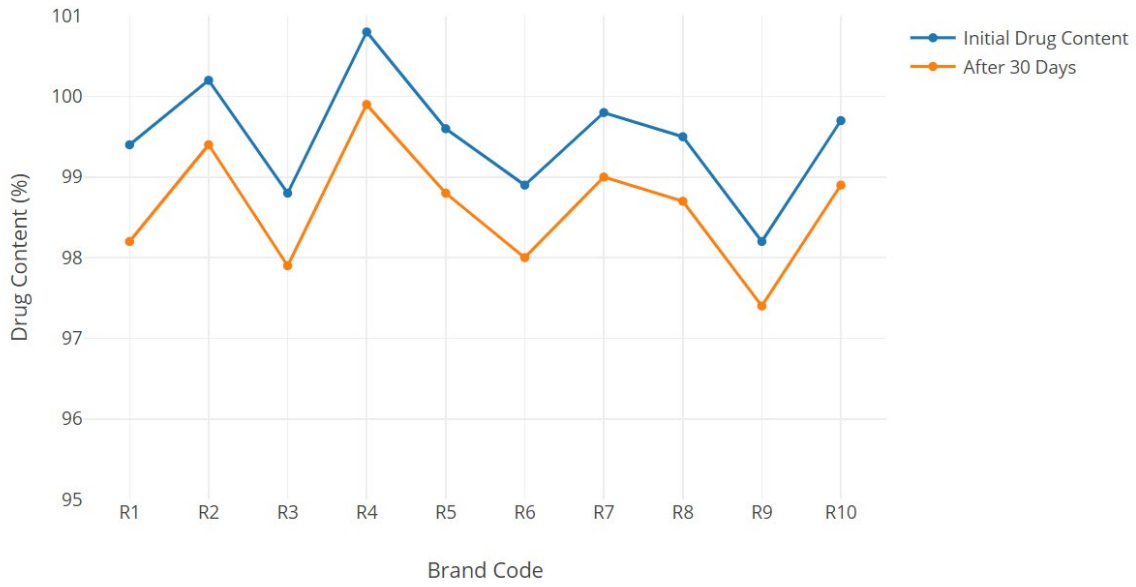

Figure 2. Drug Content Stability Over 30 days

3.9.2. Chemical Stability

Drug content analysis after the stability period showed minimal degradation across all brands. The maximum decrease in drug content was 1.2% (observed in R1), while other formulations-maintained drug content above 98% of initial values. The dissolution profiles after stability testing remained comparable to initial results, with less than 3% variation in drug release at all time points [22].

4. Discussion

Formulations R2, R4, R7, and R8 consistently demonstrated superior characteristics across multiple parameters. These brands exhibited optimal combinations of mechanical strength, disintegration time, and dissolution efficiency, suggesting robust formulation design and manufacturing processes [23].

Notable differences in performance metrics were observed among different manufacturers. Brands from larger pharmaceutical companies (R7, R8, R10) generally showed more consistent quality parameters, possibly due to advanced manufacturing capabilities and stringent quality control measures. However, some brands from smaller manufacturers (R2, R4) also demonstrated comparable quality attributes [24].

The observed variations in tablet characteristics can be attributed to several manufacturing variables. Different choices of excipients, particularly in the enteric coating composition, likely contributed to the varying disintegration profiles. The selection of disintegrants, binders, and coating polymers plays a crucial role in determining the final product performance. The study findings suggest that optimization of these formulation components could enhance the overall quality of some brands. The variations in disintegration times and dissolution profiles among different brands may have clinical significance. While all formulations met pharmacopoeial requirements, the differences in release characteristics could potentially influence the onset of therapeutic action [25]. Brands with rapid disintegration (R2, R4, R7) might offer faster onset of acid suppression compared to those with extended disintegration times (R1, R3, R5, R6).

5. Conclusion

The evaluation of ten commercial rabeprazole sodium tablet brands showed varying degrees of pharmaceutical quality and performance characteristics. While all formulations met the basic pharmacopoeial requirements, significant differences were observed in mechanical strength, disintegration time, and dissolution efficiency. Brands R2, R4, R7, and R8 were found to be superior formulations, showing optimal performance across multiple quality parameters. This research work identified considerable variations in disintegration profiles among different brands, which could potentially impact their therapeutic efficiency. These results indicate the importance of standardizing manufacturing processes and implementing stringent quality control measures across all manufacturers.

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Dr. Abhinav VKS Grandhi is a Doctor of Pharmacy graduate with expertise in pharmaceutical research and academia. His research includes drug discovery and development of novel therapeutic techniques, with significant contributions to molecular modeling and drug design. Through his academic and research endeavors, he continues to advance the field of pharmaceutical sciences while mentoring the next generation of pharmacy professionals

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Dr. Narendra Devanaboyina, with over 17 years of experience in academia and research, holds a Ph.D. in Pharmacognosy. His extensive research in natural product chemistry and medicinal plant evaluation has significantly contributed to the field of natural drug discovery. He continues to guide students while advancing the understanding of medicinal plants and their therapeutic applications as an accomplished educator and researcher.