

Comparative Evaluation of Amlodipine Besylate Generic Tablet and Capsule Brands in Riyadh, Saudi Arabia

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ABSTRACT

The objective of this study was to evaluate the physicochemical quality control parameters and pharmaceutical equivalence of amlodipine besylate generic tablets and capsules with the innovator brands (Norvasc and Amlor, respectively) available in Riyadh, Saudi Arabia. Five brands of amlodipine besylate tablets and capsules (5 mg) were compared via quality control tests according to the *United States Pharmacopoeia* (i.e., hardness, thickness, diameter, weight variation, uniformity of dosage content, friability, disintegration, dissolution by ultraviolet spectrophotometry, and Fourier-transform infrared spectroscopy (FTIR)). All selected brands were found to comply with USP-NF specifications concerning weight variation, hardness, friability, disintegration time, FTIR, and drug content analysis. The dissolution profiles for all products satisfied the USP-NF specifications. Regarding, model-dependent data, all the tested brands followed the Higuchi model of release. Using the model-independent approach (i.e., similarity factor analysis), all products were considered similar except for one generic product (ABC-3). All brands had no significant difference in mean dissolution efficiency compared to the innovator, except ABC-3.

Keywords: In vitro, amlodipine besylate, tablets, capsules, dissolution comparison

INTRODUCTION

Hypertension is considered a major health problem in many countries of the world. According to the World Health Organization (WHO), an estimated 1.13 billion people worldwide have hypertension, most (two-thirds) are living in low- and middle-income countries (1). The prevalence is also high in developing countries such as Saudi Arabia, with 6.0% in men, 4.2% in women, and 4.9% in all adults (2).

Several drugs are available in pharmacies to control blood pressure and decrease the rate of morbidity and mortality that is associated with hypertension, such as angiotensin-converting enzyme inhibitors (ACEIs), beta-blockers (BBs), and calcium channels blockers (CCBs). Amlodipine besylate is a CCB initially approved by the FDA in 1987, sold under the brand name Norvasc, manufactured by Pfizer (3). It is a basic dihydro-pyrimidine-carboxylic derivative. Amlodipine besylate is a white crystalline substance. Based on biopharmaceutics classification, amlodipine besylate is a class 1 drug, which means it has high solubility and high permeability. Generic medicines are produced after the patent protection of innovator products is over and are available commercially with different

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names, which are claimed to be chemically and biopharmaceutically equivalent to the innovator product (4). Generic drugs are useful to decrease the cost by 85% of the innovator brand; as a result, patient adherence increases, which improves patients' health outcomes (4).

However, different therapeutic responses have been observed between products containing the same active pharmaceutical ingredients (APIs) (5). These variable responses can be due to the effect of different factors, i.e., inadequate or without APIs, wrong ingredients, quantity, and quality of the APIs, methods of handling, etc. (6). These products are named as substandard, falsely labeled, falsified, counterfeit medical products, shortened as "SFFC" (4).

The consequences of SFFC drugs result in avoidable morbidity, mortality, or treatment failure, as well as loss of faith in health systems. These consequences are notable in different countries regardless of economic level (7). In developing countries such as Nigeria and Saudi Arabia, the incidence was 56.3% compared to 43.7% in developed countries (7).

The quality of pharmaceutical products is most significant for efficacy and safety reasons (8). Many research articles report that suitable physicochemical properties of different quality parameters are required to know the pharmaceutical equivalence of drugs (5, 9). This is important especially in developing countries to avoid an extensive supply of poor quality or counterfeit drug products (8). Najmi et al. evaluated four brands of amlodipine besylate 5-mg tablets available in Saudi Arabia and showed therapeutical and pharmaceutical equivalence to the innovator (Norvasc); however, there is no study for the capsule formulation, which has different dissolution behavior and is commonly prescribed (10, 11). Therefore, the present study will conduct the official and non-official quality control studies along with the model-dependent and non-dependent analysis of dissolution behavior for five common brands of 5-mg amlodipine besylate tablets and capsules in Riyadh, Saudi Arabia.

MATERIAL AND METHODS

The chemicals and reagents used to perform the experiments were as follows: innovator brand 5-mg amlodipine besylate tablets and capsules, hydrochloric acid, and distilled water. Different brands of 5 mg Amlodipine besylate tablets and capsules were bought from various pharmacy retail outlets in Riyadh, Saudi Arabia, presented in Table 1. Tablets were coded randomly as ABT-1 (innovator, Norvasc), ABT-2, ABT-3, ABT-4, capsules formulation were coded as ABC-1 (innovator, Amlor), ABC-2, ABC-3. All the brands used were within their shelf life at the time of the study. USP reference standard amlodipine besylate was donated by Al Jazeera Pharmaceutical Industries Ltd Riyadh.

Drug quality assessment experiments were done using pharmacopeial procedures described in the *United States Pharmacopoeia* (12). The performance verification test (PVT) was conducted according to the USP general chapter <711> (12). Calibration reference standard was USP Prednisone tablet RS (since amlodipine is also a disintegrating tablet). This calibration is repeated on a routine basis in our laboratory.

Table 1. Generic and Innovator Brands Information

Brand	Lot No.	Expire Date	Manufacturer	Country
Norvasc	00019683	02/2023	Pfizer	New York, USA
Lofral	20044549	4/2022	Acino-Switzerland	Zurich, Switzerland
Vasodipine	20DC94	5/2023	Riyadh pharma	Riyadh, Saudi Arabia
Amlocard	3132	4/2022	Batterjee pharma	Jeddah, Saudi Arabia
Amlor	1286024	1/2024	Pfizer	New York, USA
Amlopine	122727	3/2023	Spimaco	Riyadh, Saudi Arabia
Amvasc	XE0069	5/2022	Riyadh pharma	Riyadh, Saudi Arabia

Thickness and Diameter Measurement

Twenty tablets from each sample were placed in between the measuring jaws of an electronic digital caliper (MEGA, USA) at three different positions to determine their average diameter and thickness (13). Thickness and diameter measurements were taken for tablets only.

Hardness Test

A tablet was placed in between two anvils of hardness tester (ERWEKA, Germany). The pressure was applied to the anvils, and the crushing strength needed to break the tablet was measured (13).

Weight Variation

Twenty tablets were randomly selected from each brand and individually weighed on an analytical balance (OHAUS, Switzerland). The individual values were recorded, then the average and standard deviation were calculated.

Friability Test

Twenty tablets for each brand were randomly selected, weighed, and placed into the friabilator (ERWEKA, Germany) chamber set at 25 rpm for 4 minutes. The tablets were weighed again and the differences in weight were calculated as the percentage friability. The loss in weight indicates the friability (13).

Calibration Curve

A standard curve was plotted for amlodipine besylate using a pure reference standard to make five known concentrations (between 1.25 and 20.00 µg/mL). The standard curve was established to verify accurate analysis of the drug using an ultraviolet (UV) spectrophotometer (JENWAY, United Kingdom) at 239 nm (14). Validation of the UV method was carried out according to ICH guidelines for several parameters (accuracy, precision, and linearity) (15).

Determination of Drug Content

Ten tablets from each brand were crushed and dissolved separately in 80 mL of 0.1-N hydrochloric acid (HCl). They were sonicated in an ultrasonic bath (Jeken, China) and

filtered with a syringe filter (0.45 μm); 5 mL was taken from the filtered solution and the volume was made up to 25 mL with 0.01-N HCl. The absorbance was measured at 239 nm using UV spectrophotometry. The concentration was extrapolated from the calibration curve for amlodipine (14).

Disintegration Test

The disintegration test was performed by using the USP disintegration apparatus ED 2L (ERWEKA GmbH, Germany). Six tablets of each brand were placed individually in each of the six baskets with distilled water at $37 \pm 0.5^\circ \text{C}$ and 800 mL of simulated gastric fluid (0.1 N HCl) filled into each beaker. The test started immediately after the basket was attached. The disintegration time (DT) was recorded when no particles remained in the basket. Baskets were observed regularly to check for complete disintegration (4).

Dissolution Test

The dissolution test was carried out using a USP paddle apparatus 2 (ERWEKA, Germany) in six replicates (vessels) for each brand. The dissolution medium was simulated gastric fluid (SGF) without enzymes set at $37 \pm 0.5^\circ \text{C}$ and 50 rpm. In all the experiments, 5-mL samples were withdrawn at 5, 10, 20, 30, 45, and 60 min, and replaced with an equal volume of dissolution medium. Samples were filtered (0.45- μm , Millipore), then their absorbance was measured using the UV spectrophotometer at 239 nm to calculate the amount of drug released.

These data were used to determine the dissolution kinetics as well as the similarity (f_2) and dissimilarity factors (f_1) (13, 16). If the innovator and generic brand are identical, the similarity factor is 100, and it approaches 0 as the dissimilarity grows. A factor of 50–100 ensures that the two products are similar. A difference factor of 0–15 indicates that the two products are different and thus, not interchangeable (17, 18).

Mechanism of Drug Release

Different analytical models can be useful for describing the kinetics of drug release from dosage forms. The model that best matches the experimental results is the most favorable of these models. Formulations were characterized according to their release kinetics by determining the best fit of the drug release data to zero order, first order, Hixson-Crowell, and Higuchi models (19–23).

- *Zero-order model*: In the absence of disaggregation and if the area had not been modified, the API dissolves slowly from pharmaceutical dosage forms (zero-order equation) (20).
- *First-order model*: API is delivered from pharmaceutical dosage at a rate comparable to API remaining inside, so that API liberated per minute decreases as described in the first order equation (21).
- *Hixson-Crowell model*: Particle normal area is equivalent to the cubic root of the volume (20).
- *Higuchi model*: Higuchi's equation is an expression of "square root of time" release kinetics, which fits API formulations in modified liberation systems or semisolid dosage forms (22).

Dissolution efficiency (DE) is also used to describe drug release. It is regarded as a non-

comparative dissolution kinetics parameter. DE is the area under the drug dissolution curve (AUC) up to time t in minutes, expressed as a percentage of the area of the rectangle corresponding to 100% of the product label value in the same period of time (23).

Fourier-Transform Infrared (FT-IR) Spectroscopy

A dried powdered sample (1 mg) of the innovator tablet brand was placed directly on the surface of the FT-IR (SHIMADZU, Japan). FT-IR spectra of the sample were recorded by scanning over the transmittance range of 4000–500 cm^{-1} . The procedure was repeated for all the remaining brands. The spectra from each tablet and capsule formulation were compared with the respective innovator brand (4).

Data Analysis

Data obtained were analyzed using Origin scientific graphing software, Microsoft Excel 2010, and SPSS version 20. Comparison and statistical significance were determined by one-way analysis of variance (ANOVA) and Tukey Kramer's post hoc test. All data were analyzed at a 95% confidence level ($p < 0.05$).

RESULTS AND DISCUSSION

Thickness and Diameter

Overall, the individual thickness and diameter of each tablet were found satisfactory compared to the average thickness, as the deviation did not exceed $\pm 5\%$. It has been found that among the four brands, ABT-4 had the highest average diameter (8.2 ± 0.05 mm) and ABT-1 had the lowest (6.23 ± 0.05 mm) (Table 2). For tablets with a diameter higher than the average, the deviation obtained was positive. Whereas, for tablets with a diameter less than the average, the deviation obtained was negative. The slight deviation of diameter can either be due to the uneven distribution of granules into the die or irregular movement of the lower punch (24).

Tablets with increased thickness had less hardness, which was the case with ABT-2, and tablets with decreased thickness had more hardness, which was the case with ABT-1 (Table 2); a similar relationship was reported by Dandam et al (25). Tablet thickness can affect therapeutic response, as the thicker the tablet, the more time it takes to release its content (26). Some filling instrumentality depends on the uniform thickness of the tablets as an investigating mechanism. Therefore, uniformity of thickness and diameter of tablets are necessary for consumer requirements as well as for packaging fields (26). In this study, all the studied brands were found to be similar to the innovator in terms of their thickness and diameter.

Hardness

The lowest mean hardness (13.86 Kp) was recorded for product ABT-2, whereas ABT-1 was able to withstand the highest mechanical force (0.17 ± 0.05 N). All products had uniform average hardness ranging from (13.86-19.07 Kp), and all tablet brands passed the test.

The hardness of tablets depends on many factors such as the characteristics of granules used, the type and concentration of lubricant used, and the space between the upper and lower punches at the time of compression. It could indicate potential bonding between active ingredients and excipients, which can affect the rate of tablet disintegration, dissolution, and drug release needed for accurate dosage (27, 28). Kitazawa et al reported

a linear relationship between hardness and disintegration time, which was also found here in ABT-2 and ABT-3 (28). However, there was no relationship between hardness force and dissolution time.

Weight Variation

According to USP, the products passed the weight variation test if no more than two tablets/capsules out of 20 deviated by $\pm 7.5\%$ of the average weight. Accordingly, all products passed (Table 2).

Weight variation test serves as an indicator of Good Manufacturing Practices (GMP) as well as determining the amount of the API. Weight variation between brands can directly affect the amount of the API, owing to differences in excipients and manufacturing processes (29). Therefore, differences should be minimized to prevent the chance of receiving a subtherapeutic or suprathematic dose of the API, which might lead to an unfavorable therapeutic effect (30).

Table 2. Thickness, Diameter, Hardness, Weight Variation, Friability, Disintegration, Drug Content and Dissolution Efficiency (DE) Tests Results.

Product	Thickness (mm)	Diameter (mm)	Hardness (Kp)	Weight (mg)	Friability (% loss)	Disintegration (min)	Drug Content (%)	DE (%)
ABT-1	2.94 \pm 0.05	6.23 \pm 0.05	19.06	199.90 \pm 0.31	0.25	0.34 \pm 0.05	92.58	85
ABT-2	3.36 \pm 0.05	7.85 \pm 0.02	15.90	197.00 \pm 4.36	0.00	0.19 \pm 0.05	92.58	82
ABT-3	3.31 \pm 0.07	8.02 \pm 0.07	17.43	199.20 \pm 2.28	0.25	0.20 \pm 0.02	105.00	89
ABT-4	3.00 \pm 0.05	8.21 \pm 0.05	13.86	196.60 \pm 4.57	0.00	0.36 \pm 0.03	115.46	83
ABC-1	NA	NA	NA	100.00 \pm 3.58	NA	3.48 \pm 0.74	112.19	93
ABC-2	NA	NA	NA	85.00 \pm 1.81	NA	7.44 \pm 1.14	105.98	94
ABC-3	NA	NA	NA	179.20 \pm 4.08	NA	6.55 \pm 1.39	111.86	140

Values are presented as mean \pm standard deviation unless otherwise noted.

ABT: amlodipine besylate tablet; ABC: amlodipine besylate capsule; NA: not applicable,

Friability

According to USP, the allowed percentage of tablet mass lost is not more than 1%. Two brands ABT-1 and ABT-3 showed maximum friability of 0.25%, and ABT-2 and ABT-4 showed minimum friability of 0%. Overall, the loss percentage recorded for all the tested products was below 1%, which complies with USP specifications. In comparison to the innovators, all brands were similar, and ABT-3 was the closest (25, 31).

The mechanical strength of tablets can be determined by their hardness and friability tests. However, the hardness test is not a reliable indicator for tablet strength because when high pressure is applied to some tablets, it tends to “cap” or become powdered and fragmented (4). Friability is designed to evaluate the capacity of a tablet to withstand

pressure during handling, packaging, shipping, and transportation. High friability means that the drug product is more likely to suffer mechanical erosion, which may trigger loss of the API (25).

Calibration Curve

To conduct the in vivo drug dissolution study and drug content study, the calibration curve was plotted, which gave $R^2 = 0.999$ and the equation $y = 0.0306x - 0.0033$ to calculate the drug release profile. Amlodipine was found to be linear over a concentration range of 5 $\mu\text{g/mL}$ to 20 $\mu\text{g/mL}$ with $R^2 = 0.9996$ (32). Intraday accuracy and precision were evaluated at three different concentration points covering the entire calibration range in triplicate on the same day. The same concentrations were tested on three consecutive days using the intraday procedure. The precision was expressed as relative standard deviation (%RSD), which was $< 2\%$, and accuracy was $100 \pm 3\%$. The results showed a high percentage recovery value with small RSD value, indicating excellent methods' accuracy (10).

Drug Content

Weight variation is not sufficient to assure uniform potency of tablets of moderate and low dose drugs in which excipients make most of the tablet weight, which is the case in the tested drug (amlodipine 5 mg). The USP states the average content should be between 75–125% for tablets or capsules. The obtained results showed that all tested products had individual content within the limits of 75–125%, and a similar range was reported by Dandam et al (25). Content uniformity is an important quality control measure of oral solid dosage products, as it ensures consistency of the API in the unit dosage form (25, 33).

Tablet dosage forms had lower API content compared to capsules. ABT-1 and ABT-2 had the lowest API, 92.58% (4.63 mg) amlodipine besylate, whereas ABC-7 had 111.86% (5.59 mg) amlodipine besylate. These small differences may be related to the different manufacturing processes used for tablets and capsules.

Regarding drug assay, all brands were similar to the innovator. After establishing the calibration curve, all future measurements were close to the values of the standard curve. This was achieved during the validation of the analytical method. This standard curve was used in dissolution test calculation, drug kinetics, and drug content tests (32, 34).

Disintegration Test

According to the USP, the acceptable disintegration time for an uncoated tablet is 15 minutes, and 30 minutes for hard gelatin capsules. Based on these limits, all the selected tablet/capsule brands passed the disintegration test. Among the tested tablet products, the fastest average disintegration was for product ABT-2 (0.19 ± 0.05 min), and the slowest were the innovator, ABT-1 (0.34 ± 0.05 min) and ABT-4 (0.36 ± 0.03 min). The fastest disintegration for the capsule was for the innovator product, ABC-1 (3.48 ± 0.74 min) and the slowest was ABC-3 (6.55 ± 1.40 min).

Disintegration test provides the time for the tablet/capsule that is needed to disintegrate completely. However, complete disintegration does not necessarily imply complete dissolution, and it does not provide the drug release kinetics. These missed data can be achieved by the dissolution test (35).

Dissolution Test

One of the main issues pharmaceutical companies encounter is the need to optimize the level of drug availability to the body, where the API must be both extracted (dissolved in solution) and then absorbed into the systemic circulation to facilitate its transport to the targeted tissue site. This issue is examined and measured via the dissolution test.

Results of dissolution tests are presented in Table 3 and Figure 1. The percentage of amlodipine besylate released from the tablets at 30 minutes ranged from 85.57% to 97.46%. For capsule formulation, the percentage of drug released by the generic brands similar to the innovator. According to USP criteria for amlodipine besylate, the product should release more than 80% at 30 minutes (36). All tested products were considered pharmaceutically equivalent based on their in vitro drug release profiles (as shown in Figure 1). The minor differences might be because of different manufacturing processes, testing conditions, or excipients.

As shown in Figure 1 and Table 3, various products exhibited different dissolution profiles. To decide whether the differences in dissolution profiles were significant or not, all dissolution profiles were compared to the innovators (Norvasc and Amlor) using f_1 and f_2 analysis, as recommended by United States Food and Drug Administration (FDA).

Table 3. Dissolution Data and Dissolution Profile of Capsule Formulation Comparison Using Similarity (f_2) and Dissimilarity Factors (f_1).

Product and Factors	Q%					
	5 min	10 min	20 min	30 min	45 min	60 min
ABT-1 (Ref)	66.65	84.66	91.02	91.52	87.69	88.17
ABT-2	66.65	78.78	85.10	85.57	85.07	85.53
f_2	85.43					
f_1	2.14					
ABT-3	72.53	84.70	96.93	97.46	92.67	94.73
f_2	71.18					
f_1	5.28					
ABT-4	72.53	78.81	85.13	85.60	85.15	85.61
f_2	71.18					
f_1	3.49					
ABC-1 (Ref)	60.76	72.87	90.92	97.30	98.27	99.84
ABC-2	66.65	78.78	90.98	97.37	96.30	99.31
f_2	83.64					
f_1	1.95					
ABC-3	54.88	78.72	90.92	97.30	99.26	99.80
f_2	26.19					
f_1	27.41					

ABT: amlodipine besylate tablet; ABC: amlodipine besylate capsule.

f_1 represents the difference between the two drug release profiles at each time point, and f_2 represents the similarity in release profiles (37). The results showed $f_2 > 50$, and $f_1 < 50\%$ for all brands, which is consistent with Najmi et al (10). ABT-3 and ABC-2 were the most similar generic product to their innovators (Norvasc and Amlor, respectively). One brand of capsules, ABC-3, was not similar to the innovator, i.e., $f_2 < 50$ and $f_1 > 50\%$ (38,

39). Statistical analysis was conducted for the pharmacopeial specified time, 60 min, using Tukey's one-way ANOVA. The statistical comparison of release profiles of amlodipine besylate tablets indicated that there is no significant difference between the generic brands and Norvasc ($p < 0.05$). Similar results were recorded for the capsule formulations; however, ABC-3 differed significantly from the innovator, Amlor ($p > 0.05$), which was found in another study (40). This difference in might indicate reduced in vivo bioavailability and bioequivalence of the products (27).

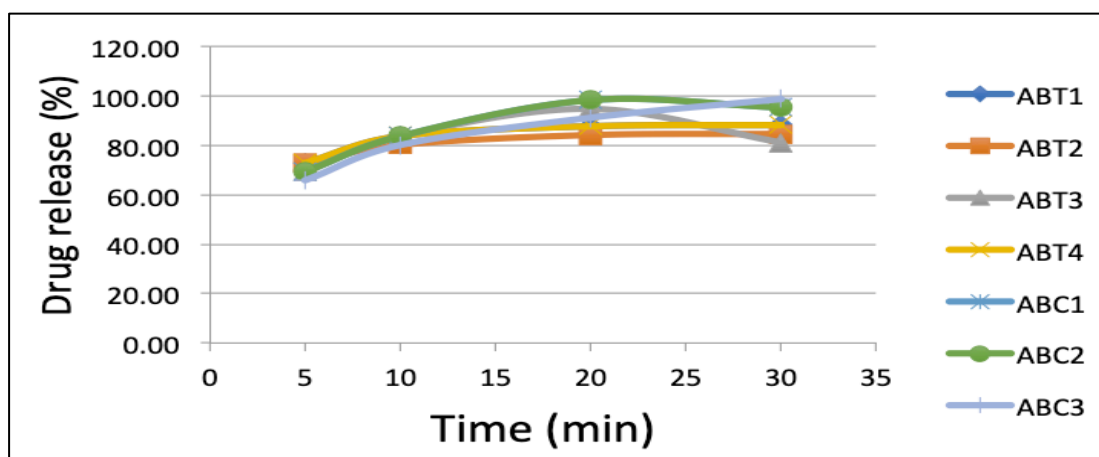


Figure 1: Dissolution of amlodipine tablets (ABT) and capsules (ABC). ABT-1 and ABC-1 are the innovator products.

Mechanism of Drug Release

Various mathematical models were used (i.e., zero-order, first-order, Higuchi, and Hixson-Crowell) to quantify the kinetics of amlodipine besylate release from tablets and capsules.

To establish a perfect correlation, model-independent approaches by means of f_1 and f_2 analysis were used to compare innovator and generic products. These results are presented in Table 4.

Table 4: Model-Dependent Data for Amlodipine Besylate Tablets (ABT) and Capsules (ABC)

	Zero-Order Model		First Order Model		Higuchi Model		Hixson-Crowell	
Equations	$Q_t = Q_0 + K_0t$		$\ln Q_t = \ln Q_0 + K_0t$		$Q = K_d \sqrt{t - t_0}$		$Q_0^{1/3} + Q_t^{1/3} = K_d t$	
Mechanism of release	Constate rate of release		Diffusion (Fick's first law)		Diffusion and permeability		Erosion release	
Constant	$^c K_0$	$^b R^2$	$^d K_1$	$^b R^2$	$^e K_H$	$^b R^2$	$^f K_s$	$^b R^2$
ABT-1	0.204	0.5736	0.001	0.5523	2.260	0.6916	0.004	0.5593
ABT-2	0.179	0.5821	0.001	0.5682	2.007	0.7199	0.003	0.5728
ABT-3	0.403	0.7702	0.002	0.7394	4.318	0.8722	0.007	0.7500
ABT-4	0.040	0.9729	0.000	0.9716	0.412	0.9980	0.001	0.9721
ABC-1	0.455	0.6620	0.002	0.6289	5.021	0.7925	0.008	0.6400
ABC-2	0.477	0.6755	0.002	0.6515	5.254	0.8067	0.008	0.6596
ABC-3	2.039	0.9660	0.008	0.9780	19.899	0.9056	0.029	0.9784

The best fit model is the one with the highest correlation coefficient or regression coefficient (R^2) (41). All brands followed the Higuchi model of release, except ABC-3 followed the Hixson-Crowell model. Higuchi model studies the dissolution profile from a planar heterogeneous matrix system, as the drug's solubility is lower than its

concentration in the matrix, therefore, the drug is released through pores from the matrix. On the other hand, the Hixson-Crowell model describes the drug release behavior depending on surface area and diameter of particles or tablets changes, which is the case with ABC-3.

Fourier-Transform Infrared (FT-IR) Spectroscopy

The FT-IR results are shown in Figure 2. The FT-IR spectrum of the innovator drug was characterized by the principal transmittance bands at 3415 and 3154 cm^{-1} due to N-H (stretching), 3065 cm^{-1} due to = C-H (aromatic stretching), 2984 and 2950 cm^{-1} due to C-H (stretching), 1696 cm^{-1} due to C=O (stretching vibration), 1615 and 1488 cm^{-1} due to C=C (ring stretching), 1445 cm^{-1} due to CH₃ (stretching), 1303 and 1125 cm^{-1} due to C-N (stretching), 1210 cm^{-1} due to C-O-C (stretching), and 836, 755, and 693 cm^{-1} due to C-H (out of plane bending of aromatic ring). Identification of active ingredients in generic products was done by comparing the FT-IR spectra with that of the innovators. The spectra of all products were compatible with that of the innovators (ABT-1 and ABC-1), and there was no significant difference in height, intensity, and position of peaks which confirms the presence of amlodipine besylate as an active ingredient in all tested tablet and capsule formulations. Similar results were reported by other researchers (42).

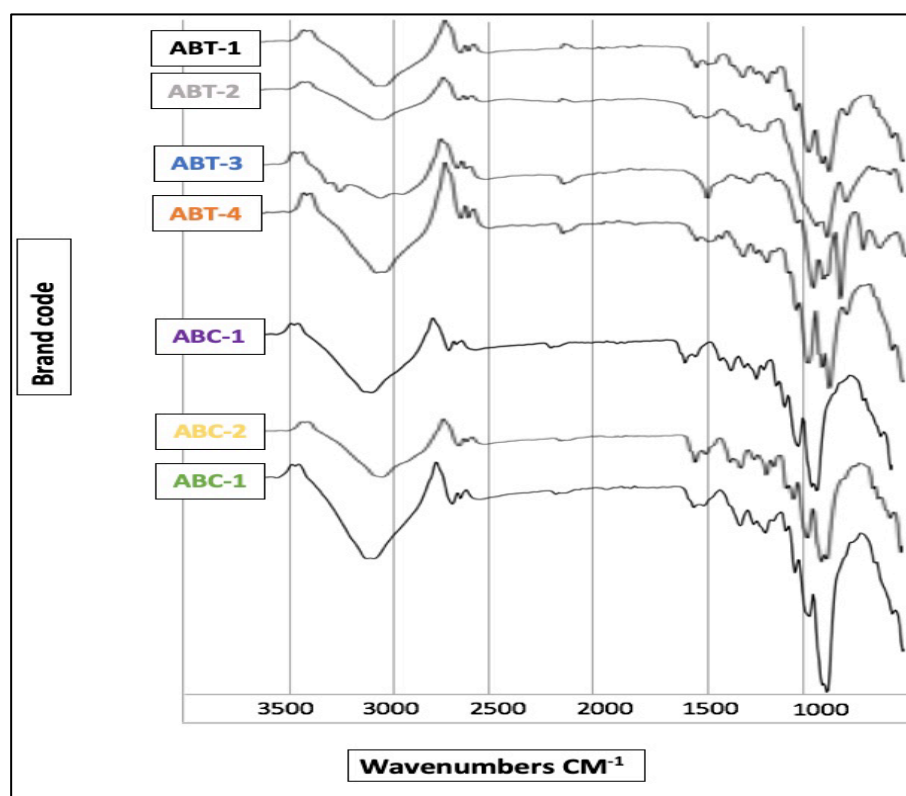


Figure 2: FT-IR spectra of amlodipine tablets (ABT) and capsules (ABC). ABT-1 and ABC-1 are the innovator products.

CONCLUSION

The pharmaceutical quality of five generic amlodipine besylate tablets and capsules in the Saudi Arabian market were compared with the innovator products, Norvasc and Amlor, respectively. The results have shown that all selected brands complied with USP specifications for weight variation, hardness, friability, disintegration time, FT-IR, and drug

content analysis. The dissolution profiles for the generic products were similar to the innovator products and satisfied USP specifications. All brands followed the Higuchi model of release, except ABC-3 followed the Hixson-Crowell model. All products had a similarity factor > 50% and dissimilarity factor < 50% and had a similar DE, except ABC-3.

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CONFLICTS OF INTEREST

The authors disclosed no conflicts of interest related to this article.

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