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Original article

Pharmaceutical Quality Control Testing of Different Brands of Aspirin Sold in AL-Bayda City Markets

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ABSTRACT

***Background and aims**. The research studied official and unofficial quality tests to evaluate the quality of randomly selected brands of aspirin tablets that are sold in Bayda City. Six different brands of aspirin tablets (75, 100 mg) were randomly selected from retail pharmacies. **Methods**. Quality control tests, which included physical appearance, weight variation, hardness, friability, disintegration, and drug content tests, were carried out on the samples. All brands were checked visually to see if there were any manufacturing errors. The manufacturing defects include shape, size, and packaging. **Results**. The physical appearance of different aspirin tablets was free from all physical defects. Six different brands of aspirin tablets passed the test of weight variation. The weight variation percentage range was between -7.182% and 7.441%. The average hardness of all brands ranged from 47 to 121 N. The lowest one was ASA2 (47N), and the highest one was ASA3 (121N). The hardness of the tablets was found to be within the acceptable limits, except for the brand ASA3, which is far from the limit. The friability values for aspirin tablet brands ranged from 0.01 to 0.65%. All sex brands of aspirin have passed the friability test and have met the specifications of USP and BP pharmacopeias. The disintegration time for all aspirin tablets was within the pharmacopeial limits of 30 minutes. The drug content assay indicated that the aspirin tables were within the pharmacopeial limits. The content of aspirin presents in the various brands of commercial aspirin tablets with the codes ASA1 through ASA6 contained aspirin in amounts between 95.9 and 102 %. **Conclusion**. Good quality control involves testing units and determining if the aspirin tablets are within the specifications for the final products. Good quality control helps companies meet consumer demand for better products.*

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INTRODUCTION

Quality control of drugs is essential and is still one of the most important methods used to ensure that pharmaceutical products are suitable for their intended use, comply with the conditions of the marketing authorization, and do not expose consumers to health risks [1]. Effective quality control systems ensure that medications meet high standards and are consistent from production to distributor to customer, and even batch to batch [2]. Especially in developing and emerging economies, low-quality drugs pose serious risks to public health [1-3] Analytical techniques are important in the pharmaceutical field for developing, manufacturing, and discovering new drugs. Furthermore, the validity of analytical techniques as a product quality control approach justifies the need for medicine marketing authorization [4]. Quality control laboratories apply approved

procedures to guarantee the identification, purity, and effectiveness of medications [1, 4]. This includes ensuring that the weight, weight variation, disintegration, dissolution, and active component content of each tablet are official tests. non-official tests are hardness and friability [3, 5]. Compliance with health standards is the foundation of the process to ensure the quality, safety, and effectiveness of pharmaceuticals [6]. These factors make it impossible to guarantee the safety, effectiveness, and quality of pharmaceutical products, particularly in developing nations, which is why post-market qualitative studies are necessary [5-7]. Aspirin is a non-steroidal anti-inflammatory agent that is prescribed to alleviate mild to moderate pain [8]. Aspirin provides analgesic properties in addition to anti-inflammatory, antipyretic, and platelet aggregation inhibitory effects [9]. Figure 1 shows the chemical structure of aspirin or acetylsalicylic acid (ASA). The chemical name of aspirin is 2-acetoxybenzoic acid. Its molecular formula is C9H8O4 and it has a molecular weight of 180.15742 g/mol [10, 11].

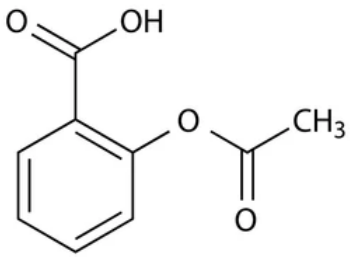


Figure 1. Structure of Aspirin.

Aspirin is also prescribed to reduce the inflammation associated with many conditions, including systemic lupus erythematosus, osteoarthritis, ankylosing spondylitis, rheumatoid arthritis, and many other illnesses that cause inflammation [12]. In addition, patients with cardiovascular disease and those who have already experienced a stroke are frequently administered low dose aspirin to prevent blood clot formation brought on by platelet aggregation [13, 14]. Aspirin functions in this situation as a blood thinner, lowering the risk of stroke and other cardiovascular disorders [14, 15].The aim of the work was to evaluate the quality assurance requirements for the different commercial brands of aspirin tablets, which include evaluation of general appearance including shape, size, color and packaging. Evaluation tests for tablets, hardness, friability, time disintegration and drug assay are included.

METHODS

Sample collection

Popular aspirin brands with a level claim of 75 and 100 mg were collected from pharmacies in Al-Bayda. For the analysis, about 120 aspirin tablets were collected from each brand. The product information, such as manufacturer name, date of expiry date at the time of procurement, is coded by letter number for each brand.

Table 1. Name, Brand code, Dosage, Manufacturer and Expiration Date of aspirin Brands.

No	Name of Aspirin brand	Brand Code	Aspirin Dosage	Manufacturer	Expiry Date
1	Aggrex uncoated	ASA1	75mg	Egypt	6/2024
2	Aspocid uncoated	ASA2	75mg	Egypt	8/2024
3	Bristol Enteric coated	ASA3	75mg	UK	5/2025
4	Bayer uncoated	ASA4	100mg	Turkey	10/2024
5	Bayer Enteric coated	ASA5	100mg	Egypt	5/2024
6	Bayer Enteric coated	ASA6	100mg	Switzealand	12/2024

Evaluation of General appearance

All brands of aspirin tablets were detected by the naked eye. The aspirin tablets were evaluated for any manufacturing mistakes, including expiration date, size shape, and organoleptic properties like color and odor. Consumer acceptance depends on the general appearance of all aspirin tablets.

Evaluation of quality control tests of tablets

Weight variation

For the weight variation test, twenty tablets were randomly selected from each brand. Every tablet was weighed individually using an electronic digital balance (Sartorius AG, ME 235S, Germany). The average weight for each brand was determined [16]. The percentage weight variation for each brand tablet was calculated using the following equation:

$$\% \text{ Weight variation} = \frac{\text{Individual Weight - Average Weight}}{\text{Average Weight}} \times 100$$

Thickness and diameter

Ten tablets were randomly selected from each brand. The digital caliper (TOTAL, TMT 322001, China), the thickness and diameter were determined individually; a tablet was placed between two external jaws and a reading in millimeters (mm). The average value was then calculated.

Hardness

Hardness is a force required to break a tablet across the diameter. It is an indication of its strength. Randomly ten tablets were taken from each brand. Electronic digital hardness test machine (ERWEKA GmbH tablet hardness tester, Model No: TBH 220 D, Germany) was used to analyze hardness of tablets. Single tablet was placed between two anvils, force was applied to the anvils and the tensile strength that just required breaking the tablet was recorded. The values of hardness were expressed in Newton unit. The average hardness was then calculated.

Friability

Percentage friability was determined by using a friability tester (ERWEKA GmbH tablet friability tester, Model No. TBH 220 D, Germany). Ten tablets from each brand were taken and weighed by using an electronic digital balance, which was considered as the initial weight. All the tablets were placed in the drum of the friability tester and allowed to rotate 100 times at 25 rotations per minute (rpm). After 100 revolutions, ten tablets were removed, dedusted, and re-weighed, which was considered the final weight. The percentage of friability was calculated by the equation below.

$$\%F = \frac{\text{Initial weight - Final weight}}{\text{Initial weight}} \times 100$$

Disintegration Test

The tablet breaks down into smaller particles; this is called disintegration by using a disintegration apparatus (ERWEKA GmbH tablet disintegration tester, Model No. TBH 220 D, Germany). Disintegration testing evaluates a tablet's capacity to disintegrate into smaller granules or particles that enable the body to absorb the active ingredient. Distilled water was used as the immersion fluid at 37±2°C for uncoated brands, and for coated brands, simulated gastric fluid (0.1M HCL) was used as the immersion fluid at 37±2°C for one hour. Then they put it in a simulated intestinal fluid phosphate buffer at pH 6.8 for two hours. The time taken for each tablet to disintegrate completely was noted. The specification states that all the uncoated tablets should disintegrate within not more than 15 minutes, and not more than two hours in simulated intestinal fluid for enteric-coated tablets.

Drug content

Twenty tablets of each brand of aspirin were precisely weighed, and the average was calculated. The tablets were crushed using a mortar and pestle to produce a fine powder of aspirin [17]. This test was performed following the titrimetric assay described in the aspirin (ASA) monograph of the British Pharmacopoeia (BP) [18]. A quantity of powder equivalent to 0.5 g ASA from tablets was transferred to a flask with 30 ml of 0.5 M sodium hydroxide. The mixture was then boiled for 10 minutes, after which three drops of phenolphthalein indicator were added. The excess alkali was then back titrated with 0.5 M hydrochloric acid. The same procedure was performed without ASA (blank). The difference between the two titrations represents the amount of sodium hydroxide consumed to change ASA to sodium acetate and salicylic acid. Each ml of 0.5 M sodium hydroxide is equivalent to 45.04 mg of ASA. The percentage of ASA was calculated according to the following equation:

Percentage of drug content = (end point of Blank (ml) − end point of experiment (ml) $\times F \times f$) / (initial weight) $\times 100$

Where F = equivalent factor and f =standardization factor of titrant

RESULTS

Evaluation of general appearance

All brands were checked visually to see if there were any manufacturing errors. The manufacturing defects include shape, size, and packaging. All aspirin tablets were medium-sized, white in color, and round in shape. They were free from all physical defects like capping, sticking, picking, mottling, and lamination.

Evaluation of quality control tests of tablets

The results of physicochemical properties including weight variation, diameter, thickness, hardness, friability, and disintegration of the six commercial brands of aspirin tablets are presented in table 2.

Table 2. Results of weight variation, diameter, thickness, hardness, friability, and disintegration time tests of commercial brands of aspirin tablets.

Brand Code	Physical Parameters						
	Weight (mg) n = 20		Diameter (mm) n = 10	Thickness (mm) n = 10	Hardness (N) n = 10	Friability (%) n = 10	Disintegration time (min) n = 6
	Average weight (±SD)	%WV					
ASA1	151.o8 (±0.005)	7.441	7.26	2.18	66	0.65	0.5
ASA2	96.711 (±0.003)	1.618	6.09	2.62	47	0.27	0.33
ASA3	199.99 (±0.003)	1.393	8.25	3.43	121	0.01	0.68
ASA4	120.08 (±0.004)	-7.182	7.08	2.96	53.7	0.26	0.68
ASA5	135.67 (±0.005)	-4.241	7.29	3.20	62.9	0.004	2.32
ASA6	137.85 (±0.006)	-2.674	7.3	3.2	65	0.011	2

%WV: Weight Variation Percentage.

Weight variation

The average weight of all commercial brands of Aspirin tablets was 151.08 mg for ASA1, 96.711 mg for ASA2, 199.99 mg for ASA3, 120.08 mg for ASA4, 135.67 mg for ASA5 and 137.85 mg for ASA6. The average percentage of weight variation of all commercial brands of Aspirin tablets was 7.441% for ASA1, 1.618% for ASA2, 1.393% for ASA3, -7.182% for ASA4, -4.241% for ASA5 and -2.674for ASA6. As a result, the range was between -7.182% and 7.441%.

Thickness and diameter

The results of the average thickness and diameter of each aspirin brand are mentioned in table No.2. The diameter and thickness of the commercial brands of Aspirin tablets were measured and according to the results obtained, the diameter of the tablets is 7.26 mm for ASA1, 6.09 mm for ASA2, 8.25mm for ASA3, 7.08mm for ASA4, 7.29mm for ASA5 and 7.3mm for ASA6. Tablet thickness is 2.18mm for ASA1, 2.62mm for ASA2, 3.43mm for ASA3, 2.96mm for ASA4, 3.20mm for ASA5, and 3.2mm for ASA6.

Table 3. Results of diameter test of commercial brands of aspirin tablets.

Brand / No	ASA1	ASA2	ASA3	ASA4	ASA5	ASA6
1	8.07mm	6.11mm	8.25mm	7.08mm	7.24mm	7.29mm
2	8.07mm	6.11mm	8.27mm	7.06mm	7.33mm	7.32mm
3	8.05mm	6.11mm	8.26mm	7.07mm	7.30mm	7.27mm
4	8.07mm	6.10mm	8.34mm	7.10mm	7.29mm	7.31mm
5	8.07mm	6.07mm	8.26mm	7.06mm	7.28mm	7.29mm
6	8.07mm	6.09mm	8.26mm	7.09mm	7.29mm	7.32mm
7	8.08mm	6.09mm	8.28mm	7.08mm	7,30mm	7.33mm
8	8.07mm	6.10mm	8.23mm	7.12mm	7.28mm	7.35mm
9	8.07mm	6.09mm	8.21mm	7.10mm	7.32mm	7.29mm
10	8.08mm	6.09mm	8.23mm	7.06mm	7.31mm	7.30mm

Table 4. Results of thickness test of commercial brands of aspirin tablets.

Brand / No	ASA1	ASA2	ASA3	ASA4	ASA5	ASA6
1	2.16mm	2.76mm	3.40mm	2.98mm	3.16mm	3.22mm
2	2.29mm	2.57mm	3.52mm	2.92mm	3.25mm	3.18mm
3	2.17mm	2.64mm	3.40mm	2.96mm	3.22mm	3.16mm
4	2.14mm	2.66mm	3.43mm	2.94mm	3.19mm	3.17mm
5	2.18mm	2.61mm	3.40mm	2.99mm	3.22mm	3.20mm
6	2.16mm	2.61mm	3.45mm	3mm	3.19mm	3.20mm
7	2.17mm	2.68mm	3.41mm	2.98mm	3.23mm	3.23mm
8	2.17mm	2.69mm	3.40mm	2.93mm	3.16mm	3.18mm
9	2.22mm	2.65mm	3.42mm	3mm	3.20mm	3.22mm
10	2.20mm	2.69mm	3.45mm	2.96mm	3.20mm	3.23mm

Hardness

The table above shows the average hardness of each commercial aspirin brand. The average hardness of ASA1 is 66N, which means that 66N is needed to break a tablet; the average hardness of ASA2 is 47N, which means that 47N is needed to break a tablet; the average hardness of ASA3 is 121N, which means that 121N is needed to break a tablet; the average hardness of ASA4 is 53.7N, which means that 53.7N is needed to break a tablet; the average hardness of ASA5 is 62.9N, which means that 65N is needed to break a tablet. The average hardness of all brands ranged from 47 to 121 N. The lowest one was ASA2 (47N) and the highest one was ASA3 (121N).

Friability

Friability results of each aspirin brand are mentioned in Table No.2. The average percentage friability of brands ASA1, ASA2, ASA3, ASA4, AAS5 and ASA6 was 0.65%, 0.27%, 0.01%, 0.26%, 0,004% and 0,011%, respectively. Tablets could be able to resist abrasion when subjected to stresses from collision and sliding towards one another and other solid substances, which can result in the removal of small fragments from tablets' surfaces. It is usually measured by a friability tester.

Disintegration time

The average disintegration time of each aspirin brand is mentioned in Table No.2. The disintegration time was performed to evaluate the time required for a drug to disintegrate in the gastric environment. It also shows the drug release profile of the drugs. Aspirin tablets were expected to disintegrate within 15 minutes. According to this study, the mean disintegration time for three uncoated aspirin brands, ASA1, ASA2 and ASA4, was 0.5, 0.33 and 0.68 minutes, respectively, and disintegration time for enteric coated aspirin brands ASA3, ASA5, and ASA6 was 0.68, 2.32, and 2 minutes, respectively, in simulated intestinal fluid for two hours after putting the tablet in simulated gastric fluid (0.1M HCL) for one hour**.**

Drug content

Figure 2 summarizes the assay results that indicate the content of aspirin present in the various brands of commercial aspirin tablets with the codes ASA1 through ASA6. They contained aspirin in amounts between 95.9 and 102 %. Aspirin content in aspirin tablets cannot fall below 95% or rise above 105% of the label claim; according to the BP. The content of aspirin of all brands within the BP limit, which suggests that the manufacturer's assertions regarding the concentrations found in each brand's products were true.

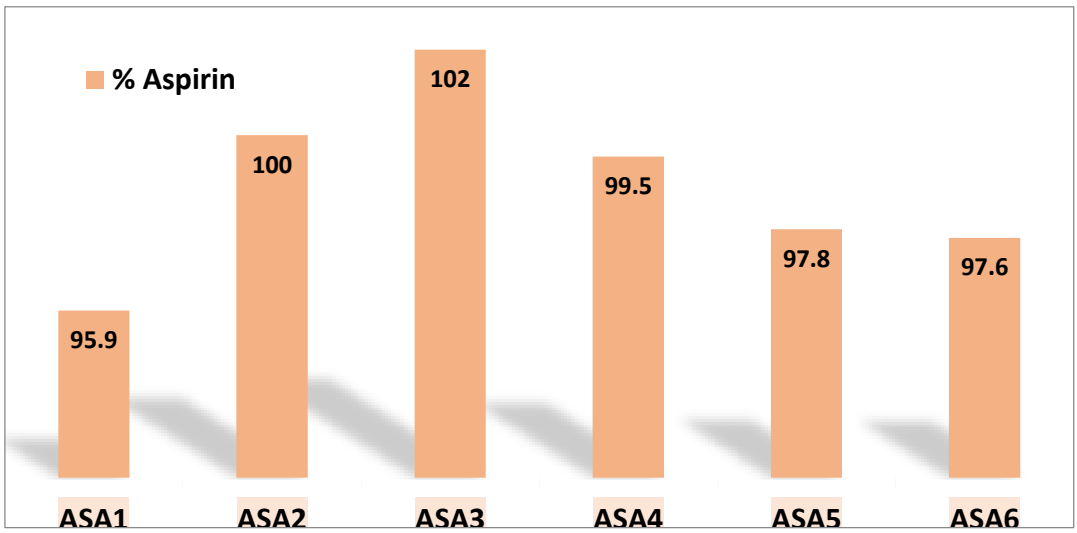


Figure 2. Drug content of commercial brands of aspirin tablets.

DISCUSSION

The USP/BP sets limits for the allowed variations in the weights of individual tablets, expressed as a percentage of the average weight of the sample, to help ease this problem [3]. The deviation of individual net weight should not exceed the limits given below [19].

The results in the table 2 revealed that the percentage of weight variation of all commercial brands of aspirin tablets fell within the limits of ± 7.5% according to BP. According to USP, the obtained results of commercial brands of aspirin tablets showed that the ASA1, ASA3, ASA5 and ASA6 respectively have a standard deviation of ± 7.5%. Two brands of aspirin tablets, ASA2 and ASA4, have a standard deviation of ± 10%. Aspirin tablets of all commercial brands have passed the weight variation test as per USP and BP standards. No weight variation was observed. The weight variation test is one of the most important quality control parameters as it relates to the content uniformity of a drug. Since a tablet is made to contain a specified quantity of medicine in a specific quantity of tablet formulation [20], it is important to measure the drug to ensure that the proper quantity is present [17]. The weight variation test enables checking whether there is homogeneity among units from the same batch. Those showing different weights may have different active levels as well [21].The diameter and the thickness are uniform according to the result shown in tables 3 and 4, which means that there is no difference in each tablet of the same brand from each other. The thickness of tablets is important in reproducing tables identical in appearance but also to insure that every production lot will be usable with selected packaging components [22]. The thickness must be controlled for patient acceptance and to make the tablet packaging easier. The diameter of the tablet influences esophageal transit [23].The hardness of the tablets was found to be within the acceptable limits. The acceptable range of hardness of tablet is 4 to 10 Kg force

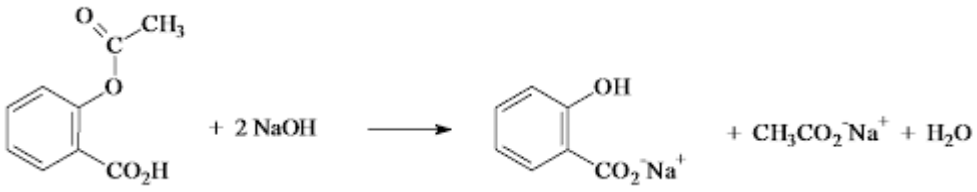
(49.03 – 98.07 N) [19]. Except the brand ASA3 far from stander limit is 121 N. The strength of a tablet during the packing, storage, and transportation stages is mostly correlated with its hardness. The tablet needs a specific level of strength or hardness to be able to endure mechanical shocks from handling during its manufacture, packing, and transportation. Additionally, when in the consumer's hands, tablets should be able to endure acceptable abuse. Consumer acceptance of tablets depends on their adequate hardness. Tablet hardness was found to increase with an increase in the weight of tablets [24]. The highest was aspirin brand ASA3 (121 N), so it was less friable and higher in weight.

In the friability test, the friability values for aspirin tablet brands ranged from 0.004 to 0.65%. All sex brands of aspirin have passed the friability test and have met the specifications of USP and BP, which specify that any brand must not lose more than 1% of its initial weight. This test determines the percentage weight loss of a tablet. The friability is evaluated as the ability of the tablet to withstand aberrations in packing , handling, and shipping [24, 25].

For uncoated tablets, the time is not more than 30 min according to USP and 15 min according to BP as table below. The disintegration time of all uncoated aspirin brands was less than 15 minutes. According to USP and BP, all brands of enteric coated aspirin did not disintegrate in simulated gastric fluid (0.1M HCL), but when placed in simulated intestinal fluid, they disintegrated within a few minutes. An important step toward a solid dosage form's bioavailability is the process of disintegration [26]. Disintegration testing is crucial for formulation development and quality assurance to guarantee product consistency from batch to batch [27].

By reacting an unknown reactant with an excess volume of an existing reactant with a known concentration, back titration is an analytical chemistry technique that enables the user to determine the concentration of an unknown reactant. Taking into account the molarity of the excess that was added, the resulting combination is then titrated back [28, 29]. Back titrations can be used in a wide range of situations, such as when the sample is not soluble in water, when it contains impurities that interfere with forward titration, or when the end-point is simpler to detect than in forward titration. By determining the aspirin in a solution using titration. Aspirin is a weak acid, making it difficult to determine the end point via titration because reactions could take a long time [30, 31]. Therefore, because this reaction involves a strong base and a strong acid, the end-point can be more easily determined by using back titration. This kind of reaction happens quickly, leading to a quick end point that is simple to identify. According to the titration for a strong acid and a strong base, pH 7 is where the equivalence point is determined. Therefore, it is possible to use the indicator phenolphthalein. When the pink solution created by adding phenolphthalein fades to colorless, the end point will be noticeable [29, 32].

As shown in the equation below, alkaline hydrolysis is the initial phase of this process. To do this, add sodium hydroxide in an amount that will be greater than the aspirin concentration to the aspirin solution. Due to the hydrolysis reaction occurring at a very low rate at room temperature, it was heated to increase the reaction rate [30, 31].



After that, the second phase, the hydrolyzed sodium hydroxide solution, is back-titrated with hydrochloric acid. Through this method, excess sodium hydroxide and hydrochloric acid are reacted as noted in the equation below [30, 31].

$$\mathbf{NaOH + HCl \longrightarrow NaCl + H_2O}$$

The amount of hydrochloric acid required to neutralize the unreacted sodium hydroxide in the solution can be calculated using the back titration method. This information, along with the quantity of sodium hydroxide added, can be used to calculate the amount of aspirin that reacted with the sodium hydroxide [28, 30, 31].

Conclusion

Good quality control involves testing units and determining if the aspirin tablets are within the specifications for the final products. Good quality control helps companies meet consumer demand for better products. Various quality control parameters for tablets like weight variation, hardness, friability, disintegration time, and drug content were tested. From the results obtained in this research, it can be concluded that, generally, all brands complied with the

standard specification. The post-market evaluation is essential to monitor the approved medicine to adequately assess its quality, therapeutic effectiveness, and safety for the end-user.

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اختبار ضبط جودة الأدوية لمختلف ماركات الأسبرين المباعة في أسواق مدينة البيضاء

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كلية الصيدلة، جامعة عمر المختار، البيضاء، ليبيا.

المستخلص

الخلفية والأهداف. درس البحث اختبارات الجودة الرسمية وغير الرسمية لتقييم جودة العلامات التجارية المختارة عشوائياً من أقراص الأسبرين التي تباع في مدينة البيضاء. تم اختيار ستة ماركات مختلفة من أقراص الأسبرين (75 ، 100 مجم) عشوائياً من صيدليات البيع بالتجزئة. **طُرق البحث**. تم إجراء اختبارات مراقبة الجودة على العينات ، والتي تضمنت المظهر الجسدي ، وتغير الوزن ، والصلابة ، والتفتت ، والتفكك، ومحتوى الدواء. تم فحص جميع العلامات التجارية بصريًا لمعرفة ما إذا كانت هناك أي أخطاء في التصنيع. تشمل عيوب التصنيع الشكل والحجم والتعبئة والتغليف. **النتائج**. كان المظهر الجسدي لأقراص الأسبرين المختلفة خاليًا من جميع العيوب الجسدية. ستة ماركات مختلفة من أقراص الأسبرين اجتازت اختبار تغير الوزن. تراوح نطاق النسبة المئوية للتباين في الوزن بين -7.182٪ و 7.441٪. تراوح متوسط الصلابة لجميع العلامات التجارية من 47 إلى 121 شمالًا. وكان أدنىها (47N) ASA2 وأعلىها .(121N) ASA3تم العثور على صلابة الأجهزة اللوحية ضمن الحدود المقبولة ، باستثناء العلامة التجارية ASA3 ، والتي تعد بعيدة عن الحد المسموح به. تراوحت قيم التفتت لأقراص الأسبرين من 0.01 إلى 0.65٪. اجتازت جميع ماركات الجنس من الأسبرين اختبار التفتت وتوافق مع مواصفات دساتير الأدوية USP و .BPكان وقت تفكك جميع أقراص الأسبرين ضمن حدود الأدوية البالغة 30 دقيقة. أشارت مقايسة محتوى الدواء إلى أن جداول الأسبرين كانت ضمن حدود الأدوية. يظهر محتوى الأسبرين في العلامات التجارية المختلفة لأقراص الأسبرين التجارية برموز ASA1 إلى ASA6 تحتوي على الأسبرين بكميات تتراوح بين 95.9 و 102٪. **الخاتمة**. تتضمن مراقبة الجودة الجيدة وحدات الاختبار وتحديد ما إذا كانت أقراص الأسبرين ضمن مواصفات المنتجات النهائية. تساعد مراقبة الجودة الجيدة الشركات على تلبية طلب المستهلكين على منتجات أفضل.

الكلمات الدالة. مراقبة الجودة ، أقراص الأسبرين ، تغيير الوزن ، الصلابة ، الهشاشة ، زمن التفكك.