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In Vitro quality assessment of different brands of 10 mg domperidone tablets

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Abstract
Background: The aim of this study was to evaluate the pharmaceutical equivalence of different brands of Domperidone tablets available in local pharmacies of Visakhapatnam, Andhra Pradesh, India, and study their kinetics models.
Methods: Two different brands of Domperidone tablets were purchased from different pharmacies in Visakhapatnam. The quality control parameters of Domperidone tablets were evaluated for weight variation, friability, hardness, wetting time, disintegration, assay, and dissolution test. Difference (f1) and similarity (f2) factors were calculated to assess *in vitro* bioequivalence requirements. Finally, drug release kinetics were studied through model-dependent calculative methods (Zero order and first order).
Results: The results of assay, weight variation, friability, hardness, disintegration tests and dissolution of tablets complied with USP specification limits. The active pharmaceutical ingredients quantitative assay showed that all the brands of Domperidone tablets were between the 95% and 105% limit of the label claim met the range of f1 (0-15) and f2 (>50). All brands have good pharmacokinetics and bioequivalence.
Conclusion: This study revealed that all the Domperidone brands met the quality specifications of the tests performed. The study also indicated a similarity in the dissolution profile of the brands of Domperidone tablets. The pharmaceutical bioequivalence of Domperidone tablets has met their needed specifications.

Keywords: Domperidone tablets, pharmaceutical equivalence, bioequivalence, dissolution profile

Introduction
Domperidone is selected as the model drug which comes under the anti-emetic class. This drug is effective in all the categories of pediatrics, adults, and geriatrics. Domperidone blocks the action of dopamine. It has strong affinities for the D2 and D3 dopamine receptors, which are found in the chemoreceptor trigger zone (CTZ) located just outside the blood-brain barrier, which regulates nausea and vomiting [1].
Domperidone, a Benzimidazole derivative, is a BCS (Biopharmaceutical classification system) Class II drug because of its poor water solubility and high permeability. It is primarily absorbed from the stomach by active transport, after oral administration, and few side effects have been reported. Being a weak base, it has good solubility in acidic pH though in alkaline pH its solubility is significantly compromised. The biological half-life of Domperidone is short (7 hr) and thus favors the development of a sustained release dosage form. Its localization outside the blood-brain barrier has made it a suitable adjunct in the treatment of Parkinson's disease. It has fewer neurological side effects [2].
The list of some Domperidone-marketed tablets is given the Table no 1.

Table 1: Marketed Tablets of Domperidone (10mg)

S. No	Brand Name	Company	Dose
1.	Vomistop	Cipla	10 mg
2.	Domstal	Tourrent Pharmaceuticals Ltd.	10 mg
3.	Motilium	Janssen	10 mg
4.	Moperidona	Sidus	10 mg
5.	Vometa	Dexamedica	10 mg

Materials

Two brands of Domperidone tablets were purchased from the local market in Visakhapatnam, Andhra Pradesh, India, and pure Domperidone drug and all other chemicals were purchased from Yarrow Chemicals, Mumbai.

Equipment used: The following equipment was used for the quality assessment of Domperidone tablets. Single beam UV visible spectrophoto meter (Lab India, dual beam, UV-3200), analytical balance (ECO-STAR, BLP3/6002), Phmeter (Elico, L1120), Hardness tester (Monsanto), Friability tester (Hicon, Rochefriabilator, 103276), Disintegration apparatus (Hicon, H1-52010112) and Dissolution apparatus (Electrolab, TDT-06L).

Methods

The tablets were evaluated for various quality control parameters. The results were compared to standard pharmacopeias. The formulation details related to both brands of tablets are given in Table 2.

Table 2: List of selected brands of tablets

Code given	Brands	Company	Mfg. Date	Exp. Date	Formulation	Dose
DOMB1	Vomistop	Cipla	8/ 2024	9/2026	Tablet	10 mg
DOMB2	Domstal	Torrent pharmaceutical LTD	3/ 2024	8/2026	Tablet	10 mg

Quality control tests of different brands of Domperidone [4, 11]

Visual inspection: A visual inspection of the uniformity of shape and uniformity of color, no physical damage, the manufacturer's address, the manufacturing date, the expiry date, cracks, packaging, and labeling information were checked using the modified World Health Organization (WHO) checklist. The colour of domb1 and domb2 are yellow and white respectively.

Weight variation test

10 tablets were selected from each brand. The weight of each tablet was measured and an average weight of 10 tablets was measured. The percentage deviation was determined.

Percentage deviation = {(individual weight of each tablet-Averege weight of 10Tablets)/Average weight of 10 tablets} X100

Hardness

The Hardness of the tablets was determined by diametral compression using a Monsanto hardness tester.

Disintegration time

The disintegration time was measured using a disintegration test apparatus. One tablet was placed in each tube of the basket. The basket with the bottom surface made of a stainless steel screen (mesh no. 10) was immersed in a water bath at 37±20C. The time required for complete disintegration of the tablet in each tube was determined using a stopwatch.

Friability: The friability of the tablet was determined using Roche friability. This device subjects the tablet to the combined effect of abrasion and shock in a plastic chamber revolving at 25 rpm and drops a tablet at a height of 6 inches in each revolution. A pre-weighted sample of tablets was placed in the friability and subjected to 100 revolutions. Tablets were de-dusted using a soft muslin cloth and reweighed. The friability

F = [(W initial – W final)/ W final] 100

Wetting time

The wetting time of the tablets can be measured using a simple procedure. Five circular tissue papers of 10 cm diameter are placed in a Petri dish with a 10 cm diameter. Ten millimeters of water-containing Eosin, a water-soluble dye, is added to the Petri dish. A tablet is carefully placed on the surface of the tissue paper. The time required for water to reach the upper surface of the tablet was noted.

Water-absorption ratio

For measuring the water-absorption ratio, the weight of the tablet before keeping it in the Petri dish was noted (Wb). The wetted tablet from the Petri dish was taken and reweighted (Wa). The water-absorption ratio, R can be determined according to the following equation:

R = 100 (Wa – Wb)/Wb.

Dispersion time: Tablet was added to 10 ml of 0.1N HCl at 37±0.5oC. The time required for the complete dispersion of the tablet was measured

Assay

The Domperidone tablets were analyzed by following the method

Ten Tablets were crushed in a mortar and transferred to a 100 ml flask. The powder equivalent to 10 mg was transferred to a 100 ml volumetric flask and dissolved in a minimum amount of ethanol, then the volume was made up to 100 ml using 0.1N HCl. The samples were analyzed by validated UV spectrophotometric method at ʎ max 284 nm. The results are given in the table.

Dissolution study

The release rate of Domperidone from selected brands of tablets was determined using United States Pharmacopoeia (USP) XXIV dissolution testing apparatus II(Paddle method). The dissolution test was performed using 900 ml of 0.1 N HCl (pH=1.2), at 37±0.50C and 50 rpm. A sample (10 ml) of the solution was withdrawn from the dissolution apparatus at 0, 5, 10, 15, 20, 25, and 30 min. The samples were replaced with fresh dissolution medium of the same quantity. The absorbance of these solutions was measured at 284 nm using a Shimadzu UV-1601 UV/Vis double-beam spectrophotometer. Cumulative percentage of drug release was calculated and the data fitted into various kinetic models. The results are given in Table 6.

Comparison of dissolution profiles [3]: The similarity factor (f2) method is a mathematical model that compares the similarity of two dissolution profiles. It's used to assess the quality and performance.

The formula to calculate the similarity factor is

$f2 = 50. \log\{[1+1/n \sum t=1 (Rt-Tt)2\ n\ ]- 0.5\ \}100$

Rt=Percent drug release of reference product at time t
Tt =Percent drug release of test product at time t
n= no of time points

Results and Discussion [3, 12-18]

Evaluating the quality of marketed products is necessary to reduce the risk of having poor-quality medicine in the supply chain. In this work, we assessed the quality of two local brands of Domperidone 10 mg tablets. The two brands were subjected to various quality control tests and also for pharmaceutical equivalence of the products.

Visual inspection: The physical inspection of the two brands has revealed that brand 1 and brand 2 are in color and did not have any odor. The labeling and packaging of the two brands indicated that the tablets did not show any signs of falsely labeled, falsely packed, or falsified products.

Table 4: Results for evaluation tests of marketed Domperidone tablets

Parameters	Domb 1	Domb2
Weifht Variation	5.8%	6.1%
Friability	<1%	<1%
Hardness	4 kg/cm^2	4 kg/cm^2
Tablet Thickness	3 mm	3 mm
Wettinf Time	20 sec	50sec
Dispersion Time	1min	1 min 30 sec
Disintegration	1 min 30 sec	5 min
Assay	98%	101%

An average weight of 20 tablets of the two different brands lies within the range of 70-100 mg. The weight variation of all other tablets lies within the acceptable range (±7.5% for tablets that weigh above 130 mg) as described in USP. Drug content for brand 1 is 98% and for brand 2 is 101% (95-105%). Disintegration time for brand 1 is 1min 30sec and brand 2 is 5min compendium states that uncoated and plain-coated tablets should disintegrate within 30 min. The dispersion time for both brands lies within the range.

Table 5: Standard curve for domperidonein 0.1N HCl

Concentration (µg/ml)	Absorbance
0	0
10	0.3897
15	0.497
20	0.6181
25	0.823
30	0.9676

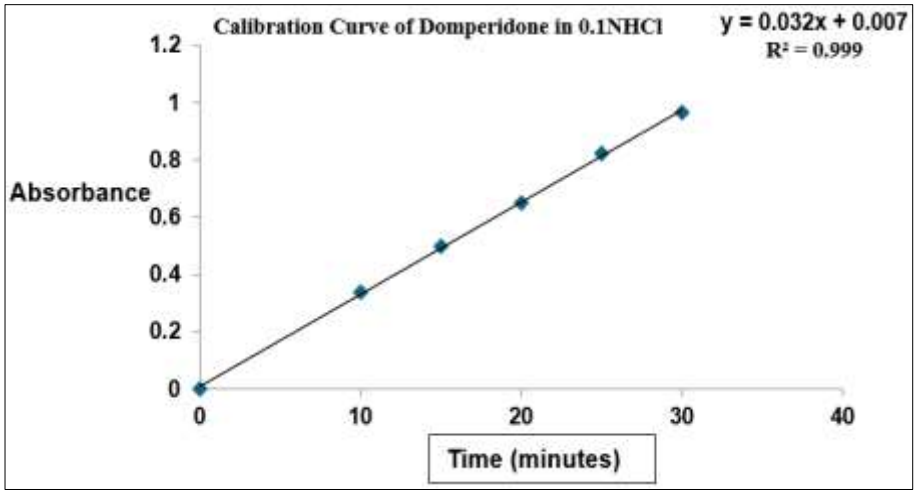

Fig 1: Calibration curve for Domperidone

The calibration curve for Domperidone was constructed in 0.1N HCl by measuring the absorbance of different concentrations of Domperidone 10,15,20,25 and 30 µg/ml in a UV visible spectrophotometer at lambda max 289 nm. The absorbance increases with an increase in concentration and the results are given in Table 4. The curve obtained is a straight line with Linear regression equation y = 0.032x + 0.007 and r2 value of 0.999 and is shown in figure 1.

Table 6: % CPD values of selected brands

Time	DOMB1	DOMB2
0	50±1	58±0.8
5	65±0.8	63±0.4
10	72±0.5	75±0.5
15	80±0.4	83±0.9
20	86±0.9	85±0.7
25	92±0.6	90±0.4
30	95±0.7	93±0.6

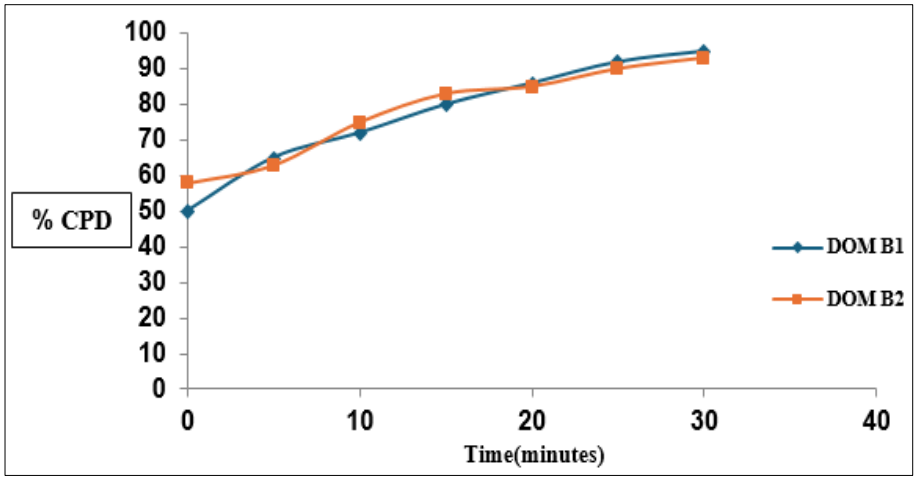

Fig 2: Zero Order Curve

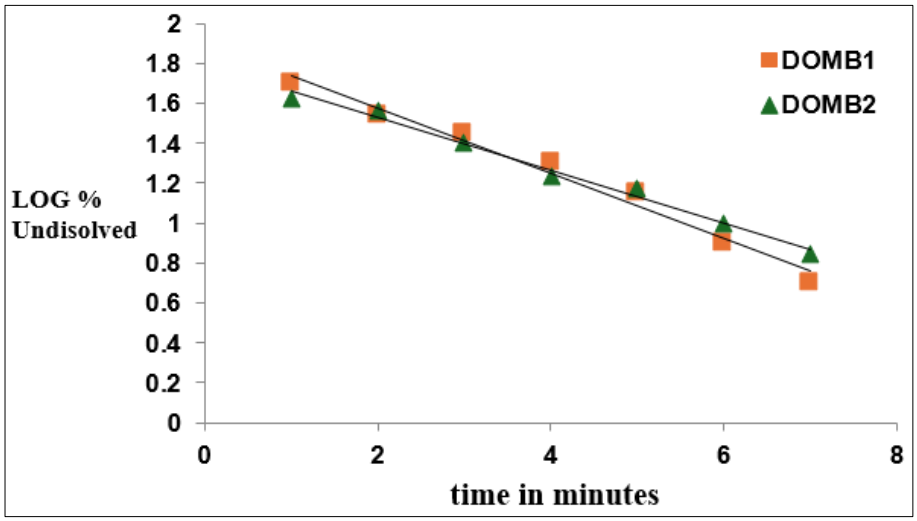

Fig 3: First order curve

Table 7: r^2 values for zero and first order curves

R2	DOMB1	DOMB2
First Order	0.981	0.986
Zero Order	0.957	0.947

The dissolution was performed in a USP Type 2 dissolution apparatus for up to 30 minutes. The results of dissolution studies are given in Table 6. The dissolution data was fitted to various pharmacokinetic models and based on r2 values the drug release follows the first order indicating the drug release depends on concentration.

Comparison of dissolution profile

A model-independent approach was used to compare the dissolution profiles of two different brands. The similarity factor (f2) was calculated by comparing the dissolution profiles of the two brands. The f2 value was found to be 53.75 and it indicated that both the brands were pharmaceutically equivalent. The results indicated to promotion of the interchangeability of the products to achieve the desired therapeutic effect.

Conclusion

The present study revealed that both the brands of Domperidone 10 mg tablets met the quality control tablets as per pharmacopoeial specifications and could be used both brands interchangeably to achieve a desired therapeutic effect.

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