African Journal of Advanced Pure and Applied Sciences (AJAPAS)
Online ISSN: 2957-644X
Volume 4, Issue 4, 2025
Page No: 327-333
Website: *https://aaasjournals.com/index.php/ajapas/index*
ISI 2025: 1.126 **SJIFactor 2024: 6.752** **معامل التأثير العربي: 1.62**

Post Marketing Surveillance on Different Brands of Propranolol Tablets

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مراقبة ما بعد التسويق لمختلف العلامات التجارية لأقراص بروبرانولول

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Received: August 15, 2025	Accepted: October 20, 2025	Published: October 30, 2025

Abstract:
Non-selective beta-adrenoceptor blockers like propranolol are commonly administered to manage cardiac issues and high blood pressure. This research attempts to ascertain whether specific brands of propranolol tablets available in Al Bayda, Libya, meet the specifications established by the US Pharmacopoeia or the British Pharmacopoeia and fulfill up to the claims stated on their labels. From a variety of retail pharmacies in Al Bayda, Libya, four different brands of propranolol tablets were randomly selected. Several quality control tests were conducted as part of the evaluation procedure. The findings demonstrated that every brand had uniformity in diameter, thickness, and weight as well as acceptable external qualities. Every brand has proven to have enough mechanical strength to withstand crumbling and breaking. Additionally, all samples (with the exception of one brand) satisfied requirements for drug content and disintegration time. All products under investigation met pharmacopoeial requirements, according to the dissolution profile, with the exception of brand Pr2. Consequently, all brands of propranolol tablets that were assessed, with the exception of brand Pr2, were determined to be of satisfactory quality. However, their dissolution profiles were not comparable to those of the innovator, and they could not be used interchangeably.

Keywords: Propranolol tablets; Pharmacopoeial specifications; Quality control.

الملخص
تُستخدم حاصرات مستقبلات بيتا الأدرينالية غير الانتقائية، مثل بروبرانولول، بشكل شائع لعلاج مشاكل القلب وارتفاع ضغط الدم. يسعى هذا البحث إلى التأكد مما إذا كانت ماركات محددة من أقراص بروبرانولول المتوفرة في البيضاء، ليبيا، تفي بمواصفات دستور الأدوية الأمريكي أو البريطاني، وتفي بالادعاءات المذكورة على ملصقاتها. من بين مجموعة متنوعة من صيدليات التجزئة في البيضاء، ليبيا، تم اختيار أربع ماركات مختلفة من أقراص بروبرانولول عشوائيًا. أُجريت عدة اختبارات لمراقبة الجودة كجزء من عملية التقييم. أظهرت النتائج أن جميع الماركات التجارية تتمتع بتجانس في القطر والسمك والوزن، بالإضافة إلى خصائص خارجية مقبولة. أثبتت كل ماركة أنها تتمتع بقوة ميكانيكية كافية لتحمل التفتت والكسر. بالإضافة إلى ذلك، استوفت جميع العينات (باستثناء ماركة واحدة) متطلبات محتوى الدواء وزمن التفكك. استوفت جميع المنتجات قيد البحث متطلبات دستور الأدوية، وفقًا لملف الذوبان، باستثناء ماركة Pr2. نتيجةً لذلك، وُجد أن جميع أنواع أقراص بروبرانولول التي خضعت للتقييم، باستثناء العلامة التجارية Pr2، تتمتع بجودة مُرضية. ومع ذلك، لم تكن خصائص ذوبانها مُقارنةً بخصائص الشركة المُبتكرة، ولم يكن من المُمكن استخدامها بالتبادل.

الكلمات المفتاحية: أقراص بروبرانولول؛ المواصفات الدوائية؛ مراقبة الجودة.

Introduction:

A non-selective beta-adrenoceptor blocker, propranolol is commonly prescribed to treat a variety of conditions, including hypertension, myocardial infraction, cardiac arrhythmias, thyrotoxicosis, capillary haemangiomas, performance anxiety, essential tremors, and chest pain. It also helps people with angina or past heart attacks avoid migraine headaches and other heart issues (Conceição et al., 2018; Jayvadan Patel, 2010; Noori et al., 2019; Olakojo et al., 2021; Soghra et al., 2010). Propranolol is a class I drug according to the Biopharmaceutical Classification System (BCS) (Conceição et al., 2018). It is mostly insoluble in ether, benzene, and ethyl acetate (Noori et al., 2019), but soluble in methanol, ethanol, and water (Shuma et al., 2021). Propranolol is a lipid-soluble compound that is entirely absorbed orally when taken as a tablet (Conceição et al., 2018; Jayvadan Patel, 2010). Propranolol is roughly 90% bound to plasma proteins and has a 24% bioavailability because of the liver's significant first-pass metabolism (Shuma et al., 2021). It is eliminated via the kidney (<1%) and has a half-life of 4–5 hours (Abdul-Hasan, M. T., Jawad, K. K., Al-Shaibani, A. J. & AL-Gburi, 2022). The following factors could be involved in the antihypertensive action: (1) kidney-induced regulation of renin release; (2) reduction in tonic sympathetic nerve outflow from brain vasomotor centers release; and (3) reduced cardiac output (Conceição et al., 2018). The growth of inappropriate medications can lead to several negative health outcomes, including drug toxicity, treatment failure, and substandard, illegal, or counterfeit medications, especially in third-world nations. False medication distribution may cause people to lose faith in healthcare providers and institutions. New product categories and brand quality differences are emerging as a result of the growing demand for pharmaceutical items. As a result, routinely assessing the quality of pharmaceutical items has become crucial. A practical way to assess the quality of these products, make sure they fulfil the necessary requirements, and identify counterfeit items would be to compare the different brands that are available with the official standard (Olakojo et al., 2021). As long as the innovator and the generic are therapeutically and bioequivalent, interchangeability is permitted (Abozaid & Saleh, 2022). Oluwatobi et al. demonstrated that, with the exception of one sample that did not meet the majority of the pharmacopoeial requirements, propranolol samples sold in Nigeria passed all pharmacopoeial tests for satisfactory quality. Therefore, in clinical practice, not all brands may be utilised interchangeably (Olakojo et al., 2021). This study's objective was to use quality control testing to verify the quality of various brands of 40 mg propranolol tablets that are sold commercially in Libya.

Experimental:

Materials and Methods:

Materials:

Powdered propranolol was acquired from AstraZeneca in Egypt. Propranolol 40 mg tablets of four different brands were all purchased from local pharmacies in Al Bayda City, Libya. Every brand's batch number, manufacturing date, and expiration date were carefully examined. The four brands were coded from Pr1 to Pr4 at random. The reference was determined to be Pr1 (Table 1). The remaining chemicals, which included hydrochloric acid, potassium dihydrogen phosphate, and sodium hydroxide, were all analytical grade.

Methods:

Visual inspection

Ten tablet samples were chosen at random from each batch, and their external characteristics such as colour, shape, surface texture, the presence of grooves, and surface defects were visually inspected (Siaan et al., 2015).

Thickness and diameter

Ten tablets were selected at random from the representative sample, and each tablet's diameter and thickness were measured. The diameter and thickness of tablets should be kept within ±5% of a defined value (Shobana et al., 2021; Siaan et al., 2015).

Determination of Uniformity of Weight

Each brand's twenty tablets were weighed separately using a ME235S, Sensitive electronic balance (SARTORIUS AG, Germany). Each brand's average weights were determined, along with the percentage deviance from the mean (Abebe et al., 2020; Chioma & Nkemakolam, 2019; Eraga et al., 2017; Nagendra et al., 2014; Saleh, 2024; Shobana et al., 2021; Siaan et al., 2015)

Hardness test

The crushing strength was measured using the TBH 220 D hardness tester (Erweka® GmbH, Germany). From each brand, ten tablets were selected at random, and each tablet's crushing pressure was recorded (Abebe et al., 2020; Chioma & Nkemakolam, 2019; Eraga et al., 2017; Nagendra et al., 2014; Shobana et al., 2021; Siaan et al., 2015).

Friability test
After weighing twenty tablets of each brand, they were put in the TAR 220 (Erweka® GmbH, Germany) Friability tester and operated for four minutes at 25 rpm. Once the tablets were dedusted, they were weighed once again. By calculating the difference between the two weights, the % friability was calculated as follows:
% Friability = $(W_1 – W_2)$ x $100/W_1$
Where W_1 = Tablets' initial weight. W_2 = Tablets' final weight following testing (Abebe et al., 2020; Chioma & Nkemakolam, 2019; Eraga et al., 2017; Nagendra et al., 2014; Shobana et al., 2021; Siaan et al., 2015).

Test of disintegration
A DTG 3000 Disintegration tester (COPLEY SCIENTIFIC, UK) was used to test six tablets of each brand at 37 ± 0.5°C in a phosphate buffer with a pH of 6.8. The time needed for disintegration was determined to be When the tester's basket was empty of particles (Ali et al., 2024).

Propranolol stock solution preparation
An accurately weighed quantity of propranolol (100 mg) was added to a 100 ml volumetric flask. Fifty millilitres of 6.8 pH phosphate buffer were added and the volume was completed to 100 ml. The resulting solution, known as "stock," had a concentration of 1 mg/ml. After that, 1 ml was withdrawn and diluted to 10 ml with buffer solution, yielding a solution with a concentration of 100 µg/ml.

Calibration Curve Preparation
The stock solution was diluted as needed to provide solutions with varying propranolol concentrations (10–50 µg/ml).
The absorbances of the solutions at λmax=290 nm were measured using the GENESYS 10S UV-Vis Spectrophotometer (Thermo Fisher Scientific, USA). Plotting absorbance against propranolol concentration allowed for the computation of the regression equation (Shobana et al., 2021).

Assay
A precisely weighed quantity of powder equivalent to 40 mg was administered after 20 tablets of each brand had been ground into a fine powder. Seventy millilitres of 6.8 pH phosphate buffer were added to a 100 millilitre volumetric flask containing propranolol, which was then shacked for 15 minutes, diluted to volume, and filtered. Following its transfer to a 100 ml volumetric flask, 10 ml of the filtrate was further diluted with a pH phosphate buffer of 6.8 to reach 100 ml.
The absorbance of the assay preparation was measured at λmax=290 nm using a GENESYS 10S UV-Vis Spectrophotometer (Thermo Fisher Scientific, USA) and 6.8pHphosphate buffer as a blank. The experiment was conducted in triplicate (Radhika, 2019).

Dissolution test
Dissolution experiments were conducted on all formulations utilising a USP-II paddle, a DT600 HH Dissolution apparatus (Erweka® GmbH, Germany), and 900 millilitres of phosphate buffer with a pH of 6.8 as the dissolution medium. The medium's temperature was allowed to rise to 37°C ±0.5°C. The tablet was inserted into the vessel, which was covered, and the device was run at 50 rpm.
Five milliliters of the dissolving sample was withdrawn at predefined intervals and was replaced with an equivalent volume of the new dissolution media in order to maintain the sink conditions. After filtering the samples, a GENESYS 10S UV-Vis Spectrophotometer (Thermo Fisher Scientific, USA) was used to perform spectrophotometric analysis at 290 nm.
A calibration curve created from standard propranolol samples was used to determine the concentration of each sample. The percentage of dissolutions was calculated (Radhika, 2019).

Analysis of similarity factor
The dissolution profiles were estimated by plotting the percentage of drug released versus time. The dissolution profiles were then compared using a model-independent method to find the similarity factor f2, which is established by the US FDA and illustrated in the following equation:

$$F2 = 50 \log \{[1 + 1/n\sum^{n=1}(R_t – T_t)^2]^{-0.5} \times 100\}$$

Where n is the number of time points, Rt and Tt are the dissolution value at each time point for reference and test products, respectively, at a time.
An f2 value greater than or equal to 50 indicates that the two dissolution profiles are similar or identical. Since F2 is less than 50, the innovator product's dissolving profile is different and cannot be substituted (Abozaid & Saleh, 2022).

RESULTS

Visual inspection

Table 1 illustrates that all examined brands exhibit a uniform pink colour, with the exception of Pr2, which is white; they possess a rounded shape with smooth surfaces, remain intact, and are devoid of any odour. All brands were scored in halves (except Pr4 was not scored).

Thickness and diameter

Every branded tablet had appropriate thickness and diameter specifications, as shown in Table 1.

Uniformity of weight

Table 2 displays the propranolol tablet's weight homogeneity. The mean weights for all brands were close. For every tablet brand, the weight ranged from 196.64 ± 2.79 mg to 206.91 ± 2.36 mg. The weight variation uniformity test revealed that all four of the Propranolol brands passed and satisfied the USP standards for weight uniformity because none of them deviated more than ± 5% from the mean value.

Friability Test

The outcomes of the friability tests for the sample brands are shown in Table 2. The percentage of friability for the brands under study satisfies the USP requirement that tablets lose no more than 1% of their initial weight. This indicates that the tablets have strong mechanical resistance and have passed the friability test.

Test of Hardness

According to Table 2, the propranolol tablets' hardness ranged from 81.52 ± 8 to 90.42 ± 6 N. As a result, the minimum force needed to achieve a good tablet hardness is around 40 N (Abebe et al., 2020).

Table 1: Characteristics and dimensions of the brands of propranolol tablets under investigation**.**

Brand code	Country of origin	Shape & Color	Surface texture & Convexity	Scoring	Coating	Thickness ± SD (mm)	Diameter ± SD (mm)
Pr1	United Kingdom	Round & pink	Smooth & biconvex	Scored	Film coated	3 ± 0.01	8 ± 0.03
Pr2	Tunisia	Round & white	Smooth & biconvex	Scored	Uncoated	4 ± 0.02	8 ± 0.01
Pr3	Greece	Round & pink	Smooth & biconvex	Scored	Film coated	3 ± 0.09	8 ± 0.07
Pr4	Egypt	Round & pink	Smooth & biconvex	Not Scored	Film coated	3 ± 0.05	8.3 ± 0.03

Table 2: Results of quality control tests conducted on the brands of propranolol tablets under study.

Brand code	Mean Weight (mg)	%Deviation from Mean Weight	Hardness ± SD (N)	Friability (%)	Disintegration time ± SD (min)	Assay ± SD (%)	Similarity factor (f2)
Pr1	206.03	±1.72	86.18 ± 6	0.010	16.1 ± 0.02	109 ± 0.04	
Pr2	196.64	±2.79	90.42 ± 6	0.003	> 30 ± 0.04	103 ± 0.007	6
Pr3	204.53	±1.95	85.59 ± 8	0.010	14.1 ± 0.3	106 ± 0.02	40
Pr4	206.91	±2.36	81.52 ± 8	0.020	12.1 ± 0.2	106 ± 0.02	45

Disintegration Test

All of the Propranolol tablet brands under investigation had observed disintegration times of less than 16 minutes, with the exception of Pr2, which was more than 30 minutes. Thus, all of the brands satisfied the quality control standards set down by the official pharmacopoeia. Table 2 shows the average disintegration time values for propranolol tablets.

Standard calibration curve of Propranolol:

It was determined that the λmax was at 290 nm. With a determination coefficient of R2 = 0.9977, the regression equation of the standard calibration curve created for the measurement of propranolol concentration with a concentration range of 10–50µg/ml was y = 0.0173x + 0.0073.

Assay results
Table 2 displays the Propranolol tablet assay findings. This investigation found that all brands of propranolol tablets met the assay criterion of (USP 32, 2009) (90–110%) and were within their specifications (Chioma & Nkemakolam, 2019).

Dissolution Test
According to the official pharmacopoeias, the amount of drug released at 30 minutes must be at least 80% of the amount on the label. As illustrated in Figure 1, every brand passed the dissolution test during the evaluation period, and the obtained dissolution rate profiles are almost super imposable except brand Pr2.

Analysis of similarity factor
Using the similarity factor (f2) value, all of the dissolution profiles that were acquired were compared with the innovator's (Pr1). The (f2) values of the brands under study with regard to brand Pr1 were displayed in Table 2. Based on similarity factor estimation, all brands under study displayed (f2) values below 50, showing that the profiles of the three marketed products Pr2, Pr3, Pr4, and the innovative brand Pr1 were not similar. Therefore, it was discovered that none of the brands under study had a dissolution profile that was comparable to that of the innovative brand Pr1.

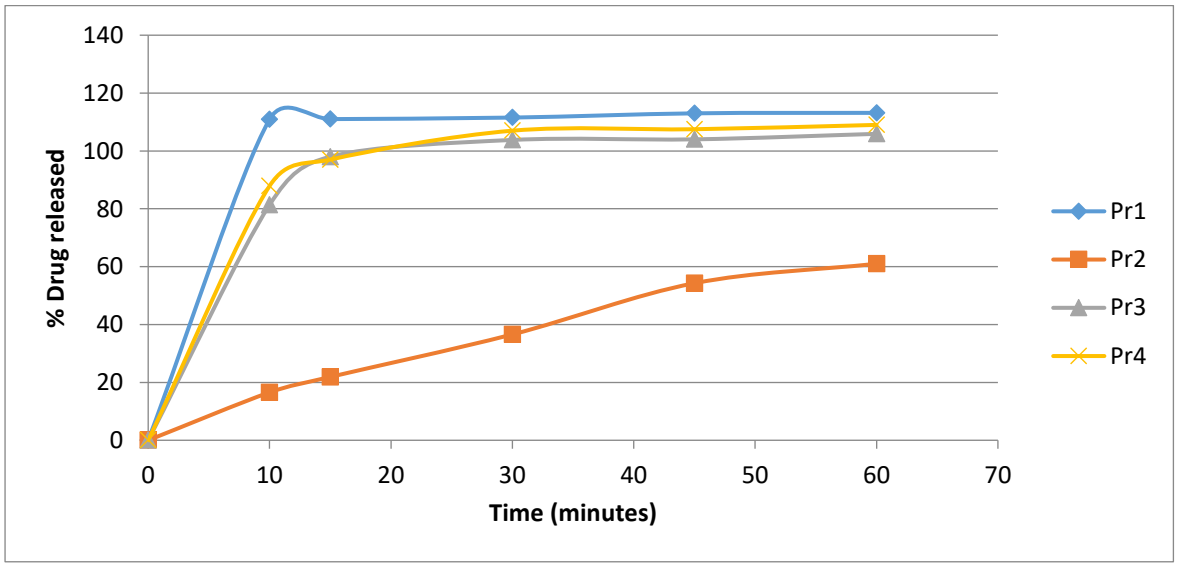

Fig. 1: The dissolution profiles of propranolol tablet brands under study.

DISCUSSION:
In accordance with the World Health Organization's definition of counterfeit goods, no visible physical defects in the tables or mislabeled Propranolol tablet brands raised suspicions that the product might be a fake. The current study found that all of the brands under investigation were round, flat-surfaced, odourless, and uniformly pink (with the exception of Pr2, which is white). With the exception of brand Pr4, every brand received a score. The tablet's score lines make it easy to separate them for more customisable dosage. However, extreme caution is necessary to prevent undesirable side effects or low treatment efficacy. All tablets, with the exception of brand Pr2, were film-coated. As an initial control parameter, tablet thickness is mostly correlated with tablet hardness (Mate et al., 2020). Tablets need to be consistent in thickness and diameter for both packaging and patient acceptance. All of the branded tablets' thickness and width measurements fell within the acceptable range.
According to the test results, each brand displayed mean weights that ranged from 196.64 ± 2.79 mg to 206.91 ± 2.36 mg. All brands passed the weight uniformity test (Abebe et al., 2020; Chioma & Nkemakolam, 2019).
Tablet strength must be sufficient to endure handling forces during packaging, breakage during storage, and transportation, therefore hardness is an important consideration (Chioma & Nkemakolam, 2019) (Abebe et al., 2020; Siaan et al., 2015). For medications that are sensitive to changing dissolution-release patterns or that have current or anticipated bioavailability issues, controlling tablet hardness may be crucial. The observed outcomes demonstrated that the hardness of each of the chosen Propranolol brands is acceptable. Brand Pr4 needed the least amount of pressure before breaking, whereas Pr2 needed the most, as seen in Table 2.
High friability medicines are more likely to be mechanically eroded, which could lead to the loss of the active ingredient and reduce the medication's effectiveness (Abebe et al., 2020; Chioma & Nkemakolam, 2019). The percentage of friability of the brands under study satisfies the USP criteria, indicating that the tablet has acceptable mechanical resistance.

In order for medications taken orally in tablet form to dissolve in the gastrointestinal tract and be fully absorbed, disintegration is a necessary condition. Higher absorption results in higher bioavailability, which in turn improves therapeutic efficacy (Siaan et al., 2015). If the disintegration time is very long, the tablet is too strongly compressed, which suggests a lack of batch homogeneity (Abebe et al., 2020). Both uncoated and film-coated tablets should to disintegrate in half an hour. The observed disintegration time for every brand under investigation was less than 16 minutes, with the exception of Pr2, which was more than 30 minutes. This indicates that every brand, with the exception of Pr2, passed the official pharmacopeia's restrictions.

In order to improve the penetration of aqueous liquids, several industries may have employed different disintegrants. The disintegration mechanism, the concentration of the disintegrant, and the manner of incorporation, all have an impact on the breakdown of tablets. The kind and strength of the binder system, as well as the amount of compression force applied during tablet manufacturing, also have an impact (Siaan et al., 2015). Regarding the assay results, every brand of propranolol tablet met the requirements of (USP 32, 2009) (90–110%) and was within their limits (Chioma & Nkemakolam, 2019)**.** A product's therapeutic impact depends on how much of an active ingredient it contains. While too much API will result in greater adverse drug reactions and poor treatment results, too little API will cause medication to be underdosed, which will have detrimental effects on treatment (Abebe et al., 2020).

According to the current study, all products under investigation met the pharmacopoeial standards criterion for dissolution rate, with the exception of brand Pr2, which did not pass this test. With the exception of Pr2, propranolol in tablets released instantly; within 30 minutes, almost 80% of the medication was released, and then the release sustained.

This investigation makes it abundantly evident that the dissolution profilesof various products vary. All dissolution profiles were compared to the innovator brand Pr1 using the similarity factor (f2) value in order to assess the significance of the alterations. All brands listed in Table 2 have Similarity Factor Analysis (f2) values below 50, which indicates non-similar profiles. Therefore, it was discovered that none of the brands under study had a dissolving profile that was comparable to the innovator's and could not be utilised interchangeably.

CONCLUSION

This investigation verified that the weight and geometrical dimension parameters of every brand of Propranolol tablet under test were consistent. The weights of the tablets deviated from the mean weight within the allowed range.

Indeed, every brand showed good mechanical strength. The amount of the active component was within the allowed limits. The disintegration time of every brand under study was also within pharmacopoeial guidelines, with the exception of brand Pr2, which took longer than 30 minutes. According to the dissolution profile, every brand under study released over 80% of its active pharmaceutical ingredient in less than 30 minutes, meeting the USP and BP specified limits. Consequently, it can be concluded that all of the propranolol tablet brands under investigation, with the exception of brand Pr2, are of good quality; nonetheless, their dissolving profiles have been determined to be non-equivalent to those of the innovator, indicating that they cannot be utilised interchangeably.

Compliance with ethical standards

Disclosure of conflict of interest

The authors declare that they have no conflict of interest.

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