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Abstract

The purpose of this study was to compare the technical quality of commercial paracetamol tablets. Three Iraqi made generic 500-mg paracetamol tablets were compared on hardness, friability, content uniformity, and dissolution with the brand of paracetamol (Doliprane®, Sanofi). All the products tests' results were within the USP acceptance limits. However, paracetamol produced by Pioneer Pharma (Piodol®) did not pass the test of friability due to tablet breaking during the test. Overall, the three of the locally manufactured generic products being sold in the Iraqi's market were of good quality and performed similarly to their brand comparator, Doliprane, except Piodol ® due to friability failure.

Introduction

Generic medicines make up a large part of the medicines used in Iraq's public healthcare system, representing approximately 70% of all essential medicines and vaccines, highlighting their importance in providing affordable treatment[1]. Since generic medications are both safe and effective while also being more cost-efficient, they provide significant advantages from both medical and financial standpoints [2,3,4]. However, it is vital to ensure that the generic drugs on the market comply with quality standards. Given the potential risks involved in the selection of generic medications by pharmacies and hospitals for use by consumers and healthcare professionals, it is crucial to guarantee the availability of safe, effective, high-quality, and equivalent generic products. Therefore, proof of their safety and efficacy must be established before they are used[5]. Paracetamol (acetaminophen) remains the most widely utilized analgesic and antipyretic worldwide[6]. Given the vast array of generic formulations available in the Iraqi pharmaceutical market, evaluating their quality is crucial to guarantee consistency and patient safety.

In this study, locally manufactured 500-mg paracetamol tablets available in the Iraqi market were selected for quality assessment and comparison with the reference brand Doliprane® (Sanofi). The tested generic products included tablets manufactured by Samarra Drug Industry (SDI) (paracetamol), UrooK Pharma (Dolorok®), and Pioneer Pharma (Piodol®). The assessment focused on how variations in formulation and manufacturing may influence the physical properties (hardness and friability), content uniformity, and dissolution profiles of these products compared to Doliprane®.

Materials and Methods

Materials

Three Iraqi-made generic and the brand paracetamol products tested in this study were obtained from local community drug stores. The primary active pharmaceutical ingredient (API) is acetaminophen (paracetamol) 500 mg, tested from three generic suppliers; SDI (paracetamol), UrooK Pharma (Dolorok®), and Pioneer Pharma (Piodol®)., and compared to the brand comparator Doliprane® (Sanofi). Phosphate buffer (pH = 5.8) and methanol were obtained from local chemicals shop supplier, and they were all made by Sigma Aldrich, Pennsylvania, USA.

Methods

Hardness

To assess tablet hardness, the mechanical strength of the tablets was evaluated using a YD-2 Tablet Hardness Tester (Guoming, Beijing, China). Ten tablets from each product (n = 10) were randomly selected and individually placed between the jaws of the hardness tester. The force required to break each tablet was measured and recorded in Newton (N). The mean hardness and standard deviation were calculated for each product.

Friability

The tablets (n=10) from each product were weighed and loaded into the friabilator drum of CS-2 Friability Tester (Guoming, Beijing, China) and rotated 100 times at a speed of 25 rpm. After completion, they were taken out, dedusted, and their weight was precisely measured. The percentage of friability was calculated using the following equation[7,8]:

$$\textit{Friability (\%)} = [(W_1 - W_2) / W_1] \times 100$$

Where W_1 = initial weight of tablets before the test, and W_2 = final weight after the test.

Content Uniformity

Content uniformity was evaluated to determine the uniform distribution of the active pharmaceutical ingredient within individual tablets. Ten tablets (n = 10) were randomly selected. Each tablet was placed in 100 mL of diluent composed of 10 mL methanol and 90 mL distilled water and vortexed for 10 minutes to obtain a final concentration of approximately 0.1 mg/mL[7]. The resulting solutions were filtered through 0.2 µm Whatman membrane filters and analyzed using a High-Performance Liquid Chromatography (HPLC) system. The drug concentration was determined using a previously established calibration curve, and the percentage recovery and standard deviation were calculated[9,10].

Dissolution

The test was carried out using an automated USP dissolution paddle apparatus II, RC-1 Dissolution Tester (Guoming, Beijing, China). A single tablet was placed in the vessel of the apparatus, which contained 900 mL of phosphate buffer (PBS) at pH 5.8, as specified in the USP product monograph (50 RPM), and maintained at a constant temperature of 37°C ± 0.2°C [9,10]. Samples were withdrawn at various time intervals (5, 10, 15, 20, and 30 minutes) and were filtered through 0.2 µm pore-size Whatman filters. An equal volume of fresh dissolution medium was added to maintain constant volume.

The collected dissolution samples were then analyzed using an HPLC system, and the percentage of drug dissolved was calculated for each sampling time[9,11].

HPLC analysis

For the HPLC analysis, a reversed-phase C18 column (4 µm particles size) (Waters Nova-Pak C18, Framingham, MA, USA) and alliance HPLC system equipped with photodiode-array (PDA) detector (Waters Nova Framingham, MA, USA) were used for the analysis of collected samples from the content uniformity and dissolution tests. The diluent is methanol + DW (10:90), the mobile phase is methanol, flow rate is 0.8 mL/min, the injection volume is 10 µL, PDA wavelength is 243 nm, and calibration curve (CC) range used for the analysis ranges from 2.5-40 µg/mL (R^2 = 0.999) [7].

Statistical Analysis

The obtained data was expressed as mean ± standard deviation (SD). Statistical comparison between the tested products and the reference product was performed using an independent Student's *t*-test. Statistical analysis was carried out using GraphPad Prism® software (La Jolla, CA, USA), and a value of $p < 0.05$ was considered statistically significant.

Results

Hardness

The tablets must possess sufficient mechanical strength to endure various processing stages, including manufacturing, packaging, and shipping, until they are ultimately consumed by patients. The mean tablet hardness values for all tested paracetamol products are summarized in Table 1.

Table 1. Mean ± SD table hardness values (Newton) of paracetamol products (n=10)

Product	Mean Hardness (N) ± SD
Doliprane®	89 ± 3.9
Paracetamol-SDI	142 ± 4.6
Dolorok-UrooK	118 ± 5.6
Piodol-Pioneer	88 ± 4.1

The mean hardness of Doliprane® (Sanofi) tablets was 89 ± 3.9 N, which served as the reference brand comparator. Among the Iraqi-manufactured generics, SDI tablets exhibited the highest hardness value (142 ± 4.6 N), followed by UrooK (118 ± 5.6 N), and Pioneer (88 ± 4.1 N). All products met the USP acceptance criteria for tablet hardness.

Friability

A friability test was conducted to assess the physical durability of compressed tablets and their resistance to shipping and handling. This test is essential to ensure that locally manufactured generic products available in the Iraq market retain the necessary physical strength throughout transportation and storage. According to USP standards, tablets must not lose more than 1% of their initial weight to pass the friability test [7,8].

Tablets made by Urook and SDI as well as the brand product met the USP friability requirement, remaining within the accepted limit of less than 1% [Figure 1]. Tablets made by Pioneer Pharma also remained within the accepted limit [Figure 1]. However, tablets fracture was observed at the end of the friability test, indicating a failure in the product compared to the other products [Figure 2].

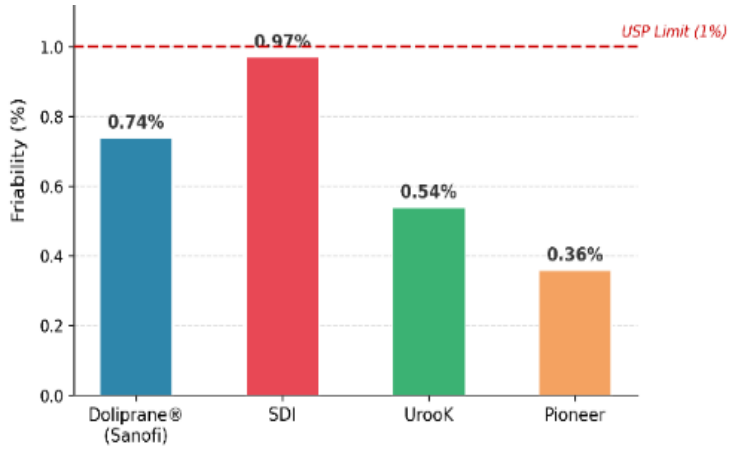

Figure 1. USP Friability (%) of Iraqi-manufactured generic paracetamol tablets and the brand, Doliprane®.

Figure 2. Tablets appearance after friability tests of Iraqi-manufactured generic paracetamol tablets and the brand, Doliprane®.

Content Uniformity

The content uniformity test is conducted to ensure that the drug substance is evenly distributed among the dosage units within a batch and that the paracetamol content in the sampled tablets complies with the USP product monograph standards.

The USP maximum allowed acceptance value (AV) to pass the content uniformity test is 15. All the products pass the test (Table 2).

Table 2. USP acceptance value for the Iraqi's manufactured generic paracetamol tablets and the brand, Doliprane®.

Product	Percent Recovery (%)	USP Acceptance Value
Doliprane®	100.2	1.73
Paracetamol-SDI	100.6	6.67
Dolorok-UrooK	99.2	3.05
Piodol-Pioneer	99.4	3.72

Dissolution

As per USP guidelines, the dissolution test is conducted to evaluate the amount of API released and dissolved from the tested dosage unit, ensuring compliance with the specifications outlined in the USP product monograph [9,11].

All tablets began dissolving instantly upon contact with the dissolution medium. The dissolution profiles of all tested products met the USP product monograph standards surpassing the USP requirement of ≥ 80% at 30 minutes [7]. (Figure 3).

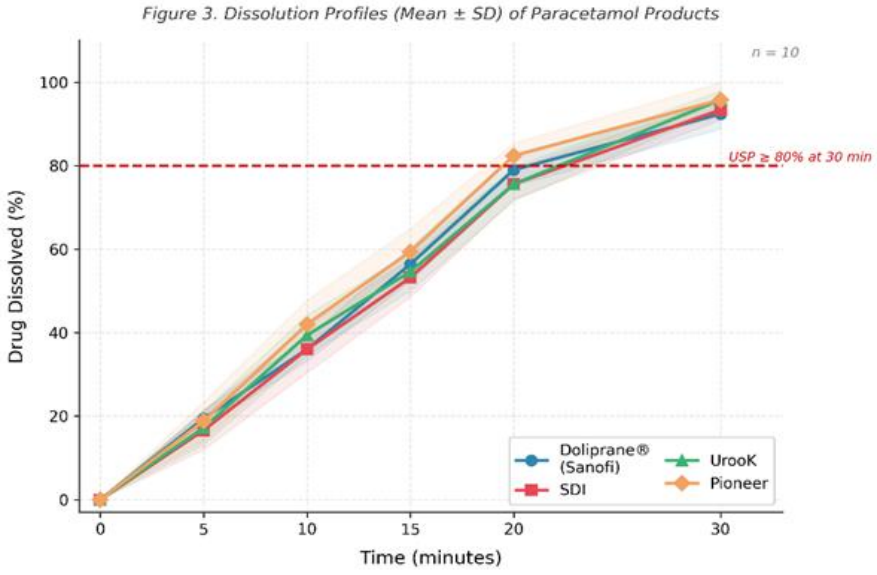

Figure 3. Mean ±SD of tablet dissolution of Iraqi's manufactured generic paracetamol tablets and the brand (Doliprane®, Sanofi).

No statistically significant differences ($p > 0.05$) were observed between the dissolution profiles of each of the generic products and Doliprane®.

Discussion

Generic medicines make up a large part of the medicines used in Iraq's public healthcare system, representing approximately 70% of all essential medicines and vaccines, highlighting their importance in providing affordable treatment [1]. The present study evaluated the pharmaceutical equivalency of three Iraqi-manufactured generic paracetamol products against the internationally manufactured brand Doliprane® (Sanofi) using standard USP quality control parameters.

The evaluation of tablet hardness demonstrated that all tested paracetamol brands exhibited adequate mechanical strength. The mean hardness values ranged from 88 N (Pioneer) to 142 N (SDI) [Table 1]. While paracetamol tablets manufactured by SDI showed the highest resistance to crushing, all tested products complied with pharmacopeial standards for handling and packaging, indicating well-controlled compression parameters and manufacturing consistency[12,9]. Differences in hardness between generic products and brand comparators are generally acceptable provided they do not adversely affect dissolution performance.

Friability testing results confirmed adequate structural integrity for all products, with all values below the USP limit of 1%. The results demonstrate sufficient resistance to abrasion and mechanical stress, ensuring stability during handling and storage [7,8]. Although the SDI product approached the upper acceptance boundary (0.97%), it remained within the permissible limit. Surprisingly, paracetamol tablets made by Pioneer Pharma (Piodol®) tablets broke at the end of the friability test. This indicates that the sample fails, even when the % weight loss is within limit.

Content uniformity results confirmed precise manufacturing for all products. The percent recovery values ranged from 99.2% (UrooK) to 100.6% (SDI), all within the USP-accepted range of 85.0–115.0%[10]. The slightly higher standard deviation observed for SDI (± 14.0 mg) suggests marginally greater tablet-to-tablet variability, though this did not compromise compliance with USP specifications. Uniformity test indicates uniform distribution of the active pharmaceutical ingredient within the tablets and reflects manufacturing consistency. The dissolution profiles showed rapid and complete drug release for all tested brands. All products achieved more than 92% dissolution within 30 minutes, meeting and exceeding the USP requirement of $\geq$ 80% at 30 minutes[9,11]. Minor differences observed in the early stages of dissolution are considered pharmaceutically insignificant, as all brands reached nearly complete dissolution by the final time point.

Conclusion

Except Piodol® which shows friability test failure due to tablets breaking, the other two Iraqi-manufactured paracetamol generic products available in the Iraqi market demonstrated good quality and performed comparably to their brand counterpart, Doliprane®. Future research will aim to broaden the scope by evaluating additional Iraqi-made paracetamol products, various dosage forms, and conducting a more detailed analysis of chemical degradant levels after storage in accordance with USP guidelines.

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