

In Vitro Evaluation of the Bioequivalence of Different Brands of Doxycycline Marketed in Burkina Faso, Africa

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ABSTRACT

Background: Post-marketing quality control of drugs is an essential activity for local health authorities. This study aimed to determine the physicochemical quality and compare the dissolution profile of four different brands of doxycycline tablets (100 mg) (as hyclate and monohydrate forms) marketed in Burkina Faso, Africa. **Methods:** Parameters such as mass uniformity, disintegration, active pharmaceutical ingredient (API) identification, assay, and dissolution were assessed according to the monograph of United States Pharmacopoeia. A bioequivalence test was performed in vitro, and comparative dissolution testing was performed in pH 1.2, 4.5, and 6.8 media according to ICH specifications. **Results:** All brands of doxycycline met the required specifications for physicochemical parameters. API content ranged from 92.49% ($\pm 0.27\%$) to 101.00% ($\pm 1.43\%$), and cumulative drug release ranged from 88.57% ($\pm 0.74\%$) to 100.15% ($\pm 3.84\%$) within 60 minutes. Only one brand of doxycycline hyclate tablet was considered not interchangeable with the comparator according to the difference factor ($f_1 = 14.83$) and similarity factor ($f_2 = 43.63$) in pH 6.8 medium. **Conclusion:** Despite the low level of doxycycline registered in Burkina Faso, quality control needs to be intensified to ensure the quality of the products marketed.

Keywords: Doxycycline, physicochemical analysis, comparative dissolution, interchangeability

INTRODUCTION

Generic medicines are manufactured to be similar to the original product, having the same active pharmaceutical ingredient (API), the exact dosage, and the same method of administration, with equivalent efficacy (1). The main advantage is economic: generic medicines are less expensive than brand-name medicines. Doxycycline is registered and marketed in Burkina Faso, Africa as an antibiotic according to the essential generic medicines list and other health products of Burkina Faso (2024 Edition) (2).

Doxycycline is used to treat various bacterial infections. It is a second-generation semi-synthetic bacteriostatic tetracycline with broad-spectrum antimicrobial action against Gram-negative and Gram-positive aerobic and anaerobic bacteria. By linking to the bacterial 30S ribosomal subunit, doxycycline inhibits protein synthesis in a time-dependent manner and inhibits bacterial ribosomes (3). Thus, doxycycline effectively treats urinary, respiratory, and gastrointestinal infections. It also has anti-malarial properties (4, 5). According to the Biopharmaceutics Classification System (BCS), doxycycline hyclate and doxycycline monohydrate are class I and borderline class I/II drugs,

respectively (4, 6). Doxycycline has better oral absorption, higher liposolubility, better tissue distribution, and a longer serum half-life than other antibiotics in the same family (3, 7). Doxycycline includes monohydrate (free base), hyclate or hydrochloride, and calcium for pharmaceutical preparations (Fig. 1). For patients with a high risk of esophageal lesions, the monohydrate form is an less acidic alternative to the hyclate form of doxycycline (4).

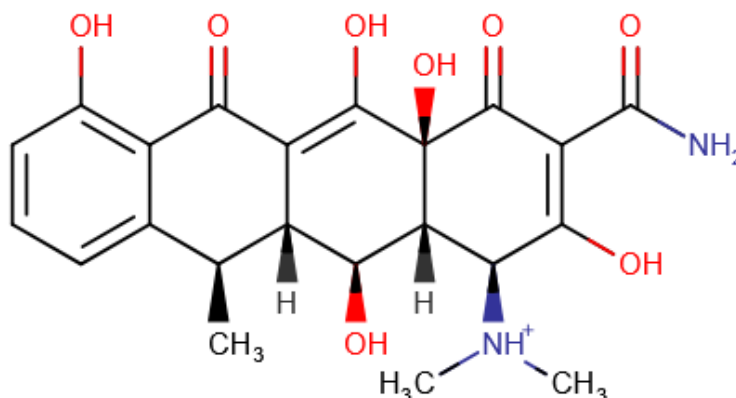


Figure 1. Chemical structure of doxycycline.

According to the ICH M13A Guideline, evaluating the bioequivalence of oral dosage forms is essential in establishing the therapeutic equivalence of generic drugs to their respective comparators (8). Bioequivalence studies are critical in determining therapeutic efficacy for registering generic drugs. The accessibility and availability of quality, safe, and effective generic medicines in Burkina Faso is one of the critical objectives of national health policy. The availability of generic drugs from multiple sources is sometimes associated with medications of lower quality, especially in developing countries such as Burkina Faso. This study aims to investigate the quality of multi-source antibiotics formulated with doxycycline salts for oral administration and marketed in Burkina Faso. The *in vitro* dissolution test was performed to predict *in vivo* performance and assess bioavailability.

METHODS

Materials

Doxycycline hyclate RS, donated by the United States Pharmacopeia (USP), was used as a USP Chemical Reference Substance. Potassium chloride 99.5–101.0%, glacial acetic acid 99.8–100.5%, sodium hydroxide (NaOH) $\geq 99\%$ w/w (AnalaR Normapur.), methanol for analysis, triethylamine 99% (Thermo Scientific), and sodium acetate trihydrate (Carlo Erba Reagents, France) were purchased from VWR Chemical (USA). Monobasic potassium phosphate (KH_2PO_4) and edetate disodium (EDTA) were purchased from Sigma Aldrich (USA). Hydrochloric acid (HCl) (0.1 N) solution was prepared from hydrochloric acid (37% w/w) purchased from PANREAC (Spain). Distilled water was freshly prepared before analysis.

Five brands of doxycycline 100 mg (four test products labeled Dox1, Dox2, Dox3, and Dox4, and one comparator) were collected from drugstores in Ouagadougou (Burkina Faso), as described in Table 1. The samples were transported to the laboratory and stored under the conditions specified by the manufacturers. Doxynor 100 mg capsule (FIRMA SpA, Italy) was chosen as an innovator following the WHO guidance and was purchased from a registered pharmaceutical wholesaler (9). The Pfizer innovator, Vibramycine N 100 mg was out of stock during the study, so Doxynor was used. It is the first brand registered in Burkina Faso.

Table 1. Samples of Doxycycline (Dox) Collected for Analysis

Product	Galenic Form	API	Batch No.	Country of Origin	Expiration Date
Comparator	Film-coated tablet	Doxycycline monohydrate	221500	Italy	08/2026
Dox1	Tablet	Doxycycline monohydrate	M712	Morocco	02/2025
Dox2	Tablet	Doxycycline Hyclate	5148	Germany	09/2025
Dox3	Tablet	Doxycycline Hyclate	H2177	India	11/2023
Dox4	Capsule	Doxycycline Hyclate	G344	Ivory Coast	02/2025

All equipment used were qualified and calibrated according to the requirements described in the USP. As described in the ICH Q2(R1) guidelines, the analytical method was validated and included accuracy, specificity, linearity, repeatability, and precision.

Physicochemical Analysis

Identification and API Content Assays

Identification of doxycycline content was performed using the USP monograph (10). A high-performance liquid chromatography (HPLC) system (Agilent 1260, USA) equipped with an ultraviolet (UV)-visible detector was used to detect doxycycline monohydrate at 270 nm and doxycycline hyclate at 350 nm. The system used a 2.1 mm × 5 cm column; 1.7 µm packing L7, maintained at 60.0 °C. Sample and standard solutions were prepared as described in the monograph (10). The gradient of the mobile phase included solution (A) and methanol. Elution was performed using the following proportions (v/v) of solution A: 90–90% at 0.0–2.0 minutes, 60.0–90.0% at 4.0–6.0 minutes, and 90.0% at 9.0 minutes. Solution A consisted of 3.1 g of KH₂PO₄, 0.5 g of EDTA, and 0.5 mL of trimethylamine. The pH was adjusted to 8.5 ± 0.2 with 1 N NaOH. Elution was performed at a 0.6 mL/min flow rate and injection volume of 5 µL.

Uniformity of Mass, Disintegration, and Dissolution Tests

Tests for uniformity of weight, disintegration, and in vitro dissolution were conducted according to USP for all products.

For dissolution studies, USP apparatus 2 (paddle) (Sotax AT, France) was used according to the monograph for doxycycline capsule and tablet dosage forms (10). Samples and standard solutions were protected from light during the analysis. The standard solution was prepared using USP doxycycline hyclate RS in the appropriate medium: 0.01 M HCl and distilled water (900 mL) was used for the monohydrate and hyclate forms, respectively, maintained at 37.0 ± 0.5 °C and 75 rpm. At the end of the time allowed (30 min for hyclate capsule, 60 min for monohydrate tablet, and 90 min for hyclate tablet), an aliquot (10 mL) of the sample solution (*n* = 12) was filtered (0.45 µm, Millipore). After dilution (1/10), the absorbance was measured at 268 nm and 276 nm for the monohydrate and hyclate forms, respectively, with a visible spectrophotometer (Agilent Cary 3500, USA) to determine the amount of doxycycline content released from of each product.

In Vitro Comparative Dissolution Tests

Comparative in vitro dissolution tests were performed using the BCS-based biowaiver approach (11).

The standard solution was prepared at 0.01 mg/mL in an appropriate medium, and absorbance was measured as indicated in the USP monograph (10). For the sample test, 900 mL of each media, buffer pH 1.2 (0.1 N HCl), acetate buffer pH 4.5, and phosphate buffer pH 6.8 were prepared according to the USP monograph (10). Aliquots of 10 mL ($n = 12$) were removed after 10, 15, 20, 30, 45, and 60 minutes, filtered (0.45 μm , Millipore), and immediately replaced with fresh dissolution medium to maintain sink conditions throughout the test.

Data Analysis

For comparative dissolution tests, the profile of the test product was considered similar to the comparator if cumulative drug release reached more than 85% in 15 minutes (12). Otherwise, the 'fit factor' statistical method was performed using cumulative dissolution values (mean %) to calculate the difference factor (f_1) and similarity factor (f_2), which measure the relative error between the dissolution profiles (13, 14). The coefficient of variation for the comparative dissolution tests must be less than 20% for samples withdrawn at 15 and 30 minutes and less than 10% for samples withdrawn at 45 and 60 minutes. The two profiles are *identical* if $f_1 = 0$ and $f_2 = 100$. The two profiles are *similar* if $f_1 \leq 15$ and $f_2 \geq 50$. However, similarity cannot be claimed if $f_1 > 15$ and $f_2 < 50$, which indicates possible differences in vivo performance (15).

RESULTS AND DISCUSSION

There is a correlation between organoleptic characteristics, uniformity of mass, disintegration, and the dissolution performance of drugs; hence, there is a need to investigate these parameters. According to the Ministry of Health, only the doxycycline 100-mg tablet is registered and marketed in Burkina Faso. The five products studied represent all doxycycline brands available in drugstores at the time.

Physicochemical Quality

The pharmaceutical quality parameters are summarized in Table 2. The average tablet weight varied substantially, ranging from 203.67 (± 1.56) mg for Dox1 (monohydrate tablet) to 309.71 (± 7.32) mg for Dox3 (hyclate tablet). The average mass of the comparator was 414.46 (± 6.14) mg (monohydrate film-coated tablet), the highest of all the samples. This weight variation indicates diversity in the qualitative and quantitative composition of the samples; however, only the leaflets for the comparator and one generic (Dox2) listed the qualitative excipients. The disintegration time for all samples complied with USP specifications (< 5 mins), ranging from 0.21 (± 0.01) min for Dox1 to 4.33 (± 0.19) min for Dox4 (hyclate capsule).

All tested samples and the comparator had API content that complied with USP requirements, ranging from 92.49% (± 0.27) for Dox4 to 101.00% (± 1.43) for Dox1. These findings are in line with results obtained in Ethiopia by Abraham et al., who studied 10 brands of doxycycline hyclate tablets (92.60–119.62%) and capsules (93.40–116.00%) (16). In contrast, Meos et al. reported that six out of 47 samples of a single doxycycline capsule brand manufactured in Russia and marketed in Estonia had API content ranging from 81–86%, thus not complying with USP specifications (17). The tested sample and the comparator retention times (R_t) were compared to the USP chemical reference substance in our study. The R_t were 7.23 minutes and 7.13 minutes for the monohydrate and hyclate forms, respectively.

Disintegration time did not correlate with the API release for dissolution, as Yaméogo et al., reported in Burkina Faso (15). All brands released 80% of API within 60 minutes, as required by USP specifications (range: 88.57% \pm 0.74% to 100.15% \pm 3.84%). The monohydrate form (comparator and Dox1) had the highest drug content but the lowest amount of release. Meos et al. reported that the

API release was more than 85% after 90 minutes for all tested brands; however, three capsules failed the dissolution test.

Table 2. Pharmaceutical Quality Parameters of Doxycycline (Dox) 100-mg Tablets

Product	Average Mass (mg)	Maximum Mass Deviation (%)	Disintegration Time (min)	API Rt (min)	Assay (%)	Dissolution (%)
Comparator	414.46 ± 6.14	2.88	1.70 ± 0.63	7.235	98.79 ± 1.76	90.14 ± 1.40
Dox1	203.67 ± 1.56	1.16	0.21 ± 0.01	7.232	101.00 ± 1.43	88.57 ± 0.74
Dox2	264.41 ± 1.64	1.71	1.02 ± 0.36	7.135	95.78 ± 0.38	100.15 ± 3.84
Dox3	309.71 ± 7.32	5.82**	2.56 ± 1.73	7.133	95.49 ± 0.89	92.46 ± 0.95
Dox4	279.21 ± 12.23	11.57*	4.33 ± 0.19	7.131	92.49 ± 0.27	97.79 ± 7.72

Values are mean ± SD, n = 3.

**Mass of 2 tablets was greater than 5.0%; *Mass of 1 capsule was greater than 10.0%.

USP specifications: ≤ 5% average mass deviation for tablet form, ≤ 10% average mass deviation for capsule form, ≤ 15.00 min disintegration time for capsule form, ≤ 30.00 min disintegration time for capsule form, 90–120% API content, and ≥ 80% dissolution within 60 min.

API: active pharmaceutical ingredient; Rt: chromatographic retention time.

Comparative Dissolution Profiles In Vitro

Accuracy, specificity, repeatability, and intermediate precision of the dissolution method complied with ICH requirements. The results are shown in Table 3 and Figure 2.

In pH 1.2 (Fig. 2A), the initial release of API was deficient (< 60%) before 15 minutes, for Dox3 and Dox4. However, after 15 minutes, the release was substantial (> 90%) for all samples. In pH 4.5 (Fig. 2B), only Dox2 released more than 85% API after 15 minutes. In pH 6.8, the release was higher than 85% from 15 minutes for brands containing doxycycline hyclate (Dox2, Dox3, and Dox4). After 45 minutes, all products released more than 85%.

Drug release was the lowest in pH 4.5, compared with pH 1.2 and 6.8. Generally, for all pH levels tested, the release was between 35% and 99% before 15 minutes and greater than 83% (Dox4) at 60 minutes. At pH 4.5, release after 60 minutes was incomplete for the Dox4. The highest dissolution in this medium was more than 89% (Dox1 and Dox3). Doxycycline hyclate capsules had a slower release profile than the tablet form. According to the WHO specifications, a profile comparison is unnecessary if the dissolution rate of the comparator and tested product is greater than 85% within 15 minutes (14). As such, f_2 was not calculated at pH 1.2. However, these factors were applied to compare the dissolution behavior of the generic brands with the comparator after 15 minutes in pH 4.5 and 6.8.

Table 3. Similarity Factor Analysis of Dissolution Profiles for Doxycycline (Dox) 100-mg Tablets Versus Comparator Brand

Product	pH = 1.2		pH = 4.5		pH = 6.8		Similarity with Comparator
	f_1	f_2	f_1	f_2	f_1	f_2	
Dox1	NA		9.44	57.28	3.79	70.31	Similar
Dox2	NA		4.41	67.72	14.83	43.63	Not similar at pH 6.8
Dox3	NA		6.77	60.94	9.18	52.41	Similar
Dox4	NA		2.18	82.02	3.73	64.64	Similar

NA: not applicable.

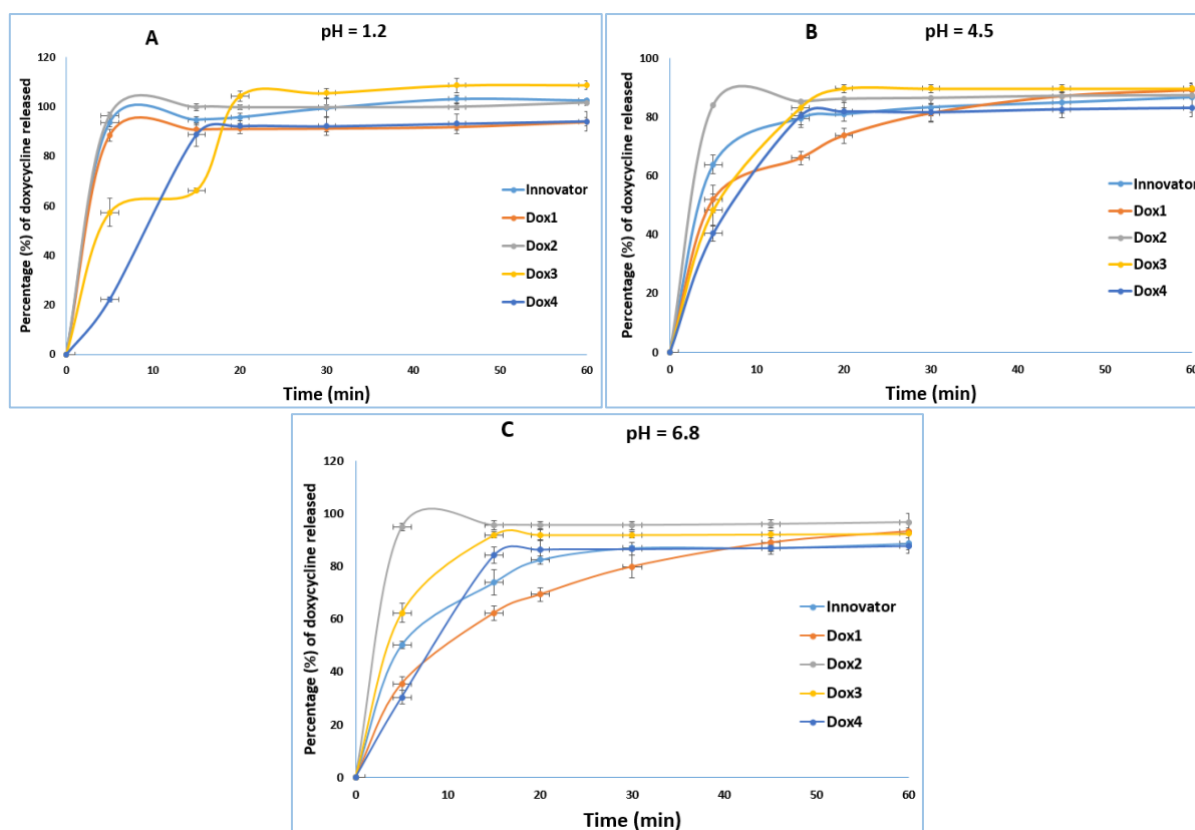


Figure 2. In vitro dissolution profiles of doxycycline samples in different media pH 1.2 (A), pH 4.5 (B), and pH 6.8 (C).

Generic brands Dox1, Dox3, and Dox4 had an f_2 greater than 50 and f_1 less than 15 in all media, meaning that their dissolution profiles were similar to the comparator. These drug brands are considered to be interchangeable, having equivalent bioavailability as the comparator. For Dox2, the f_2 value was less than 50 in pH 6.8, so it was not considered similar to the comparator (Table 3). Both the comparator and Dox2 contained the hyclate form, but the comparator was a film-coated tablet, whereas Dox2 was a dry tablet. The results obtained by Abraham et al., also showed that the hyclate tablets were dissimilar to the comparator (16). In contrast, a study of six different brands of doxycycline hyclate (100 mg) capsules in Pakistan showed very rapid dissolution (> 85% in 15 min) (18). The doxycycline hyclate form is considered highly soluble and highly permeable (3, 18).

A comparative dissolution of the hyclate forms was performed, with Dox2 used as the comparator, and the results are provided in Table 4. These results showed that the hyclate forms were similar in all media ($f_2 > 50$).

Table 4. Similarity Factor Analysis of Dissolution Profiles for Doxycycline (Dox) Hyclate 100-mg Tablets Versus Dox2 Brand

Sample Code	pH = 1.2		pH = 4.5		pH = 6.8		Similarity with Dox 2
	f_1	f_2	f_1	f_2	f_1	f_2	
Dox3	NA	3.73	73.48	4.93	65.55		Similar
Dox4	NA	5.51	65.32	10.18	50.26		Similar

NA: not applicable.

In previous studies, the physicochemical quality and performance of other drugs in Burkina Faso, such as artemether/lumefantrine tablets and powder for oral suspension, amoxicillin 500-mg capsules, and amoxicillin/clavulanic acid (500 + 62.5 mg) tablets, have been recorded by Yaméogo et al. (15, 19, 20). The results showed that 2.45% (3 out of 122) of artemether/lumefantrine samples were noncompliant for physicochemical tests, with a 98% interchangeability ratio. Two out of eight amoxicillin brands tested were noncompliant for bioequivalence tests, and two out of six brands of amoxicillin/clavulanic acid were not interchangeable. These results highlight the need for increased monitoring of the quality of the various brands of medicines used in Burkina Faso.

CONCLUSION

In developing countries such as Burkina Faso, generic medicines have played a vital role since the Bamako initiatives in 1980, which established reforms in the management of health systems. As a result, quality control has become crucial to ensuring the pharmaceutical quality of medicines marketed in these countries. Among these parameters, bioequivalence through comparative dissolution tests is critical. Performance tests on different brands of doxycycline used in Burkina Faso showed that one of four brands was not similar to the comparator and, therefore, not interchangeable. Despite the out-of-stock situation and the limited number of registered brands available in the market, the relevant health authorities need to improve quality control of doxycycline as an antibiotic in Burkina Faso. The regulatory authorities should also increase the vigilance system and work to make antibiotics such as doxycycline more widely available in all its forms.

DISCLOSURES

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