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Original Article

In Vitro Quality Assessment of Commercially Available Azithromycin Tablets in Dhamar City, Yemen: A Comparative Study

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Abstract

Background: Azithromycin is a critically important macrolide antibiotic and is listed by the World Health Organization (WHO) as an essential medicine. However, this classification does not ensure the quality of marketed products, especially in regions with weak regulatory systems. Continuous evaluation of available formulations is therefore necessary to maintain therapeutic effectiveness and protect patient safety. **Objective**: This study aimed to evaluate the in vitro quality of five commercially available azithromycin 500 mg tablet brands in Dhamar City, Yemen, and compare them with international pharmacopeial standards. **Methods**: Five brands (coded A1–A5) were tested for physical characteristics, weight variation, hardness, friability, disintegration time, assay (active ingredient content), and dissolution profile. All procedures followed the guidelines of the United States Pharmacopeia (USP), British Pharmacopoeia (BP), and Indian Pharmacopoeia (IP). **Results**: All brands met pharmacopeial limits for weight variation, hardness, disintegration, and dissolution (each released more than 80% of azithromycin within 30 minutes). However, Brand A5 failed the assay test, containing only 77.1% of the labelled amount (USP acceptance range: 90–110%). Brand A1 also failed the friability test, as the tablets fully disintegrated and exceeded the acceptable weight loss limit of ≤1%. **Conclusion**: Although four of the five brands met pharmacopeial standards, two substandard products were identified—one with a critically low active ingredient content and another with poor mechanical strength. These issues represent a serious public health concern. The results highlight the urgent need for stronger post-market surveillance and regulatory control in Yemen to prevent the distribution of ineffective or unsafe medicines.

Keywords: Azithromycin; Quality Control; Assay; Friability; Dissolution; Yemen

1. Introduction

Quality assurance (QA) refers to a set of systematic procedures designed to ensure that products and services consistently meet defined standards and customer expectations. Its main purpose is to prevent defects during the stages of design, development, and production [1]. According to ISO 9000, QA provides confidence that quality requirements will be met by emphasizing early prevention rather than correction after production [2, 3]. Quality control (QC), on the other hand, involves monitoring and evaluating the production process to verify compliance with established standards. ISO 9000 defines QC as "a part of quality management focused on fulfilling quality requirements" [4]. QC practices include applying process controls, setting performance criteria, ensuring staff competence, and conducting inspections to detect defects such as cracks or surface irregularities [5-8].

Azithromycin is a second-generation macrolide antibiotic that inhibits bacterial protein synthesis through its large macrolide ring, giving it strong activity against a wide range of respiratory pathogens [9, 10]. It is commonly prescribed for respiratory tract infections, sexually transmitted infections, and soft tissue infections due to its broad antibacterial activity and favorable pharmacokinetic characteristics [11]. The World Health Organization (WHO) lists azithromycin as an essential and critically important medicine, and it is available worldwide under many brand names [12]. Several analytical methods have been developed to detect and quantify azithromycin [13-15], but many of these techniques require complex and time-consuming sample preparation. Therefore, this study aims to evaluate and compare the quality of five commercially available azithromycin 500 mg tablet brands in Dhamar City, Yemen. The assessment includes physicochemical parameters such as weight variation, hardness, friability, disintegration time, and dissolution profile, using established pharmacopeial standards and procedures.

2. Method and Materials

2.1 Area of Study

This experimental study was carried out in the Department of Chemistry in collaboration with the Department of Pharmacy at the Institute for Continuous Learning, Thamar University, Yemen. All laboratory work was completed over a two-month period, from August to September 2023.

2.2 Materials

Five commercially available azithromycin tablet brands, each labeled as containing 500 mg per tablet, were purchased from retail pharmacies in Dhamar City, Yemen. To ensure objectivity, the brands were coded as AZITHROMYCIN STAR, AZROMAX, AZICURE, ZITHROX, and AZBACT. All brands were evaluated using standard quality control tests, including physical examination (appearance, color, break-line, and edge integrity), weight variation, content uniformity (assay), thickness, hardness, friability, disintegration time, and dissolution. All analyses were performed according to official pharmacopeial guidelines [16, 17] to determine pharmaceutical quality and in vitro performance. The following instruments were used during testing: an electronic analytical balance, a digital friability tester (Tnnco), a Monsanto hardness tester, a disintegration test apparatus, a dissolution test apparatus, and a UV–visible spectrophotometer (Systronics Smart).

2.3 Analytical Methods

In this study, several standard tests were performed to evaluate the quality of all selected azithromycin tablet brands.

2.3.1 Physical Examination

The physical characteristics of the tablets were assessed through visual inspection. For each brand, ten tablets were randomly selected and examined with the naked eye to evaluate their appearance, color, break-line, edge integrity, and the presence of any cracks or deformities. This procedure was applied to all brands to maintain consistency. Physical examination provides an initial indication of product quality and helps detect manufacturing defects that may affect patient acceptability, dosing accuracy, or product stability [18, 19].

2.3.2 Weight Variation Test

The weight variation test verifies that tablets contain a uniform amount of active ingredient and is a key parameter in quality control. According to the British Pharmacopoeia (BP, 2023) [16], tablets with an average weight of more than 80 mg should not deviate by more than ±5%, while tablets weighing 80 mg or less should not deviate by more than ±10%. In this study, twenty tablets from each brand were individually weighed using an analytical balance. The average tablet weight was calculated, and the deviation of each tablet from this average was recorded. The percentage weight variation was calculated using the following equation:

$$Weight\ variation\ (\%) = \frac{(Iw - Aw)}{Aw} \times 100$$

where:

Iw = Individual weight of tablet
Aw = Average weight of tablet

This test helps identify inconsistencies in the manufacturing process, such as variations in die filling, compression force, or powder flow, which can affect content uniformity and, consequently, the therapeutic efficacy of the tablets [20].

2.3.3 Assay of the active ingredient

For the quantitative determination of azithromycin, twenty tablets from each brand were randomly selected, accurately weighed, and finely powdered. An amount of the powdered sample equivalent to 667 mg of azithromycin was transferred into a 200 mL volumetric flask. A suitable volume of diluent was added, and the mixture was sonicated for 15 minutes to ensure complete extraction of the active pharmaceutical ingredient. The solution was then allowed to cool to room temperature and diluted to volume with Diluent A to obtain a final concentration of 0.4 mg/ml. The resulting solution was filtered through a 0.45 µm membrane filter to remove insoluble excipients. The same procedure was applied to all tested brands. A standard solution of azithromycin was prepared under identical conditions for quantitative comparison. Chromatographic analysis was performed using a high-performance liquid chromatography (HPLC) system equipped with a UV detector. Separation was achieved on a reversed-phase C18 column (250 mm × 4.6 mm, 5 µm particle size). The mobile phase consisted of a mixture of acetonitrile and phosphate buffer (pH 6.0) at a 60:40 (v/v) ratio, delivered at a flow rate of 1.0 mL/min. The detection wavelength was set at 210 nm, with an injection volume of 20 µL and a total run time of 10 minutes. System suitability testing was performed prior to analysis to ensure the reliability of the chromatographic system. The parameters evaluated included theoretical plate count (N ≥ 2000), tailing factor (≤ 2), and relative standard deviation (RSD ≤ 2%) for replicate injections. Diluent A consisted of a mixture of phosphate buffer (pH 6.0) and acetonitrile in a ratio of 50:50 (v/v). Quantification of azithromycin was carried out by comparing the peak area of the sample solutions with that of the corresponding standard solution. The method was performed in accordance with the pharmacopeial monograph for azithromycin tablets (e.g., United States Pharmacopeia). This method ensures accurate quantification of the active ingredient and allows reliable comparison with pharmacopeial specifications [21].

2.3.4 Hardness Test

The mechanical strength (hardness) of the tablets was evaluated using a Monsanto-type hardness tester (China). Ten tablets from each brand were randomly selected and individually tested to determine the force required to break each tablet. The mean hardness for each brand was calculated using the following formula:

$$Hardness\ (kg/cm^2) = \frac{Total\ hardness\ of\ all\ tablet}{Number\ of\ tablets}$$

This test determines the tablet's resistance to chipping, abrasion, and breakage during handling, packaging, and transportation [22].

2.3.5 Friability Test

Friability testing was carried out using an Electro Lab EF-Friabilator following United States Pharmacopeia (USP) guidelines. Ten tablets from each brand were accurately weighed and placed in the apparatus, which was operated at 25 rpm for 4 minutes (equivalent to 100 revolutions). After the test, the tablets were reweighed, and the percentage friability (%F) was calculated using the following equation:

$$\%\ of\ Friability = \frac{weight\ before\ test - weight\ after\ test}{weight\ before\ test} \times 100$$

Friability assesses the tablet's ability to withstand mechanical stress during handling and transportation. For conventional tablets, a friability value not exceeding 1% is considered acceptable [23].

2.3.6 Disintegration Time Test

The in vitro disintegration time was evaluated using a USP disintegration tester with a disc and distilled water as the medium. For each brand, three tablets were placed individually into the tubes of the basket rack, which was then lowered into a 1-liter beaker containing water maintained at 37 ± 0.5 °C. The disintegration time was recorded as the time required for each tablet to completely break down into fine particles and pass through the mesh at the bottom of the tube. The average disintegration time of the three tablets was taken as the disintegration time for that brand [17].

2.3.7 Dissolution Study

In vitro dissolution profile of azithromycin tablets was determined using USP Dissolution Apparatus II (paddle method). Each of the six vessels was filled with 1000 mL of phosphate buffer (pH 6.0) maintained at 37 ± 0.5°C. After the medium reached equilibrium, one tablet from each brand was placed into the vessels, and the paddle speed was set to 75 rpm. Samples (13 mL) were collected at 10, 20, and 30 minutes using a syringe and replaced with an equal volume of fresh buffer to maintain sink conditions. The samples were filtered through a 0.45 µm membrane filter, and 11.25 mL of each filtrate was transferred to a 25 mL volumetric flask and diluted with diluent (USP 36/NF 31) [24] to obtain a concentration of approximately 0.25 mg/mL, similar to the standard. A 50 µL volume of both the sample and standard solutions was injected into a UV–visible spectrophotometer, and absorbance was measured at 298 nm. The percentage of drug release was calculated using the following formula:

$$\%\ Content\ of\ drug\ release = [Ru/Rs] \times [Cs/L] \times V \times 100$$

where:

Ru = response of the sample, Rs = response of the standard, Cs = concentration of the standard, L= label claim, and V = volume of dissolution medium, and V= volume of dissolution medium. The obtained results were compared with the United States Pharmacopeia (USP) acceptance criteria for azithromycin tablets [17].

3. Results and Discussion

The quality of pharmaceutical products is a key factor determining their safety, efficacy, and therapeutic reliability. In this study, five commercially available azithromycin tablet brands marketed in Dhamar City, Yemen, were evaluated for their compliance with international pharmacopeial standards, including the United States Pharmacopeia (USP), British Pharmacopoeia (BP), and Indian Pharmacopoeia (IP). The parameters assessed included physical characteristics, weight variation, assay (active ingredient content), hardness, friability, disintegration time, and dissolution profile.

3.1 Physical Examination

As shown in Table 1, all tested brands exhibited acceptable physical characteristics, with uniform oblong shapes, smooth surfaces, and intact edges. These features suggest adherence to good manufacturing practices during the compression and coating stages. However, Brand A1 showed surface fragility during the friability test, indicating a possible deficiency in binder concentration or insufficient compression force during manufacturing. A noticeable color difference was also observed in Brand A5, which appeared yellowish compared with the white tablets of the other brands. This variation may be related to differences in excipients or the intentional use of colorants for product identification or stability purposes. Although color differences do not directly influence drug efficacy, they may affect patient confidence and adherence, especially when inconsistencies appear between different batches [18]. Overall, the physical examination results indicate that most brands meet pharmacopeial appearance requirements and maintain acceptable structural integrity, reflecting generally satisfactory formulation quality.

Table 1. Physical Characteristics of Different Azithromycin Tablet Brands.

Brands	Description
A1	White colour, and oblong shape, tablets with regular edges
A2	White colour, and oblong shape, tablets with regular edges
A3	White colour, and oblong shape, tablets with regular edges
A4	White colour, and oblong shape, tablets with regular edges
A5	Yellow colour, and oblong shape, tablets with regular edges

3.2 Weight Variation

As shown in Table 2, all five azithromycin tablet brands met pharmacopeial specifications, with weight variation falling within the acceptable ±5% limit specified in the USP and BP standards [16, 17]. The mean tablet weights ranged from 0.680 g for Brand A4 to 0.881 g for Brand A3, reflecting slight differences in excipient composition and formulation strategies among manufacturers. The low standard deviation values (0.013–0.021 g) indicate excellent uniformity in die filling and compression during tablet production. Such consistency suggests a well-controlled manufacturing process with stable powder flow properties across all brands. Maintaining uniform tablet weight is essential to ensure accurate dosing of the active pharmaceutical ingredient (API), which supports therapeutic reliability and reduces the risk of underdosing or overdosing [20]. The results confirm that all tested brands demonstrated acceptable weight uniformity, indicating compliance with international pharmacopeial requirements and reflecting effective control of production parameters.

Table 2. Weight Variation of Different Azithromycin Tablet Brands.

Brands	Weight (Mean ± SD)
A1	0.685 ± 0.0134
A2	0.744 ± 0.0134
A3	0.881 ± 0.0144
A4	0.68 ± 0.0179
A5	0.871 ± 0.0212

3.3 Assay of the Active Ingredient

As shown in Table 3 and Figure 3, the assay results revealed clear variability among the five azithromycin tablet brands. Four brands—A1, A2, A3, and A4—were within the USP specification range of 90–110% of the labelled claim [17], indicating proper formulation, good uniformity of drug distribution, and adequate chemical stability during manufacturing and storage. However, Brand A5 contained only 77.1% of the labelled amount, which is far below pharmacopeial requirements and therefore failed the assay test. This low drug content is a serious quality and public health concern. Subtherapeutic antibiotic doses may lead to ineffective treatment, longer illness duration, and an increased risk of antimicrobial resistance (AMR)—a growing global challenge, especially in low-resource settings such as Yemen [25-27]. Possible causes of this deviation include poor mixing during formulation, inaccurate weighing of the active ingredient, or degradation of azithromycin due to improper storage conditions, such as high humidity or elevated temperatures [19, 28]. Similar issues have been reported in previous studies from Nigeria and Ghana, where some azithromycin brands were found to be subpotent and non-compliant with pharmacopeial assay limits [28, 29]. Overall, these findings highlight the need for strong regulatory oversight, strict quality assurance practices, and routine post-market surveillance to ensure that all antibiotic products meet international quality standards before they reach consumers.

Table 3. Assay Results of the Active Ingredient in Different Azithromycin Brands

Brands	Assay (%)
A1	96.60
A2	90.11
A3	97.50
A4	102.30
A5	77.10

3.4 Hardness and Friability

As shown in Table 4, the hardness results indicate that all azithromycin tablet brands had sufficient mechanical strength, with values above 9.6 kg—well above the USP minimum requirement of about 4 kg [17]. This confirms that the tablets can withstand normal mechanical stress during handling, packaging, and transportation. Among the tested products, A2 and A4 recorded the highest hardness values (14.6 kg and 14.99 kg, respectively), which may be linked to the use of higher compression forces or greater amounts of binding agents.

Table 4. Hardness of Different Azithromycin Tablet Brands

Brands	Hardness (kg)
A1	13.9
A2	14.6
A3	13.44
A4	14.99
A5	9.64

Despite its relatively high hardness (13.9 kg), Brand A1 failed the friability test because it completely disintegrated during the 4-minute tumbling process. This unusual result suggests poor internal cohesion or uneven binder distribution, leading to structural weakness even though the tablet surface appears firm. According to pharmacopeial standards, friability should not exceed 1% for conventional tablets [16, 30]. As presented in Table 5 and Figure 5, the remaining brands (A2–A5) showed friability values between 0.114% and 0.522%, which are within acceptable limits. These results indicate that their formulations are robust and reflect good manufacturing practices with effective control of granulation and compression steps. These observations are consistent with previous studies conducted in India and Bangladesh, where most azithromycin tablet brands complied with both hardness and friability requirements [31, 32]. Overall, the present results suggest that the majority of the tested products have suitable mechanical integrity for normal handling and distribution. However, Brand A1 requires further formulation improvements to meet friability standards.

Table 5. Friability of Different Azithromycin Tablet Brands

Brand	Initial weight (g)	Final weight (g)	Result (%)
A1	Failed	Failed	Failed
A2	7.65	7.61	0.522
A3	8.81	8.80	0.114
A4	6.81	6.80	0.15
A5	8.65	8.62	0.35

3.5 Disintegration Time

As shown in Figure 1, all five azithromycin tablet brands complied with pharmacopeial limits, with disintegration times ranging from 3 minutes (A5) to 15 minutes (A2), well within the 30-minute maximum specified for film-coated tablets by the USP and BP [16, 17]. The rapid disintegration observed for Brands A3 (5 min) and A5 (3 min) suggests the presence of effective disintegrants, such as croscarmellose sodium or sodium starch glycolate, which enhance water uptake and promote tablet swelling, leading to faster breakdown. Rapid disintegration is generally associated with improved dissolution rates and higher bioavailability, which can result in a faster onset of therapeutic action [33, 34]. Conversely, Brand A2 had the longest disintegration time (15 min). While still pharmacopeial compliant, this may slightly delay drug release and onset of action. Differences in disintegration behavior among brands likely reflect variations in formulation design, including disintegrant type and concentration, binder ratios, coating thickness, and compression force applied during tableting [18, 33]. Overall, the results suggest that all brands meet official standards, with A3 and A5 potentially offering superior in vitro disintegration performance.

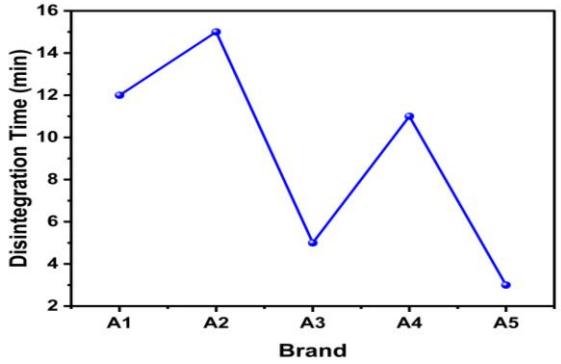

Figure 1: Disintegration Times of Different Azithromycin Tablet Brands.

3.6 Dissolution Profile

As presented in Figure 2, the dissolution profiles of all five azithromycin tablet brands complied with USP and BP specifications, which require that at least 80% of the labelled drug content be released within 30 minutes for immediate-release tablets [16, 17]. All brands released more than 80% of the drug within 30 minutes under standard dissolution conditions. Brand A5 showed the highest dissolution efficiency (97.5%), followed by Brand A3 (93.75%), indicating optimized formulation parameters that enhance wetting, disintegration, and drug solubilization [34]. In contrast, Brand A2 had the lowest release (82.0%), which, while acceptable, may reflect higher binder content, denser granule structure, or reduced tablet porosity, slowing fluid penetration and drug release. The dissolution results correlate with disintegration behavior: tablets that disintegrated faster (A3 and A5) also dissolved more quickly, highlighting the strong relationship between disintegration and drug availability. These findings are consistent with previous studies in Nigeria and Uganda, which reported that most marketed azithromycin tablets met pharmacopeial dissolution standards [15, 35, 36]. However, Brand A5, despite its excellent dissolution, failed the assay test (77.1% of labelled content). This indicates that even though the tablet dissolves efficiently, the total drug content is insufficient for therapeutic effectiveness. This underscores a critical quality concern: high dissolution cannot compensate for subpotent tablets, as this may still lead to subtherapeutic dosing and contribute to antimicrobial resistance.

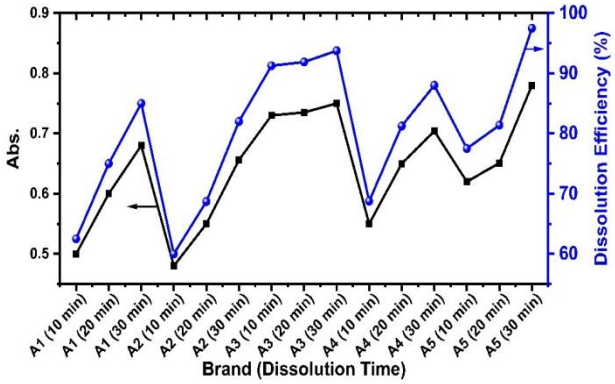

Figure 2: Dissolution Profile Data of Different Azithromycin Tablet Brands.

4. Conclusion

This study assessed the in vitro quality of five commercially available azithromycin 500 mg tablet brands in Dhamar City, Yemen, against USP, BP, and IP standards. All brands met pharmacopeial requirements for weight variation, hardness, disintegration, and dissolution, with more than 80% drug release within 30 minutes. However, two critical issues were identified. Brand A5 contained only 77.1% of the labelled azithromycin, well below the USP acceptable range of 90–110%, posing a significant risk of therapeutic failure and contributing to antimicrobial resistance. Brand A1 failed the friability test, completely disintegrating during mechanical stress, which indicates poor mechanical strength and unsuitability for handling or patient use. These results demonstrate that not all marketed brands meet essential quality standards, despite claims of compliance. The presence of substandard and physically unstable products highlights a critical gap in pharmaceutical regulatory oversight in Yemen. Routine post-market surveillance, mandatory laboratory testing of random samples, and public disclosure of non-compliant products are strongly recommended to protect public health and ensure the efficacy of essential medicines.

Data Availability

The datasets used and analyzed during the current study are available from the corresponding author upon reasonable request.

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Conflict of Interest

The authors declare no conflicts of interest.

References

[1] World Health Organization. (2024) *Quality assurance of pharmaceuticals: a compendium of guidelines and related materials*. Volume 1: Good manufacturing practices and inspection, 9240099425; World Health Organization, Geneva, Switzerland, ISBN: 978-92-4-009942-5, pp 534.

[2] Sanjeev Salvi, S., Kerkar, S. (2020) Quality Assurance and Quality Control for Project Effectiveness in Construction and Management, *International Journal of Engineering Research & Technology* **9**: 133–137.

[3] Arachchi, S.M., Chong, S.C., Madhushani, A. (2015) Quality assurance and quality control in ERP systems implementation, *American Scientific Research Journal for Engineering, Technology, and Sciences (ASRJETS)* **11**: 70-83.

[4] Leong, T.K., Zakuan, N., Saman, M.Z.M. (2014) Review of quality management system research in construction industry, *International Journal of Productivity and Quality Management* **13**: 105-123.

[5] Teasdale, A., Elder, D., Nims, R.W. (2017) ICH Quality Guidelines: An Implementation Guide, John Wiley & Sons, Inc., *Hoboken, New Jersey, USA*, pp. 808.

[6] Montgomery, D.C. (2020) Introduction to Statistical Quality Control, 8th ed., *John Wiley & Sons, Inc.*, Hoboken, New Jersey, USA, pp. 768.

[7] Taylor, R., Shakoor, O., Behrens, R., Everard, M., Low, A., Wangboonskul, J., Reid, R., Kolawole, J. (2001) Pharmacopoeial quality of drugs supplied by Nigerian pharmacies, *The Lancet* **357**: 1933-1936.

[8] Neyestani, B. (2017) Seven Basic Tools of Quality Control: The Appropriate Techniques for Solving Quality Problems in the Organizations, **SSRN Article No. 2955721.** https://doi.org/10.5281/zenodo.400832.

[9] Hoepelman, I., Schneider, M. (1995) Azithromycin: the first of the tissue-selective azalides, *International Journal of Antimicrobial Agents* **5**: 145-167.

[10] Idkaidek, N.M., Najib, N., Salem, I., Jilani, J. (2014) Physiologically-based IVIVC of azithromycin, *American Journal of Pharmacological Sciences* **2**: 100-102.

[11] Retsema, J., Girard, A., Schelkly, W., Manousos, M., Anderson, M., Bright, G., Borovoy, R., Brennan, L., Mason, R. (1987) Spectrum and mode of action of azithromycin (CP-62,993), a new 15-membered-ring macrolide with improved potency against gram-negative organisms, *Antimicrobial Agents and chemotherapy* **31**: 1939-1947.

[12] Piscitelli, S., Danziger, L., Rodvold, K. (1992) Clarithromycin and azithromycin: new macrolide antibiotics, *Clinical Pharmacy* **11**: 137-152.

[13] Al-Rimawi, F., Kharoaf, M. (2010) Analysis of azithromycin and its related compounds by RP-HPLC with UV detection, *Journal of Chromatographic Science* **48**: 86-90.

[14] Jaber, S.H., Salih, Z.T., Salmo, H.M. (2012) Formulation of azithromycin suspension as an oral dosage form, *Iraqi Journal of Pharmaceutical Sciences* **21**: 61-69.

[15] Kalamuzi, P.M. (2018) A pharmaceutical equivalence study of the selected Azitiiromycin 500 mg brands on the Ugandan Market. *Bachelor of Pharmacy (BPharm) Research Project Report*, BPharm Thesis, Kampala International University, Ishaka, Bushenyi, Uganda.

[16] British Pharmacopoeia Commission. (2022) *British Pharmacopoeia*. The Stationery Office, London, UK, ISBN: 9780113230921, pp

[17] United States Pharmacopeial Convention. (2020) *The United States pharmacopeia: USP 43–National formulary: NF 38*. United States Pharmacopeial Convention, Inc., Rockville, Maryland, USA, ISBN-13 (5-Volume Print Set): 978-1936424948, pp 8760.

[18] Aulton, M.E., Taylor, K. (2013) Aulton's pharmaceutics: the design and manufacture of medicines, 4th ed., *Churchill Livingstone / Elsevier*, London, UK, pp. 908.

[19] World Health Organization. (2017) *A study on the public health and socioeconomic impact of substandard and falsified medical products*. World Health Organization, Geneva, Switzerland, ISBN: 978-92-4-151343-2, pp 72.

[20] Mekasha, Y.T., Chali, B.U., Feissa, A.B., Godena, G.H., Hassen, H.K., Wega, S.S. (2023) Quality evaluation of the Azithromycin tablets commonly marketed in Adama, and Modjo towns, Oromia Regional State, Ethiopia, *Plos One* **18**: e0282156.

[21] Huber, L. (2007) Validation and Qualification in Analytical Laboratories, 2nd ed., *CRC Press*, Boca Raton, Florida, USA, pp. 288.

[22] Amin, M.R., Biswas, S., Rahman, M.R., Bhuiyan, J.R., Rana, M.S. (2014) Study and impact evaluation of particle size distribution on physicochemical properties of three different tablet formulations through sieve technology, *International Journal for Pharmaceutical Research Scholars* **3**: 448–463.

[23] Almuzaini, T., Choonara, I., Sammons, H. (2013) Substandard and counterfeit medicines: a systematic review of the literature, *BMJ Open* **3**: e002923.

[24] United States Pharmacopeial Convention. (2013) *Vehicle for Oral Solution, Vehicle for Oral Solution Sugar-Free and Vehicle for Oral Suspension*. In United States Pharmacopeia 36–National Formulary 31 (USP 36–NF 31), United States Pharmacopeial Convention, Rockville, MD, USA, pp n.pag.

[25] World Health Organization. (2015) *Guidance on The Selection of Comparator Pharmaceutical Products for Equivalence Assessment of Interchangeable Multisource (Generic) Products*. WHO Expert Committee on Specifications for Pharmaceutical Preparations: 49th report, TRS No. 992; World Health Organization, Geneva, Switzerland, ISBN: 978-92-4-120992-2 pp 185–195.

[26] Newton, P.N., Green, M.D., Fernández, F.M. (2010) Impact of poor-quality medicines in the 'developing'world, *Trends in Pharmacological Sciences* **31**: 99-101.

[27] Okeke, I.N., Lamikanra, A., Edelman, R. (1999) Socioeconomic and behavioral factors leading to acquired bacterial resistance to antibiotics in developing countries, *Emerging Infectious Diseases* **5**: 18.

[28] Okeke, I., Lamikanra, A. (2001) Quality and bioavailability of ampicillin capsules dispensed in a Nigerian semi-urban community, *African Journal of Medicine and Medical Sciences* **30**: 47–51.

[29] Egbo, H.A. (2013) Quality Evaluation of a Selection of Antibiotics Distributed in Accra (Ghana) and Lagos (Nigeria). *Department of Chemistry*, Master's Thesis, University of Ghana, Legon, Ghana.

[30] Indian Pharmacopoeia Commission. (2020) *Indian Pharmacopoeia 2020*. Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Government of India, Ghaziabad, Uttar Pradesh, India, ISBN: 978-93-89098-61-0, pp

[31] Singh, R., Saxena, M., Sahay, D., Singh, S. (2017) In-vitro study of quality control parameters of three different brands of azithromycin tablets, *International Journal of Basic & Clinical Pharmacology* **6**: 1572–1575.

[32] Bari, F.S.N.U., Islam, M.R., Moghal, M.M.R., Ira, I.J. (2017) Release Kinetics Study of Azithromycin from Bi-layered Tablets, *Bangladesh Pharmaceutical Journal* **20**: 54-63.

[33] Tarke, S., Shanmugasundaram, P. (2017) Formulation and evaluation of fast Dissolving tablets of Antihypertensive Drug, *Research Journal of Pharmacy and Technology* **10**: 155.

[34] Leuner, C., Dressman, J. (2000) Improving drug solubility for oral delivery using solid dispersions, *European Journal of Pharmaceutics and Biopharmaceutics* **50**: 47-60.

[35] Dressman, J.J., Kramer, J. (2005) Pharmaceutical Dissolution Testing, 1st ed., *CRC Press*, Boca Raton, Florida, USA, pp. 429.

[36] Ukwueze, S., Nwachukwu, I., Ezealisiji, K. (2018) Ultraviolet Spectrophotometric Evaluation of Different Brands of Azithromycin Dihydrate Tablets and Capsules Sold in Nigeria, *European Journal of Pharmaceutical and Medical Research* **5**: 112–118.