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ORIGINAL CONTRIBUTION

In vitro assessment of pharmaceutical equivalence and analysis of drug release kinetics of Domperidone 10mg tablets available in Bangladesh market

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ABSTRACT

Background: The aim of this study was to evaluate the pharmaceutical equivalence of different brands of Domperidone tablets marketed in Bangladesh and study their release kinetics model.

Methods: Five different brands of Domperidone tablets were purchased from different pharmacies from Dhaka, Bangladesh. The quality control parameters of domperidone tablets were determined by identification, weight variation, disintegration, assay and dissolution tests and the results were compared with USP and BP pharmacopoeia standards. Difference (f_1) and similarity (f_2) factors were calculated to assess in vitro bioequivalence requirements. Finally, drug release kinetics were studied through model-dependent calculative methods.

Results: The results of assay, weight variation and disintegration tests indicated that all samples 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 f_1 (0-15) and f_2 (>50). All brands best fitted in Korsmeyer-Peppas model indicating diffusion mediated release and also shown low AIC in Hixson-Crowell model assuming the release governed by velocity of dissolution.

Conclusion: This study revealed that all the domperidone brands met the quality specification of weight variation, disintegration, assay and dissolution. The study also indicated similarity in the dissolution profile of the brands of domperidone tablets with the reference product. Hence, selected generic brands could be substituted with the reference product in clinical practice.

Keywords

Domperidone 10mg Tablet, *In vitro* Dissolution, Drug Release Kinetics, Pharmaceutical Equivalence

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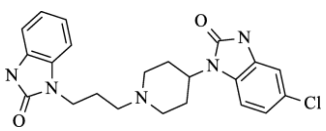
INTRODUCTION

Dissolution testing is a quantitative and qualitative technique that assesses how efficiently a drug is released from its dosage form [1]. Dissolution profiles play a key role in evaluating the impact of formulation composition and other process parameters on the bioavailability of the drug. However, dissolution study is incomplete without its validation, which ensures consistency and accuracy with repeated results. In manufacturing, dissolution test is routinely performed as a requirement of quality control (QC) release test to ensure batch-to-batch consistency. It is also a part of regulatory requirement to apply for a waiver of *in vivo* bioequivalence studies [2,3].

Domperidone, a benzimidazole derivative, is classified as a BCS (biopharmaceutical classification system) Class II drug because of its poor water solubility and high permeability [4]. 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 development of a sustained release dosage form [5-7]. Its localization outside the blood-brain barrier has made it a suitable adjunct in the treatment of Parkinson's disease. Recently, there has been renewed interest in prokinetic agents like Domperidone since the withdrawal of cisapride from the market [8]. Domperidone is a great alternative to metoclopramide for treatment of upper gastrointestinal motility disorders because it has fewer neurological side effects [9].

The present study was performed to evaluate the commercially available domperidone tablets in Bangladesh for pharmaceutical equivalence using in vitro dissolution techniques. In order to claim a branded version bioequivalent with reference brand, it must contain the same amount of API and there should not be any significant different in their bioavailability. The bioavailability of a drug depends on two parameters-solubility and permeability, hence drug dissolution is important for assessing bioequivalence.

Table 1: Product Information

Product Name	***Domperidone***
Molecular Weight	315.71 g/mol
Molecular Formula	$C_{26}H_{28}ClN_5O_6$
Chemical Structure	

METHODS

Drugs and Chemicals

Four brands of domperidone 10mg tablets (DOM1, DOM2, DOM3 and DOM4) were purchased from local pharmacies in Dhaka, Bangladesh and compared with the market leader brand (DOMR). The brands were randomly coded so as to avoid unethical marketing practice. The samples were checked for their manufacturer license no., DAR No., batch number, manufacturing and expiry dates and physical appearance.

Table 2: List of Brands of Domperidone 10mg tablets used *in vitro* analysis**.**

Brand Code	***MFG. Country***	***Batch No.***	***MFG. Date***	***EXP. Date***
DOMR	Bangladesh	SEB019	FEB21	JAN23
DOM1	Bangladesh	19021	AUG19	JUL21
DOM2	Bangladesh	000151	DEC20	DEC22
DOM3	Bangladesh	1095320	JUL20	JUL23
DOM4	Bangladesh	0L00967	NOV20	OCT22

Standard API of Domperidone was obtained from Sigma-Aldrich. Methanol (RCI LABSCAN Limited, Thailand) and Acetonitrile (SAMCHUN, Korea) used in the experiments were of HPLC grades.

Instruments and Devices

BK-RC3 Dissolution Tester (Biobase, China), BK-BJ2 Disintegration Tester (Biobase, China), BA2004N Analytical Balance (Biobase, China), BK-UV 1800 Spectrophotometer (Biobase, China), PH-10S pH Meter (Biobase, China), UC-20A Water Bath Sonicator (Biobase, China) were used for the experiments.

Instrument Calibration and Method Validation

A half-yearly internal calibration was performed on a routine basis following the recommended procedures as stated by the United States Pharmacopoeia (USP) as per the General Chapter <711> [10] to establish the control on absorbance and wavelength, stary light limit, photo-metric linearity, resolution power and appropriateness of baseline and sample cells. USP Prednisone Tablets RS and USP Prednisone RS served as the reference standard. The

Table 3: Specifications for calibration.

Parameters	***Specifications***
Medium	Degassed purified water
Volume	500 mL
Rotation Speed	50 rpm
Bath Temperature	37 ± 0.5 °C
Time Point	30 minutes
Absorbance Wavelength	242 nm

dissolution test was carried out according to the specifications mentioned at Table 3. The release of the reference drug was assessed through spectrophotometer. Alongside, the dissolution method was validated for domperidone 10mg tablet with official medium (hydrochloric acid, HCl) by the spectrophotometer at 286 nm using 10 mm quartz cell. The method was performed according to ICH Q2 (R1) guideline [11]. The following criteria was met to validate the spectrophotometric method as described at Table 4.

Table 4: Method validation report summary.

Validation parameters	***Acceptance criteria***		***Results***
System suitability & Specificity	RSD (%) of five replicate absorbance of standard should be ≤ 2.0		≤ 2.0
	Interference of diluent and placebo		No interference
Linearity	R^2 value should be ≥ 0.999	50%, 100%, 125% 150% and 200% (0.01 mg/mL as 100%)	0.999
Accuracy	Average Recovery (%) of three sample at each recovery level should be within 98.0 to 102.0	50% (0.005 mg/mL)	100.8
		100% (0.01 mg/mL)	99.1
		150% (0.015 mg/mL)	99.5
Precision	RSD (%) six tablets after 45 min should be ≤ 2.0		1.6
Intermediate precision	RSD (%) six tablets after 45 min in different day with different analyst should be ≤ 2.0		1.8
	RSD (%) 12 tablets of both Precision Intermediate precision should be ≤ 2.0		1.5
Filter Compatibility	There should be no interference of filter paper		Filter paper did not adsorb the active.

Where, RSD is relative standard deviation.

Construction of Standard Curve

A stock solution of domperidone (1mg/mL) was prepared in methanol. The stock solution was then diluted with dissolution media to prepare working solutions just before use (0.005 – 0.02 mg/mL). Domperidone concentration was analyzed by UV-spectrophotometer.

Assay

Ten domperidone tablets were weighed and powdered. Sufficient methanol was added to produce a solution containing 0.02% Domperidone, followed by sonication for 20 minutes. The mixture was filtered using Whatman filter paper. 1ml of 0.1M HCl was added to 50ml of the filtrate and sufficient water was added to make a 100ml solution. The sample was analyzed by UV/Vis spectrophotometer at 286 nm [9].

Weight uniformity

Twenty tablets were randomly selected and weighed individually using an analytical balance. The individual weights were compared with the average weight for determination of weight variation [12].

Disintegration test

USP disintegration apparatus was used for this test. Six tablets from each brand were placed in the tube in the basket rack containing 900ml distilled water at 37 ± 2 °C. As per the USP-NP standards, the time required for all the tablets to pass through the 10-mesh screen was recorded [13].

Dissolution test

USP type II apparatus was used to perform the *in-vitro* dissolution study. The official dissolution media was 900 ml of 0.01 N HCl, which was maintained at 37 ± 0.5 °C and 75 RPM. In each five minutes time interval up to 45 minutes, 10 ml of dissolution sample was withdrawn from every vessel and simultaneously replaced with the equal volume of fresh dissolution media. Collected samples were filtered through #41 Whatman filter paper and assayed, for determination of released Domperidone concentrations, by a UV–VIS spectrophotometer against a blank at 286 nm [14].

Model-Independent Fit Factors

Dissolution profiles of sample products were compared with the reference product using fit factors. While the difference factor (f_1) measured the difference in percentage between the sample and the reference drug at each time point, the similarity factor (f_2) expressed the closeness between the two curves using the formula (1) and (2) respectively [15]:

$f_1 = \{[\sum_{t=1}^{n}|R_t - T_t|]/[\sum_{t=1}^{n} R_t]\} \times 100$ ..... (1)

$f_2 = 50.\log\left\{\left[1 + \frac{1}{n}\sum_{t=1}^{n}(R_t - T_t)^2\right]^{-0.5}\right\} \times 100$..... (2)

where, n is the number of time points, R_t is the dissolution value of reference product at time t and T_t is the dissolution value for the test product at time t.

f_1 score within 0 to 15 signified the standard difference between the two curves whereas f_2 value above 50 represents the equivalence between test samples and reference drug [16-18].

As indicators of efficient control of drug release, mean dissolution time (MDT) and dissolution efficiency (DE) were determined using the following formula (3) and (4) respectively [15,19]:

$$MDT = \frac{\int_0^{W\infty} t.\ dW\ (t)}{\int_0^{W\infty} dW\ (t)} \quad \text{..... (3)}$$

Where, *W(t)* is the cumulative amount of drug dissolved at time t.

$$DE = \frac{\int_0^t y.\ dt}{y_{100}\ (t_2 - t_1)} \times 100 \quad \text{..... (4)}$$

Where, *y* is the percentage of dissolved product. DE is the area under the dissolution curve between time points t_1 and t_2 expressed as a percentage of the curve at maximum dissolution, y_{100}, over the same time period.

Model-Dependent Dissolution Kinetics

In vitro drug release kinetics and release mechanism were investigated using various mathematical kinetic models which described dissolution of drug from solid dosage forms [20]. From the analysis of dissolution data, drug release kinetics were studied through several dependent models, such as zero-order, first-order, Hixson-Crowell's cube root law, Higuchi's square root equation and Korsmeyer-Peppas model. Coefficient of determination (*R*2), adjusted *R*2, and Akaike information criterion (AIC) were deduced from the best fitting equation [21]. The lowest AIC and highest *R*2 adjusted values were considered the best-fit model [22].

Zero-order kinetics: $Q_t = Q_0 + K_0 t$

First-order kinetics: $\log Q_t = \log Q_0 - K_1 t/2.303$

Higuchi model: $Q_t = K_H t^{1/2}$

Korsmeyer–Peppas kinetics: $Q_t/Q_0 = Kt^n$ $Q_t/Q_0 = K_{kp} t^n$

Hixson-crowell model: $Q_0^{1/3} - Q_t^{1/3} = K_{HC} t$

where, K_0, K_1, K_H, K_{HC} and K_{kp} indicates zero-order, first-order, Higuchi, Hixson-crowell and Korsmeyer–Peppas rate constants respectively, Q_t/Q_0 means fraction of drug released at time t, K means rate constant and n means release exponent.

Statistical Analysis

Data were presented as mean ± standard deviation, calculated mathematical parameters using DDSolver (add-in for Microsoft Excel), analyzed statistically through one-way analysis of variance (ANOVA), followed by Dunnett's t-test by using SPSS 24 for windows. The obtained results were compared with the reference drug. $p<0.05$ were considered as statistically significant.

RESULTS & DISCUSSIONS

The granulation process ensures that all tablets are similar in weight and have uniform drug content, since it is correlated to granules' flow [14]. Table 5 shows the relative standard deviation (RSD) in weight variation, disintegration time and assay results for all the brands.

Table 5: Summary of quality attributes of Domperidone 10mg tablets

Brand Code	*Weight variation (RSD)*	*Disintegration Time (sec.)*	*Assay %*
DOMR	2.29	70 ± 3.58	99.1
DOM1	1.13	20 ± 2.71	100.6
DOM2	1.84	60 ± 2.39	102.6
DOM3	2.02	49 ± 1.86	101.7
DOM4	0.97	27 ± 3.07	101.3

An average weight of twenty tablets of the different brands was found in the range of 139-190 mg. Apart from brand, the weight variation of all the other tablets were within the acceptable range (±7.5 % for tablets that weigh

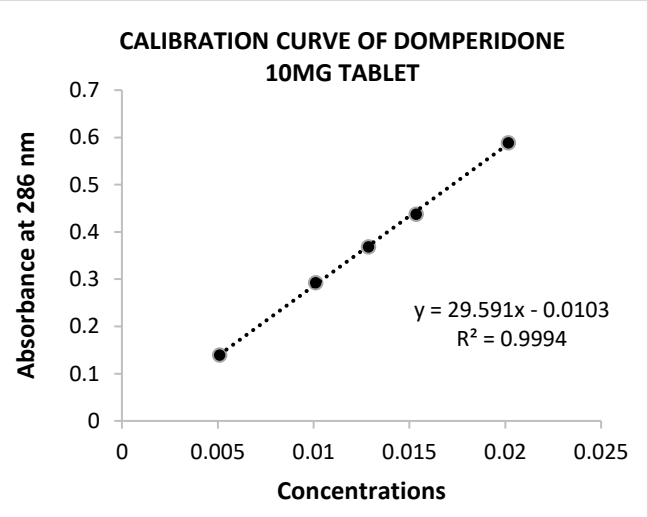


Figure 1: Calibration curve of domperidone 10mg tablet. Where, concentrations applied in mg/mL unit. Absorbance pattern was evaluated in linear regression.

above 130mg) as described by USP and the SD was less than 2.0, which indicates acceptable flow of the granules [23]. Drug content was found in the range of 99.1%-102.6% (95.0-105.0%). Disintegration times of all tablet formulations were within the acceptable limit. USP compounding compendium states that uncoated and plain-coated tablets should disintegrate within 30 min.

Dissolution Profiles

According to USP, solid oral dosage forms should exhibit 85% dissolution in 60 minutes [24]. Figure 2 showed the result of the dissolution test of domperidone tablets were within the specification of pharmacopoeia. Almost all the brands released more than 85% of API within 15 minutes.

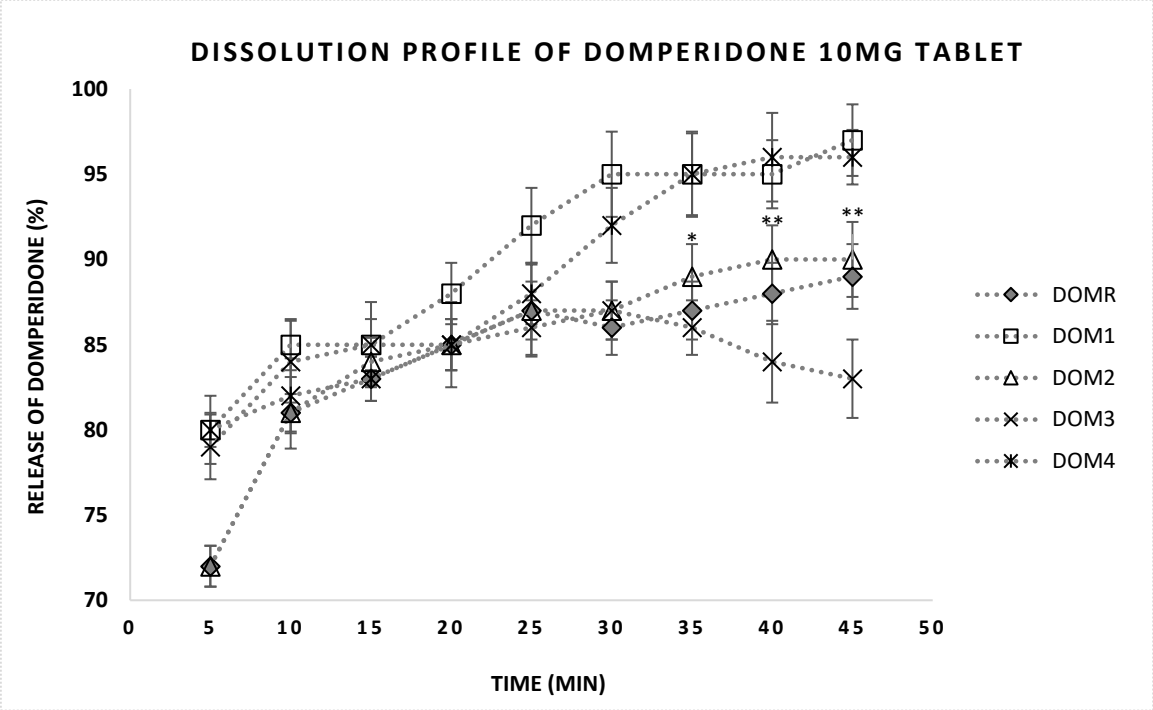


Figure 2: Comparative dissolution profile of Domperidone 10mg tablets between reference brand and sample products. Data were presented as mean ± standard error mean. Drug release profiles (% dissolution) of brands (DOM 1-4) (n=6) were analyzed in 5 minutes intervals up to 45 minutes and compared with the reference brand DOMR. *, ** means $p<0.05$, 0.01respectively.

Comparison of dissolution profiles by model-independent method

Dissolution is considered an important tool to predict in vivo bioavailability and has been used to prove bioequivalence to allow interchangeability. Very often USFDA considers dissolution testing to be more discriminating than an in vivo test. The difference factor *(f_1)* is proportional to the percentage (%) difference between the two profiles at each time point and is a measurement of the relative error between the two curves, whereas the similarity factor *(f_2)* is a logarithmic reciprocal square root transformation of the sum of squared error and is a measurement of the similarity between the two curves [25].

For curves to be considered similar, f_1 values should be close to 0, and f_2 values should be close to 100. Generally, f_1 values up to 15 (0-15) and f_2 values greater than 50 (50-100) ensure sameness or equivalence of the two curves

Table 6: Calculated difference factor *(f_1)*, similarity factor *(f_2)*, dissolution efficiency (DE) and mean dissolution time (MDT) for all Domperidone 10mg tablets.

Samples	*f_1*	*f_2*	*DE*	*MDT*
DOMR	-	-	84.6	4.9
DOM1	7.12	59	82.9	5.6
DOM2	0.92	91	84.4	5.0
DOM3	1.06	76	90.8	1.8
DOM4	5.15	62	82.1	6.0

and, thus, of the performance of the test (postchange) and reference (prechange) products [17,18]. If the f_2 value was less than 50, then the dissolution profiles were considered significantly different [26]. Similarity test has been used frequently for in vitro bioequivalence studies by comparing the dissolution profiles of different brands of pharmaceutical dosage forms with the reference product. However, one disadvantage of this method is the dependency on the dissolution profile length. Nevertheless, USFDA has adopted it for in vitro

dissolution release profile comparison. Since the value of f_2 is greater than 50 for all brands, it can be concluded that these products show similar dissolution to that of reference brand. In comparison DOM2 showed highest f_2 and lowest f_1 values indicating best match with reference.

The similarity between the sample brands and reference brand were also assessed by studying DE and MDT where the sample products were considered similar if the obtained values fell within 10% variation (±) from the reference drug [17,27]. It can be observed from Table 6 that all four test brands closely met the requirement in DE and MDT outputs except for brand DOM3 which resulted in a lower MDT (1.8) than that of DOMR (4.9), indicating DOM3's lower drug retaining ability of the polymer [28].

From the analysis of model-independent methods, it can be summarized that all the brands successfully met the equivalence criteria with the reference brand and thus can be considered interchangeably for prescribed use.

Table 7: Comparison of release profiles by R^2, slope and AIC determination.

Model	*Parameters*	*DOMR*	*DOM1*	*DOM2*	*DOM3*	*DOM4*
Zero order model	R^2	0.5108	0.5183	0.5164	0.4434	0.4942
	Slope (K_0)	2.0857	2.2286	2.1071	1.9714	2.1071
	Intercept (AIC)	39.286	41.571	39.250	42.714	41.250
First order model	R^2	0.685	0.8177	0.7014	0.5603	0.7264
	Slope (K_1)	-0.0238	-0.0343	-0.0245	-0.0217	-0.0272
	Intercept (AIC)	1.6987	1.7045	1.7006	1.6311	1.6865
Higuchi model	R^2	0.7877	0.7857	0.7923	0.7263	0.7636
	Slope (K_H)	14.885	15.769	15.000	14.501	15.053
	Intercept (AIC)	19.066	20.437	18.955	22.112	20.772
Korsmeyer-Peppas model	R^2	0.8611	0.8505	0.8650	0.8045	0.8297
	Slope (K_{kp})	56.683	59.752	57.083	55.579	57.143
	n	0.315	0.334	0.412	0.396	0.339
	Intercept (AIC)	13.474	14.811	13.357	16.300	15.296
Hixson-Crowell model	R^2	0.6196	0.7069	0.6317	0.5126	0.6352
	Slope (K_{HC})	0.0591	0.0743	0.0603	0.0545	0.0638
	Intercept (AIC)	0.8781	0.9149	0.8750	1.0231	0.9274

Where, r^2 is regression coefficient, slope refers the release rate constant (K), n is the diffusion coefficient and intercept refer the Akaike Information Criteria (AIC).

Comparison of dissolution profiles by model-dependent method

From the assessment shown in Table 7, it was observed that all the test brands fitted well to the Korsmeyer-Peppas model. The best linearity was obtained in this model with highest r^2 values which indicated that the drug release was diffusion controlled [7]. This model is generally of use in analyzing the release of pharmaceutical exponents, indicated for polymeric dosage forms in case the release pattern is not well known or multiple release phenomena is associated [29]. Moreover, the values of dissolution coefficient (n) were found below 0.45 for all brands which implied that the release pattern was predominantly Fickian diffusion (case I) [7]. However, considering the lowest AIC, all drugs also fitted to the Hixson-Crowell model. This model assumes that the release mechanism is mainly governed by the velocity of dissolution and less by the diffusion through the matrix [30]. Hixson-Crowell equation is used to interpret the dissolution data of dispersible or immediate release dosage formulations. Therefore, a higher correlation coefficient indicates that change in surface area and diameter of particles during the process of dissolution have an effect on drug release [31]. From the kinetic release analysis, it can be confirmed that all domperidone sample brands along with the reference brand demonstrated a similar release pattern.

The results obtained in this study indicate that all brands of Domperidone (10mg) tablets, complied with the USP specifications and can be considered equivalent to the reference product. It can be assumed that these dosage form may have similar bioavailability.

Conclusion

The results of this study clearly demonstrated that all the leading brands of domperidone selected from Bangladesh market comply with the criteria laid in the official monograph. Since dissolution test is a critical part of quality control so all pharmaceutical products must meet this quality parameter to be therapeutically effective. The data obtained in this study indicates that all sample brands can be considered bioequivalent with the reference market leader brand. However, further *in vivo* test is needed to support this statement.

Abbreviations

USP: United States Pharmacopoeia; BP: British Pharmacopoeia; DAR: Drug Administration Registration; USFDA: United States Food and Drug Administration; API: Active Pharmaceutical Ingredient; AIC: Akaike Information Criteria.

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Authors' Contributions

This work was carried out in collaboration between all authors. Authors RRT designed, coordinated and supervised the project and also performed the statistical analysis. SH performed in vitro experiments and participated in data acquisition. FA assisted in the tests, drafted the manuscript. LJ provided technical support and assisted in the experiments. MAH developed the discussion and critically revised the manuscript.

Competing Interests

All authors agreed on the article before submission and had no conflict of interests.

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Availability of Data and Materials

Datasets are available from the corresponding author on reasonable request.

Ethics Approval and Consent to Participate

This study was exempted for ethical clearance.

Consent for Publication

Not applicable.

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