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Quality Evaluation of Different Brands of Telmisartan Tablets in Bangladesh for Ensuring Therapeutic Reliability in Hypertension Management

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Abstract

Telmisartan, an angiotensin-II receptor blocker, is widely prescribed for hypertension in Bangladesh. This study aims to compare the quality of various brands of telmisartan tablet by evaluating key quality control parameters, including weight variation, hardness, friability, thickness, diameter, disintegration time, potency and dissolution profiles. The weight variation test revealed that five brands (F1-F5) complied with the pharmacopeial ±7.5% limit, with brand F3 being the only exception. Tablet thickness and diameter varied across brands, likely due to differences in granule density and manufacturing processes. Hardness testing showed that brand F6 had the highest average hardness, while brand F4 had the lowest. In the disintegration test, all brands met the pharmacopeial standard, with brand F4 exhibiting the fastest disintegration time. Friability testing demonstrated low friability across all brands. Dissolution profiles indicated significant differences in drug release rates. Kinetic analysis revealed that brands F1, F3 and F5 followed a diffusion-controlled release mechanism, whereas brands F2, F4, and F6 exhibited dissolution-controlled release. Potency testing confirmed that all brands fell within the acceptable potency range of 95-110%. Among all the brands, brand F4 stood out as the best, demonstrating superior performance in various parameters. Overall, the results of all these quality control parameters for the different brands were within the limits specified by pharmacopoeia. Therefore, it can be concluded that the marketed telmisartan tablets of these brands are safe, effective and efficacious, as well as compliant with the required quality control standards. Patients can, therefore, safely switch from one brand to another without compromising therapeutic efficacy.

Key words: Telmisartan, hypertension, quality control, tablet evaluation, Bangladesh.

Introduction

Hypertension is a serious global public health concern, contributing significantly to cardiovascular morbidity and mortality (Sharma *et al.*, 2024). According to the latest report of World Health Organization (WHO), approximately 1.4 billion adults aging between 30 to 79 years suffered from hypertension worldwide in 2024, with nearly two-thirds residing in low and middle income countries (WHO, 2025a). Concerningly, only about one in four individuals with hypertension have their blood pressure adequately controlled, highlighting a significant gap in global management of this condition (WHO, 2025b). In Bangladesh, the situation is particularly alarming, with only around 16% of hypertensive adults achieving adequate blood

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pressure control, underscoring the urgent need for effective and reliable antihypertensive therapy (The Business Standard, 2025).

The effective management of hypertension not only depends on diagnosis and adherence, but also on the quality and reliability of the medications used. Among the commonly prescribed antihypertensive agents in Bangladesh, Telmisartan, an angiotensin-II receptor blocker (ARB), is widely available in the market as an immediate-release oral formulation and is favored because of its well-established safety profile and suitability for long-term therapy (Bayas *et al*., 2019). Telmisartan exerts its antihypertensive action by selectively antagonising angiotensin-II at the type 1 (AT_1) receptor, thereby inhibiting vasoconstriction and aldosterone-mediated sodium and water retention, which are the key drivers of systemic hypertension (Rada, 2024; Burnier and Brunner, 2000). It exhibits a long elimination half-life (~24 hours) and high lipid solubility that facilitates extensive tissue distribution and sustained systemic concentrations of this drug (Rada, 2024). In addition to renin–angiotensin system blockade, telmisartan uniquely exhibits partial peroxisome proliferator-activated receptor-γ (PPAR-γ) agonistic activity, which may confer additional metabolic and anti-inflammatory benefits, particularly in patients with metabolic syndrome or type-2 diabetes (Imenshahidi *et al*., 2024). Importantly, while safety concerns have been raised for certain ARBs such as valsartan due to nitrosamine impurities (e.g., NDMA) linked to potential carcinogenic risk, telmisartan itself has not been shown to possess intrinsic carcinogenicity and remains well tolerated during chronic use (Tascilar *et al*., 2016; Ray *et al*., 2020).

In the Bangladeshi market, multiple brands of telmisartan tablets, including both generics and branded formulations, are available, providing patients and prescribers with various therapeutic options. However, the therapeutic outcome of any ARB may be significantly influenced by the pharmaceutical quality of the tablet formulation. Evidence from certain prior research demonstrated that in-vitro formulation characteristics, such as dissolution rate and excipient composition can reliably predict in-vivo drug absorption, establishing a validated link between pharmaceutical quality and therapeutic efficacy (Kostewicz *et al*., 2014). Therefore, ensuring consistent quality across different brands of ARB is essential to guarantee therapeutic efficacy, patient safety and interchangeability. Standard quality control (QC) tests for solid oral dosage forms include physical properties such as weight variation, hardness, friability and thickness/diameter; chemical parameters such as active pharmaceutical ingredient assay and content uniformity; and biopharmaceutical parameters such as disintegration and dissolution (Dasari *et al*., 2017). These parameters can directly influence drug release, absorption and ultimately, clinical outcomes (Pande *et al*., 2024; Ghori *et al*., 2019). Studies have shown that physical parameters such as tablet hardness and disintegration affect biopharmaceutical behavior (dissolution) and some validated in vitro–in vivo correlation (IVIVC) models for drugs like bicalutamide, itraconazole and candesartan cilexetil demonstrated that differences in dissolution/disintegration profiles can predict differences in systemic exposure (AUC, C_{max}), thereby linking QC parameters with therapeutic efficacy (Ozaksun and Incecayir, 2025; Coutinho *et al*., 2025; Figueroa-Campos *et al*., 2020)

Internationally, several in-vitro studies have assessed the QC and dissolution performance of marketed telmisartan tablets, revealing that while many brands comply with basic pharmacopeial specifications, there can be marked variability in dissolution rates and release kinetics among formulations (Bayas *et al*., 2019; Pande *et al*., 2024). Despite this body of international evidence, there appears to be no peer-reviewed study published from Bangladesh that systematically evaluates multiple brands of telmisartan tablets available in local pharmacies, assessing a comprehensive set of QC parameters. Given the high burden of hypertension in Bangladesh, low rates of effective blood pressure control and widespread use of generic ARBs like telmisartan, such a study is timely and essential. Systematic QC evaluation of locally marketed brands

would provide critical evidence regarding their pharmaceutical quality, therapeutic reliability and interchangeability, ultimately supporting safer and effective hypertension management in Bangladesh.

Therefore, the present study aims to perform a comparative quality evaluation of different brands of telmisartan tablets marketed in Bangladesh, focusing on standard QC parameters (weight variation, hardness, friability, thickness/diameter, disintegration time), active-drug assay and dissolution profile in order to assess whether these brands meet pharmacopeial standards and to provide evidence-based recommendations on their therapeutic reliability and interchangeability.

Materials and Methods

Materials

Sample collection: The marketed telmisartan tablets were procured from reputable local pharmacies in Farmgate, Dhaka. Comprehensive details, including manufacturing licenses, production and expiry dates, batch numbers, as well as the physical characteristics of the tablets, were thoroughly documented to ensure traceability and compliance with regulatory standards.

Equipment and apparatus: The in-vitro testing procedures were carried out using a variety of advanced laboratory apparatus. The Ohaus Pioneer PA213 Electrical Analytical Balance (USA) was utilized for weight variation analysis. Friability testing was conducted using the Roche Friabilator (Switzerland) and tablet hardness was measured with the Dr. Schleuniger Pharmatron 8M Tablet Hardness Tester (Switzerland). The Electrolab ED-2L Tablet Disintegration Tester (India), adhering to USP standards, was used for disintegration testing. Potency was assessed using the Shimadzu UV1280 UV Spectrophotometer (Japan), and stability studies were conducted using the Witeg WGC-P4 Stability Chamber (Germany). Dissolution testing was performed with the Electrolab EDT-08LX USP Dissolution Apparatus-II (India). Additionally, the Mitutoyo Vernier Caliper (Series 530) (Japan) was used for precise dimensional measurements of tablets, the Power Sonic-420 Sonicator (Hwashin Technology Co., Korea) for sample processing, and the pH 211 Microprocessor pH Meter (Hanna Instruments, Romania) for pH analysis. Other general laboratory apparatus included test tubes, holders, beakers, measuring cylinders, volumetric flasks, spatula, glass rods, funnels, mortar and pestle, pipettes with pipette fillers, wax and filter paper, stopwatch and UV pyrex cells. These instruments were crucial in ensuring the accuracy and reliability of the testing and measurements for the study.

Methodology

Weight variation test: An electronic balance was used to measure the weight of 20 individual telmisartan tablets. The average weight was then calculated. The percentage deviation for each tablet was then determined using the following formula.

$$\% \text{ Weight variation} = \frac{\text{Individual weight} - \text{Average weight}}{\text{Average weight}} \times 100$$

The weight variation limits for tablets were adhered to as specified by the United States Pharmacopoeia (Hamrah *et al.*, 2020).

Diameter and thickness measurement: A vernier caliper is used to measure the diameter and thickness of the tablets in order to provide a consistency in the dimensions. Twenty tablets of each brand were sampled in order to assess tablet diameter and thickness.

Hardness test: Tablet hardness is a key quality factor that plays a major role in determining characteristics like disintegration, dissolution and friability. In this experiment, three telmisartan tablets were tested using an automated tablet hardness tester. Each tablet was positioned between two opposing plates that move toward each other to measure the force required to crush the tablet.

Friability test: The friability of the tablets was assessed using a Roche friabilator. Twenty tablets from each brand were weighed, then subjected to 100 revolutions at 25 rpm for 4 minutes in the friabilator. After tumbling, the tablets were reweighed, and the percentage friability was calculated by comparing the

initial and final weights. A friability value of less than 1% was considered acceptable (Shah *et al.*, 2019).

$$\% \text{ Friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

Disintegration test: In order to determine the disintegration time, a tablet disintegration tester equipped with a disc was used. Three telmisartan tablets were placed in the basket rack of the tester. The test was carried out using 700 ml of water in a 1-liter beaker, maintained at a specific temperature throughout the experiment. The disintegration test was carried out at 37 ± 0.5 °C, with discs placed on top of the tablets.

In vitro dissolution test: Dissolution testing was conducted using USP Apparatus-2 at 50 rpm and 37 ± 0.5°C with 900 ml of phosphate buffer solution (pH 6.8). Six tablets from each brand were placed in separate containers. At intervals of 0, 5, 15, 30, 45 and 60 minutes, 10 ml of sample was withdrawn and replaced with an equivalent volume of buffer. The samples were filtered, diluted, and analyzed at 296 nm using a UV-Vis spectrophotometer, with the buffer solution as the blank (Pande *et al.*, 2024).

Determination of release kinetics: The obtained dissolution data were analyzed using the zero-order, first-order, higuchi, Hixson-Crowell and Korsmeyer Peppas kinetic models to determine the mechanism and rate of telmisartan release from different marketed brands (Pal and Panda, 2014). The R^2 values were calculated and nearing 1 considered as the best fitted kinetic model.

Potency test: The potency of the drug was assessed by determining the amount of medication contained within it. The average weight of four tablets was first recorded. These tablets were then crushed into a fine powder, which was measured. The powdered tablets were dissolved in phosphate buffer, with continuous stirring to ensure uniformity. The resulting solution was then filtered to yield a clear liquid. To quantify the drug's concentration, the absorbance of the solution was measured at 296 nm using a UV-visible spectrophotometer.

Results and Discussions

Weight variation test: Six different marketed formulations of 20 mg telmisartan tablets (F1–F6) were were tested for weight uniformity. Five brands (F1, F2, F4, F5, F6) stayed within the USP ±7.5% limit, with F2 and F5 showing the most consistent weights (below ±2% deviation). F1 showed moderate but acceptable variation. Only F3 failed to comply with pharmacopeial standard, showing large deviations (+16.26% and –13.01%), as shown in table 1. Overall, all brands except F3 met pharmacopeial weight uniformity standards.

Table 1. Analysis of average weight and deviations across different brands.

Brand	Average weight (mg)	Maximum deviation	Minmum deviation
F1	129.60	+4.93	–4.32
F2	207.25	+2.29	–0.60
F3	123.00	+16.26	–13.01
F4	89.80	+2.81	–4.81
F5	215.04	+1.75	–1.32
F6	147.205	+3.74	–4.62

Thickness and diameter: The thickness and diameter of the tablets may vary between brands, depending on their shape and weight. This variation is a result of differences in the density of the granules used and the pressure applied during the tablet pressing process. Additionally, tablet thickness and diameter can be influenced by the specific requirements and preferences of each manufacturer. All 6 branded tablets dimensions show variations in diameter and thickness, as shown in table 2. Brand F2 has the largest diameter (8 mm) and the thickest tablet (5 mm), suggesting a more robust design. Brand F4 and brand F5 feature the smallest diameters (6 mm) and thinner tablets, indicating more compact designs. Brand F1 and brand F3 have a standard diameter of 7 mm and thickness of 4.2 mm, providing a balanced tablet size. Brand F6 also has an 8 mm diameter but a thinner thickness (3.2 mm).

Table 2. Comparison of diameter and thickness among different brands.

Brand	Diameter (mm)	Thickness (mm)
F1	7	4.2
F2	8	5
F3	7	4.2
F4	6	3
F5	6	3.3
F6	8	3.2

Hardness: The hardness values of six brands (F1–F6) of 20 mg telmisartan tablets were evaluated using three randomly selected tablets from each brand. Hardness is an important mechanical parameter that reflects the tablet's ability to withstand handling, packaging, and transportation stresses. The analysis of average hardness and standard deviation across various brands revealed that the brand F3 had an average hardness of 8 kPa with a standard deviation of 0.13, brand F2 showed an average hardness of 9.15 kPa and a standard deviation of 0.23, while brand F1 exhibited an average hardness of 9.2 kPa with a standard deviation of 0.55. Brand F4 demonstrated the lowest average hardness among all brands (4.26 kPa ± 0.113), while brand F5 had the highest average hardness of 9.97 kPa but with a high standard deviation of 1.467 and brand F6 showed the highest overall average hardness of 11.5 kPa with a standard deviation of 0.84. The lowest average hardness of brand F4 may be attributed to several formulation and process related factors. A primary reason could be the higher proportion or greater efficiency of superdisintegrants used in this formulation, which tend to weaken interparticulate bonding and reduce the mechanical strength of tablet (Bolhuis and De Waard, 2016). Additionally, the use of excipients with poor compressibility or a lower binder concentration may have resulted in insufficient cohesion during compaction (Singha *et al.*, 2025). Manufacturing parameters such as lower compression force or shorter dwell time during tableting could also contribute to reduced hardness (Shipar *et al.*, 2014). Furthermore, differences in granule size distribution or higher residual moisture content may have interfered with optimal particle bonding (Shipar *et al.*, 2014). Collectively, these factors likely led to the comparatively softer tablets observed for brand F4.

The comparative hardness among different brands of telmisartan are presented in figure 1.

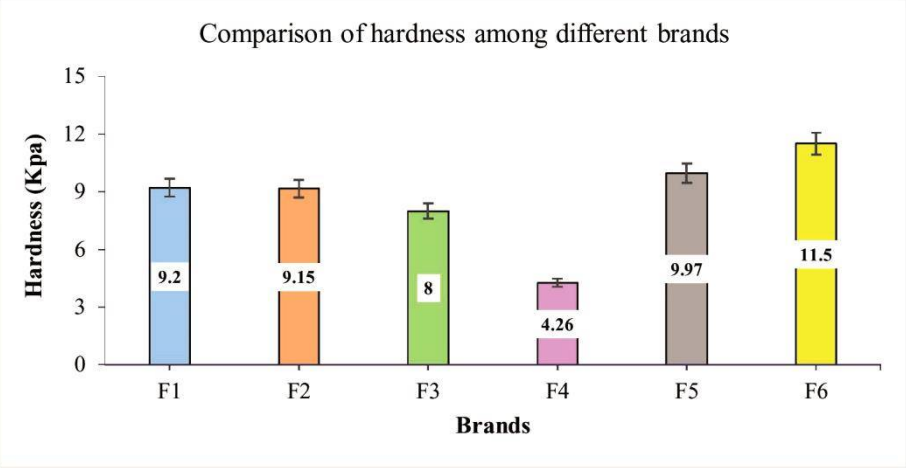

Figure 1. Comparison of average hardness with SD among different brands.

Disintegration test: The disintegration times of telmisartan tablets varied across six brands, as presented in figure 2. brand F2 had the fastest disintegration time of 3.43 min with a standard deviation of 0.10 min, followed by brand F4 at 2.8 min with a standard deviation of 0.10 min and brand F6 at 2.94 min with a standard deviation of 0.36 min. Brand F5 showed a disintegration time of 4.04 min

with a standard deviation of 0.38 min, while brand F3 had a disintegration time of 6.88 min with a standard deviation of 0.40 min and brand F1 had the longest time of 6.30 min with a standard deviation of 1.90 min. All brands disintegrated faster than the pharmacopeial standard (15 min), indicating overall good performance. The observed variations suggest differences in formulation excipients or compression forces across batches.

An inverse relationship between tablet hardness and disintegration time was evident. Brand F4, which exhibited the lowest hardness, also showed one of the fastest disintegration times, supporting the notion that reduced mechanical strength facilitated quicker penetration of dissolution medium and tablet breakup. Conversely, the higher hardness observed for brand F6 was associated with a slightly longer, yet still acceptable, disintegration time. These findings suggested that differences in excipient composition, superdisintegrant efficiency and compression parameters play a significant role in governing the balance between mechanical strength and disintegration performance (Singha *et al.*, 2025).

Overall, the results presented in figures 1 and 2 demonstrated that although all evaluated brands met pharmacopeial specifications for hardness and disintegration, variations in formulation and manufacturing processes influenced their mechanical and performance characteristics (Shipar *et al.*, 2014).

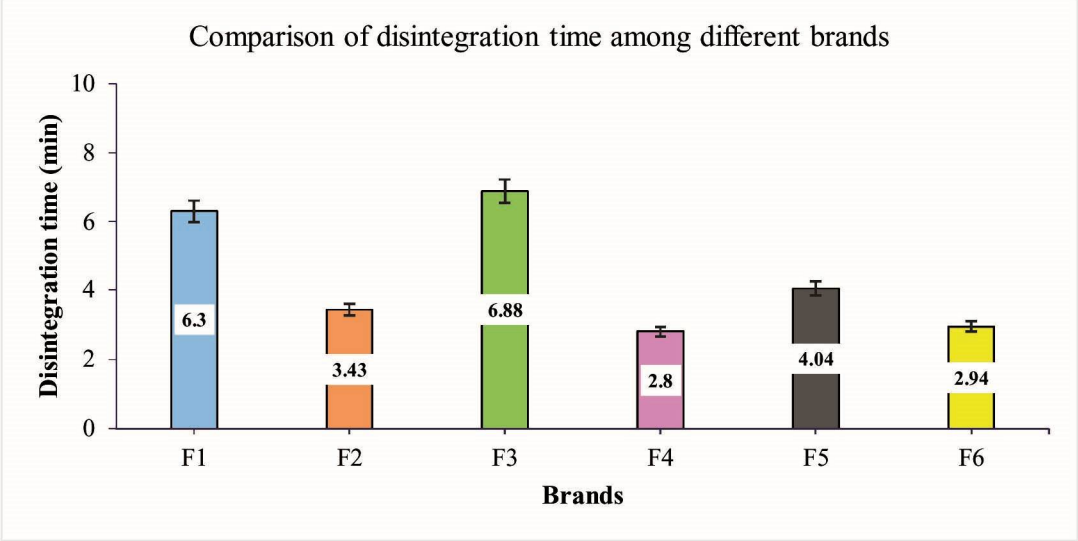

Figure 2. Comparison of average disintegration time with SD among different brands.

Friability test: The friability of telmisartan tablets was tested across six brands, and the results showed that all of them had very low friability, meaning they maintained their integrity well. Brand F1 had the least friability at just 0.002%, while brand F3 and brand F6 both had an even lower friability of 0.001%. Brand F2 came in at 0.07%, brand F5 at 0.09%, and brand F4 showed the highest friability at 0.15%, as presented in table 3. Overall, these results suggest that the tablets are durable and experience minimal weight loss during handling.

Table 3. Comparison of friability among different brands.

Brands	% Friability
F1	0.002
F2	0.07
F3	0.001
F4	0.15
F5	0.09
F6	0.001

In-vitro dissolution study: The dissolution profiles of the six brands reveal distinct differences in performance across time intervals. At 0 min, all brands show no dissolution. Table 4 shows that by 5 min, brand F2 exhibited the fastest dissolution with 80.41 ± 1.16, while brand F1 dissolved more slowly at 30.01 ± 0.29. Over time, brand F2 reached 98.95 ± 0.77 at 60 min, while brand F1 reached 94.57 ± 0.68. Brand F3 and brand F4 showed good dissolution rates, with brand F4 reaching 95.3 ± 3.46 at 60 min. On the other hand, brand F5 and brand F6 displayed moderate dissolution, with brand F6 ending at 92.93 ± 3.61 by 60 min. Figure 3 shows the dissolution profiles of different brands over time. At 60 min, all brands meet the pharmacopeial specifications of ≥75% drug release within 45 minutes. However, among all these brands, only brand F2 showed an unusually rapid drug release, with ~80% release within 5 min. This behavior can be attributed to the higher efficiency or optimal level of superdisintegrant, which promoted rapid tablet breakup, as supported by its short disintegration time (3.43 min) despite moderate hardness (Lepa, 2024). In addition, the presence of hydrophilic excipients or improved wettability may have facilitated faster penetration of dissolution medium and enhanced drug dissolution (Umeh *et al*., 2013). Overall, the rapid release pattern of F2 reflects formulation-driven effects rather than inconsistency or quality issues.

Table 4. Comparison of drug release among different branded tablets of telmisartan.

Time (min)	% Cumulative drug release from different brands					
	F1	F2	F3	F4	F5	F6
0	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0
5	30.01 ± 0.29	80.41 ± 1.16	42.74 ± 1.84	21.68 ± 2.97	40.54 ± 2.16	39.82 ± 3.63
15	48.74 ± 1.30	84.01 ± 2.80	73.29 ± 1.68	51.71 ± 3.67	67.37 ± 1.68	51.21 ± 3.06
30	63.3 ± 1.59	87.91 ± 4.67	93.45 ± 0.50	76.13 ± 5.03	76.01 ± 2.37	74.22 ± 2.15
45	79.72 ± 0.72	92.83 ± 3.10	94.3 ± 0.09	87.67 ± 5.34	91.03 ± 9.84	82.59 ± 1.87
60	94.57 ± 0.68	98.95 ± 0.77	94.32 ± 0.10	95.3 ± 3.46	98.84 ± 0.63	92.93 ± 3.61

*All values are presented as mean ± standard deviation

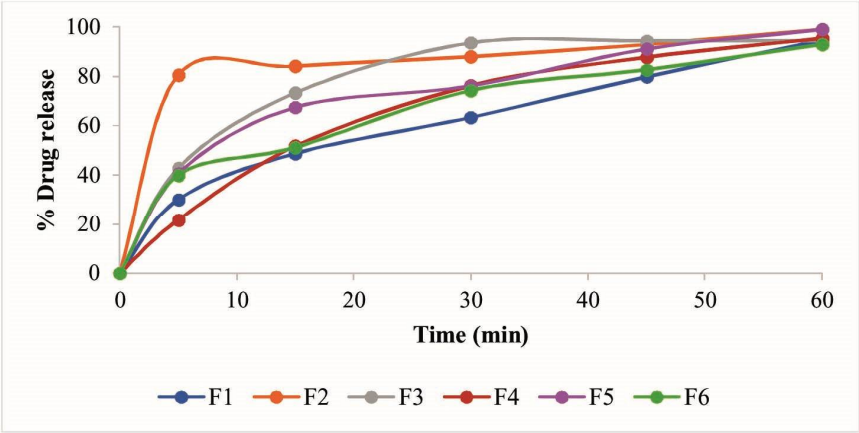

Figure 3. Dissolution profiles of different branded telmisartan tablets over time.

The variations in dissolution times across brands suggest differences in formulation excipients or manufacturing processes, though all brands perform well within pharmacopeial standards for dissolution. Overall, the dissolution data demonstrated that the marketed tablets provide consistent and acceptable drug release profiles, suitable for therapeutic use.

Interpretation of release kinetics of telmisartan from different brands: The dissolution profile analysis of different tablet brands (F1 to F6) was conducted to evaluate the drug release mechanisms using various kinetic models. The results indicate distinct release patterns for each brand based on model fitting. brands F1, F3 and F5 exhibited the best fit with the Higuchi model, which is indicative of a diffusion-controlled drug release mechanism. This suggests that the release of the drug from these formulations is governed by diffusion processes, which is typical for systems where drug release is controlled by the dissolution of the drug in the medium. In contrast, brands F2, F4 and F6 were best described by the First Order model, which suggests a dissolution-controlled release mechanism. This implies that the release rate of the drug from these formulations is concentration-dependent, and the drug is released in proportion to its remaining concentration in the formulation. The R^2 values of the models confirm the validity of the best-fit model for each brand, with the Higuchi model providing the highest correlation for F1, F3 and F5, while the First Order model was most appropriate for F2, F4 and F6, as shown in table 5.

Table 5. Interpretation of release kinetics of telmisartan from different marketed brands.

Brands	Zero order model	First order model	Hixson-Crowell model	Higuchi model	Korsmeyer-peppas model		Best Fitted model	Drug release mechanism
	R2	R2	R2	R2	R2	n		
F1	0.915	0.940	0.975	0.996	0.932	3.25	Higuchi	Diffusion controlled
F2	0.459	0.850	0.748	0.705	0.602	0.98	First order	Dissolution controlled
F3	0.689	0.851	0.812	0.904	0.834	1.33	Higuchi	Diffusion controlled
F4	0.892	0.996	0.989	0.985	0.965	2.03	First order	Dissolution controlled
F5	0.800	0.929	0.960	0.964	0.774	2.44	Higuchi	Diffusion controlled
F6	0.841	0.979	0.977	0.963	0.953	1.71	First order	Dissolution controlled

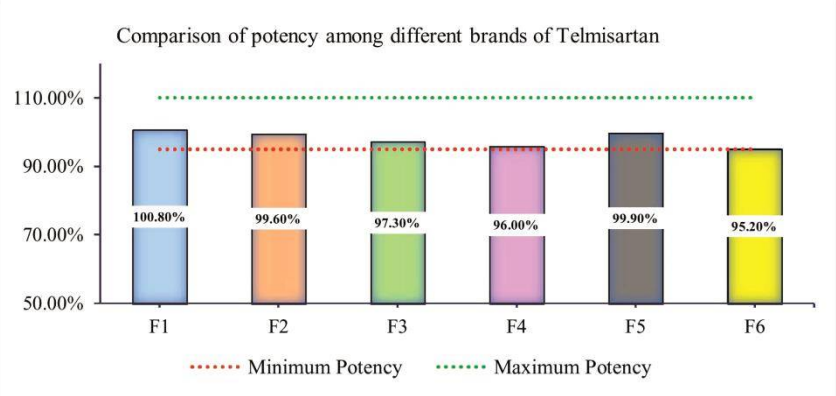

Figure 4. Comparison of potency of telmisartan among different branded tablets.

Potency test: The potency of telmisartan tablets is a critical factor in ensuring their therapeutic efficacy. Potency refers to the strength of the active pharmaceutical ingredient (API) in the tablets, which should fall within an established specification range for the drug to be effective.

The potency of six brands of telmisartan tablets was evaluated, with all brands meeting the acceptable

potency range of 95-110% (Figure 4). Among all brands, brand F1 (100.8%) and brand F5 (99.9%) showed high consistency, while brand F6 (95.2%) was at the lower end of the acceptable range. Brand F3 (97.3%) also met the acceptable range, while brand F4 (96.0%), although compliant, was closer to the minimum threshold. Overall, the results are consistent with the observations of Sri *et al*. (2025) and demonstrate that all evaluated tablets conform to pharmacopeial standards, thereby substantiating their quality, reliability and appropriateness for therapeutic application (Sri *et al*., 2025).

Conclusion

The quality evaluation of the different brands of telmisartan tablets marketed in Bangladesh demonstrated that all brands complied with the pharmacopeial standards. The tablets exhibited acceptable weight variation, friability, hardness, disintegration time and drug release profiles. The drug content ranged from 95.2% to 100.8% and all brands showed drug release of over 75% within 45 minutes. These findings confirm that the tablets were manufactured to a satisfactory standard, ensuring their therapeutic efficacy and safety for hypertension management. Therefore, patients can confidently use these brands for effective treatment.

Conflict of interests

The authors declare that they have no conflict of interest regarding the publication of this paper.

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