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Evaluation of Quality Attributes of Commercially Available Domperidone Tablets in Bangladesh

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Abstract

This study aimed to evaluate the quality attributes of marketed 10 mg domperidone tablets available in Bangladesh, providing a comprehensive assessment of their pharmaceutical performance in line with British Pharmacopoeia (BP) standards. The study examined granule flow properties, including angle of repose, bulk density, tapped density, compressibility index as well as critical tablet characteristics such as weight variation, hardness, friability, thickness, diameter, disintegration, potency and dissolution behavior. Four branded tablets of renowned pharmaceuticals of Bangladesh and formulated tablets demonstrated compliance with BP specifications for weight, diameter and thickness indicating uniformity in size and consistent mass distribution. Mechanical strength and disintegration assessments revealed that all samples possessed sufficient hardness and moderate disintegration profiles, although some marketed tablets occasionally exhibited slightly lower hardness compared to formulated counterparts. Dissolution testing confirmed that all tablets released ≥75% of their active ingredient within 45 minutes, meeting BP requirements for immediate-release dosage forms. Potency analysis further indicated that the active pharmaceutical ingredient content ranged between 90% and 110% across all products, reflecting accurate dosing and reliable therapeutic potential. These results collectively affirm that both marketed and formulated 10 mg domperidone tablets fulfill pharmacopeial standards, supporting their safety, efficacy and suitability for patient use.

Key words: Domperidone maleate, quality control, dissolution, potency, tablet evaluation, comparative study.

Introduction

The domperidone is an antagonist of dopamine (D2 receptor) which is a benzimidazole-derived drug used as medication in the treatment of gastrointestinal (GI) motility abnormalities, functional dyspepsia, nausea and vomiting. As opposed to centrally acting antiemetics, domperidone has a more peripheral action due to lack of easy penetration of the blood-brain barrier. This property contributes greatly to the minimization of the side effects of extrapyramidal, which is safer in terms of therapeutic profile than other dopamine antagonists, e.g. metoclopramide (Reddymasu *et al.*, 2007).

The antiemetic effect combined with the mechanism of increasing motility in the gastrointestinal tract and gastric emptying, which is exhibited by the drug, make it of significance in various pathological disorders. Since domperidone is often administered as immediate-release tablets, and because pharmaceutical quality such as sufficient

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dissolution, disintegration and efficacy are paramount to its efficacy, pharmaceutical quality is also critical to the achievement of clinical efficacy (Barone, 1999).

There are a number of diseases that warrant the therapeutic use of domperidone. One of the key indicators is gastroparesis, either idiopathic, diabetic or postoperative. Gastroparesis patients are characterized by delayed gastric emptying and nausea, bloating, vomiting and early satiety, all of which seriously affect the quality of life (Stevens, 2013).

Domperidone is used to improve coordinated gastric contractions by blocking the peripheral dopamine receptors thereby increasing gastric transit without any central neurological effects. In the gastroesophageal reflux disease (GERD), domperidone enhances lower esophageal sphincter pressure and facilitates the emptying of the gastrointestinal tract, amplifying the effect of proton pump inhibitors (PPIs) on the illness. Secondly, domperidone has been employed in nausea caused by migraine, vomiting after surgery, chemotherapy, gastrointestinal dysfunction in patients with Parkinson and as a complement to agents that increase dopamine to avert nausea caused by levodopa (Smith *et al.*, 2012; MacGregor, 1993).

The use of domperidone goes even deeper to the use of domperidone in the pediatric GI motility disorders and lactation therapy. Domperidone has been found to be effective as a galactagogue in neonatal and postpartum care by raising the levels of prolactin and milk production; however, attention should be paid to safety monitoring when using this agent because of cardiac risks that increase with an increase in its dosage (Grzeskowiak *et al*., 2018; Paul *et al*., 2015). The worldwide regulatory attitude to domperidone varies due to the risk of it leading to the QT-interval lengthening and severe arrhythmias, especially when combined with a CYP3A4-inhibitor (Doggrell and Hancox, 2014). Formulation characterized optimization is, therefore, valuable to ensure that efficacy is achieved at the minimal effective dose and that the therapeutic delivery is consistent.

Regarding the pharmaceutical formulation, domperidone has various challenges because of its physicochemical profile. The drug is virtually insoluble in water, average lipophilic and light and moist sensitive. These properties have an effect on the behavior of granulation, compressibility and dissolution. This implies that the formulation should be developed with regard to the flow characteristics of the granules like angle of repose, bulk and tapped density and Carr index which would facilitate easy die filling during the tablet operation (Gao *et al.*, 2002). Un-good flow characteristics may result in variation of weight, lack of accurate dosage and quality of the tablet. The important quality parameters that need to be tested in regard to pharmacopeial standards after the manufacture of the tablets include weight variation, hardness, thickness, friability, disintegration, dissolution and potency (Nikam *et al*., 2025).

The comparison of laboratory and marketed domperidone oral tablets are also part of formulation performance evaluation. Differences in excipient, binder concentration, lubricant concentration and compression force have direct influence on the hardness, friability, disintegration and dissolution rate of the tablet. An example of this is that, over compression could lead to hard tablets that cannot disintegrate, but lack of sufficient lubrication can lead to tablets with friability issues. By comparing marketed tablets (which are usually industrialized by manufacturing processes) and laboratory-prepared equivalents, it is possible to find out the robustness of their formulations, the strategies to improve the flow of their granules and the potential to improve the development of in-house products (Mou *et al*., 2024).

An overview of the existing pharmaceutical and clinical data shows that domperidone is a potentially useful medication, especially when taken under controlled dosage. It equally exhibits consistent prokinetic and antiemetic effects in various GI and endocrine-associated diseases. Despite cardiac safety issues that require a careful prescription of the drug,

domperidone remains a preferred medication in most countries as it is efficacious and has a positive peripheral action profile. Its therapeutic efficacy is strongly associated with the formulation development, consistency during production and compliance with the pharmacopeial quality criteria to achieve maximum release and bioavailability of the drugs (Puoti *et al*., 2023).

The present study aimed to evaluate domperidone maleate formulated and marketed tablets as well as to ensure compliance with pharmacopeial standards.

Materials and Method

Materials

Sample collection: Domperidone API was provided by Beximco Pharmaceuticals Ltd. Marketed domperidone 10 mg tablets were procured from local pharmacies in Farmgate, Dhaka.

Equipment and apparatus: The study utilized various instruments and laboratory apparatus. Equipment included an Electronic Balance (ATY 224, Shimadzu, Japan), Vernier Caliper (Series 530, Mitutoyo, Japan), Tablet Hardness Tester (HT-50P, Thermonik, India), Friability Tester (Electro Lab, India), Tablet Disintegration Tester (VDTO-2, Electro Lab, India), Tablet Dissolution Tester (Electro Lab, India), UV-VIS Spectrophotometer (UV-1280, Shimadzu, Japan), Sonicator (Power Sonic-420, Hwashin Technology Co., Korea), and a pH Meter (pH 211 Microprocessor pH Meter, Hanna Instrument, Romania). Laboratory apparatus included test tubes and holders, beakers (100, 250, 500 mL), measuring cylinders, volumetric flasks (10, 50, 100 ml), mortar and pestle, spatula, glass rods, funnels, pipettes with pipette fillers, wax and filter paper, stopwatch, and UV Pyrex cells.

Methodology

Pre-formulation studies

Pre-formulation studies are conducted to evaluate the physical properties of the powder mixture and to assess its compatibility with other excipients.

Angle of Repose: Binder is used in powders, dried and sieved to enhance flow and compressibility.

$$\text{Angle of repose: } \theta = \tan^{-1}(h/r)$$

Bulk density: Bulk density displays the way powder is packed without being tapped.

$$\text{Bulk density} = (\text{Mass of powder})/\text{Bulk volume.}$$

Tapped density: Once taps have been made, decrease in volume means that it is able to compress the powder.

$$\text{Tapped density} = \text{Mass of powder} / \text{Tapped volume.}$$

Compressibility index: Carr's index shows the flow of powder; a high value shows a bad flow.

$$\% \text{ Compressibility} = 100\ (Dt - Di) / Dt$$

Preparation of tablets

Domperidone Maleate tablets were prepared by wet granulation of excipients (Lactose, maize starch, avicel PH 101) using povidone K30 as a binder, followed by incorporation of the drug (table 1), addition of lubricants (Magnesium stearate, talc) and compression into tablets using a single-punch machine.

Table 1. Ingredients and justification of formulated domperidone tablets.

Sl. No.	Ingredients	Amount for 1 tablet (mg)	Amount for 10 tablets (mg)	Justification
1	Domperidone maleate	10	100	API
2	Sodium starch glycolate	3	30	Super disintegrante
3	Purified talc	4	40	Glidant
4	Granules	180	1800	Excipients
5	Mg stearate	6	60	Lubricant

Weight variation test

A check of 20 tablets is carried out to make sure that there is uniformity; a deviation indicates variance between average weight and the tablets.

% Weight variation = (Individual weight − Average weight) / Average weight × 100

Diameter and thickness measurement

A digital Vernier caliper is used to measure the diameter and thickness of the tablets in order to provide a consistency in the dimensions. Average dimension = (Sum of all measurements) / Number of tablets

Hardness test

The strength of tablet crushing is determined to determine breakage resistance during handling.

Average hardness = (H1 + H2 + H3) / 3

Friability testing

The Roche Friabilator was used to conduct the friability test. Seven tablets in all were selected at random, weighed, and then subjected to four minutes of 25 revolutions per minute, or 100 total revolutions, of rotation in the friabilator. The friability is then calculated as a percentage by weighing the difference between the two weights.

% Friability = (Initial weight (W1) - final weight (W2)) × 100

Disintegration test

Tablets are disintegrated in a 37^0C disintegration apparatus to determine time of disintegration where water served as the immersion medium in the apparatus. Dissolution far below the pharmacopeial limit of uncoated tablet ≥15 minutes, which is a good performance. Each tube contained three tablets along with discs.

Dissolution test

One of the most important measures to bioavailability and therapeutic effect is the rate and extent of the drug to be released out of the tablet in a given media, which is a measure used in the dissolution test. USP apparatus 2 (paddle) at 50 RPM was utilized in 900 ml of 0.1 N HCl at 37± 0.5°C. Samples (10 ml) were taken at 5, 15, 30, 45, and 60 minutes and refilled with fresh medium to provide sink conditions. The absorbance of the sample was measured at XX nm using a UV spectrophotometer. Calculation of % drug release:

% Drug Release = (Cumulative amount released / Strength) × 100

Potency test

UV spectrophotometry involves the establishment of API concentration based on a standard calibration curve. Potency testing determines the amount of active pharmaceutical ingredient (API) present in the tablet, ensuring accurate dosing. Firstly, four tablets were weighed, and the average weight was calculated. Then tablets were crushed, and a portion equivalent to 10 mg of domperidone was dissolved in 100 ml of 0.1 N HCl. The solution was filtered, and then the absorbance was measured at 286 nm using a UV spectrophotometer. The potency was calculated using the formula:

% Potency = (Concentration × dilution factor × total weight × average weight) / (Sample taken × strength × 100)

Results and Discussion

Pre-formulation studies of formulated tablets

The pre-compression properties of the formulated granules were assessed to determine their flowability and compressibility. The angle of repose was found to be 38.66°, indicating fair to passable flow characteristics. The bulk density and tapped density were 0.50 g/ml and 0.69 g/ml, respectively, resulting in a Carr's Index of 27.5%, which suggests moderate compressibility. Table 2 shows the pre-compression properties of the formulated granules.

Weight variation

The table 3 on weight-variation presents the highest positive and negative percentage changes of samples A, B, C, and D, which gives an evaluation of uniformity in manufacturing. All of the samples were

within the pharmacopeial acceptance limit of ± 7.5% that signifies good control of the granules flowing and filling the die during compression. Sample A had the least variation and thus displayed the most uniformity and sample C recorded the most negative deviation indicating a relatively high variability in fill weight. Sample D had the most positive deviation though within reasonable ranges. All in all, the findings substantiate that all the batches had good weight consistency, which means that the dosage accuracy is reliable (Jakubowska and Ciepluch, 2021).

Table 2. Granule flow properties (formulated granules).

Sample	Angle of repose (°)	Bulk density (g/ml)	Tapped density (g/ml)	Carr's index (%)
Formulated	38.66	0.5	0.69	27.5

Table 3. Weight variation of marketed tablets.

Sample	Average weight (mg)	Max (+) % Deviation	Max (-) % Deviation
Sample A	189.60	1.630	-0.580
Sample B	190.73	1.505	-1.431
Sample C	132.50	1.887	-3.774
Sample D	125.80	2.544	-1.431

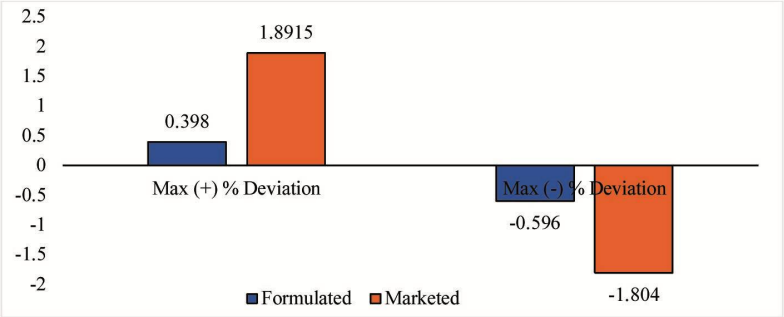

Figure 1. Comparison of % weight variation between formulated and marketed tablets.

The deviation rates (positive + 0.398 and negative -0.596) in the prepared tablets are considerably lower which means that there are better weight control and more regulated granulation and compression. Conversely, the variations are higher in the tablets sold in the markets (+1.8915 and -1.804), implying the presence of relatively more fluctuations in die filling or powder flow. Despite these differences, both the formulated and marketed tablets comply with BP standards, indicating reliable dosage accuracy, as depicted in figure 1.

Tablet diameter

The figure 2 shows the average diameter of the sold tablets in four samples where there are slight differences between batches. Sample A and B have a little bit bigger diameter (8.0 mm and 8.1 mm) than sample C and 7.1 mm (Sample D) which are within the acceptable pharmacopeial tolerance of dimensional uniformity.

These results show that there has been acceptable consistency in manufacturing without any noteworthy variance in the size of the tablets.

Comparison of the average tablet diameter reveals that the developed tablets (8.0 mm) are

marginally bigger than the tablets sold in the market (7.575 mm). Although this is a small difference, the two values are within pharmacopeial dimensional tolerance limits which mean that there is acceptable uniformity in the size of the tablet. This uniformity reflects good control of tooling and compression during the manufacturing of both formulations, as depicted in figure 3 (Lura *et al*., 2025).

Tablet thickness

The thickness profile of the sold tablets demonstrates hardly any change with the Samples A, B and D having an average thickness of 3.4 mm, whereas the sample C has a slightly higher value of 3.8 mm, as depicted in table 4. All the measurements are within pharmacopeial tolerance range of + -5% meaning that there is acceptable uniformity of thickness of the tablet in a batch to a batch. This uniformity indicates regulated compressibility and constant granule characteristics when being produced.

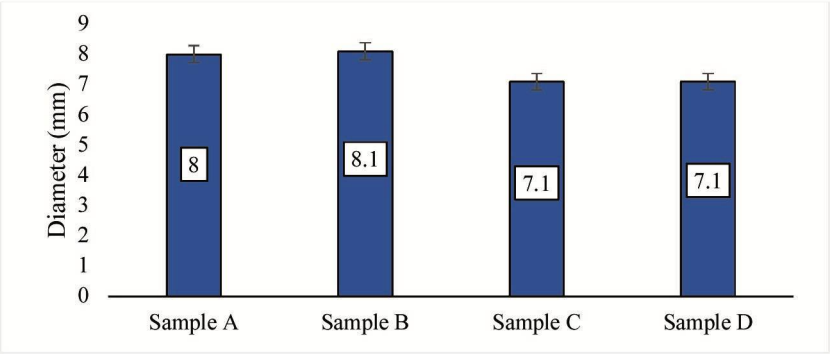

Figure 2. Diameter of marketed tablets diameter.

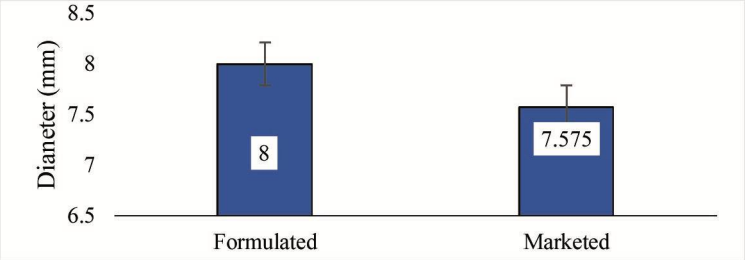

Figure 3. Average diameter of formulated and marketed tablets.

Table 4. Thickness of marketed tablets.

Sample	Average thickness (mm)
Sample A	3.40
Sample B	3.40
Sample C	3.80
Sample D	3.40

Comparison of the average thickness shows that the tablets formulated (3.0 mm) are a little thinner than the tablets available in the market (3.5 mm), as depicted in figure 4. Regardless of this disparity, the two values are within the acceptable pharmacopeial tolerance range, and it acts as an indicator of sufficient control of compression forces in the manufacturing process. This difference is probably due to the difference in the composition of formulation or the compression parameters of the two products.

Tablet hardness

The hardness profile of tablets sold indicates a gradual tendency of decrease among samples, with a starting hardness of 5.03 Kp in sample A and the ending hardness of 2.68 Kp in sample D. Whereas, samples A and B are within the pharmacopeial range of 4-10 Kp hardness, samples C and D are lower in value, indicating lower mechanical strength and perhaps increased vulnerability to fracture, as shown in table 5. The variation is an indication of inconsistencies in compression force or granule properties in the manufacturing process.

The comparison of the mean hardness indicates that the prepared tablets (4.52 Kp) have higher mechanical strength as compared to the commercial tablets (3.91 Kp). The designed batch fulfills the pharmacopeial hardness of 4-10 Kp requirement, but the batch on the market is slightly less than this. This implies high compression consistency and structural integrity of the formulated tablets as compared to the commercial product (Mou *et al*., 2024).

Table 5. Hardness of marketed tablets.

Sample	Average hardness (Kp)
Sample A	5.03
Sample B	4.45
Sample C	3.48
Sample D	2.68

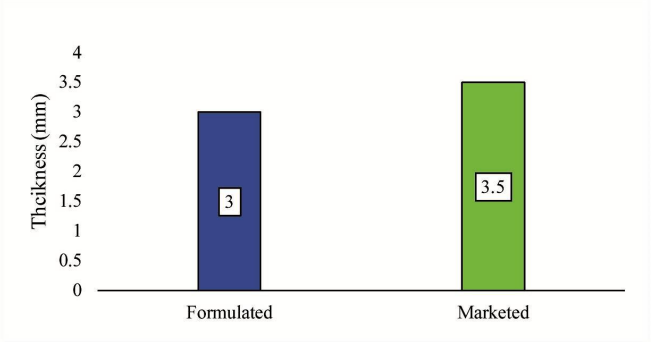

Figure 4. Average thickness of formulated and marketed tablets.

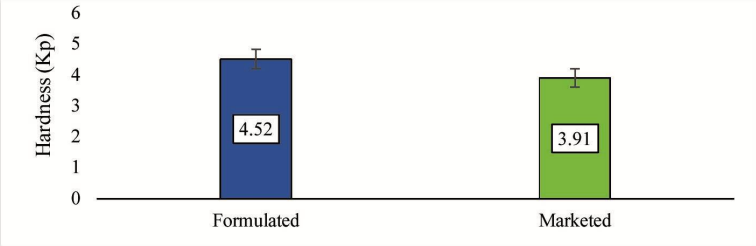

Figure 5. Average hardness of formulated and marketed tablets.

Tablet friability

The comparative friability study between the marketed Domperidone 10 mg tablets and the newly formulated tablets demonstrates a clear improvement in mechanical strength. The marketed tablets showed % friability values ranging from 0.40% to 0.70%, with an average of 0.55%, whereas the formulated tablets exhibited significantly lower friability, ranging from 0.18% to 0.25%, with an average of 0.21% (table 6). These results indicate that the formulated tablets are more resistant to abrasion and handling, while all values remain well within the BP/USP limit of ≤1%, confirming compliance with pharmacopeial standards. The low variability (SD 0.01) among formulated tablets also reflects consistent batch

uniformity, ensuring reproducible mechanical properties. Overall, the formulated domperidone tablets display enhanced friability performance compared to marketed brands, supporting their robustness for routine handling, packaging, and distribution.

Table 6. Comparison of friability among different brands with the formulated ones.

Tablet	Marketed Tablets % friability (Mean ± SD)	Formulated tablets % friability (Mean ± SD)
A	0.50 ± 0.01	0.21 ± 0.01
B	0.70 ± 0.02	
C	0.60 ± 0.01	
D	0.40 ± 0.01	

Disintegration time

The disintegration study of the marketed domperidone 10 mg tablets revealed some variability among the four samples, with disintegration times ranging from 21 ± 1.2 seconds (Sample C) to 52.67 ± 2.5 seconds (Sample A), as shown in figure 6. Despite this variation, all tablets disintegrated well below the BP/USP pharmacopeial limit for uncoated tablets (≥15 minutes), indicating satisfactory performance. The observed variability, reflected in the standard deviations, may be attributed to differences in formulation excipients, granule properties, or compression forces applied during tablet manufacture (Wood *et al.*, 2025). Overall, all marketed tablets demonstrate rapid and consistent disintegration, suitable for immediate-release performance.

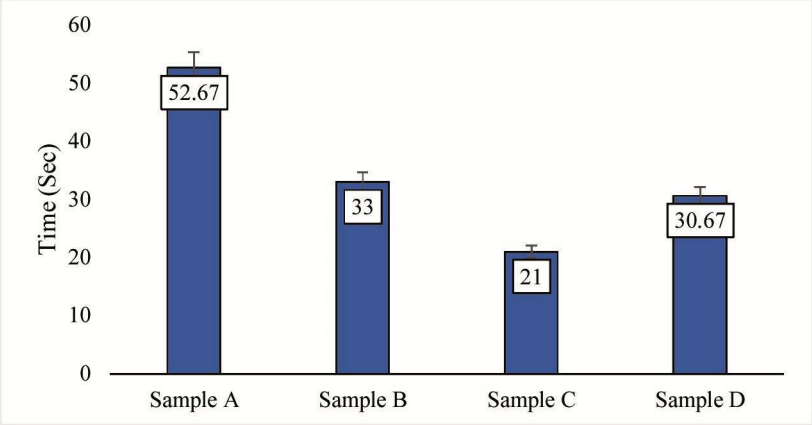

Figure 6. Average disintegration time of marketed tablets.

Dissolution profiles

Table 7 presents the dissolution profiles of four marketed domperidone 10 mg tablet samples (A–D). All samples showed a gradual release of the active ingredient over 60 minutes. At 5 minutes, Sample D exhibited the fastest initial release (61.50%), while sample A showed the slowest (45.52%). By 30 minutes, samples B and C achieved higher drug release (76.47% and 76.90%, respectively) compared to Samples A (66.25%) and D (67.61%). At 60 minutes, the cumulative drug release ranged from 81.00% (Sample D) to 92.85% (Sample C), indicating that all marketed tablets met pharmacopeial specifications of ≥75% drug release within 45 minutes. The differences in release rates may reflect variations in excipient composition, manufacturing processes, or tablet hardness among the marketed brands. Overall, the dissolution data demonstrate that the marketed tablets provide consistent and acceptable drug release profiles suitable for therapeutic use.

The general dissolution traces of a rapid initial release and a slow plateau suggest that most of the tablets are of first-order kinetics where the rate of release is determined by the remaining concentration of the drug (table 8). This predictable kinetic

behavior also enhances the predictability and reliability of the formulations marketed (Costa and Lobo, 2001). Figure 7 represents % drug release of 4 marketed drugs.

The dissolution of both the formulated and marketed tablets shown in figure 8 reveals that both medications have a good release profile and both exhibit over 75 percent drug release in 45 minutes, thus passing the pharmacopeial criteria of an immediate-release product. The prepared tablets exhibit slightly greater percentages of release at each point in time, which means a slightly increased dissolution efficacy. In general, both formulated and marketed tablets exhibit good and similar drug-release activity. The overall release data for formulated tablets followed 1st order kinetics where the R^2 = 0.988 and the release mechanism is dissolution controlled.

Table 7. Dissolution profile of marketed tablets.

Time (min)	Sample A	Sample B	Sample C	Sample D
0	0	0	0	0
5	45.52 ± 1.35	56.70 ± 0.52	56.86 ± 0. 68	61.50 ± 2.18
15	58.74 ± 2.10	65.72 ± 1.05	68.04 ± 1.81	64.03 ± 1.62
30	66.25 ± 1.56	76.47 ± 1.14	76.90 ± 1.65	67.61 ± 0.84
45	78.87 ± 0.85	83.44 ± 1.20	85.04 ± 0.54	76.23 ± 1.12
60	86.71 ± 0.97	90.80 ± 0.35	92.85 ± 1.21	81.03 ± 0.95

Table 8. Release kinetics of domperidone from different marketed brands.

Sample	Zero order	First order R^2	Higuchi R^2	Korsmeyer–peppas R^2	Hixson–crowell R^2	Best-fit model	Release mechanism
A	0.979	0.989	0.982	0.980	0.920	1st order	Dissolution-controlled
B	0.982	0.988	0.999	0.981	0.997	Higuchi	Diffusion controlled
C	0.979	0.991	0.978	0.986	0.972	1st order	Dissolution-controlled
D	0.976	0.988	0.966	0.834	0.921	1st order	Dissolution-controlled

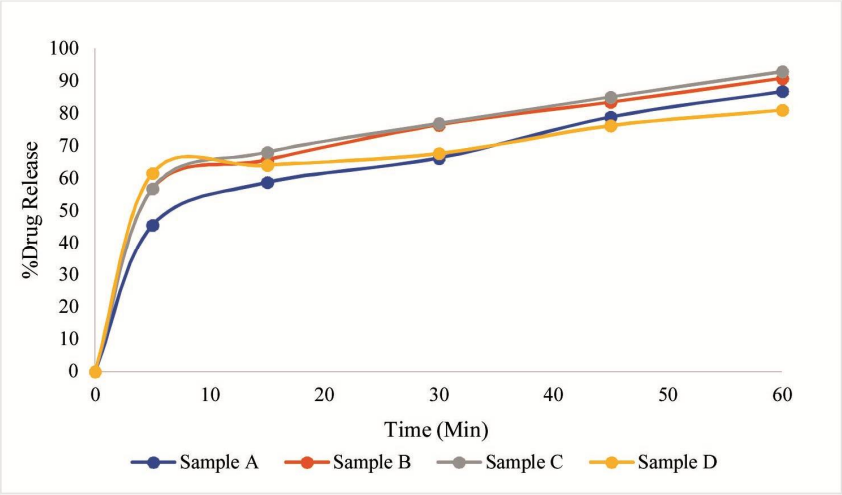

Figure 7. Average cumulative drug release of marketed tablets.

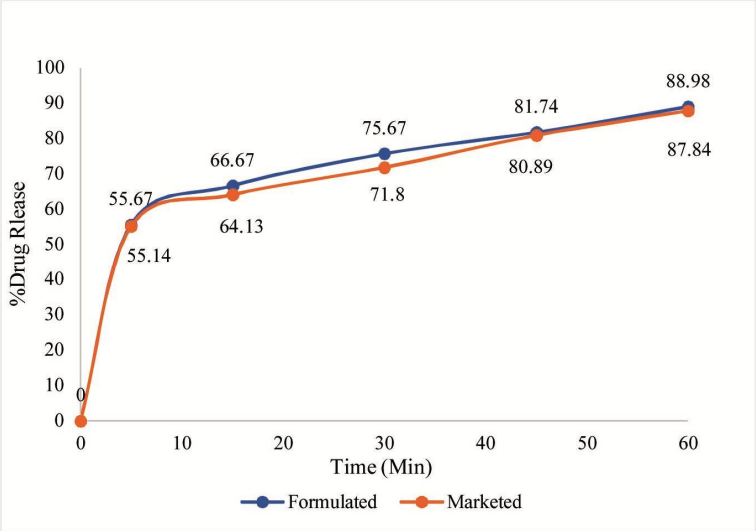

Figure 8. Average % drug release of formulated and marketed tablets.

Potency

The marketed tablets have satisfactory results of variability in their potency with a range of 94.11 to 103.96, as shown in figure 9. The samples are all within the pharmacopeial range of 90-110% which denotes that every lot of samples consists of the necessary amount of active pharmaceutical ingredient. The observed variation could be due to differences in the precision of the assay, composition of formulation or manufacturing controls, but the overall consistency of potency is satisfactory.

The formulated tablets showed a potency of 99.1%, while the marketed tablets exhibited a slightly lower potency of 97.94%, as shown in figure 10. Both values fall within the acceptable pharmacopeial limits, indicating that the active ingredient in both formulations is within the specified range.

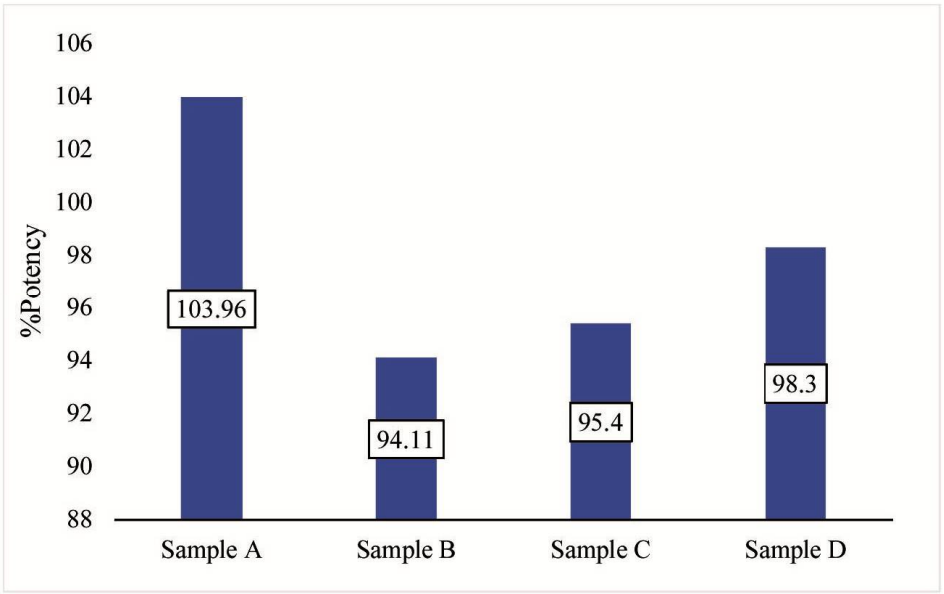

Figure 9. Average potency of marketed tablets.

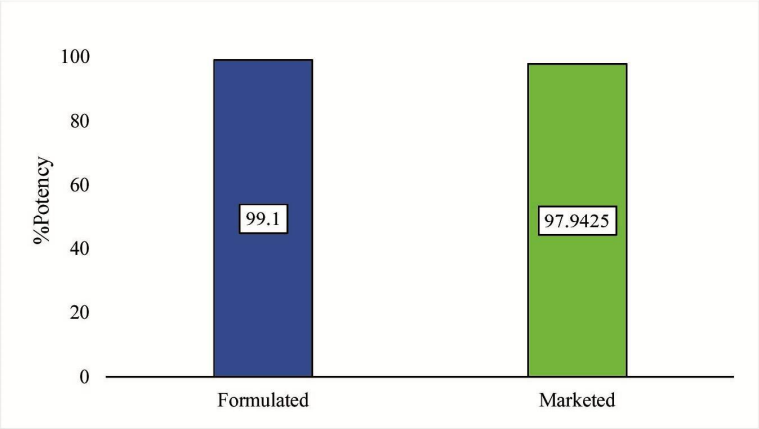

Figure 10. Average potency formulated and marketed tablets.

Conclusion

The potency study of the commercially available domperidone tablets showed decent consistency among all four samples with a range of assay values parameters of 94.11 to 103.96 being within the pharmacopeial specification of 90-110. The statistical analysis showed a mean of 97.94 and a standard deviation of 3.79 which shows that there is low to moderate variable condition between the batches. Sample A had a relatively high potency, but Sample B had the lowest value and the range of 9.85% is indicative of steady production. Such results indicate that marketed tablets have the right quantity of active pharmaceutical ingredient and a satisfactory potency reliability, which are in line with the required standards of quality.

The comparison of the formulated and commercialized tablets shows that there is a good and properly developed correlation between the hardness, disintegration time and drug-release performance. The hardness of the formulated tablets was higher (4.52 Kp) and thus the disintegration time was longer (77 seconds) compared to the commercial tablets that had a low hardness (3.91 Kp) and thus disintegrated quickly (34.33 seconds). This contraindication is in line with the known principles of pharmaceutics, when the greater the compression force, the harder the tablets become, which in turn makes them difficult to penetrate by the dissolution medium and delays the process of disintegration and subsequent extraction of the drug. Although these are physical differences, both formulations exhibited similar dissolution profiles with each formulation exceeding the pharmacopeial standard of ≥75% release in 45 minutes, which indicates that the two types of dosage forms perform well in the short-term. The similar dissolution profiles also confirm that the dissolution of most of the drug occurred at first order rate with the rate of dissolution dependent on the concentration and decreasing with time. So, to recapitulate, all the *in vitro* parameters of both formulated and branded tablets comply with the pharmacopoeial standard.

Conflict of interest

The authors declare no conflict of interest.

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