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Pharmaceutical Quality Evaluation of Commercial Baclofen Tablets in the Yemeni Market: An *In Vitro* Study

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ABSTRACT

Background: For good health and improved trust in the pharmaceutical products, quality control tests must be conducted continuously for both local and imported products to ensure safety and effectiveness.

Objective: To evaluate the *in vitro* characterization of different imported and local pharmaceutical products of the muscle relaxant (baclofen 10 mg) available in Taiz City.

Methods: According to the USP standards, different quality control tests were conducted to physicochemically characterize various baclofen 10 mg tablets (one local and two imported brands) available in the Yemeni market.

Results: The results of the three brands of baclofen 10 mg tablets showed that product (C) disintegrated more slowly (6.39 minutes) than products (B) and (A) (0.35 and 3.00 minutes, respectively). Every brand has a satisfactory level of friability below 1% loss. The maximum assay content (98.39%) and drug release (105%) were displayed by local product (A). Although product (B) test content was lower (88.98%), its drug release was still satisfactory (96%). By contrast with product (B) (5.35 kg) and product (A) (5.38 kg), C product's hardness (2.26 kg) was below USP standards (4-6 kg), and its drug release was 85%; however, the assay content was significantly satisfactory (96.98%).

Conclusion: The outcomes of this study show a high dissolution rate and quick disintegration time, with assay content falling inside the acceptable range. While the imported products decomposed slowly, within the drug content limit, and had a lower hardness value than USP criteria, the local product had the best results in different characterizations. All results confirm the necessity of continuous monitoring for pharmaceutical products.

Keywords: Diabetes, HbA1c, Monitoring, Patient Compliance, Cross sectional study, Aden, Yemen.

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INTRODUCTION

An analog of gamma-aminobutyric acid (GABA), baclofen is a centrally acting muscle relaxant medication used to treat spasticity associated with conditions like multiple sclerosis, spinal cord injuries, and cerebral palsy [1]. Its activity depends on distributing accurate drug plasma concentration to provide the maximum therapeutic response while at the same time decreasing unwanted side effects. The oral solid dosage forms, such as tablets and capsules, are most commonly used in the pharmaceutical market due to their maximum stability and high efficacy. In the pharmaceutical market, especially in developing countries like Yemen, patients and medical professionals have access to a variety of trade names, including both domestically produced and those produced in foreign countries. The imported products may originate from various manufacturing areas and various GMP guidelines that lead to differences in vital quality control properties even when being pharmaceutically equivalent and composed of the same active materials [2, 3].

The need to confirm that all the available products in the market must meet the pharmacopeial standards to ensure the maximum therapy and minimum toxicity for patients, regardless of their origin. Differences in the quality control tests of tablets have an important effect on the absolute bioavailability, therapeutic efficacy, toxicity, and patient safety [4,5]. Good-quality medicines are a prerequisite for a successful treatment; however, access to medicines in terms of availability and affordability remains a major global health concern. The safety, effectiveness, and efficacy of pharmaceutical dosage forms can only be ensured when their quality is reliable [6, 7].

Therefore, many essential studies must be done to assess the different physicochemical tests of these brand names that originate from different regions. Such studies produce many correct results that can advise the medical healthcare providers with patients and inform regulatory decisions, ensuring that all marketed baclofen tablets are safe and effective [8, 9].

The main aim of this study is to apply a comparative quality evaluation of three commercially available brands of baclofen 10 mg tablets, expressed by national (domestic) and imported foreign products in the Yemeni market—particularly in Taiz city. The main objective is to assess the different *in vitro* physicochemical characteristics, including weight variation, hardness, friability, disintegration time, *in vitro* drug release, and potency of active drug content, against the pharmacopeial standards as the United States Pharmacopeia (USP) [10]. It also aims to determine the significant variances between the chosen products and to ensure that these products comply with the proved pharmacopeial standards.

METHODOLOGY

Materials

Pure baclofen was kindly provided from the Yemeni-Egyptian company Sana'a, Yemen. Three commercially available brands of baclofen (10 mg) tablets were procured from local pharmacies for this study, as detailed in Table 1.

All chemicals and reagents used were of analytical grade. Distilled water was used throughout the study. For the dissolution test, a suitable dissolution medium as specified in the United States Pharmacopeia (USP) for baclofen tablets was used.

Table 1: Different brand products of baclofen 10 mg used in the study

Brand Code	Batch No.	Man. Date	Exp. Date
A	22475	11/2022	11/2025
B	1204012	09/2024	09/2027
C	R24369	10/2024	09/2027

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Analytical Methods

A laboratory-based analytical study was conducted to evaluate the quality of three commercially available products of baclofen 10 mg tablet brands. All *in vitro* tests were performed in accordance with United States Pharmacopeia (USP) specifications [10]. Results for quantitative analyses are presented as mean ± standard deviation from a sample size of ten replicates (n=10).

Spectrophotometric Method Development and Validation

The quantification of baclofen was performed using a validated UV-Vis spectrophotometric method. The instrument was initially calibrated using a standard baclofen solution .

The stock solution of baclofen was provided by dissolving 10 mg of baclofen in 200 mL of 0.1 N HCl (pH 1.2) to produce a solution of concentration of 50 µg/mL. Then different standard drug solutions of various concentrations, such as 5, 10, 15, 20, 25, and 30 µg/mL, were prepared accurately by suitable dilution of the stock solution prepared previously with the diluent used, 0.1N HCl [11].

For all prepared solutions, the absorbance was determined at λmax 220 nm using a UV-Vis spectrophotometer. A calibration curve was then formulated by plotting absorbance against concentration. The data showed a linear relationship, and a least-squares linear regression analysis yielded the equation y = 0.063x + 0.0234 with a correlation coefficient (R^2) of 0.9968, confirming the linearity of the way on the range used, and the resulting calibration curve is shown in Figure 1.

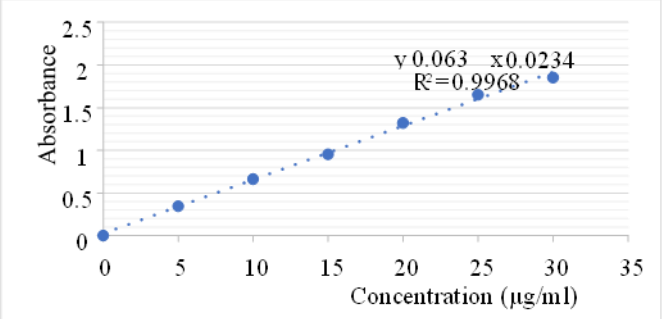

Figure 1: Standard calibration curve of baclofen in pH 1.2 solution at 220 nm .

In-Vitro Quality Control Tests

To compare between different products, the following physicochemical characterization studies were achieved on all brands of baclofen tablets 10 mg used in this study depending on the United States Pharmacopeia (USP) standards [10, 12]. For each study, a sample of tablets was determined randomly.

Weight Variation

The purpose of this test is to ensure uniformity of dosage form weight. Twenty tablets from each brand were individually weighed on an analytical balance. The average weight was calculated, and the percentage deviation for each tablet was determined. Depending on USP guidelines, the study is within the limit if not more than two tablets deviate from the average weight by more than ±10% for tablets weighing 130 mg or less, ±7.5% for tablets weighing between 130 mg and 324 mg, and ±5% for tablets weighing more than 324 mg [10, 12].

Thickness

The distance between the upper and lower surfaces of ten tablets for each brand was measured using a calibrated digital micrometer. Precise management of tablet thickness ensures proper tablet appearance, uniformity, correct dose, and good packaging fit. After statistical analysis, the registered values were displayed as the mean ± standard deviation [10, 12].

Hardness Test

Using a hardness tester, the crushing force needed to break 10 tablets separately of each brand was used to calculate the mechanical strength of the tablets. The force needed, measured in kilograms (kg), gives a numerical representation of each tablet's ability to resist mechanical stress during handling, storage, and transit. The acceptance range of hardness is 4-6 kg, which is commonly regarded as indicative of suitable strength for handling and packaging without being too hard to disintegrate or too soft to break during handling [10, 12].

Friability Test

This test evaluates a tablet's resistance to abrasion and shock. A pre-weighed sample of twenty tablets was placed in a friabilator and rotated at 25 revolutions per

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minute for 4 minutes (100 revolutions). The tablets were then de-dusted and reweighed. The percentage friability was calculated. As per USP, a loss of less than 1.0% of the initial weight is generally considered acceptable for most compressed tablets [10, 12].

Disintegration Test

The disintegration time was determined using a USP disintegration apparatus with distilled water as the medium maintained at 37 ± 0.5°C. Six tablets were tested individually. For uncoated tablets, the USP specification requires disintegration within 5 to 30 minutes [10, 12].

In-Vitro Drug Release Test

The *in vitro* drug release profile was measured through a dissolution apparatus (USP Apparatus II, paddle type) at 50 rpm. The study was done in 900 mL of 0.1N hydrochloric acid (pH 1.2) maintained at a constant temperature of 37 ± 0.5°C. Samples were withdrawn at predetermined time intervals (5, 10, 15, 25, and 30 minutes), then filtered, and then the concentration of drug was measured by UV-Vis spectrophotometry at λmax 220 nm [10, 13].

Drug Content Test

The drug content was determined to verify the amount of active pharmaceutical ingredient. Ten tablets of different trade names were preciously weighed and then ground to a powder state. A small amount of tablet powder that was equal to the weight of one tablet was dissolved in 0.1N HCl, agitated strongly for 15 minutes, and diluted to 200 mL. The solution was then filtered, and the absorbance was measured at 220 nm. The percentage of the labeled claim was calculated against a standard calibration curve. The USP acceptance criterion for the assay is 90% to 110% of the labeled amount of baclofen [10, 13].

RESULTS

Physical Parameters

All three brands demonstrated acceptable performance in terms of weight variation and thickness as shown in Table 2 and Figures 2 and 3, with values falling within the USP acceptance criteria. The friability test also showed (as in Table 2 and Figure 4) that all products—(A) with (0.342%), (B) with (0.283%), and (C) with (0.530%)—exhibited weight loss below the 1.0% USP limit, confirming their resistance to abrasion.

However, a small deviation was noticed in the data of the hardness test as represented in Table 2 and Figure 5. Product (A) with 5.380 kg and product (B) with 5.350 kg showed hardness values within the acceptable limits of the USP range of 4-6 kg, while product (C) showed a low value of hardness of 2.266 kg, which is lower than the standard limits that could affect the stability and durability during packaging and transport.

Table 2: Hardness, Friability, Thickness and Weight variation results of different brands of baclofen tablets.

Brand Code	Friability (%) ± SD	Thickness (mm) ± SD	Weight Variation (%) ± SD	Hardness (kg) ± SD
A	0.342 ± 0.23	3.751 ± 0.11	3.07 ± 0.43	5.380 ± 1.32
B	0.283 ± 0.15	2.882 ± 0.21	2.72 ± 0.61	5.350 ± 1.65
C	0.530 ± 0.38	3.793 ± 0.35	3.85 ± 1.2	2.266 ± 0.76

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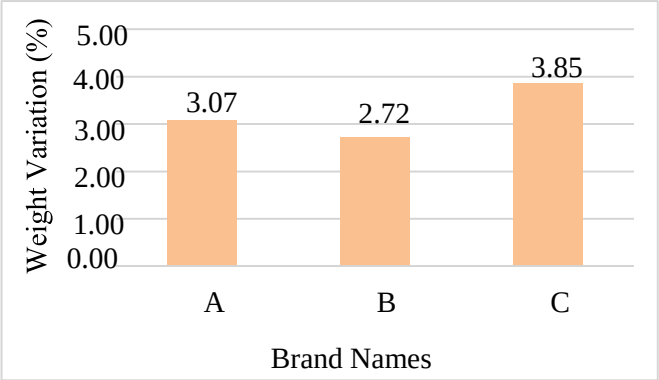

Figure 2: Weight variation of different brands of baclofen tablets

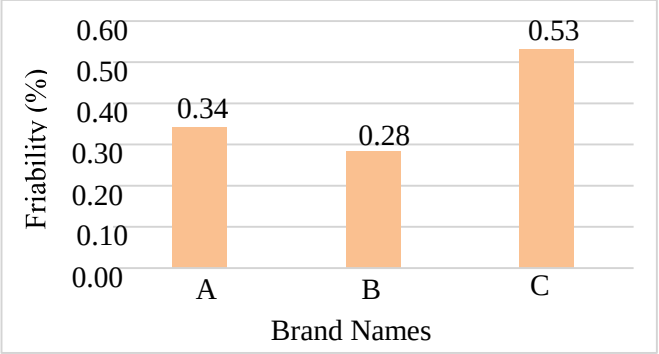

Figure 3: Friability data of different brands of baclofen tablets

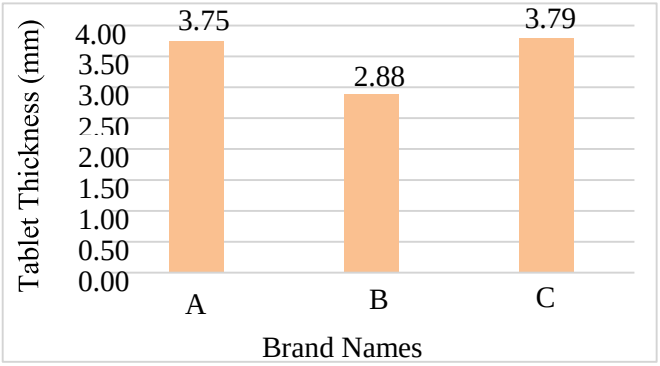

Figure 4: Thickness data of different brands of baclofen tablets

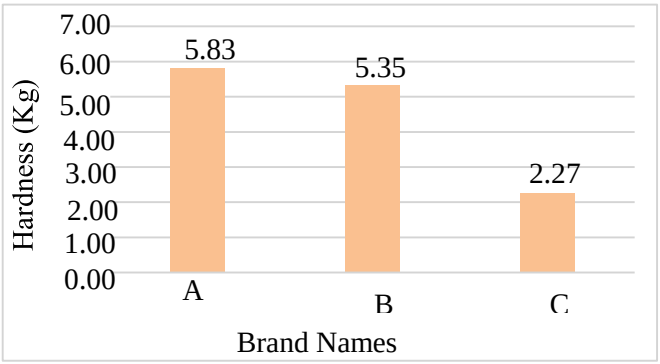

Figure 5: Hardness data of different brands of baclofen tablets

Performance Parameters

The disintegration time, a critical factor for drug absorption, varied considerably, as shown in Table 3 and Figure 6. Both product (A) (2.35 min) and product (B) (3.00 min) disintegrated rapidly, well below the USP specification of 5-30 minutes for uncoated tablets. In contrast, product (C) disintegrated within the acceptable range but at a slower rate of 6.39 min.

Table 3: Drug content assay and Disintegration time of different brands of baclofen tablet.

Brand Code	Disintegration Time (min.) ± SD	Assay (%) ± SD
A	2.35 ± 0.76	98.39 ± 1.09
B	3.00 ± 1.06	88.98 ± 0.79
C	6.39 ± 0.96	96.98 ± 1.13

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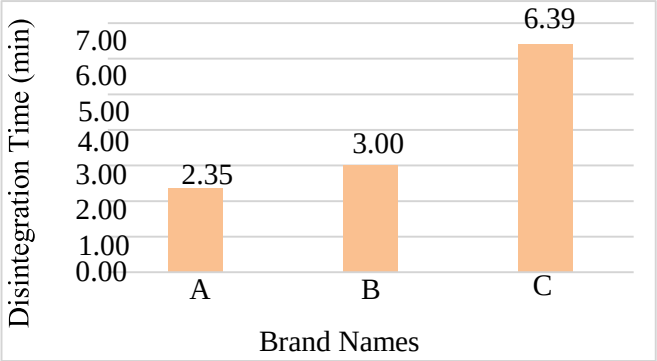

Figure 6: Disintegration time of different brands of baclofen tablets

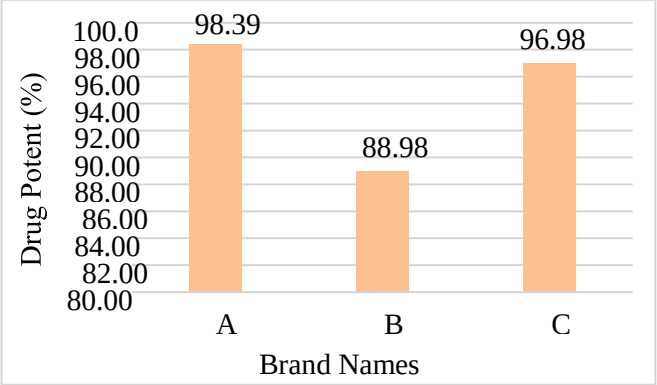

Figure 7: Drug content assay of different brands of baclofen tablet

The *in vitro* release or dissolution profile after 30 minutes (as shown in Table 4 and Figure 8) and assay content (as shown in Table 3 and Figure 7) further highlighted quality differences. Product (A) showed perfect performance, indicating effective release of the right amount of medication, with a high dissolution rate (105%) and an assay content (98.39%) that was very close to the declared claim.

Product (B) sub-potent assay content (88.98%) is outside the USP acceptable range of 90-110%; despite its high dissolving rate (96%), this suggests that there may be issues with the content's stability or consistency. Product (C), on the other hand, demonstrated a dissolution rate that was around the expected value (85%) but a considerably greater assay content (96.98%), substantially above the USP limit and indicating an overage in the active ingredient (Table 2).

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Table 4: *In vitro* release profiles of baclofen 10 mg tablet brands

Time (min.)	Product (C)	Product (B)	Product (A)
5	15 ± 1.09	22 ± 0.65	34 ± 1.97
10	25 ± 2.97	30 ± 2.98	56 ± 4.98
15	36 ± 1.98	47 ± 1.07	87 ± 2.07
25	67 ± 3.23	83 ± 3.09	102 ± 3.21
30	85 ± 0.99	96 ± 4.31	105 ± 1.98

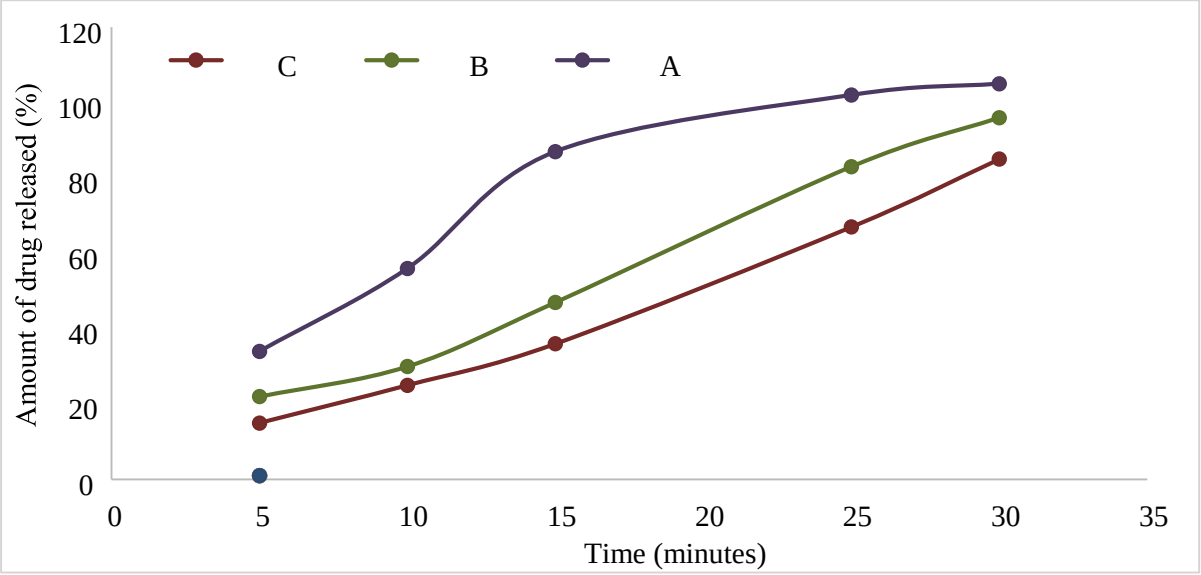

Figure 8: The *in vitro* release profiles of baclofen 10mg tablet brands

DISCUSSION

Healthcare professionals are concerned about choosing pharmaceutical medications from a variety of generic drug items that have the same active ingredients. Assuring a drug's chemical and biologic equivalency is the first step in ensuring its therapeutic equivalency. Ensuring the quality and interchangeability of multisource pharmaceutical products is a challenge in developing nations. There have been reports of batch variance and clinical response variability among generic medications [14]. The stability and effectiveness of NSAID tablets may be affected by improper storage conditions, such as exposure to high temperatures and humidity [15].

The three baclofen brands that are marketed in Yemen, specifically in Taiz City, are compared in this study through quality control tests. In light of current pharmacopeial standards and the available research, the results revealed variations in quality that can be critically examined. One noteworthy discovery is that product (C) hardness (2.26 kg) is significantly less than that of the other brands and the USP recommended (4–6 kg). The hardness of a tablet is directly influenced by the excipients used during the manufacturing process and the compression force. Low hardness can lead to problems like chipping, breaking during handling, and increased friability, which can affect the dose and product stability [16]. Although product (C) friability was still within acceptable ranges (0.530%), its low hardness suggests a formulation or manufacturing technique that would not provide adequate mechanical strength. Studies evaluating other generic drugs from

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overburdened supply networks have brought up this concern [7, 17].

The reported disintegration times are in line with the hardness results. The rapid disintegration of product (B) (3.00 min) and product (A) (0.35 min) aids in the tablet's rapid breakdown and release of the active ingredient. Product (C) delayed disintegration (6.39 min) may be directly connected to its manufacturing process even though it is below the pharmacopeial limit. Research indicates that the type and amount of disintegrants are crucial, and improper concentrations can delay disintegration [18]. Super disintegrants were successfully added to the formulations of products (A) and (B), as evidenced by their faster disintegration.

The most important findings are the assay content and dissolution profiles. Product (A) assay result (98.39%) fell within the acceptable USP range (90–110%) and demonstrated precise control over the active ingredient during manufacturing. However, because product (B) sub-potent assay value (88.98%) suggests the patient would receive a sub-therapeutic dose, which could jeopardize therapy efficacy, it presents serious quality difficulties [4]. These discrepancies, which are frequently linked to differences in raw material quality or insufficient quality control procedures, have been shown in numerous investigations comparing imported generics [3, 19]. On the other hand, product (C)'s super-potent assay result of 85% raises the possibility of an ineffective dose because it may result in a non-therapeutic dose and a higher likelihood of the diseases not being treated [1]. This large overage clearly indicates an extreme failure in the content uniformity step of the production process [20].

One important indicator of in vivo bioavailability is the dissolution rate. Excellent drug release properties are suggested by the high dissolution rates of product (B) (96%) and product (A) (105%). However, the dissolution result must be interpreted alongside the assay content. For product (B), the high dissolution rate is misleading because the tablet contains less active ingredient. For product (C), the two properties, *in vitro* release after 30 minutes (85%) with a high value of drug content, mean that the amount of drug released is directly proportional to each other, and this confirms that these two factors have an important role in the determination of the quality of products [5,9]. In summary, while product (A) demonstrated overall compliance with USP pharmacopeial guidelines, products (B) and (C) showed significant deviations, particularly in drug assay content, which could have direct clinical effects for both patient safety and efficacy. These results highlight the need for thorough post-market monitoring to verify the quality of pharmaceutical goods [8, 17].

CONCLUSION

Three commercially available baclofen tablets underwent quality control testing, and the results showed considerable variation. The sole locally manufactured product that satisfied all USP quality requirements was product (A), which demonstrated acceptable friability, hardness, and—most importantly—an assay content within the USP standard range. The imported products, on the other hand, showed critical deviations; product (B) was sub-potent with low drug content, which is less than the pharmacopeial limits (out of limits) and acceptable therapeutic efficacy. Product (C) displayed a low discrepancy, with a lower drug content and a hardness value below the USP guidelines.

These findings emphasize two concepts. First, they disprove the popular notion that local medications are of poorer quality because product A demonstrated superior compliance in this evaluation. Second, they highlight how comprehensive and continuous post-market quality monitoring is important. Such monitoring is crucial to identify noncompliant products, ensure consistent pharmaceutical quality, and ultimately protect public health by ensuring that patients receive safe and effective medication, especially in a market with a diversity of drug sources.

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Authors' Contributions

Bassam Abdo Ali and Mohammed Kaid Hassan contributed to the study conception and design, overall supervision, and critical revision of the manuscript. Sarah Ali Farea Alwan, Nora Abdusalam Sultan, Shaima Hamood Ahmed, Rawan Sufyan Al-Helali, Doa'a Abdullah Ahmed, Aya Ameen Rawah, Noran Nasr

Abdulela, and Rabia'a Adel Salem participated in methodology development, literature review, data collection and interpretation, and manuscript drafting. All authors reviewed and approved the final version of the manuscript and agree to be accountable for all aspects of the work.

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Conflict of Interest

The authors declare that there is no conflict of interest.

REFERENCES

[1] Ghanem, C. I., Pérez, M. J., Manautou, J. E., & Mottino, A. D. (2021). Acetaminophen from liver to brain: New insights into drug pharmacological action and toxicity. *Pharmacological Research, 169*, 105679.

[2] World Health Organization. (2022). *WHO global benchmarking tool (GBT) for evaluation of national regulatory systems*. World Health Organization.

[3] Ozili, P. K. (2020). The impact of non-performing loans on bank lending in emerging economies. *Journal of Financial Crises, 2*(3), 1–15.

[4] Gray, A., & Manasse, H. R., Jr. (2022). Shortage and mitigation of essential medicines: A review. *Clinical Pharmacology & Therapeutics, 111*(4), 815–824.

[5] Dressman, J. (2021). The BCS biowaiver scheme: 25 years of experience. *Journal of Pharmaceutical Sciences, 110*(7), 2591–2596.

[6] Khan, M. A., & Khan, T. (2021). A comparative study of the quality control parameters of paracetamol tablets marketed in Bangladesh. *Journal of Applied Pharmaceutical Science, 11*(04), 086–092.

[7] Al-Kassim, M. Y., Al-Maqtari, T. A., & Al-Adhal, L. M. (2020). Quality assessment of different brands of amoxicillin capsules available in Yemeni market. *Yemeni Journal of Medical Sciences, 14*(1), 1–10.

[8] Ravisankar, P., & Nair, A. G. (2020). A comprehensive review on pharmaceutical surveillance and drug recall. *Systematic Reviews in Pharmacy, 11*(12), 570–577.

[9] Shohin, I. E., Kulinich, J. I., Ramenskaya, G. V., Abrahamsson, B., Kopp, S., Langguth, P., Polli, J. E., Shah, V. P., Groot, D. W., Barends, D. M., & Dressman, J. B. (2021). Biowaiver monographs for immediate-release solid oral dosage forms: Baclofen. *Journal of Pharmaceutical Sciences, 110*(4), 1513–1521.

[10] The United States Pharmacopeial Convention. (2020). *United States pharmacopeia and national formulary (USP 43–NF 38)*.

[11] Sreekanth, D., & Patil, P. A. (2020). Development and validation of UV spectrophotometric method for the estimation of baclofen in bulk and tablet dosage form. *International Journal of Pharmaceutical Sciences and Research, 11*(5), 2301–2305.

[12] The United States Pharmacopeial Convention. (2020). 〈1217〉 Tablet breaking force. In *United States pharmacopeia and national formulary (USP 43–NF 38)*.

[13] The United States Pharmacopeial Convention. (2020). 〈711〉 Dissolution. In *United States pharmacopeia and national formulary (USP 43–NF 38)*.

[14] Othman, G. Q. (2017). Quality assessment of seven brands of albendazole tablets marketed in Yemen. *Yemeni Journal for Medical Sciences, 11*(1), 46–52.

[15] Almahmoodi, H., Alyousofi, D. M., Shaiban, E. A., Ahmed, H. A., Ateik, I. A., Abdullah, M. H., Ahmed, S. S., & Mohammed, S. A. (2025). Comparative study between commercial meloxicam tablets in Yemen. *Yemeni Journal for Medical Sciences, 19*(4).

[16] Al-Zuheiri, A., AlHajj, N., AlHalawani, O., & Awad, R. (2022). The impact of excipient variability on the quality attributes of directly compressed tablets. *Pharmaceutical Development and Technology, 27*(4), 405–416.

[17] Bansal, D., Malla, S., Gudala, K., & Tiwari, P. (2020). Antimicrobial resistance and post-marketing surveillance of medicines in resource-limited settings. *Journal of Global Antimicrobial Resistance, 22*, 798–800.

[18] Desai, P. M., Liew, C. V., & Heng, P. W. S. (2023). A review of disintegration mechanisms and measurement techniques. *Pharmaceutical Research, 40*(2), 317–335.
[19] Kratz, A., & Sejko, D. (2021). The quality of medicines in middle-income countries: A systematic review of the literature. *World Development, 138*, 105304.
[20] Yu, L. X., Amidon, G., Khan, M. A., Hoag, S. W., Polli, J., Raju, G. K., & Woodcock, J. (2022). Understanding pharmaceutical quality by design. *The AAPS Journal, 24*(2), 41.