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Pharmaceutical quality of dispersible diclofenac tablets in the Saudi market

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ABSTRACT

The fundamental objective in developing any drug delivery approach is to achieve effective and safe therapy. Medications classified as generics are those that contain the same active ingredients and have the same quality as the reference medications. Several generic drugs are available on the market, all at a reasonable cost. In this study, the quality of Three generic brands of diclofenac dispersible tablets available in the Saudi market was assessed, namely: G1 and G2, and G3.

Except for the borderline performance of one generic formulation (G3), all formulations passed in vitro quality tests according to the United States Pharmacopoeia. According to the US Pharmacopoeia, every generic formulation passed in vitro quality tests, except for one generic formulation (G3) that performed inconclusively. All brands showed low weight variation, minimum weight loss in the friability test, and a rapid dispersion time of around 5 s. The chemical potency results demonstrated that all three brands complied with United States Pharmacopeia (USP) specifications, typically falling between 90% and 110% of the labeled amount. G1 and G2 passed the content uniformity test in their first attempt. G3 initially failed the content uniformity test but passed upon retesting with additional samples. G1 and G2 tablets passed the USP Acceptance criteria in stage one, and G3 tablets met the requirements in stage two. G1 showed the highest DE (%78.83), followed by G2 (%72.23), and G3 (%67.50). The G1 dissolution data, which showed the highest dissolution efficiency, were used as the reference product to calculate the similarity factor (f2 (ratio. G1 (Reference) and G2 with an f2 of (58.3) have similar dissolution profiles, however, the dissolution profiles for the two products may be considered similar without f2 calculation since more than 85% of the drug was dissolved within 15 min (SFDA Guidelines for Bioequivalence, Similarity while G3, with an f2 of (47.5) suggest a lack of similarity between the two dissolution profiles. This study highlights the importance of post-marketing evaluations of generic drug performance.

1. Introduction

Generics are medications that contain the same active ingredients and have the same effects as reference brand medications. There are several brands of generic medications on the market, all at reasonable costs, which reduce budgetary impact and facilitate the cost-effective use of available resources (WHO, 2015). Moreover, in recent years, the Saudi government has been pushing for generic medication by distributing it at no cost to government hospitals. Manufacturers receive numerous benefits in exchange for producing less expensive medications. Therefore, the use of generic medications has increased globally in recent years (Alrasheedy et al., 2014). In 2012, the global sales of generic drug products were valued at 67 billion USD and are predicted to increase to 99 billion USD by 2026. This represents a 32 billion USD increase in sales over the previous 14 years (Matej Mikulic, 2024). Similar to branded medications, generic medications must receive Saudi Food and Drug Authority (SFDA) approval to ensure their effectiveness. According to the SFDA, generic medications must meet the same high standards for purity, potency, and stability as branded medications. Bioequivalence testing was performed according to the manufacturer's instructions (SFDA, 2024). Even though bioequivalence testing is required before generic drugs can be sold in Saudi Arabia, continuous evaluation is necessary to guarantee that the intended quality is upheld after marketing. Several generics in Saudi Arabia have passed the bioequivalence testing and still need a post-marketing evaluation (SFDA, 2021).

Diclofenac is one of the most widely used generic drugs in the Saudi Arabian market. Diclofenac is a non-steroidal anti-inflammatory medication (NSAIDs) used for the treatment and management of acute and chronic pain associated with inflammatory conditions, especially those involving the musculoskeletal system. Diclofenac is available in various tablet forms to suit the needs of different patients. These forms include

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modified-release, enteric-coated, and film-coated tablets; sustained-release tablets; and dispersible tablets. Diclofenac side effects include gastrointestinal (GI) irritation, wind or loss of appetite, mild rash, and severe stomach pain (NHS, 2021). Severe stomach pain is the most undesirable side effect observed in these patients. Thus, dispersible tablet formulations can overcome GI problems; in such cases, administration of the dispersion prevents localization of the drug in the stomach.

Dispersible tablets are defined in the European Pharmacopeia as «uncoated or film-coated tablets intended to be dispersed in water before administration to produce a homogeneous dispersion» (European Pharmacopoeia, 2024). Dispersible tablets are typically dispersed within 3 min in approximately 5 to 15 mL of water at 15 to 25 °C (European Pharmacopoeia, 2006). Dispersible Tablets have several advantages such as ease of manufacturing and transportation, good physical and chemical stability, precise dosage and ease of administration which make them a great substitute for elderly and pediatric patients who struggle with swallowing (Dey and Maiti, 2010). In addition, they undergo rapid disintegration and absorption of medicines, which provides a rapid onset of action.

Dispersible tablets differ from conventional disintegrating tablets, as they are made to dissolve in water before being administered.. Therefore, Dispersible tablets combine the simplicity of administration provided by a liquid formulation with the benefits of a traditional tablet formulation (stability) (Aher et al., 2018).

Our initial market research identified dispersible tablets as potential areas for investigation. However, upon closer examination, we were surprised to find the need for the current study to specifically focus on dispersible tablets containing diclofenac in the Saudi market. This gap in knowledge provides valuable opportunities.

This study has aimed to assess the quality of three locally generic diclofenac dispersible tablets available in the Saudi market. To achieve this objective, quality control studies were conducted based on the pharmacopeial criteria.

2. Materials and methods

2.1. Chemicals and reagents

Diclofenac sodium salt (DS) was purchased from Sigma-Aldrich (SIGMA, MO). Various local marketed generic diclofenac products (G1, G2, and G3), each containing 46.5 mg diclofenac acid equivalent to 50 mg diclofenac sodium salt were used as seen in Table 1. All other chemicals and solvents were high-quality reagent grade. (Table 2).

3. Methods

3.1. Calibration curve

Two assays were performed using UV spectrophotometry and HPLC, in which UV spectrophotometry was used to quantify amount of drug released in in vitro dissolution tests, while HPLC was used to determine the content uniformity and chemical potency.

3.1.1. UV Spectrophotometric assay

A Calibration curve was constructed in phosphate buffer (pH 6.8), and 50 mg of DS was accurately weighed using an analytical balance (Model no. B203-S, Mettler Toledo, Switzerland). DS powder was dissolved in 50 ml methanol (1000 µg/ml) to form a stock solution. Different concentrations: (3,6,9,12,15, and 18 µg/ml) were made using phosphate buffer at pH 6.8 and measured at 276 nm wavelength against a blank using UV spectroscopy. A calibration curve was constructed by plotting absorbance against the corresponding concentration.

Table 2
Acceptability value conditions for content uniformity.

Conditions	Value
if 98.5 % ≤ X- ≤ 101.5 %	M = X-, (AV = Ks)
If X- < 98.5 %	M = 98.5 %, (AV = 98.5-X- +Ks)
If X- > 101.5 %	M = 101.5 %, (AV = X– −101.5 + Ks)

3.1.2. High-performance liquid chromatography (HPLC) assay

The method described in USP 41 was followed with some modifications. The mobile phase comprised an isocratic mixture of acetonitrile and 0.1 M ammonium acetate solution at a 1:1 (v/v) ratio. The mobile phase was freshly prepared daily for analysis, filtered through a 0.45 µm Millipore filter, and degassed via sonication prior to experimentation. For the analysis of DS samples, 50 µl of each sample was injected into HPLC Waters system consisting of an Autosampler (model no. 717) (plus), pump model (no. 1525), and Dual λ Absorbance UV detector model (no. 2487) that adjusted at 276 nm. DS separation was performed using (Nova-Pak®) column (C18, 4 µm, 3.9 × 250 mm). The column temperature was kept at 29 °C during the analysis, and the flow rate was adjusted at 1 ml/min (USP, 2024).

The calibration curve was established by precisely weighing 50 mg of diclofenac tablet with an analytical balance (Model No. B203-S, Mettler Toledo, Switzerland) and dissolving it in 50 ml of methanol (1000 µg/ml). Serial dilutions were prepared at concentrations of 15.6, 31, 62.5, 125, 250, and 500 µg/ml and analyzed via HPLC using the previously described method. A calibration curve was constructed by plotting absorbance against the corresponding concentration.

3.2. Quality control tests

3.2.1. Physicochemical characteristics

3.2.1.1. Hardness, thickness and diameter. Ten tablets of each brand were used in the hardness testing. Each tablet's strength was measured using a hardness tester (EH01P, Electrolab, India). A micrometer (M&W, Sheffield, England) was used to measure the thickness and diameter of twenty tablets from each of the three brands under investigation. Each dimension's average value was noted.

3.2.1.2. Dispersibility. The mechanical breakdown of a tablet or granulated particles into smaller particles is known as dispersibility. This is a physical process that occurs when the granulated particles of the active pharmaceutical ingredient (API) and excipients are compressed into tablets. Typically, a liquid disintegrates and breaks down into tiny particles after wetting the tablet's surface and penetrating its pores.

Dispersibility is a physical process involving the mechanical breakdown of interparticle interactions created during compression of the tablet which result in smaller particles and disintegrates. This process

Table 1
Diclofenac marked products in Saudi Arabia.

Product	Manufacturer	Strength	Batch number/lot number	Manufacturing date	Expiry Date
G1	SPIMACO	50 mg	1144317	MAY 2023	MAY 2025
G2	GLOBAL PHARMA	50 mg	B254	APRIL 2022	APRIL 2025
G3	JAMJOOM PHARMACEUTICALS COMPANY	50 mg	ZN0184	DECEMBER 2022	DECEMBER 2025

occurs when liquid wets the tablet surface and enters the pores inside tablets. The criteria for dispersible tablets require disintegration within 3 min when using water at a temperature range of 15–25 °C. To test the dispersibility, one tablet was placed in 25 ml of water and stirred until it was completely dispersed. The test was repeated using six tablets of each brand (European Pharmacopoeia, 2006).

3.2.2. Friability

The friability of tablets is determined according to USP41-NF36. Briefly, 20 tablets were weighed (W1) and place them in the friability instrument (Erweka, TA3R, Heusenstamm, Germany) and they rotated at 25 rpm for 4 min. Then, the tablets were weighed again after removing the residue (W2) and the friability was calculated as follows:

$$\%Friability = \frac{W1 - W2}{W1} * 100 \quad (1)$$

For tablet unit weight equal to or less than 650 mg, take a sample of whole tablets as near as possible to 6.5 g (USP, 2010).

3.2.3. weight variation

A weight-variation test was performed to ensure uniformity in the weight of the prepared tablets. Twenty tablets from each formulation batch were randomly selected and accurately weighed one by one using a digital scale, and their average weights were calculated and recorded as mean ± SD.

3.2.4. Content uniformity

Content uniformity was determined by taking a sample of not less than (NLT) 30 tablets. Ten units were individually assayed as directed in the individual monograph assay. The requirements are met USP41-NF36 if the acceptance value of the first 10 dosage units is less than or equal to L1 % (i.e. ≥ 15). If the acceptance value was greater than L1(%, i.e., > 15), the next 20 units were tested. The requirements are met if the final acceptance value of the 30 dosage units is less than or equal to L1 %(i.e. ≥ 15) and all individual dosage units fall within the range [1+(0.01) (L2)]M to [1(0.01) (L2)] M. I. no dosage unit result can be less than [1-(0.01) (L2)] M while on the high side no dosage unit result can be greater than [1+(0.01) (L2)]. SP41-NF36 (10). The acceptance value (AV) was calculated using the following formula:

$$AV = (M - X) + ks \quad (2)$$

where, k = acceptability constant.n = sample size (no. of units):if n = 10 then k = 2.4if n = 30 then k = 2.0s = sample standard deviation.M = Reference

3.2.5. Chemical potency

We evaluated the chemical potency by taking a sample of 10 tablets from each brand, grinding them together, and then measuring a portion equivalent to the average tablet weight. For a product to be considered acceptable, its weight should be within 90 % to 110 % of the amount stated on the label (USP, 2024).

3.2.6. In vitro dissolution

Dissolution test is one of the standard requirements for the tablets to evaluate the drug release. The dissolution test was performed according to USP 41-NF 36 using (apparatus 2 (DT-70 dissolution test instrument, manufactured by (Pharma Test, Germany). The paddle was driven at 50 rpm in 900 ml of phosphate buffer (pH 6.75–6.85). The samples were withdrawn at 5, 10, 15, 20, 30, and 45 min. The amount of diclofenac dissolved in the dissolution medium was determined using spectrophotometry at a wavelength of 276 nm. Phosphate buffer (pH 6.8) was prepared by mixing sodium dihydrogen phosphate (ROMIL UK) 34 g, and sodium hydroxide (Loba Chemie India) 4.5 g in a volumetric flask containing 5 L distilled water.

The dissolution efficiency (DE) was calculated according to the following formula:

$$DE = \frac{\int_{t1}^{t2} ydt}{y100X(t2 - t1)} X100 \quad (3)$$

The Similarity factor (f2) values were calculated using the following equation (FDA, 2024):

$$f2 = 50\log\{[1 + \frac{1}{n}\sum_{n=1}^{n}(Rt - Tt)^2]^{-0.5}\} * 100\} \quad (4)$$

4. Results

4.1. Physicochemical characteristics

Color: A white color.
Odor: Clean and neutral, with no detectable odor.
Shape: Square for G1, round for G3 and G2.
Table 4 summarizes the main result.

4.1.1. Hardness, thickness, and diameter

The hardness values of all three generic brands (G1, G2, and G3) met the established acceptance criteria (4–8 kp) for uncoated tablets. The individual crushing strengths measurements were 6.07(0.3), 6.015(0.2) and 5.87(0.4), for G1, G2, and G3 respectively. Statistical evaluation of the diameter was performed to determine the diameter consistency of G1, G2, and G3. The analysis revealed minimal variation, with average values of 10.1(0.01), 8.02(0.05) and 9.50(0.08), respectively. This uniformity ensures that all of the brands comply with the stringent quality control standards.

The thickness should be controlled within ± 5 % variation of standard value, and the results showed G1 4.50(0.006), G2 3.53(0.005), and G3 4.53(0.006) fell within the acceptable range of ± 5 % variation from the average value as shown in Table 4.

4.2. Calibration curves

4.2.1. UV Spectrophotometric assay

The absorbance was linear over the concentration range (21–3 μg/ml) R-squared as seen in Fig. 1. We also determined the coefficient of determination (R^2 = 0.999). The drug concentration was calculated using the following equation:

$$A = 0.0356C - 0.0042.$$

4.2.2. High-performance liquid chromatography assay

The reported analytical method gave a well-detectable linear response for the concentrations studied (500–15.6 μg/ml) as seen in Fig. 3. R-squared or coefficient of determination (R^2) of 0.9999 with a well-resolved diclofenac peak at 2 min elution (Fig. 2). The drug concentration can be calculated from the equation:

$$A = 93696C + 321549$$

4.3. Dispersion test

Table 4 shows the results for all three brands and the results were as follows: G1 5 sec ± 0.63 %, G2 5 sec ± 0.63 %, and G3 5.16 sec ± 0.75 %. These results, with average dispersion times around 5 sec and minimal variation, indicate that all of the brands studied meet the established criteria.

4.4. Friability

The friability of G1, G2, and G3 was assessed by weighing 20 tablets before and after the process. Generally, a weight loss of less than 1 % is considered acceptable for most products. The initial test results showed

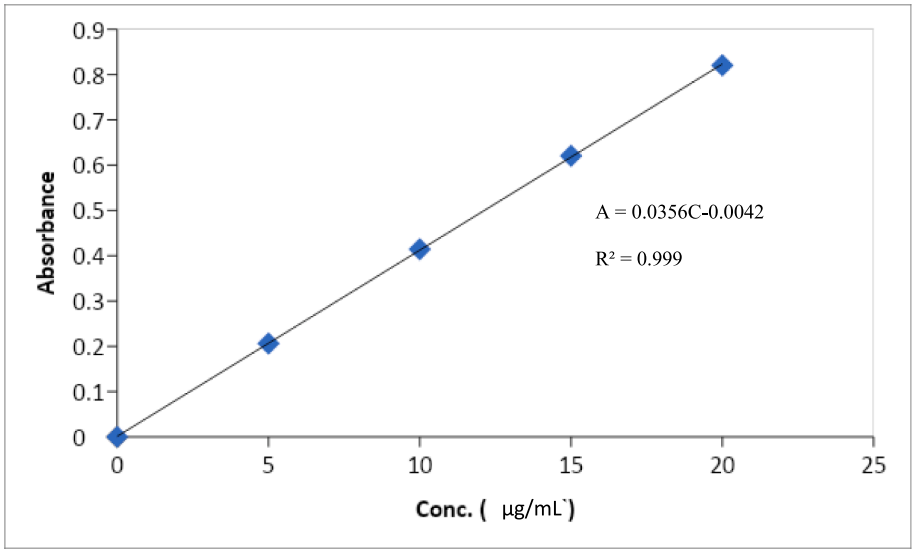

Fig. 1. Calibration curve of DS at 276 nm using UV Spectrophotometry.

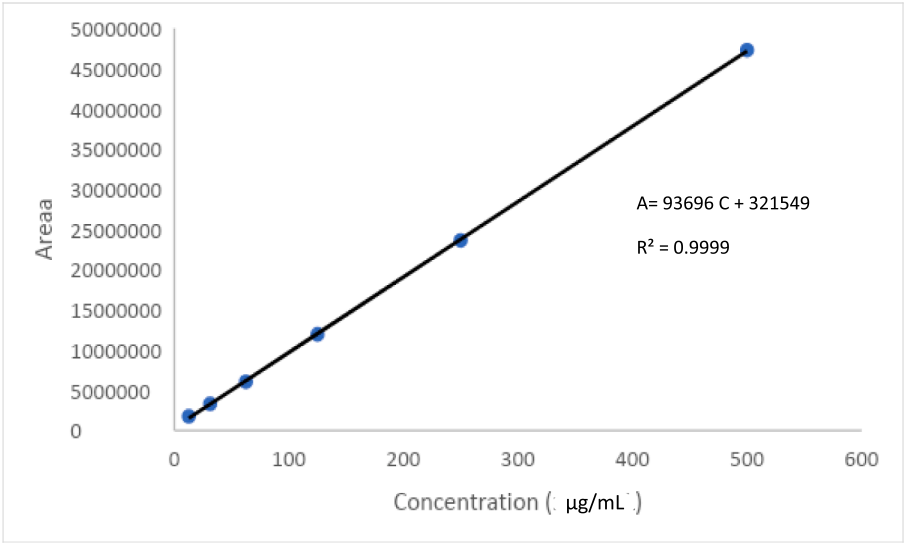

Fig. 3. Calibration curve of DS using HPLC assay.

that G1 and G2 performed well, with weight losses of 0.62 % and 0.94 %, respectively, falling within the acceptable range. However, G3 initial test revealed a higher weight loss of 1.54 %, exceeding the recommended limit. To ensure accuracy and rule out random variations, retests on G3 using two additional samples of 20 tablets each were undertaken. The retest results were significantly lower, with weight losses of 0.23 % and 0.17 %, respectively. By calculating the average weight loss across all three tests for G3 (0.064 %) confirmed that it too met the acceptable friability criteria Table 3.

4.5. Weight variation

A weight variation test was conducted on the three generic diclofenac brands (G1, G2, and G3), and the results are presented in Table 4. This test involved meticulously weighing 20 tablets from each brand and calculating the average weight and standard deviation. G1 showed an average weight of 304.10 ± 4.54 mg. G2 had an average weight of 198.91 ± 1.190 mg. Finally, G3 showed an average weight of 301.13 ± 1.048 mg. Generally, a weight variation of less than ± 5 % from the average weight is considered acceptable. As evident from the results, all three brands fell within this limit.

4.6. Content uniformity and potency

All brands contained (G1, G2, and G3) tablets formulated with diclofenac acid equivalent to 50 mg of diclofenac. A content uniformity test was conducted using 10 tablets from each brand. Individual tablets were extracted with methanolic sodium hydroxide 0.1 M and the concentration was measured after dilution using the previously mentioned HPLC method. Both G1 and G2 demonstrated acceptance values (AV) of 10.32 and 11.53, respectively, which fell within the acceptable range established by the USP. The requirements are met if the acceptance value of the first 10 dosage units is less than or equal to L1 (% i.e., ≤15) = However, the result for G3 was not compiled. The result of the first 10 tablets shows an AV of 21.35 and according to the USP, if the AV is greater than L1 (% i.e., > 15) then the test should be conducted on the next 20 units and the result of AV of the total 30 units was 11.56. For G3, the requirements were met because the final AV of the 30 dosage units was less than or equal to L1 % (i.e., ≤15). The potency results shown in Table 3 demonstrate that all three brands comply with the USP

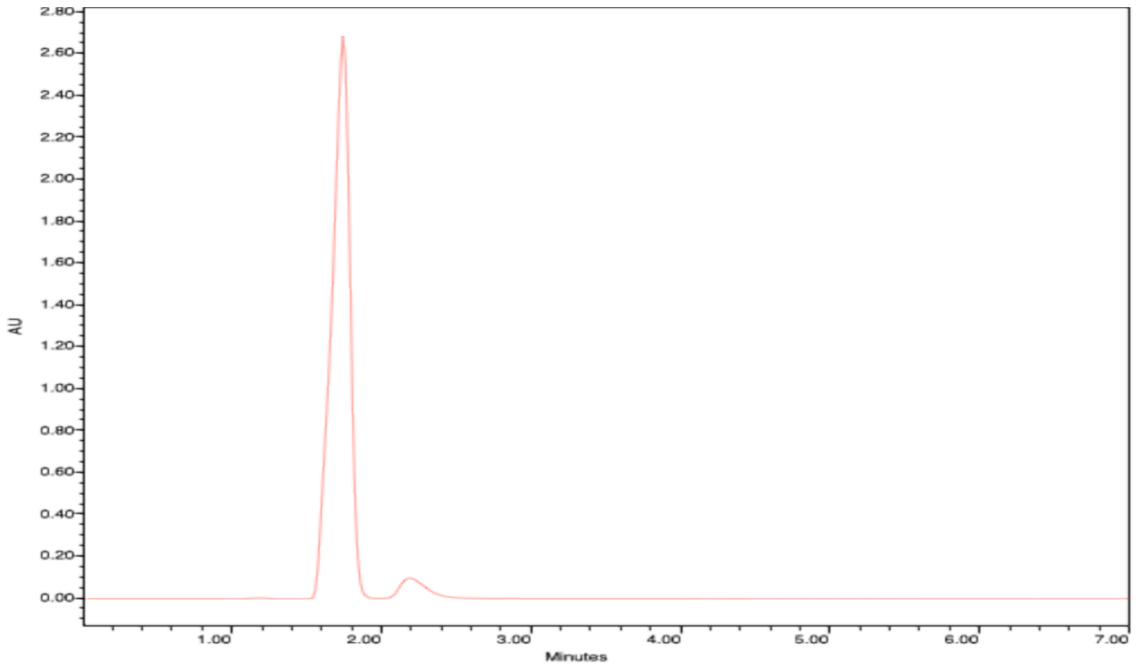

Fig. 2. HPLC Chromatogram of DS.

Table 3
In-vitro quality tests of three generic dispersible tablets containing diclofenac available on the Saudi market.

	Hardness (*Kp) mean (±SD%) n = 10	Thickness (mm) mean (±SD%) n = 10	Diameter (mm) mean (±SD%) n = 10	Dispersion Test (*sec) mean (±SD%) n = 6	Friability % loss n = 20 or 60	Weight variation (mg) mean (±SD%) n = 20	Potency Average content %)) mean (±SD%) n = 10
G1	6.07 (0.3)	4.50 (0.006)	10.1 (0.01)	5 (0.63)	0.62 %	304.10 (4.54)	106.5 % (2.17)
G2	6.015 (0.2)	3.53 (0.005)	8.02 (0.05)	5 (0.63)	0.94 %	198.91 (1.190)	105.4 % (4.4)
G3	5.87 (0.4)	4.53 (0.006)	9.50 (0.08)	5.16 (0.75)	0.64 %	301.13 ((1.048	104.2 % (4.8)

* Kp = kilogram force.
* Sec = second.

Table 4
Results of content uniformity.

T value G2	**100.0 %**	**T value G1**	**100.0 %**	**T value G3**	**100.0 %**	**T value G3**	**100.0 %**
L1	15.0	**L1**	15.0	**L1**	15.0	**L1**	15.0
L2	25.0	**L2**	25.0	**L2**	25.0	**L2**	25.0
Average of 10 values	101	**Average of 10 values**	106.6	**Average of 10 values**	103.98	**Average of 30 values**	104.25
The standard deviation of 10 values	4.8	**The standard deviation of 10 values**	2.178	**The standard deviation of 10 values**	7.866	**The standard deviation of 10 values**	4.4
M = X-, (AV = Ks)	101	**M = X-, (AV = Ks)**	101.0	**M value: (If X > 101.5 %)**	101.5	**M value: (If X > 101.5 %)**	101.5
AV = Ks	11.53	**AV = X −101.5 + Ks = (106.6–101.5) + 2.4 (2.78)**	10.33	**AV = X −101.5 + Ks = (103.98–101.5) + 2.4 (7.86)**	21.35	**AV = X −101.5 + Ks = (104.25–101.5) + 2.0 (4.4)**	11.56
Result	Pass	**Result**	Pass	**Result**	Fail	**Result**	Pass

specifications. This means the diclofenac content of each brand was within the acceptable range established by USP which typically falls between 90 % and 110 % of the labeled amount as seen in Table 4.

4.7. In vitro dissolution

In vitro dissolution testing was used to assess the release profiles of G1, G2, and G3. The USP (United States Pharmacopeia) establishes minimum requirements for the percentage of drug released S1: it should be not less than Q + 5 % i.e and the Q of diclofenac sodium should be 75 % of the labeled amount after 45 min. The results for G1 and G2 showed that all individual units tested passed the USP Acceptance criteria S1, as shown in Table 5. However, the initial testing S1 for G3 tablets presented two out of six tablets did not achieve the minimum USP criteria; a repeat test was conducted on another six tablets of G3, and the results showed the average of the 12 tablets was 90.32 %, which is more than 75 %, and not less than 60 %, which means it met the USP requirement at S2.

Dissolution efficiency(DE).

Fig. 4 shows the dissolution profiles of the three generics of diclofenac tablets the average amount dissolved after 45 min was 105 ± 3.7, 95.2 ± 7.7, 90.3 ± 5.4 for G1, G2, and G3 tablets respectively.

Results of calculated dissolution efficiencies show values as follows:

Table 5
% Diclofenac dissolved from the tested products.

Stage	Time (min)	% Diclofenac dissolved G1					
		Tablet 1	Tablet 2	Tablet3	Tablet 4	Tablet 5	Tablet 6
buffer stage at 6.8	45	106.12	99.77	95.15	114.44	113.80	91.47
	% Diclofenac dissolved G2						
	45	90.03	95.38	86.16	100.57	88.79	97.52
	% Diclofenac dissolved G3						
	45	84.69	83.20	88.80	92.48	75.97	70.59
		102.83	99.27	102.81	79.13	104.80	99.29

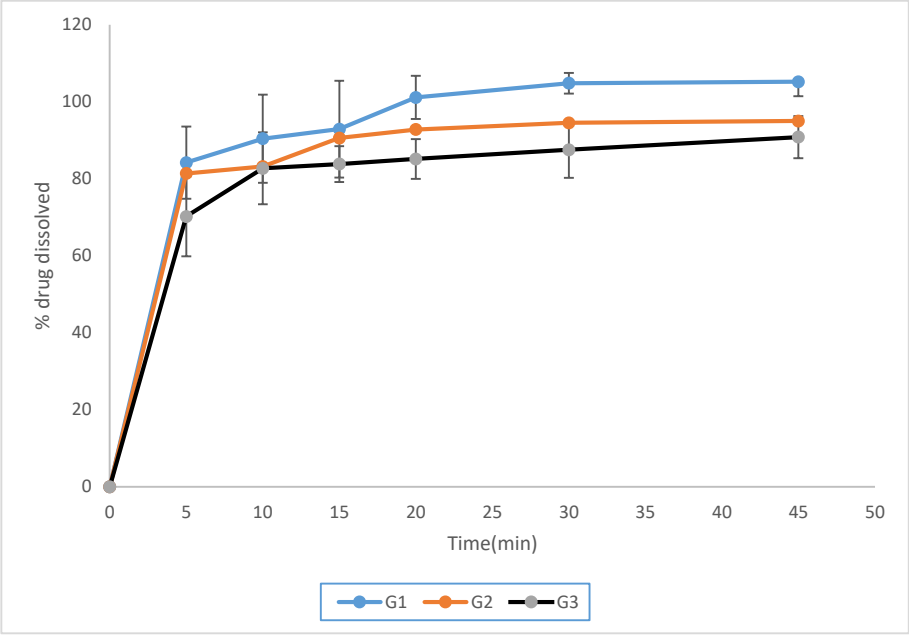

Fig. 4. Dissolution profile for different Diclofenac generic tablets.

G1, 78.83 %; G2 72.23 %; and G3, 67.50 %.

The similarity factor values(f2):

According to US Food and Drug Administration (FDA) guidelines, a similarity coefficient (f2) value greater than 50 (50–100) indicates similarity of dissolution profiles (FDA, 2024).

G1 (Reference) and G2 with an f2 of 58.3 had similar dissolution profiles, the dissolution profiles for the two products may be considered similar without f2 calculation since more than 85 % of the drug was dissolved within 15 min (SFDA Guidelines for Bioequivalence, Similarity while G3 had an f2 of 47.5 did not show a similar dissolution profile to the reference.

5. Discussion

Achieving safe, stable, and effective therapy is the primary goal of developing the drug delivery system. For many years, oral drug delivery was the most preferred method. In current study, we evaluated the in vitro quality of three generic acid-free formulations of diclofenac equivalent to 50 mg of diclofenac sodium dispersible tablets commercially available in Saudi Arabia. Except for the borderline performance of one generic product (G3), all formulations have passed in vitro quality testing according to the US Pharmacopeia and European Pharmacopoeia.

Regarding the strength assay, HPLC confirms that excipients in pharmaceutical formulations do not interfere with UV absorption at 276 nm. The potency results demonstrated that all three brands complied with USP specifications. Thus, the diclofenac content in each brand was within the acceptable range established by USP (USP, 2024), which typically falls between 90 % and 110 % of the labeled amount. All brands demonstrated minimal weight variation, with average weights falling within the acceptable range of ± 5 % from the mean. This ensures consistent dosing across tablets within each brand, which agrees with the results of a previous study on enteric-coated diclofenac tablets and sustained-release diclofenac sodium tablets (Hammami Muhammad et al., 2020; Hammami et al., 2020) In addition, we found a remarkably rapid dispersion time of approximately 5 s for all of the three generic brands studied. This was significantly faster than the 3.25 to 3.75 min reported in an Indian study on dispersible tablets (Shrivastav et al., 2023).

All the brands displayed acceptable friability and minimal weight loss. G1 and G2 passed the content uniformity test in their first attempt. G3 initially failed the content uniformity test but passed upon retesting with an additional sample.

Notably, there is no monograph on dispersible diclofenac tablets; therefore, we used the dissolution criteria stated for delayed-release diclofenac tablets (buffer phase). G1 and G2 tablets passed the USP Acceptance criteria S1, as shown in Table 1.

However, the initial testing S1 for G3 tablets presented two out of six tablets did not achieve the minimum USP criteria; a repeat test was conducted on another six tablets of G3 and the result showed the average

12 tablets was (90.32 %) more than 75 % and not less than 60 %, which means it met the USP requirement at S2. For comparison, the DE was calculated for the three generics. G1 showed the highest DE (78.83 %), followed by G2 (72.23 %) and G3 (67.50 %).

According to the Food and Drug Administration (FDA) guidelines, similarity factor values (f2) greater than 50 (50–100) (FDA, 2024) indicate similarity of the dissolution profiles; the reference product Voltaren-D is not yet available in the Saudi market. Therefore, we used the G1 dissolution data, which showed the highest DE, as the reference product for calculating the f2 ratio. G1 Reference and G2, had an f2 of 58.3. This meant they had similar dissolution profiles, whereas G3 with an f2 of 47.5 showed borderline performance.

The quality of generic drug products marketed in Saudi Arabia is guaranteed by the present results, as well as the outcomes of multiple pre-marketing, post-marketing, and in vivo bioequivalence studies on the most popular pharmaceutical products. These findings highlight the importance of continuous monitoring of marketed formulations.

6. Conclusions

We have evaluated the in vitro quality of three generic 50 mg diclofenac dispersible tablets commercially available on the Saudi market. All of the generics passed in vitro quality tests according to USP (41-NF 36). While all three generic brands (G1, G2, and G3) initially appeared to meet the USP standards, further testing with a larger sample size is needed for G3 to definitively confirm its compliance with the dissolution, friability, and content uniformity criteria. Further research should involve in vivo studies to assess the bioavailability and clinical effectiveness of these generic brands compared to the reference product. To guarantee the continued safety and efficacy of multisource medications, a robust national quality control system should prioritize post-marketing evaluation of drug performance.

Declarations.

Ethics approval and consent to participate.

The study did not involve human or animal subjects. Not applicable.

Consent for publication

Not applicable.

Availability of data and materials.

Raw data are available from the corresponding author upon request.

Authors' contributions.

All the authors contributed to the conception, design, and implementation of the study. The manuscript was drafted and critically revised by Samiah Alhabardi and Gamal Mahrous.

CRediT authorship contribution statement

Samiah Alhabardi: Writing – review & editing, Supervision, Project administration, Methodology, Funding acquisition. **Gamal Mahrous:** Writing – review & editing, Validation, Supervision, Project administration, Methodology. **Asma Alshahrani:** Writing – original draft, Methodology, Investigation, Data curation. **Ehab Taha:** Writing – original draft, Validation, Methodology.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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