AlQalam
Alq J Med App Sci
https://journal.utripoli.edu.ly/index.php/Alqalam/index eISSN 2707-7179

*Original article*

# Post-Marketing Quality Control of Different Brands of Paracetamol and Paracetamol Plus Caffeine Tablets Available in Libyan Markets

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**ARTICLE INFO**

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***Received****: 06-10-2024*
***Accepted****: 08-12-2024*
***Published****: 19-12-2024*

***Keywords****. Paracetamol, Caffeine, Comparative, Post Marketing, Quality Control Parameters.*



**ABSTRACT**

*Paracetamol (PA) is a widely used non-prescription analgesic and antipyretic medicine. This active pharmaceutical ingredient (API) available alone or in a combination formula as with caffeine (CA). Hence, it is essential to evaluate and compare the quality control parameters for different brands of paracetamol and paracetamol+caffeine tablets in order to assess their effectiveness. This study tested six tablets' brands have both formulations, which are popular brands available in Tripoli retail pharmacies. Physical and chemical parameters were examined as a post marketing evaluation. The chemical tests included identification by Fourier-transform infrared (FTIR) spectroscopy and assay of drug content using UV-Vis spectroscopy for tablets of paracetamol labeled with A1, B1 and C1. However, physical analysis done for both brands, that containing paracetamol only (A1, B, and C1) and tablets of paracetamol plus caffeine (A2, B2 and C2), which included evaluation of appearance, weight variation, hardness, disintegration time and dissolution test. The results obtained showed that all the brands showed acceptable parameters according to Pharmacopeial specifications, and showed diverse physical properties. All brands demonstrated sufficient mechanical strength to resist fracture and crumbling. Additionally, samples were in compliance with the specifications of disintegration time and weight variation test. However, the chemical testing for the percent content according to BP2008 showed that product B1 was not comply with pharmacopoeia specifications with lowest API content of 91.2%. On the other hand, dissolution test revealed that the sample A2 (99%), C2(100%) paracetamol/caffeine had better release at 40 mints than brand A1(90%), C1(96%) tablets containing paracetamol only. Whereas, brands B2 (92.2%) paracetamol/caffeine tablets dissolved in slower rate compared with brand B1(92.76%) containing paracetamol alone. The results of this study indicated that the brands of Paracetamol and paracetamol combined with caffeine tablets available in the Tripoli drug market cannot be used interchangeably.*

***Cite this article.*** *Elbaroudi Z, Rbeida O, Kamour R, Ghrew R, Al-Dali N, Gammo R. Post-Marketing Quality Control of Different Brands of Paracetamol and Paracetamol Plus Caffeine Tablets Available in Libyan Markets. Alq J Med App Sci. 2024;7(4):1558-1565. https://doi.org/10.54361/ajmas.247489*

## INTRODUCTION

Paracetamol, also known as acetaminophen, is a commonly used over-the-counter pain reliever and fever reducer [1]. It is typically utilized to alleviate headaches, minor aches, and pains, as well as in treatments for colds and flu. Additionally, it can be employed in managing more severe pain when used alongside other medications [2]. As the time

to onset of action are important considerations when choosing a medication for relief of pain, Currently, in addition to paracetamol, a new formulation of paracetamol and caffeine has been developed to provide a faster dissolving and more rapidly absorbed drug product [3]. Caffeine is frequently included in common painkillers like paracetamol and ibuprofen to enhance their effectiveness in relieving pain. Studies have indicated that combining caffeine with pain medications can be beneficial for various acute pains, such as migraines, menstrual cramps, post-surgical dental pain, and postpartum discomfort. One study revealed that adding a small amount of caffeine to pain relievers provided better pain relief for twice as many individuals compared to using the medications alone. Another study found that paracetamol with caffeine led to quicker pain relief onset and extended its effects for up to three hours. [4]. This combination of caffeine along with paracetamol, is also a widely accepted and well-established treatment in Libya.

Paracetamol tablets are a solid dosage form created by compressing powdered materials into a compact unit. The therapeutic efficacy of the tablets depends on many factors such as, the drug loaded amount must be matched the labeled amount, and the drug bioavailability, with no doubt that these factors are highly related to the physiochemical properties of the active ingredients and excipients of the drug product [5].

Quality control (QC) refers to the entire set of procedures implemented to ensure the quality of all elements involved in the production of a specific pharmaceutical product. It not only safeguards the manufacturer from liability claims but also ensures that the patient receives a safe and effective product. Post-market assessment encompasses all activities aimed at evaluating the quality, therapeutic effectiveness, and safety of a product, in order to gather additional data after the product has been launched in the market [5]. pharmacopoeias (USP/IP/BP) have set the diverse specified limits specification to confirm the quality of the pharmaceutical tablets, which considered as “fit for use” only when it complies with its established quality standards [7]. In this study various chemical and physical quality control assessment was done for six brands of two formulations of paracetamol and paracetamol-caffeine tablets distributed in the pharmacies in Tripoli. Through performing official and non- official quality tests.

## METHODS

### *Materials*

Orthophosphoric acid 85% from Carlo Erba Spain, Sodium Carlo Erba Spain, Potassium dihydrogen phosphate ISO from ISOLAB chemicals Germany, Disodium hydrogen orthophosphate $2H_2O$, ISO from ISOLAB chemicals Germany; Sodium hydroxide and freshly distilled water.

### *Apparatus*

balance from Sartorius, Germany; dissolution Tester (Erweka DT600) Germany; disintegration tester Erweka-ZT320 Germany; hardness tester from PHARMA Test PTB, Germany; FT-IR Prestige-21 spectroscopy from Shimaduz Japan; Specord-200 Spectrophotometer from Analytikjena Germany.

To conduct the study, six brands of film coated tablets of both formulations of paracetamol and paracetamol/caffeine were purchased from the pharmacies in Tripoli-Libya. Three brands were labeled to contain 500 mg paracetamol per tablet. whereas, the other three types from the same brands with a label strength of 500 mg of paracetamol and 65 mg of caffeine per tablet. All tests were conducted within product expiry dates. The study carried out during the period from July/2024 to October/2024 at department of Industrial Pharmacy, Faculty of Pharmacy, University of Tripoli, Libya and at chemical unit, Drug Administration, Food and Drug quality Control Center, Tripoli, Libya

The three brands of paracetamol were coded as A1, B1 and C1. The Three brands of paracetamol/caffeine were coded with A2, B2 and C2. the coded samples were separated as a pair of paracetamol and paracetamol/caffeine of the same manufacturer as shown in table 1.

***Table 1. The Different brand of paracetamol and paracetamol-caffeine tablet.***

| Code | Dosage form | Batch no/E.D. |
|---|---|---|
| **A1** | **tablet** | **HH4V** |
| **A2** | **tablet** | **759K** |
| **B1** | **tablet** | **1854** |
| **B2** | **tablet** | **O717** |
| **C1** | **tablet** | **C5708** |
| **C2** | **tablet** | **C5383** |

***Physical evaluation***

***Weight Variation***

Twenty tablets were randomly chosen from each brand and weighed individually using an analytical balance. The average weight of all the tablets was calculated and considered as the standard weight of the individual tablet. Subsequently, the percentage of weight variation from the average weight was determined using the following formula:

% of Weight variation = $\frac{IndividualWeightoftablet-averageWeight}{averageweight}\ x\ 100$

***Hardness test***

10 tablets were taken from each brand. Individually, and the crushing strength that caused the tablet to break was recorded, using hardness tester from PHARMA Test PTB, the reading was taken in kg from the sliding scale and was compared with official standard of British Pharmacopeia (BP) which states that the minimum strength must be 5kg. (The British Pharmacopeia does not specify a particular hardness limit; however, other studies indicate that a crushing strength of 4 Kg to 10 Kg is regarded as the minimum requirement for satisfactory tablets).

***Friability test***

The friability test could not be conducted. European Pharmacopeia provides guidance indicating that friability testing is intended primarily for uncoated tablets, considering that their film coating serves to protect the tablet core and the friability test could damage the coating, making the results unreliable [8].

***Disintegration test***

According to BP, to perfume the test, six tablets from each brand were tested using disintegration tester Erweka-ZT320. The test was carried out in medium of 800ml purified water with temperature of 37±2°C. Maximum and minimum time required for each tablet to disintegrated completely in the medium was checked visually and recorded.

***Dissolution test***

The dissolution test was conducted using apparatus II (paddle apparatus) with six replicates for each chosen brand. A phosphate buffer solution (900 ml at 37 ± 0.5°C) with a pH of 5.8 ± 0.05 served as the dissolution medium, and the rotation speed was set at 50 RPM. All parameters were set according to BP specifications. 40 minutes later, a 25 ml sample of the dissolution medium was pipetted, diluted to 200 ml with the buffer, and filtered. A 10 ml portion of the filtrate was then diluted to 100 ml with phosphate buffer. Finally, the absorbance of filtrates was measured at 257 nm.

***Chemical evaluation***

***Fourier-transform infrared spectroscopy***

Identification The test was done simply by grinding 1 tablet to a fine powder, and about 3mg was added to 200 mg of KCl powder (FT-IR background window) then mixed together till homogenous mixture was obtained. The prepared sample mixture was compressed in order to obtain a pellet (disc) finely measured for spectrum [9]. The resulted IR spectra for each generic of paracetamol has to compared to the spectra of the standard.

***Determination of percent content***

Twenty tablets from each brand were randomly collected, crushed into a fine powder. In 200ml volumetric flask a quantity of powder equivalent to 0.15 g paracetamol was added to 50 ml of 0.1 M NaOH, diluted with water to 100 ml and shake for 15 min, then completed the volume to 200ml with water and filtered. 10 ml of the filtrate diluted to 100ml with water. Then 10 ml from the resulted solution added to 10 ml 0.1M NaOH and further diluted to 100 ml volume with water. The absorbance of the solution was measured using Specord-200 Spectrophotometer against E1%at λmax 257 nm.

## RESULTS

Three commercial brands of paracetamol 500 mg and the three combined paracetamol 500mg-caffiene 60mg tablets of the same brand were assessed for their apparent physical characteristics based on visual inspection as described in (Table 2). All tablets were film coated tablets, and found to have an attractive appearance with smooth surface texture, biconvex and oblong in shape, with uniform white colors.

*Table 2. Appearance features of the different brands of the studied tablets*

| Parameter | A1 | A2 | B1 | B2 | C1 | C2 |
|---|---|---|---|---|---|---|
| **Shape, color** | Oblong, White | Oblong, White | Oblong, White | Oblong, White | Oblong, White | Oblong, White |
| **Surface texture and convexity** | Smooth and biconvex | Smooth and biconvex | Smooth and biconvex | Smooth and biconvex | Smooth and biconvex | Smooth and biconvex |
| **Score line** | yes | yes | yes | yes | yes | yes |
| **Defect in the ablet coat** | No | No | No | No | No | No |
| **Packaging information** | Clear and sufficient | Clear and sufficient | Clear and in sufficient | Clear and in sufficient | Clear and sufficient | Clear and sufficient |

***FT-IR identification***

Figure (1) shows IR spectrum of standard paracetamol, figures (2,3,4) show the IR spectrum of different commercial brands of paracetamol. It was observed that all the obtained spectra for different samples are similar to the IR spectrum of standard paracetamol. However, the highest percentage of similarity to the standard was 97.2% that observed with product B1. Whereas, 92.2% and 92.1% were obtained for A1 and C1 respectively. Assay of paracetamol content in the selected tablets was within the BP specifications (95-105%), ranged from 91.2% To 97.3%. where the product B1 had lowest % content of the drug 91.2%.

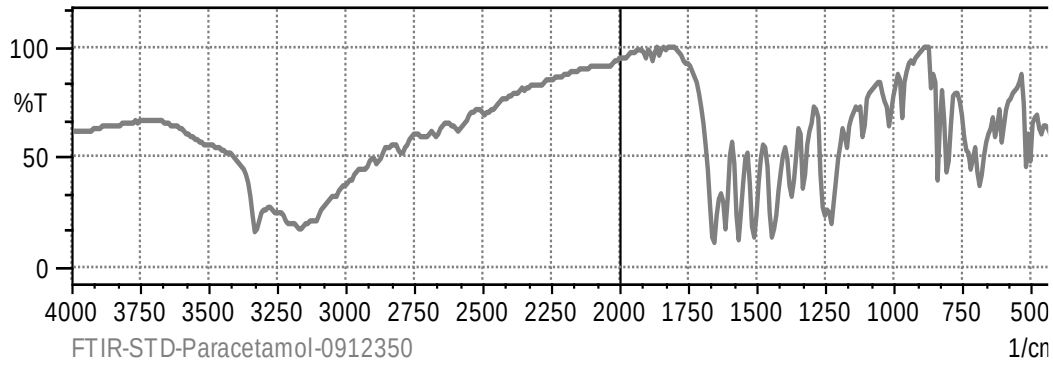


*Figure 1. IR spectroscopy result for standard Paracetamol*

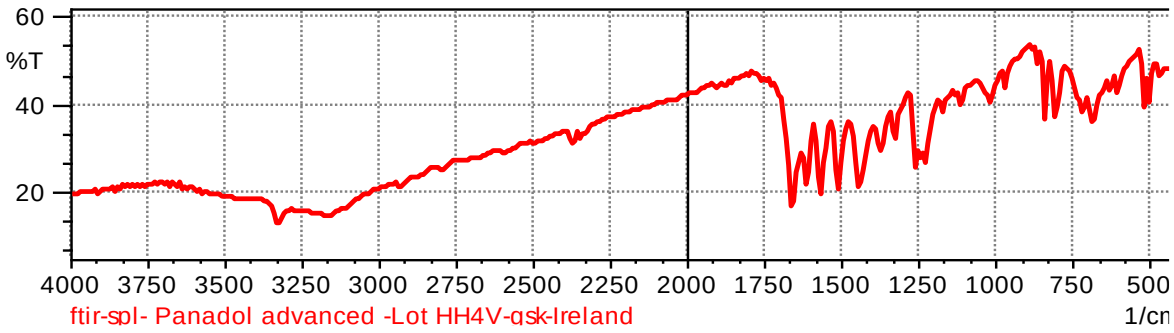


*Figure 2. IR spectroscopy result for product A1 Paracetamol with similarity of 92.2%*

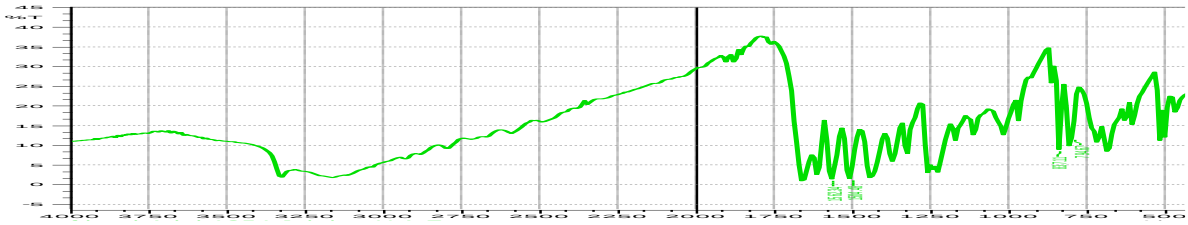

*Figure 3. IR spectroscopy result for product B1 Paracetamol with similarity of 97.2%*

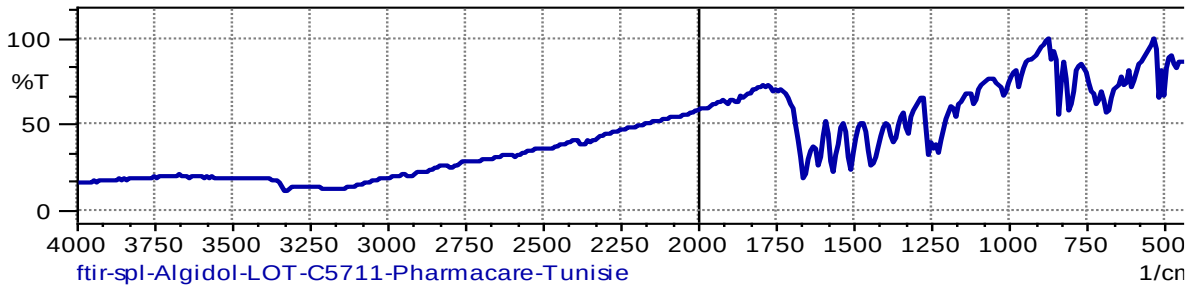


***Figure 4. IR spectroscopy result for product. C1 Paracetamol with similarity of 92.1%***

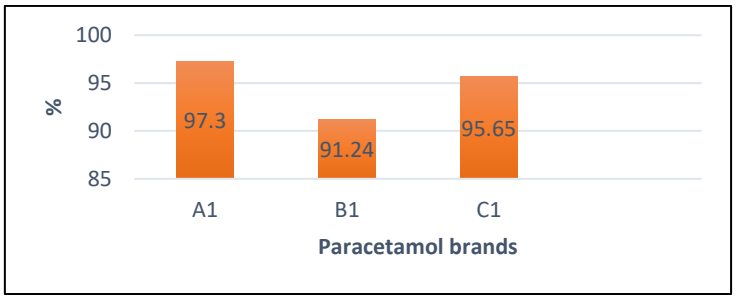


***Figure 5. % Content of paracetamol tablets.***

The acceptance criteria for a product's quality control tests are typically determined by pharmacopeial standards, internal (or manufacturer) limits and specific product specifications. Different chemical and physical quality parameters were evaluated and the obtained data were demonstrated in this study.

The results for the assay of the three drugs revealed that products A1and C1 comply with the standards as they contain the specified dose of API. However, B1 had the lowest content, falling outside the acceptable range specified by BP2008, Similar result was reported in the literature [10] for the same brand. The deviation from pharmacopeial specifications BP limit in assay test is a considering result to reject any product batch.

***Table 3. Evaluation of different quality control parameters of paracetamol and paracetamol/caffeine tablets***

| Sample | Weight variation (mg) n=20 | Hardness (Kg) | Disintegration (min) n=6 |
|---|---|---|---|
| **A1** | 0.65 ± 5% | 8.7kg | 2:45 |
| **A2** | 0.70 ± 5% | 10.99kg | 4:26 |
| **B1** | 0.63 ± 5% | 11.96kg | 1:09 |
| **B2** | 0.64 ± 5% | 13.22kg | 15.24 |
| **C1** | 0.55 ± 5% | 8.9kg | 13.52 |
| **C2** | 0.68 ± 5% | 8.9kg | 11:38 |

*A1, B1, C1= Tablet brands of paracetamol alone A2, B2, C2= Tablet brands of paracetamol/caffeine combination. The weight of tablets varied between brands due to differences in the formulation used by each manufacturer. However, Tablets for all tested brands were within the BP range of the average weight ± 5%.*

The results indicated that, the average values of hardness of the different brands of paracetamol and paracetamol /caffeine tablets tested were in the range 8.7 kg to 13.2kg. According to BP 2008 limit (4 -12kg), both formulations of single and combined paracetamol had acceptable crushing strength between 8.6 k to 11.9 kg (Table 3). However, B2 brand of paracetamol /caffeine tablets was the hardest, out of the pharmacopeial stated limit, with crushing strength of 13.22kg. it required the highest-pressure load to break up. The study revealed that the brands of paracetamol/caffeine combination were harder than the brands of paracetamol, in contrast brands C1 and C2 had identical crushing strength of 8.9kg. In general, the variation in tablets hardness it might be the cause of increasing tablet weight regarding combined formulation [11], applying high compression forces during tablet production leads to harder tablets that may not disintegrate within the desired time. Furthermore, the characteristics of the granulation process directly influence the hardness of the tablets. [12,13].

The disintegration of tablets is necessary for their dissolution and the subsequent drug absorption [14]. Disintegration time of paracetamol and paracetamol-caffeine tablets was determined according to the procedure reported in the USP and BP [15]. At the end of the time limit specified is (15 minutes for uncoated tablets and 30 minutes for coated tablets);

all of the tablets should disintegrate completely. As the studied tablets were all coated tablets, all were disintegrated within the pharmacopoeia limits. Evidently, tablets of paracetamol/caffeineA2, B2, and C2 showed prolonged disintegration time (maximum limit of 30minutes). The overall disintegration time for paracetamol tablet brands was in the ranged from 1:09 minutes for product B1 to 13:52 minutes product C1, while paracetamol/caffeine tablet brands! ranged from 4:26 minutes to 15:24 minutes. Hence, the hardest product B2 consumed the longest disintegration time. Perceptibly ,the disintegration time for paracetamol/caffeine tablet brands is much higher than the paracetamol tablet brands [16]. However, the exception shown with product C. As product C2 with caffeine disintegrated with about 3 minutes faster than C1. This might be corelated to the type of disintegrating agent(s) used in the formulation, mechanism of disintegration, disintegrant concentration and the way of its incorporation. It is also influenced by the type and concentration of binder system and the amount of compression force used in the production of tablets [17]. The results obtained in the study showed that the hardness or breaking strength of the tablets directly relates with the disintegration time, i.e. more hardness of paracetamol/caffeine tablets increased their disintegration time than the tablets of paracetamol [16].

Both products B2 and A2 showed high hardness value 13,2kg 10.9 kg respectively (table 3). However, A2 showed faster disintegration rate (4:26 min) (B2 15:24 min). This can be attributed to the technology in A2 formulation, its formulation contains excipients not found in the other tested brands like Alginic acid and in-organic materials like calcium carbonate. Alginic acid absorbs a significant amount of water, causing it to swell and resulting in the breakdown of the tablet. whereas calcium carbonate reacts with stomach acid, which triggers the release of the active ingredient [18]. Dissolution was another studied important quality control parameters directly related to the absorption and bioavailability of drug [16]. All the brands were examined to determine the percentage of drug release after 45 minutes through a dissolution test, and the results are presented in table 4.

***Table 4. Show % of drug release from tables during dissolution test.***

| % Drug Release (Through 40 min) | A1 | A2 | B1 | B2 | C1 | C2 |
|---|---|---|---|---|---|---|
| Not less than of 75% of API dissolved within 45 min. | 90.4% | 99% | 92.7% | 92.2% | 96% | 100% |

The study revealed that All brands of both groups showed more than 90 % drug release within 45 minutes. Furthermore, the percentage of drug release was better in paracetamol/caffeine tablet brands than tablets of the paracetamol alone, this might be due to the impact of caffeine, as the solubility of paracetamol is accelerated by caffeine [19,20]. However, B group showed almost identical dissolution. Moreover, brand B1 showed higher dissolution rate than B2. Therefore, brand B paracetamol and its combined formula with or without caffeine were bioequivalent. It worth to mentioned that, all brands were film coated tablets, and the coating layer did not affect the release pattern, as it is used to mask the taste only [21,22].

## CONCLUSION

Six generic brands of paracetamol 500 mg and paracetamol-caffeine 500-60mg tablets available in the local market of Tripoli Libya fulfilled all the pharmacopoeial specifications for weight variation, hardness, disintegration time, and correct dose content. Except for product B1 was out of the stated limit in its percent content and hardness test. It should be strictly considered that an ideal tablet will have sufficient API and hardness to maintain its mechanical stability. On the other hand the analgesic effect of combined caffiene with paracetamole is limited to the pain source and clinical foundations Therefore, it cannot be assumed that the same APIs within same dosage forms produced by different manufacturers will necessarily have the same characters and effects and therefore would be interchangeable. Hence, more focusing on the post-marketing evaluation of pharmaceutical products is required.

***Acknowledgments***

We would like to express our sincere gratitude to Chemical unit, Drug Administration, Food and Drug Quality Control Center, Tripoli, Libya for conducting some of the tests and providing some of the reagents.

***Conflicts of Interest***

The author declares that they have no conflict of interest.

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https://journal.utripoli.edu.ly/index.php/Alqalam/index eISSN 2707-7179

# مراقبة الجودة بعد التسويق لأنواع مختلفة من أقراص الباراسيتامول والباراسيتامول مع الكافيين المتوفرة في الأسواق الليبية

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[2]وحدة الكيمياء، إدارة الأدوية، مركز مراقبة الأغذية والأدوية، طرابلس، ليبيا

المستخلص
الباراسيتامول هو دواء مسكن وخافض للحرارة يُستخدم على نطاق واسع ويمكن صرفه بدون بوصفة طبية. هذه المادة الفعالة متوفرة إما بمفردها أو في تركيبة مع مادة الكافيين. لذلك، من الضروري تقييم ومقارنة معايير الجودة للعلامات التجارية المختلفة لأقراص الباراسيتامول والباراسيتامول مع الكافيين لتقييم فعاليتها. في هذه الدراسة، تم اختبار ستة شركات تجارية للأقراص التي تحتوي على التركيبتين، والتي تُعد من العلامات التجارية الشهيرة المتوفرة في صيدليات طرابلس- ليبيا. تم فحص المعايير الفيزيائية والكيميائية كجزء من تقييم ما بعد التسويق. شملت الاختبارات الكيميائية التحقق من وجود المادة الفعالة باستخدام التحليل الطيفي بالأشعة تحت الحمراء باستخدام وتحديد نسبة تواجد المادة الفعالة باستخدام التحليل الطيفي للأشعة فوق البنفسجية لأقراص الباراسيتامول المسجلة باسم A1 و B1و .C1أما التحليل الفيزيائي فقد تم إجراؤه على العلامات التجارية التي تحتوي فقط على الباراسيتامول A1و B و C1والتي تحتوي علي الباراسيتامول مع الكافيين A2) و B2و(C2، وشمل تقييم المظهر، التفاوت في الوزن، الصلابة، وقت التفكك، واختبار الذوبان. أظهرت النتائج التي تم الحصول عليها أن جميع العلامات التجارية أظهرت معايير مقبولة وفقًا لمواصفات الصيدلة، وأظهرت خصائص فيزيائية متنوعة. أظهرت جميع العلامات التجارية قوة ميكانيكية كافية لتحمل الكسور والتفتت. بالإضافة إلى ذلك، كانت العينات متوافقة مع مواصفات اختبار وقت التفكك واختبار التفاوت في الوزن. ومع ذلك، أظهر الاختبار الكيميائي لمحتوى المادة الفعالة وفقًا للـ BP2008 أن المنتج B1 لم يتوافق مع مواصفات الصيدلة بمحتوى أقل للمادة الفعالة بنسبة 91.2%. من ناحية أخرى، أظهر اختبار الذوبان أن العينة A2 (99%) و C2 (100%) من الباراسيتامول/الكافيين كانت تُطلق المادة بشكل أفضل بعد 40 دقيقة مقارنة بالعلامات التجارية A1 (90%) و C1 (96%)التي تحتوي على الباراسيتامول فقط. بينما ذابت أقراص العلامة التجارية B2 (92.2%) من الباراسيتامول/الكافيين بمعدل أبطأ مقارنة بالعلامة التجارية B1 (92.76%) التي تحتوي على الباراسيتامول فقط. أظهرت نتائج هذه الدراسة أن العلامات التجارية لأقراص الباراسيتامول وأقراص الباراسيتامول المدموجة مع الكافيين المتوفرة في سوق الأدوية في طرابلس لا يمكن استخدامها بالتبادل.

**الكلمات الدالة**. باراسيتامول، كافيين، مقارنة، ما بعد التسويق، مراقبة معايير الجودة.