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RESEARCH ARTICLE

MJM BIOLABS

Assessment of *In Vitro* Dissolution Profiles of Marketed Albendazole Tablets in Nakuru County, Kenya

Sarah VUGIGI[1*], Nathan KIPSANG[1], and Anderson CHEBON[1]

Authors' Affiliation

[1] Department of Pharmaceutical Chemistry & Pharmaceutics, School of Pharmacy, Kabarak University, Kenya

*Corresponding Authors: svugigi@kabarak.ac.ke

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ABSTRACT

Albendazole, a benzimidazole derivative, is widely used to treat helminth infections. The average prevalence of helminthiasis in Kenya is approximately 12.9%. Albendazole is classified as a BCS II class drug, exhibiting low solubility and high permeability, which can result in erratic bioavailability. In vitro dissolution testing provides valuable information for predicting the bioavailability of a drug, particularly in cases where absorption is limited by the dissolution rate. This study aimed to assess the *in vitro* dissolution profiles of seven brands of albendazole tablets sold in various pharmacy outlets in Nakuru County, Kenya. The tablets were randomly selected and subjected to standard quality control tests. Content of the drug substance in the tablets was determined by UV spectrophotometry. Disintegration and dissolution tests were performed as described in the USP monograph. All tested brands exhibited assay values within the acceptable range of 90% to 110%, ranging from 95.4% to 103.3%. Four brands complied with the specification for the disintegration test for immediate-release tablets which require disintegration within 15 minutes. One brand disintegrated in 33 minutes, whereas two did not disintegrate within 60 minutes. Four brands failed to meet the dissolution test specifications, releasing only 0.9%, 1.6%, 7.3%, and 20.8% of the labeled content, respectively, after 30 minutes. Their dissolution profiles were dissimilar to that of the reference brand. These findings indicate the presence of substandard albendazole tablets in the Kenyan market and underscore the need for regular post-marketing surveillance and quality assessments to ensure pharmaceutical equivalence among brands and safeguard patient safety.

Keywords: lbendazole, Bioavailability, Dissolution Test, In vitro Testing, Pharmaceutical equivalence.

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INTRODUCTION

Albendazole is a benzimidazole derivative that exhibits broad-spectrum anthelmintic activity against both intestinal and tissue parasites. Helminth infections affect over 1.5 billion people across more than 166 countries (Pullan et al., 2014), with significant endemicity in sub-Saharan Africa, Asia, China and south America (World Health Organization, 2023). In Kenya, over five million individuals, particularly school-aged children are at risk of infection (Okoyo et al., 2020), with an estimated national prevalence of 12.9% (Galia et al., 1999; Okoyo et al., 2020). Helminths such as *Trichuris trichiura, Ascaris lumbricoides*, and hookworms (*Necator americanus, Ancylostoma duodenale*) commonly reside in the intestinal lumen but may also affect internal organs such as the liver, lungs, muscles, and blood vessels (Mulcahy et al., 2005). Therefore, the absorption of albendazole (ABZ) from the gastrointestinal tract to the site of action is essential.

Albendazole is categorized as a Class II compound in the Biopharmaceutical Classification System (BCS), characterized by high permeability and low solubility (Dayan, 2003). Additionally, ABZ powder exhibits poor flow properties, which negatively affect both weight and content uniformity during the manufacturing process. The solubility and flowability of a drug are critical parameters in dosage formulation and should be carefully considered during product development to ensure consistent product quality and efficient production. Albendazole tablets were originally developed and introduced to the market in 1996 by GlaxoSmithKline (GSK).

Albendazole is primarily formulated as chewable tablets to facilitate disintegration and enhance drug release. Disintegration precedes the dissolution of the drug substance, which is essential for its systemic absorption (Markl & Zeitler, 2017). Dissolution measures the extent and rate at which a drug dissolves at a specific time, impacts bioavailability, and consequently influences its pharmacological action. Appropriate acceptance criteria for these quality attributes should be established during product development, as outlined in the Quality Target Product Profile (QTPP), which defines the desired quality characteristics of a drug product. The United States Pharmacopeia (USP) states that at least 80% (Q) of the labeled drug amount of ABZ must dissolve within 30 minutes (USP, 2020). Dissolution testing is a key tool for assessing pharmaceutical equivalence by comparing drug release profiles to a reference product, which provides better characterization than single-point tests (Muselík et al., 2021). The pharmaceutical equivalence of various commercial brands of a product serves as a marker of their therapeutic equivalence. Therefore, generic ABZ tablets should be formulated to ensure interchangeability with the innovator's product.

Albendazole presents formulation difficulties primarily due to its poor aqueous solubility, which may contribute to variability in the dissolution behavior of generic products (Galia et al., 1999; Amidon et al., 1995). Drug dissolution is influenced by critical parameters of both the drug substance and manufacturing process (Bojnanska et al., 2014). These factors should be thoroughly evaluated and validated during product development to ensure consistent product quality. The dissolution of the ABZ tablets can be improved by using micronized drug particles or nano particles in the formulation (Koradia & Parikh, 2012). Also, excipients such as diluents, disintegrants, and surfactants are intentionally incorporated to enhance the solubility of the drug substance. For instance, Kimaro et al. (2019) identified an optimal ABZ formulation containing sodium lauryl sulfate, polyvinylpyrrolidone, and sodium croscarmellose, which achieved rapid disintegration of 2 to 5 minutes and a dissolution rate of 91.5%. Notably, these factors can be identified during product development using Quality by Design (QbD) principles. Quality by Design approach enables systematic identification of formulation and process variables that impact critical quality attributes (CQAs), such as disintegration and dissolution, to meet a predefined QTPP (Sitre & Kamble, 2021; Aru et al., 2024)

The complexity of albendazole tablet formulation development, combined with limited research and development (R&D) capacity at some manufacturing facilities, presents a potential risk of dissolution test failures and the presence of substandard products on the market. The assurance of pharmaceutical equivalence and interchangeability of different drug product brands is a global challenge (Jouni et al., 2023; Yu & Maliepaard, 2018; Al-Jazairi et al., 2008). Market surveillance reports by the Kenya Pharmacy and Poisons Board (PPB) have shown that between 2018 and 2022, ten batches of ABZ 400 mg were recalled due to non-compliance with the dissolution test (Pharmacy and Poisons Board, 2022). The absence of assurance of pharmaceutical equivalence, combined with limited R&D capacity and the presence of non-compliant products, represents a significant gap in ensuring the quality and effectiveness of albendazole tablets in Kenya. Comparing the dissolution profiles of the albendazole innovator product and marketed tablet brands is important for assessing formulation similarity. Nakuru, one of the four cities in Kenya, with population of

approximately 2.1 million people (Abiri Kenya, 2025), was selected due to its proximity to the study site. Additionally, it has a young demographic profile that is more likely to be impacted by substandard anthelmintics (Covenant of Mayors, 2021, Masaku et al., 2017). This study evaluated the in - vitro dissolution profiles of seven albendazole chewable tablet formulations available and sold among pharmacy outlets in Nakuru County, Kenya. The innovator brand (Zentel tablets) was used as the reference. Disintegration and assay tests were also performed on the tablets, as both parameters impact dissolution. Testing adhered to the International Pharmacopoeia (Twelfth Edition, 2025), which specifies that chewable tablets must contain 90.0% to 110.0% of the labeled drug content, disintegrate within 15 minutes, and release not less than 80% (Q) of the labeled drug in 30 minutes. By comparing dissolution profiles and assessing pharmaceutical equivalence, this study provides evidence to support regulatory post-marketing surveillance and guides formulators in the development of high-quality ABZ generics.

METHODOLOGY

Study Design

The study employed an in vitro quantitative analysis design. Seven brands of albendazole chewable tablets marketed in Nakuru, Kenya, were evaluated for three key quality attributes: assay, disintegration, and dissolution. The analysis was designed and conducted in accordance with protocols outlined in the United States Pharmacopeia (USP) and the International Pharmacopoeia (Ph. Int).

Study Location

Sample collection was carried out in Nakuru County, located in the Rift Valley region of Kenya All laboratory analyses, including drug assay, disintegration, and dissolution tests, were conducted at the pharmaceutical chemistry and pharmaceutics laboratories of Kabarak University.

Sample Size Calculation

The study evaluated ABZ brands commonly available from wholesale distributors with current marketing authorization in Nakuru County, Kenya. Seven ABZ tablet brands were included in the study.

Sampling Technique

Convenience sampling was employed to select ABZ brands available within wholesale pharmacies in Nakuru County, Kenya, at the time of the study. This method was chosen as it reflects the actual market accessibility faced by consumers. All selected brands had valid market authorization from the Pharmacy and Poisons Board of Kenya. The brands were coded C001 to C007 based on the order of recording, to preserve blinding during analysis.

Sample Collection

All selected brands had valid market authorization from the Pharmacy and Poisons Board of Kenya. The brands were coded C001 to C007 based on the order of recording, to preserve blinding during analysis.

Equipment and Materials

All weight measurements were taken using the FA22105SEM Laboratory 0.01mg/0.1mg Electronic Semi-micro–Analytical Balance. Assay of the ABZ tablets for each brand was done using the Double Beam UV-VIS Touch Screen Spectrophotometer (Model No-LI-2904). Dissolution test was carried out using the RC-8 Dissolution Tester (Model No-UMS-RC8). Disintegration of the tablets was conducted using the Labtech disintegration test apparatus. Analytical grade 0.1N HCl, 0.1N NaOH, and methanol were used as solvents. Solutions were filtered through the Whatman membrane filter No. 1 with a pore size filter of 0.45-µm. Seven brands of albendazole tablets, including the innovator product, with market authorization for sale in Kenya were used in this study. Of the six generic brands evaluated, three were manufactured in Kenya, two in India, and one in Bangladesh. All products were purchased in their original packaging, coded for identification, and used within their shelf life. Albendazole working standard with a potency of 99.9 % was used for all tests, as required.

Assay of Drug Content

Drug content in each of the test albendazole tablets brands was determined by UV method. Maximum absorbance at about 308 nm and minimum absorbance at about 350 nm of the final solution was measured and recorded. The assay was carried out in duplicate. The content of ABZ was determined by comparing the absorbance of the sample with that of a working standard (WS) of known concentration.

Standard solution

A solution containing 0.009 mg/mL of ABZ was prepared by accurately weighing approximately 90 mg of albendazole WS and transferring it to a 250 mL volumetric flask.10 mL of acidified methanol was added and shaken to dissolve. The resulting solution was diluted with 0.1N HCl to volume and mixed. 5.0 mL of this solution was transferred to a 200-mL volumetric flask and diluted with 0.1N NaOH to volume and mixed.

Maximum absorbance at about 308 nm and minimum absorbance at about 350 nm of the final solution was measured and recorded.

Sample preparation

A portion of powder containing about 20 mg of albendazole was placed in a 50 mL volumetric flask and 30 mL of acidified methanol was added. The mixture was shaken using a mechanical shaker for 30 minutes and diluted with acidified methanol to volume. The solution was filtered and 4 mL transferred to a 200 mL volumetric flask and diluted with 0.1N NaOH to volume and mixed. Maximum absorbance at about 308 nm and minimum absorbance at about 350 nm of the final solution was measured and recorded. Sample concentrations were calculated by comparing absorbance values to those of the working standard.

Disintegration test

Disintegration testing was carried out in compliance with USP guidelines. To summarize, six tablets from each brand were placed in separate six tubes of the disintegration basket rack, then immersed in 1L of distilled water maintained at 37±0.5°C. Disintegration time was recorded as the time taken for complete dispersion of the tablet, with no visible residue on the mesh screen.

Dissolution test

In this study, dissolution testing of ABZ brands was performed at multiple time points to develop drug release profiles. The dissolution profiles were determined using the paddle method (USP Apparatus II) at 50 rpm with 900 mL of 0.1N HCl as the dissolution medium, maintained at 37±0.5°C. From each vessel, 10.0 mL aliquots were withdrawn at 5, 10, 15, 25, and 30 minutes, filtered, and diluted to 250 mL with 0.1N NaOH. Absorbance was measured using UV-Vis spectrophotometric method at 308 nm and 350 nm using 0.1N NaOH as the blank. Results were compared with those of the ABZ reference standard. The USP dissolution specification for albendazole tablets (not less than 80% (Q) of the labeled drug amount should dissolve within 30 minutes) was used as the evaluation threshold.

Data Analysis

Collected data was analyzed using descriptive statistics. Absorbance data were converted to percentage drug content and plotted over time to generate dissolution profiles for each brand. Data on disintegration time for each brand sampled is presented in form of tables.

Ethical Consideration(s)

This study did not involve human or animal subjects. All procedures were conducted on commercial pharmaceutical products using in vitro methodologies, and no ethical approval was required. However, ethical standards of data handling, product anonymization, and academic integrity were strictly observed.

RESULTS

Assay of Drug Content

The seven brands met the pharmacopeial specification for drug content per tablet, which was required to be between 90% and 110% of the labeled claim. Drug content assay results ranged between 96% to 103.32% as shown in Table 1 below.

Table 1:

Concentration of ABZ Drug Content Among the Seven Sampled Brands

ABZ Brand Code	Assay (%)
Innovate brand (reference)	101.3
C002	101.3
C003	95.4
C004	102.3
C005	96.0
C006	103.3
C007	101.2

Disintegration Test

Table 2 presents the results of the disintegration test. Four brands complied with the requirement for the disintegration test for immediate-release tablets (less than 15 minutes). One brand disintegrated after 33 minutes, and two showed no observable disintegration after 60 minutes. Brand C005 showed no significant observable disintegration even up to 90 minutes.

Table 2:

Disintegration Time in Minutes of the Seven Sampled ABZ Brands

ABZ Brand Code	Disintegration time (Minutes)
Innovate brand (reference)	3
C002	2
C003	6
C004	33
C005	>90
C006	62
C007	5

Dissolution test

As shown in Table 3, the dissolution test results after 30 minutes indicate variability in the extent of drug substance dissolution among the seven brands. Brands C001, C002 and C007 complied with the pharmacopeial requirement for the dissolution of ABZ tablets, which is 80% (Q), showing dissolution values of 83.5 %, 85.9%, and 81.7% respectively. Four brands (C003, C004, C005, COO6) did not meet the requirement for the dissolution test, releasing 20.8%, 7.3%, 0.9%, and 1.6% of the labelled content respectively, after 30 minutes.

Table 3:

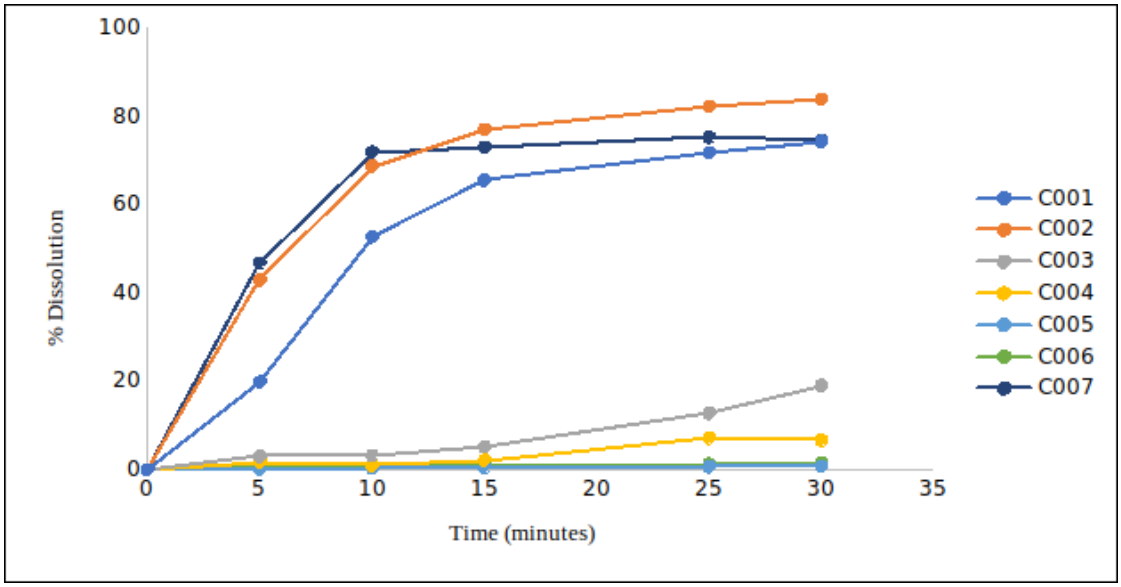
Dissolution Profiles of the Sampled ABZ Brands After 30 Minutes

Brand Code	Dissolution at 30 min (%)
C001	83.5
C002	85.9
C003	20.8
C004	7.3
C005	0.9
C006	1.6
C007	81.7

The dissolution profiles of the seven tablet brands during the 30-minute test are presented in Figure 1. These profiles reveal marked differences in drug release rates over time. Brands C001, C002, and C007 exhibit rapid and efficient dissolution, reaching over 70% within the first 15 minutes and showing slight increases thereafter. In contrast, Brand C003 displays a significantly lower dissolution profile than the stipulated amount. Similarly, Brands C004, C005, and C006 demonstrated negligible dissolution, with minimal increases over time, suggesting poor drug release.

Table 3:

Dissolution Profiles of the Sampled ABZ Brands After 30 Minutes



DISCUSSION

This study evaluated the in vitro dissolution characteristics of ABZ chewable tablet formulations available in Nakuru, Kenya, using the innovator product, Zentel, as a reference. All sampled brands were assayed for drug content concentration and complied with pharmacopeial specifications, indicating satisfactory assay results for the active pharmaceutical ingredient (API).

Disintegration Profile

Disintegration testing was used to assess how rapidly ABZ tablet breaks into smaller fragments in a liquid medium. According to USP, complete disintegration occurs when only a soft mass or residue of insoluble coating remains. In this study, significant variation in disintegration times was observed among the tested brands. Four brands complied with the USP requirement for immediate-release tablets (≤15 minutes), while one brand disintegrated in 33 minutes, and two failed to disintegrate within 60 minutes. These discrepancies may largely be attributable to formulation variables, including excipient choice, manufacturing processes, and the presence or absence of disintegrants. Notably, some pharmacopoeias do not mandate disintegration testing for chewable tablets, which can contribute to these inconsistencies. This study parallels findings from study done by Nyamweya et al. (2020), where disintegration times for antacid chewable tablets ranged from 6 to over 60 minutes.

Dissolution Profile

Dissolution testing was used to measure the extent and rate at which ABZ-tablet API is released from a dosage form under standardized conditions. This is a crucial test for drugs in BCS Class II and IV, such as ABZ, which are poorly soluble. Findings from the current study showed that only three brands met the criterion of ≥80% drug release within the specified time frame (International Pharmaceutical Federation, 2018), indicating potential bioavailability concerns with the remaining four. The probable cause of this failure is variation in the physicochemical properties of the drug substance used in the various brands, as well as differences in the types of excipients used, tablet formulation, and the manufacturing process, all of which significantly influence the performance attributes of the final product (Hamishehkar et al., 2016).

It is noteworthy that all brands that failed disintegration testing also failed the dissolution test, reinforcing the relationship between the two performance attributes. However, one exception was observed: brand C003 passed disintegration (6 minutes) but failed dissolution. This might likely be due to the use of non-micronized API, which slows drug release despite adequate disintegration. Evidently, the dissolution of the ABZ tablets can be improved by using micronized drug particles or nano particles in the formulation (Koradia & Parikh, 2012).

Pharmacopeial Inconsistencies

One of the contributing factors to the variability in disintegration time could be the different requirements for disintegration across different pharmacopeias.The USP (2018) and International Pharmacopoeia require chewable

The European Pharmacopoeia similarly mandates disintegration for chewable formulations. In contrast, the Indian Pharmacopoeia exempts chewable tablets from disintegration requirements. These inconsistencies can lead to divergent manufacturing standards and affect product quality across markets.

Impact of Formulation on Disintegration and Dissolution

Further, formulation factors such as the absence of disintegrants and varying manufacturing methods can significantly influence tablet disintegration and dissolution behavior (Markl & Zeitler, 2017). Disintegration is a critical quality test that facilitates drug release by increasing the surface area exposed to the dissolution medium. Many manufacturers, particularly those following outdated pharmacopeial standards, may not include disintegrants in chewable formulations (Nyamweya et al., 2020), potentially compromising drug release and therapeutic effectiveness. It is important to note, although a failed disintegration test often leads to poor dissolution, the converse is not necessarily true, as other formulation attributes, such as particle size and solubility may also influence dissolution performance.

Market Implications

Only three of the seven albendazole brands tested demonstrated acceptable performance in all quality tests (assay, disintegration, and dissolution). This raises concerns about the therapeutic equivalence of the remaining products. Poor *in vitro* performance may translate to suboptimal clinical efficacy, particularly in populations relying on generics for mass drug administration or routine deworming. Global studies have highlighted similar concerns. A 2017 study in Yemen found that only two out of seven albendazole tablet brands met British Pharmacopoeia (BP) quality standards (Othman, 2017). Similarly, research by Kimaro et al. (2019) reported that generics in developing countries often show inferior dissolution profiles compared to the innovator brand. An Ethiopian study of two albendazole products concluded that pharmaceutical products may vary significantly in quality attributes and recommended regular quality assessments to ensure therapeutic efficacy (Belew et al., 2015). Thus, there is a clear need for regulatory alignment and enforcement of stringent quality standards to ensure consistency in quality across pharmaceutical products. Harmonizing disintegration and dissolution requirements for chewable tablets is one vital step to protect public health and ensure patient outcomes.

Market Implications

This study was limited by its geographical scope,as all samples were sourced from Nakuru,Kenya. Additionally, only seven brands were evaluated, and no in vivo bioequivalence data were collected. Future research should consider including pharmacokinetic studies to comprehensively assess therapeutic interchangeability.

CONCLUSION

This study demonstrates that albendazole tablet brands containing the same drug content may exhibit inconsistent drug release profiles, potentially affecting therapeutic efficacy. Moreover, the variation in the in vitro performance of ABZ brands, with four brands failing to pass dissolution test, suggests a lack of pharmaceutical equivalence among some brands available in pharmacy outlets across Nakuru County. This underscores the need for regular market surveillance and quality assessments of marketed pharmaceutical products by the drug regulatory authority to ensure pharmaceutical equivalence, product interchangeability, and patient safety.

CONFLICT OF INTEREST

Authors declare no conflict of interest.

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